

(2018) 02 BOM CK 0026
In the Bombay High Court
Case No : 175 of 2017

Ravi Rascendra Mazumdar,?Director & Anr. Vs Union of India

Date of Decision : 13-02-2018

Acts Referred:

[Drugs and Cosmetics Act, 1940](#), [Section 18B](#), [Section 28A](#), [Section 18\(a\)\(i\)](#), [Section 27\(d\)](#) - Maintenance of records and furnishing of information - Penalty for not keeping documents, etc., and for non-disclosure of information - Prohibition of manufacture and sale of certain drugs - Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter

Citation : (2018) 02 BOM CK 0026

Hon'ble Judges : C. V. Bhadang

Bench : Single Bench

Advocate : N. Sardesai, Shivraj Gaonkar, Ashish?Verma, Laxman R. Sawant, Susan Linhares

Judgement

1. Rule, made returnable forthwith. The learned Special Public Prosecutor waives service for the Respondent. Heard finally by consent of parties.
2. The challenge in this petition is to the order dated 10/2/2017 passed by the learned Judicial Magistrate First Class at Vasco, issuing process against the petitioners for the offence punishable under section 18 (a) (i) r/w section 27 (d), Section 18 B and section 28 A of the Drugs and Cosmetics Act, 1940.
3. The gravamen of the allegations in the complaint are that; a drug, namely, "Sarratiopeptidase" manufactured by the original accused no.1 i.e. M/s. Biocon Ltd. was found to be a substandard drug. The petitioners happen to be the directors of the company and are arrayed as accused nos. 2 and 3 in the complaint.
4. Mr. Sardesai, the learned Senior Counsel for the petitioners has raised three contentions. Firstly, it is submitted that there is no averment in the complaint that the petitioners were in-charge or were responsible for the conduct of the business of the company. It is submitted that under section 34 of the Act only such of the officers who are in-charge of and were responsible for the conduct of

the business of the company can be found guilty of any offence committed by the company. It is submitted that the entire complaint is silent on this aspect as to what is the role played by the petitioners and whether they were in-charge or were responsible for the conduct of the business of the company. Secondly, it is submitted that as per DCC Guidelines (Annexure A to the petition) only administrative action is contemplated in respect of defects other than Category B defects. The learned Senior Counsel has pointed out that Category B defects in respect of "capsules" is where the contents of the drug is found to be less than 70% of the "Assay" in respect of "thermolabile products". The learned Senior Counsel points out that the drug which has been allegedly found to be substandard in this case is a thermolabile product. It is pointed out that in the analysis of the drug conducted on 11/12/2013, it was found that the content was 78.72%. It is submitted that thus this is not a case involving Category B defects. It is pointed out that as per the said guidelines no prosecution is contemplated unless and until the product is found to have a Category B defect. Thirdly it is submitted that the impugned order is an unreasoned order and does not show that the Magistrate has applied mind to the contents of the complaint and the ingredients of the offence as alleged.

5. Ms. Linhares, the learned Special Public Prosecutor for the respondent has submitted that the respondent has filed an application for amendment of the complaint which is pending before the learned Magistrate. In so far as the reliance placed on the guidelines is concerned, it is submitted that they are guidelines framed by the State Government and the prosecution is by an officer of the Central Government and would not be binding.

6. I have carefully considered the circumstances and the submissions made. Prima facie it appears that the impugned order lacks reasons. The impugned order even does not show as to for what offences the process has been issued. This would be relevant inasmuch as according to the respondent the petitioners and the company are guilty of the offence under more than one sections. Secondly, the complaint as it stands today does not show any averment, indicating the role of the petitioners and whether they were in charge or were responsible for the conduct of the business of the company. It may be mentioned here that in this regard an application for amendment is pending before the learned Magistrate. It is neither necessary nor appropriate to deal with the merits of the said application at this stage.

7. There is also an arguable issue about the applicability of the guidelines raised and whether the prosecution is contemplated in respect of drugs which are not found to be having Category B defects. In such circumstances in my considered view, it would be appropriate that the matter is remitted back to the learned Magistrate for deciding the question of issue of process afresh in accordance with law. Needless to mention that it will be open to the learned Magistrate to consider whether cognizance of the complaint can be taken and whether process needs to be issued. In that view of the matter the petition is partly allowed. The

impugned order is hereby set aside. The matter is remitted back to the learned Magistrate for deciding the question of issue of process afresh and in accordance with law.