IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on: 30.10.2024

Pronounced on: 21.12.2024

CORAM:

The Hon`ble Mr.Justice P.DHANABAL

CRL OP.No.7288 of 2022
and
Crl. M.P. Nos.4166, 4165 of 2022 and 12034 of 2024

K. Anil Kumar Karusala S/o. K. Tata Rao …Petitioner / Accused 2

Vs.

Union of India
represented by its Drugs Inspector,
office of the Deputy Drugs Controller (India),
Central Drugs Standard Control Organization,
South Zone, 2nd Floor, Shastri Bhawan Annex,
Chennai-600 006. .... Respondent / Complainant.

PRAYER :-This Criminal Original Petition has been filed under Section 482 of Criminal Procedure Code to call for the records in respect of Criminal case in C.C. No.5298 of 2022 on the file of the X Metropolitan Magistrate Court, Egmore, Chennai pending as against the petitioners / accused 2 to 4 and to quash the same.

For petitioners : Mr. T. Saikrishnan

For Respondents : Mr. L. Infant Dinesh,
Central Government Standing Counsel.

ORDER

This Criminal original petition has been filed to quash the proceedings in C.C. No.5298 of 2022 on the file of the X Metropolitan Magistrate Court, Egmore, Chennai as against the petitioners / accused 2 to 4.

2. The case of the prosecution is that the 1st accused is the company namely M/s. Mino Pharm Laboratories Pvt. Ltd., and now functioning in the changed name of M/s. Revat Laboratories Private Limited represented by Managing Director K. Anil Kumar Karusala, Andhra Pradesh. The 2nd accused is the Managing Director, 3rd accused is the Chief Operating Officer of the said company. On 30.11.2016, the authorities conducted an investigation at Government Stanley Hospital, Chennai and drawn the samples under section 23 of the Drugs and Cosmetics Act of Erythromycin Stearate Tablets IP 250 mg, Batch No.ES-1611, Date of Manufacturing - April 2016, Date of expiry -

March 2018, quantity - 400 tablets manufactured by M/s.Minopharm Laboratories Pvt. Ltd., now functioning in the new name of M/s. Revat Laboratories Private Limited. Thereafter on 02.12.2016, they sent samples for the chemical analysis through Form-18 and on 13.04.2017, they received a report in Form-13 from the Central Drugs Laboratory, Kolkata. As per the report, the drugs was declared as not of standard quality with respect to test for 'dissolution' claim 250 mgs, Result - Average Drugs release 17.47% of claim, Limit: not less than 70%. After receipt of said report, they issued a letter to the Medical Stores Officer and directed to furnish the data from whom they acquired the said product. In turn, the Government Stanley Hospital replied that they procured medicine from the Tamil Nadu Medical Services Corporation Ltd., K.K. Nagar, Chennai. Thereafter, a letter dated 07.06.2017 was issued to the Drug Warehouse, TNMSC and they informed that the drugs were supplied by the 1st accused company M/s. Minopharm Laboratories Pvt. Ltd., through invoice dated 24.09.2016. Thereafter on 20.07.2017, a Show Cause Notice was issued to the 1st accused company along with original test report in Form-13 and sealed samples were also sent and

thereafter, a reminder letter dated 12.09.2019 was also sent. But no reply was received from the 1st accused company. Thereafter, joint investigation was also conducted and there are gross violations of the provisions of good manufacturing practices as envisaged under Schedule M of Drugs and Cosmetics Act and Rules 1945. Thereafter stop production order was issued on 22.06.2016.

2.1. On 30.01.2017, the Drugs Inspector inspected the Government Kasturibai Gandhi Hospital for Women and seized Erithromycin Stearate Tablets IP 250 mg, Batch No.ES-1611, date of manufacturing - April 2016, Date of expiry March 2018, Quantity 400 tablets . The said samples were sent for Central Drugs Laboratory, Kolkata for lab analysis and report received on 13.04.2017 as not of standard quality. Therefore, a Show cause notice issued to the 1st accused on 11.10.2017 along with copy of report and sample, but the 1st accused refused to receive the same. During joint investigation, it was found that the manufacturer did not follow the test procedure of dissolution of Erithromycin Stearate tablets as mentioned in Indian

Pharmacopoeia 2014 and has grossly violated the good manufacturing procedures as per the provisions of the Drugs and Cosmetics Act. Thereafter, prosecution permission was obtained on 25.06.2019. The accused manufactured the drug which is prohibited to manufacture for sale or for distribution, or sell or stock or exhibit or offer for sale or distribute as per Section 18(a)(i) of the Act. Therefore, they lodged a complaint.

3. The learned counsel appearing for the petitioners would contend that the respondent has filed a criminal complaint under Section 200 Cr.P.C. and Section 32 of Drugs and Cosmetics Act against the petitioners and others for violation of Section 18a(i) of Drugs and Cosmetics Act punishable under Section 27(d) of Drugs and Cosmetics Act. The X Metropolitan Magistrate Court, Egmore has taken cognizance and the same is pending in C.C. No.5298 of 2022. M/s. Revat Laboratories Private Limited, previously known as M/s. Minopharm Laboratories Private Limited is a company manufacturing quality drugs in accordance with license procured by it from the

competent authorities. The company has manufactured Erythromycin Stearate tablets IP 250 mgs among the many other drugs. On 30.11.2016, the respondent Drugs Inspector visited the premises of Medical Stores, Government Stanley Hospital, Chennai and drawn the samples of Erythromycin Stearate tablets IP 250 mg, Batch No.ES-1611, date of manufacture - April 2016, date of expiry - March 2018, Quantity - 400 tablets manufactured by M/s. Revat Laboratories Private Limited previously known as M/s. Minopharm Laboratories Pvt Ltd., On 20.07.2017, the respondent issued a Show Cause Notice to the 1st accused company to explain the contravention of the provision of Section 18(a)(i) of the Drugs and Cosmetics Act to the accused, who has manufactured and sold the drugs of not of standard quality. Again on 30.01.2017, the Drugs Inspector inspected the medical stores of Kasturibai Gandhi Hospital for Women and Children, Chennai and drawn samples of Erythromycin Stearate Tablets IP 250 mg, Batch No.ES-1611, date of manufacture - April 2016, date of expiry - March 2018, Quantity - 400 tablets manufactured by the petitioner company. Thereafter, on 11.10.2017, issued a Show Cause Notice to the 1st

accused company. There are allegations in the complaint that the firm surrendered their manufacturing license of injectables section with immediate effect and could not able to comply with good manufacturing practices in the solid dosage forms. Hence declared that they will not do the production till they comply. Consequently, Director and license authority cancelled the manufacturing license of subject drugs with effect of date of service of the said order. In the complaint, nowhere stated that these petitioners are involved in day to day affairs of the company and they were involved in the manufacturing process of the company. In the complaint, it is alleged that all the accused are responsible for the manufacturing of not of standard quality drug, all the directors are responsible for the day to day activity, marketing, selling and getting business profit by selling and marketing of not of standard quality drug. These petitioners are the Directors of M/s. Minopharm Laboratories Pvt. Ltd.,, but merely because they are the Directors, that itself is not sufficient to bring them within the clutches of law. If the said directors are not responsible for the day to day affairs of the company. The allegations are vague and bald and therefore, pending proceedings

against the petitioners are liable to be quashed.

4. The learned Government Advocate appearing for the respondent / defacto complainant would submit that the 1st accused company manufactured various drugs declared as not of standard quality since 2016. Hence the company suddenly changed its name as M/s. Revat Laboratories Private Limited with effect from 21.04.2017. The 2nd accused is the Managing Director, 3 and 4 are the Directors and the 5th accused is the Chief Operating Officer of the 1st accused company. On 30.11.2016, the complainant inspected the Government Hospital for Women and Children, Egmore and at that time, they had drawn the samples of Erythromycin Stearate tablets IP 250 mg, Batch No.ES-1611, Date of Manufacturing - April 2016, Date of expiry - March 2018, quantity - 400 tablets manufactured by the 1st accused company, under section 23 of the Drugs and Cosmetics Act. Thereafter, on the same day, the samples were sent to the Central Drugs Laboratory, Kolkata for medical analysis and received a report dated 17.11.2017 in Form-13 stating that the drugs are declared as 'not of standard quality', as the

sample does not conform to IP standards with respect to test for 'Dissolution' (Claim 250 mgs, Result - Average Drugs release 17.47% of claim, Limit: not less than 70%). Thereafter, a Show Cause Notice dated 18.12.2017 was sent to the 1st accused company to explain the contravention of provision of Section 18(a)(i) of the Drugs and Cosmetics Act. The original test report in Form-13 and a portion sealed sample were also sent along with letters, but no reply was received from the 1st accused company. On 30.01.2017, the Drugs Inspector inspected the Government Kasturibai Gandhi Hospital for Women and seized Erithromycin Stearate Tablets IP 250 mg, Batch No.ES-1611, date of manufacturing - April 2016, Date of expiry March 2018, Quantity 400 tablets . The said samples were sent for Central Drugs Laboratory, Kolkata for lab analysis and report received on 13.04.2017 as not of standard quality. Therefore, a Show cause notice issued to the 1st accused on 11.10.2017 along with copy of report and sample, but the 1st accused refused to receive the same.

4.1. During the joint inspection, it was found that the manufacturer did not follow the test procedure of dissolution of

Erithromycin Stearate tablets as mentioned in Indian Pharmacopoeia 2014 and has grossly violated the good manufacturing procedures as per the provisions of the Drugs and Cosmetics Act. Therefore, they filed a complaint. The participation of the Directors in day to day activities of the company is to be decided by the trial Court after evidence, but not at this stage. The accused 2 to 5 have actively participated in the day to day activities of the 1st accused company and hence they are liable to be prosecuted.

5. This Court heard both sides and perused the materials available on record.

6. In this case, there is no dispute that 1st accused company manufactured the drugs which were seized by the concerned authorities. As per the lab report, the samples drawn were declared as 'not of standard quality'. There is no dispute in this case that a Show Cause Notices were issued to the 1st accused company. The main contention of the petitioners is that in the complaint, nowhere stated about the involvement of the petitioners in day to day affairs of the company and the

manufacturing products of the company. In the complaint, there is a mention about the 2nd accused, who is the Managing Director, 3rd and 4th accused, who are the Directors and the 5th accused, who is the Chief Operating Officer. Therefore, all the accused are responsible for the conduct of the business of the company and also stated that all the accused are responsible for the day-to-day activities, marketing, selling and getting business profit by selling and marketing of not of standard quality drug. The above said averments are prima facie show the day to day affairs of the company and the contention of the petitioners that whether they actively participated in the day to day affairs of the company has to be decided through trial and not at this stage.

7. The ground raised by the petitioner is that in the complaint, the respondent by relying on Section 34 of the Drugs and Cosmetics Act made the Directors of the company vicariously liable is totally silent in respect of the role of the petitioners in the M/s.Minopharm Laboratories Pvt. Ltd., Further, the learned counsel appearing for the petitioners has relied upon the following judgments:

(i) ***State of Haryana vs. Brijlal Mittal reported in (1998) 5 SCC 343***

(ii) Medipol Pharmaceuticals India Pvt. Ltd., and another vs. State of Gujarat.

(iii) Ramprakash Gulati A.N. Gulati and Ors vs. State of Maharashtra reported in 2018(1) Bom CR (Cri) 112.

(iv) Rajesh Kumar and another vs. Drug Inspector Kishtwar reported in 2017 SCC Online Jammu & Kashmir 471.

8. On perusal of the above said judgments, it is clear that simply because a person is a Director, it does not necessarily mean that he fulfills both the requirements and at the material time, he was incharge and was also responsible to the company for the conduct of its business to make him liable. If the director, Manager, Secretary or any other officer of the company is shown to be an accused in the complaint, it is obligatory on the part of the complainant to show that the offence is committed with the consent or connivance. Merely because that a person is director is not self sufficient to establish that the offence is committed

with his consent or connivance in the absence of basic pleading in that behalf.

9. In the case on hand, in the complaint, there are pleadings in respect of the day to day affairs of the company, marketing, selling and getting business profit by selling and marketing of not of standard quality drug. Moreover, as per complaint, apart from lab report, other procedural violations were also found during the joint inspection and those violations are to be tested through trial and not at this stage. Therefore, it is to be decided before the trial Court and the same cannot be decided under Section 482 of Criminal Procedure Code. Therefore, the said case laws will not be applicable to the present facts of the case.

10. Yet another contention raised by the learned counsel appearing for the petitioner is that as per the Central Government order dated 02.12.2017, the lab has to conduct the test within 60 days from the date of receipt of the samples. But in this case, the test was not conducted within 60 days from the date of receipt of samples by the lab

authorities. Therefore, the complaint has to be quashed.

11. This Court perused the entire records. In this case, the 1st sample was sent to the lab on 02.12.2016 and the second sample was sent to the lab on 31.01.2017. The Central Government Order is dated 02.12.2017. Therefore, the sample drugs involved in this case were sent to the lab for analysis prior to the date of the Central Government order. Therefore, the applicability of the Central Government Order to this case is also to be decided after full trial. Further the question that whether the said government order is mandatory or not has to be decided after trial. The lab authorities have to be given opportunity to explain about the delay in testing the samples and without giving opportunity to the lab authorities to explain the delay, it is not appropriate to decide the case at this stage without any evidence. Therefore, the petitioner is at liberty to agitate all the grounds raised in this petition as defence in the trial Court.

12. In view of the above discussions, this Court is of the opinion that this petition has no merits and deserves to be dismissed.

13. Accordingly, the criminal original petition is dismissed. No costs. Consequently, the connected miscellaneous petitions are closed.

14. At the time of pronouncing orders and before signing, the learned counsel appearing for the petitioner requested this Court to dispense with the personal appearance of the petitioner before the trial Court. Considering the facts and circumstances of the case, the request of the learned counsel appearing for the petitioner is accepted and the personal appearance of the petitioner before the trial Court is dispensed and it is for the learned trial Judge to decide the appearance of the petitioner as and when required for adjudication during the trial proceedings.

21.12.2024

index: Yes/No
Internet: Yes/No
Speaking/Non Speaking order
mjs

P.DHANABAL,J
mjs

To

1. The X Metropolitan Magistrate Court, Egmore, Chennai.
2. The Public Prosecutor, High Court, Madras.
3. Union of India
represented by its Drugs Inspector,
office of the Deputy Drugs Controller (India),
Central Drugs Standard Control Organization,
South Zone, 2nd Floor, Shastri Bhawan Annex,
Chennai-600 006.

CRL. O. P. No.7288 of 2022

21.12.2024