

IN THE HIGH COURT OF JUDICATURE AT BOMBAY
BENCH AT AURANGABAD

CRIMINAL REVISION APPLICATION NO. 292 OF 2019

1. Mr. Sandeep V. Bambolkar,
Age Major, Occu. Service,
R/o. 901, Tiara Tower, Central Avenue,
Santacruz West, Mumbai-400054
2. Mr. Pramod G. Bagi,
Age Major, Occu. Service,
R/o. Kasliwal Prangan, Opp. Garkheda
Stadium, Ulkanagari, Aurangabad
3. Mr. Nitin C. Datar,
Age Major, Occu. Service,
R/o. E-1, Chanyaka Puri, Shahanurwadi,
Aurangabad
4. Mr. N. A. Joshi,
Age Major, Occu. Service,
R/o. Girija Shankar Vihar,
Behind Best Price Mall, Satara,
Aurangabad
5. Mr. M. R. Bharaswadkar,
Age Major, Occu. Service,
R/o. D-12, Kasliwal Tarangan,
Padegaon, Aurangabad
6. Mr. U. A. Naik,
Age Major, Occu. Service,
R/o. Akruti Enclave, Flat No.B-11,
Khadkeshwar, Aurangabad
7. Indoco Remedies Limited
through it's Authorized officer,
B-20, MIDC, Waluj, Aurangabad .. Applicants
(Accused)

Versus

The State of Maharashtra
through Drug Inspector
Food and Drug Administration
Ramkrushna-Nagar, Vasmat Road,
Parbhani .. Respondent

Mr. Shailesh S. Chapalgaonkar, Advocate for Applicants;
Mr. S. P. Deshmukh, A.P.P. for Respondent/State

CORAM : S. G. MEHARE, J.

Reserved on : 28.03.2023

Pronounced on : 26.04.2023

JUDGMENT

1. Rule. Rule made returnable forthwith. By consent of the parties, heard finally.

2. The applicants have impugned the order below Exhibits-27 and 28 declining discharge, in Special (Drug) Case No.2 of 2018, of the learned Additional Sessions Judge-3, Parbhani, dated 29.08.2019.

Facts:

3. Applicant No.7 is a pharmaceutical company that manufactures Viscid Gel (the tested drug). The remaining applicants are and were the employees of applicant No.7. They sell their drugs through their agents and shopkeepers throughout the State. The respondent is the authority controlling and regulating the drugs.

4. On 29.06.2015, the then Drugs Inspector visited M/s. Sunil Enterprises, Dr. Hedgewar Marg, Parbhani, and draw the drug sample in dispute. On 29 June 2015, the Drugs Inspector sent one

sealed sample of the drug to the Government Analyst as per the procedure under the Cosmetics and Drugs Act and the Rules. The manufacturing date of the said drug was 10/2014, and its shelf life was to expire on 09/2016. After testing the sample vide its report dated 30 November 2015, the Analyst declared the said drug as "Not of Standard Quality" because "the sample does not comply with USP 37 requirements for Microbial Enumeration Test". On 4 December 2015, the Drugs Inspector received the original copy of the analysis report in form XIII in triplicate from the Analyst. Thereafter, some procedures were done, and vide letter dated 4th December 2015, applicant No.7 was informed that the drug was not of standard quality and asked to comply with the directions in the said letter. However, the said letter does not mention the Drugs Inspector had filed a complaint. On 30 November 2015, the Drugs Inspector filed a complaint in the Court of Chief Judicial Magistrate, Parbhani. He, accordingly, issued a process on 21 September 2016. The applicants appeared in Court and filed their respective discharge applications.

5. The learned counsel for the applicants would argue that Rule 45 of the Drugs and Cosmetic Rules, 1945 has not been strictly complied with, and the delay in testing the sample was not explained. Therefore, the right of the applicants to get the sample tested through the Court had been limpidly denied. Hence, the complaint would not stand. The complaint has been lodged

belatedly, knowing well the expiry date of the shelf life of the drug in question. Therefore, the applicants have lost their right under Sections 25(3) and 25(4) of the Drugs and Cosmetics Act 1940 due to the delay in filing the complaint. On this legal aspect, the applicants are liable to be discharged. However, the learned Additional Sessions Judge, Parbhani, did not consider these legal aspects and erroneously passed the impugned order. It has also been erroneously observed that the supplier of applicant No.7 did not convey to the Drugs Inspector within 28 days of the receipt of the copy of the report that he intends to adduce evidence in contravention of the report. Its supplier did not avail of that opportunity. For non-availing this opportunity, the Government Analyst's report before this Court needs to be treated as conclusive. To bolster his arguments, the learned counsel for the applicants relied on the case of (i) ***Medicamen Biotech Limited and another Versus Rubina Bose, Drug Inspector, (2008) 7 Supreme Court Cases 196*** and (ii) ***Quixotic Healthcare and Others Versus State of Maharashtra and others, 2020 All M.R. (Cri) 1880.***

6. Per contra, the learned A.P.P. for the State argued that there is no question, affecting the rights as per Sections 25(3) and 25(4) of the Cosmetic and Drugs Act arise as Section 25(3) has not been complied with. The impugned order is well-reasoned, legal, proper and correct. There is sufficient evidence to proceed against the

applicants and to frame the charges. He prayed to dismiss the application.

7. A very short question falls for consideration, whether Rule 45 of the Drugs and Cosmetic Rules, 1945 was followed and the applicants have lost their rights available under Sections 25(3) and 25(4) of the Drugs and Cosmetics Act, 1940.

8. Rule 45 of the Drugs and Cosmetics Rules, 1945 reads thus:

"Duties of Government Analysts.—

(1) The Government Analyst shall cause to be analysed or tested such samples of drugs 1 [and cosmetics] as may be sent to him by Inspector or other persons under the provisions of Chapter IV of the Act and shall furnish reports of the results of test or analysis in accordance with these rules [within a period of sixty days of the receipt of the sample:

Provided that where it is not possible to test or analyse the sample within the specified period, the Government Analyst shall seek extension of time from the Government giving specific reasons for delay in such testing or analysis.]

(2) A Government Analyst shall from time to time forward to the Government reports giving the result of analytical work and research with a view to their publication at the discretion of Government."

9. The above rule is specific that the Government Analyst has to test the samples within sixty days of the receipt of the sample. The samples were seized on 29 June 2015 and sent to the

Government Analyst on 4 July 2015. The testing report was received on 14.11.2016. The copy of the test report dated 30 November 2015 placed on record reveals that the Analyst had received the samples on 04.07.2014. The Analyst knew the expiry date was 9/2016. The complaint was lodged on 20.09.2016, and in September itself sample expired. Considering these dates, it is apparent that the drug was not tested within sixty days of receiving the samples.

10. Sections 25(3) and 25(4) of the Drugs and Cosmetics Act 1940 give the accused a right to test the drugs again. The Drugs inspector was well aware, the shelf life of the sample drug was to expire in September 2016, and he filed the complaint in the same month. After filing the complaint, the applicants appeared in Court as per the process in March 2017. There is no explanation for why the complaint was filed in the same month, the shelf life of the drug was to expire. There is absolutely no reason why the complaint was not filed earlier, and the fourth sample was sent for testing well within time. These facts suggest that the right of the applicants to seek the test of the fourth sample has been taken away. In view of the facts of the case, the case laws relied upon by the applicants are squarely applicable.

11. Every person involved in the drug business has a right to challenge the Government Analyst report seeking the remedy

available under the Law by sending the fourth sample through the Court for testing. However, here is the case that the sample was not tested within sixty days of its receipt' therefore, the possibility of an incorrect result like "not of standard quality" cannot be ruled out.

12. Appreciating the facts of the case as discussed above and examining the reasons recorded by the learned Additional Sessions Judge-3, Parbhani, this Court is of the view that the learned Additional Sessions Judge-3, Parbhani did not consider the relevant provisions of Law and came to the erroneous conclusion. In the facts and the circumstances, even if the documents before the Court are considered as it is, the prosecution would not be able to prove the crime against the accused. The offences under the Drugs and Cosmetics Act are technical. Hence, time has a significant importance. The process was supposed to be done in a prescribed or scheduled time. The rules and provisions of the Act have not been followed strictly. Therefore, the statutory rights of the accused given under the said Act have *been prima facie affected*. In view of that matter, the Court is of the view that the applicants deserve the discharge. For these reasons, the Court believes that the impugned order warrants interference. Hence, the following order:-

ORDER

- i) The criminal revision application is allowed.

- ii) The order below Exhibit-27 and 28 in Special (Drug) Case No.2 of 2018 of the learned Additional Sessions Judge-3, Parbhani, dated 29 August 2019, is quashed and set aside.
- iii) Applications below Exhibits-27 and 28 are allowed, and the accused stand discharged in the present crime.
- iv) The bail bonds and surety bonds are cancelled.
- v) The surety stands discharged.
- vi) Rule made absolute in above terms.

**(S. G. MEHARE)
JUDGE**

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