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.7281 of 2022
and
Crl. M.P. Nos.4161, 4162 of 2022 and 12032 of 2024

1. K. Anil Kumar Karusala S/o. K. Tata Rao
2. K. Aruna W/o. K. Tata Rao
3. Vijetha Gorrepati W/o. K. Anil Kumar…Petitioners / Accused 2 to 4

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.1095 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.1095 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 and 4th accused are the Directors and the 5th accused is the Chief Operating Officer of the said company. On 30.05.2017, the authorities conducted an investigation at Government Hospital for Women and Children, Egmore, Chennai and drawn the samples under section 23 of the Drugs and Cosmetics Act of Erythromycin Stearate Tablets IP 250 mg, Batch

No.ES-1602, 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 30.05.2017, they sent samples for the chemical analysis through Form-18 and on 17.11.2017, 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'. 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 Hospital replied that they procured medicine from the Tamil Nadu Medical Services Corporation Ltd., K.K. Nagar, Chennai. Thereafter, a letter dated 05.12.2017 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 03.11.2016. Thereafter on 18.12.2017, 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 29.01.2018 was also sent. But no reply was received from the 1st accused company. Thereafter, they received a mail dated 23.03.2018 from the DDC (I), CDSCO, Hyderabad Zone along with the joint investigation report of M/s. Minopharm Laboratories Pvt Ltd., and reported that the manufacturer M/s. Minopharm Laboratories has changed the name of the firm to M/s. Revat Laboratories Pvt. Ltd., and holding the license in the changed name of the firm from 21.04.2017 and not manufactured as per the Master formula and the master formula record was not signed either by prepared or verified by or approved personnel, not carried out the production activities as per the required timing during granulation, drying, moisture content etc., which are the critical steps in the manufacturing of the product. Thereafter, prosecution permission was obtained on 06.11.2019. 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.1095 of 2020. 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 30.05.2017, the respondent Drugs Inspector visited the premises of Medical Stores, Government Hospital for Women and Children, Egmore, Chennai and drawn the samples of Erythromycin Stearate tablets IP 250 mg, Batch No.ES-1602, 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., M/s. Revat Laboratories Private Limited is a

company manufactured quality drugs in accordance with license procured by the company from the competent authorities. The company has manufactured Erythoromycin Stearate Tablets IP 250 mg as one among the many other drugs. In the complaint, there are allegations that on 18.12.2017, 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. Thereafter, 'stop production order' was issued by the concerned authorities through an order dated 26.02.2016 and 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 counsel 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 30.05.2017, 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-1602, date of manufacture - 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 18.13% 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 letter stating that if he is intend to adduce evidence in contravention of report of Government Analyst under Section 25(3) in writing within 28 days from the date of receipt of the letter. A reminder was also sent on 29.01.2018, but no reply was received from the 1st accused company.

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 Notice was issued to the 1st accused company and the license was also cancelled. 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 these petitioners 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, Secretar7 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 that violations are to be tested through trial, 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. As per the complaint,

the Drug Inspector and others have inspected on 30.05.2017 and drawn the samples and the said samples were sent for chemical analysis on the same day i.e., on 30.05.2017. The test report was received by the authorities in Form-13 on 17.11.2017 i.e., for more than 5 1/2 months delay and as rightly contended by the learned counsel appearing for the petitioner, the test has not been conducted within 60 days. However, 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 petitioners are 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 petitioners requested this Court to dispense with the personal appearance of the petitioners before the trial Court. Considering the facts and circumstances of the case, the request of the learned counsel appearing for the petitioners is accepted and the personal appearance of the petitioners before the trial Court is dispensed and it is for the learned trial Judge to decide the appearance of the petitioners as and when required for adjudication during the trial proceedings.

21.12.2024

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

P.DHANABAL,J
mjs

CRL O.P. No.7281 of 2022

21.12.2024