IN THE HIGH COURT OF JUDICATURE OF BOMBAY
BENCH AT AURANGABAD

CRIMINAL APPLICATION NO. 809 OF 2021

Ravindra s/o Deoram Sonawane,
Age; 49 years, Occ; Business,
R/o; Mukundwadi, N-2, CIDCO,
Aurangabad. ...Applicant

VERSUS

1. The State of Maharashtra,

2. Raj-Gopal Mulchandji Bajaj,
Age; 55 years, Occ; Business,
R/o; Drug Inspector Office of
Joint Commission, Food and Drugs
Maharashtra State, Aurangabad ...Respondents

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Advocate for Applicant : Mr. D.S. Bharuka
APP for Respondents-State Mrs. G.L.Deshpande

...

CORAM : SURENDRA P.TAVADE , J.

Date of Reservation : 17th August, 2021.
Date of Pronouncement : 06th October, 2021.

JUDGMENT :

1. Rule. Rule made returnable forthwith. By consent of learned counsel for both the parties, heard finally at the admission stage.

2. This Criminal Revision Application is directed against the order of 'issue of process' passed by the Additional Chief Judicial Magistrate, (Corporation Court), Aurangabad in RCC No. 41 of 2018.

3. The applicant is a Medical Whole-seller having shop in the name and style as "M/s. NTMED Pharmaceutical, Shop No. G-7-B and 8-B, Kasliwal Market-B, Mukundwadi, N-2, CIDCO, Aurangabad. He is doing the business of stock for sale and distribution of drugs.. On 30.09.2016, the complainant (respondent No. 2) visited the premises of the applicant for the purpose of drawing the sample. Accordingly, he has drawn the sample of Rabeprazole and Domperidone Capsules "NTDOM-DR" B. No. AC1601287, D/mfg. 01/2016, D/Exp. 12/2017, manufactured by Accura Health Care Pharmaceuticals Pvt. Ltd, village Moginand, Nahan Road Kala Amb. Dist. Sirmour (Haryana), 173030, vide Invoice No. 0077 dated 19.01.2016 and invoice No. 00118 dated 10.02.2016, through TCI, Transport in the name of original accused No. 8. As per the procedure laid down in the Drugs and Cosmetics Act, 1940 and Rules there under (for short the "Act 1940"). The said sample was sent to the Government Analyst, Drug Control Laboratory, Mumbai along with Form No. 18 dated 30.09.2016. On 07.06.2017 the complainant (respondent No. 2) received the test report of the subject drug from the Government Analyst, Mumbai (for short "G.A."). It was declared

that the subject drug was not of standard quality for the following reasons :

> "Content of Rabeprazole Sodium in the sample is less (i.e. 74.09% of the labelled amount) than permissible limits."

4. After receiving the report from G.A., a copy of the same was given to the applicant as per the provisions of Section 25 (3) of the Act, 1940 and called upon him to disclose the name of the supplier of the drug by a letter. The complainant (Respondent No. 2) issued notice under Section 18-B of the Act, 1940 dated 28.08.2017, to the original accused No. 2 and asked to submit the details from whom he had acquired the subject drug. He also received a letter along with documents from accused No. 2 and they disclosed that they acquired the subject drug from accused No. 8.

5. The applicant has disclosed to the complainant that original accused No. 2 has supplied him the subject drug vide their invoice No. 0077 dated 29.01.2016 and invoice No. 00118 dated 10.02.2016 respectively. Accordingly, one copy of test report was furnished to original accused No. 8 by letter dated 07.06.2017. Original accused No. 8, the Manufacturer challenged the said report and demanded one part of sample for sending it to the Central Drugs Laboratory, Kolkata for re-analysis. Accordingly a demand draft was

sent by original accused No. 8 to the complainant (Respondent No. 2). The complainant deposited the sample part of the subject drug along with demand draft received from original accused No. 8, in the Court and sent the subject sample portion to the Central Drugs Laboratory, Kolkata on 03.07.2017.

6. The Central Drugs Laboratory, Kolkata sent the test report in Form No. 2 to complainant (respondent No. 2) wherein, it was opined that "The Subject Sample Drug Was Not Of Standard Quality" for the reasons stated thereunder as "the sample does not confirm to Manufacturer's specification with respect to Assay/Content of 'Rabeprazole Sodium' i.e. 73.15%". It is alleged that the contents of Rabeprazole Sodium in the sample was found to be 74.09% as per G.A. Maharashtra and 73.15% as per the Director of Central Drugs Laboratory, Kolkata. From both the reports, it is clear that the sample was of not of standard quality with respect to the Rabeprazole Sodium. The complainant (respondent No. 2) sought permission to prosecute the applicant and others. Accordingly the complainant (respondent No. 2) received the prosecution order on 29.05.2018, from the Joint Commissioner (Drugs) (Head Quarter) Cum Controlling Authority, Maharashtra. Thereafter, he filed the complaint before the Additional Chief Judicial Magistrate, (Corporation Court), Aurangabad. On the basis of said complaint and

other material, the C.J.M. issued process against the applicant and others, which is under challenged.

7. It is contended on behalf of the applicant that the applicant had purchased the subject drug, manufactured by Accura Health Care Pharmaceuticals Pvt. Ltd, village Moginand, Nahan Road Kala Amb. Dist. Simour (Haryana) (accused No. 8), (hereinafter referred as "Accura Health Care Pharmaceuticals Pvt.") vide Invoice No. 00077 dated 19.01.2016 and invoice No. 118 dated 10.02.2016 through TCI Transport in the name of original accused No. 2 (Distributor). The subject drug was purchased by the applicant was stored in proper condition. The applicant also received the certificate of analysis, which was carried out by the Manufacturer Company i.e. "Accura Health Care Pharmaceuticals Pvt.", through its Quality Control Department dated 06.01.2016, in respect of the subject drug. The said report shows that the subject drug was of standard quality, as per the provisions of the Act 1940. The sample drug was out of the drug purchased by the applicant from "Accura Health Care Pharmaceuticals Pvt." through accused No. 2, through their invoice.

8. It is contended that the applicant had acquired the subject drug from M/s BIOTECH Health Care Pvt. Ltd., Panchkula, Haryana, Dist Chandigarh (Accused No. 2). It had specified itself about the quality and standard of the subject drug on the basis of

report of the analyst. He could not know and did not know with reasonable diligence that the subject drug in any way contravened the provisions of law. It is further contended that the applicant is protected under Section 19 (3) of the Act, 1940. The legislature had provided this protection to avoid unnecessary prosecutions of sellers. It is contended that after receiving the notice from the complainant (respondent No. 2) under Section 18-A of the Act, 1940, the applicant had disclosed the name of the supplier, i,.e. original accused No. 2 and submitted the invoice and report of the analyst of subject drug to the complainant (respondent No. 2). It is contended that the supplier and manufacturer of the subject drug is arrayed as an accused. The applicant was the retailer, therefore, he should not have made accused in the case. It is contended that the trial Court has not considered the provisions of Section 19 (3) of the Act, 1940, in proper perspective and wrongly issued the process, hence it is prayed that the order of issue of process be quashed and set aside.

9. Heard the learned counsel for the applicant and the learned APP for the respondents-State.

10. Perused the complaint. It is not in dispute that the applicant is a competent person of M/s. Rabeprazole and Domperidone Capsules “NTDOM-DR” capsule manufactured by Accura Health Care Pharmaceuticals Pvt. Ltd, to store and distribute

the medicine, etc. It is not in dispute that on 30.09.2016 the Drug Inspector (respondent No. 2) collected the sample of the subject drug from the shop of the applicant. The applicant himself is not a manufacturer of the subject drug. He had purchased it from M/s Biotech Health Care Pvt. Ltd., (original accused No. 2). M/s BIOTECH Health Care Pvt. Ltd., is a distributor of the said drug. It is not in dispute that Accura Health Care Pharmaceuticals Pvt. Ltd., is manufacturer of the said drug. The applicant had conveyed these facts to the complainant (respondent No. 2), in pursuance of a notice issued by the complainant (respondent No. 2). It is contended that if the said drug turned out to be of sub standard quality, the applicant possibly could not be blamed and penalized for it. To substantiate his contention the learned counsel for the applicant relied on the **provisions of Section 19 (3) of Act, 1940**. The said provisions are as under :

> *"[Section 19 (3) A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of section 18 if he proves ---*
> *(a) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;*
> *(b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and*

(c) that the drug or cosmetic, while in his possession was properly stored and remained in the same state as when he acquired it.]"

11. Now it is to be seen, whether, the applicant is entitled to the benefit of the provisions of Section 19 (3) of the Act, 1940. To start with the first thing is that the applicant has to prove is that he had acquired the subject drug from duly licensed manufacturer, the distributor, or the dealer thereof. The complainant (respondent No. 2) issued notice to the applicant under Section 18-A of the Act, 1940 and called upon him to disclose the name of the supplier of the subject drug. Accordingly the applicant informed the complainant (respondent No. 2) that he acquired the subject drug from M/s BIOTECH Health Care Pvt. Ltd., under the invoice No. 0077 and 00118, along with certificate of the analyst issued by the Quality Control Department of Manufacturer namely Accura Health Care Pharmaceuticals Pvt. Ltd., (accused No. 8). It is the case of the applicant that he relied on the report of analyst of the subject drug, furnished to him by the distributor namely M/s BIOTECH Health Care Pvt. Ltd. So it can be said that he did not know and could not possibly know that the subject drug by way of sample from his shop was of sub standard. Admittedly sealed capsules of the subject drug had been taken/purchased by the complainant (respondent No. 2). The subject drug was received by the applicant directly from the

distributor M/s BIOTECH Health Care Pvt. Ltd. In the certificate of analyst, there is warranty that the subject drug contained standard quality as defined in the Act, 1940 and Rules thereunder. The applicant had no reason to doubt the correctness of this warranty, therefore, things stood, the applicant possibly could not have known the subject drug was of sub standard quality. It is only for ascertaining the circumstances emerging from the document that will speak that the applicant had or had no knowledge of the fact that the said drug was of sub standard. The applicant had produced on record the invoices and certificate of the analyst, which show that the applicant had relied on the warranty given in the certificate of analyst. He did not know and could not know with reasonable diligence that the drug in question in any way contravened the provisions of the Act, 1940. It is also contended by the applicant that he had properly stored the subject drug in his shop, which was inspected by respondent No. 2.

12. Learned counsel for the applicant submitted that if a retailer disclosed the name of the Manufacturer/ Seller with proof of bills, then the manufacturer should also have to be made a party, then the prosecution against a retailer is an abuse of process of law. To substantiate his contention he relied on the ratio laid down in **Ghanshyam Mulchand Keshwani & Anr. Vs. State of Maharashtra &**

Anr. 2008 ALL MR (Cri) 701 wherein it is held that

> "*10. It was vehemently urged by the learned APP that under the provisions of Section 19 (2) of the Act, the burden of proving the defence that they are the retailers and they purchased food article from a manufacturer under warranty lies on the accused namely the petitioners. Unless and until the said burden is discharged by them, they cannot be absolved of the criminal liability. Since the petitioners have not yet adduced defence evidence, it cannot be said that they have discharged the burden lying upon them and as such the prosecution against the petitioners cannot be quashed.*
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> *11. The principle set out by the learned APP is quite correct. However, in the present case it is the version of the complainant (Food Inspector) himself that the petitioners are retailers and they disclosed him that they had purchased the packets of chilly powder from respondent No. 2 (the manufacturer). Not only this the petitioners also produced Bill No. C-460 dated 21.6.1995 containing warranty about the quality of the chilly powder on the back of the bill. It may further be noted that the manufacturer has also been impleaded as accused No. 3. In view of these circumstances there is no force in the submission made by the learned APP that the petitioners have not discharged the burden of proof lying on them. Had the manufacturer not been joined as co-accused, then perhaps it was necessary for the petitioners to lead evidence in support of their defence. But as pointed out above in the present case it is not necessary and the prosecution against the*

petitioners cannot be proceeded with."

13. The learned counsel for the applicant also relied on the ratio laid down in **M/s. Sanjay Medical Stores, Allahabad Vs. State of U.P. 1978 (I) Allahabad High Court 237** wherein, it is held that

> "*a drug purchased by the applicant from the licensed distributor for selling the same under a written warranty found to be sub-standard by the Government Analyst – applicant proved that he purchased the drug from a licensed distributor, that he did not know and could not with reasonable diligence know that the drug in question in any way contravened the provisions of the Act and that he had properly stored those capsules – he is entitled to the benefit of Section 19 (3) of the Act."*

In present case the applicant has produced invoices and certificate of the analyst, wherein, there is warranty that the subject drug obtained is of standard quality as defined in the Act and Rules.

14. There is no prima-facie case against the applicant under Section 18 (a) (i) and Section 16 punishable under Section 27 (d) of the Act, 1940. Therefore he is entitled for discharge. With this I proceed to pass following order :

ORDER

(a) Application is allowed.

(b) Order of issue of process passed against the applicant by the Additional Chief Judicial

Magistrate, (Corporation Court), Aurangabad in RCC No. 41 of 2018, is hereby quashed and set aside.

(c) Rule is made absolute.

(SURENDRA P.TAVADE)
JUDGE

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