123 IN THE HIGH COURT OF PUNJAB AND HARYANA AT CHANDIGARH

CRM-M-58313-2023
Reserved on: 30.01.2024
Pronounced on: 22.02.2024

M/s Zee Laboratories Ltd. and others ....Petitioners

Versus

Union of India (represented by Drugs Inspector,
Central Drugs Standard Control Organisation,
Ministry of Health and Family Welfare) ...Respondent

CORAM: HON'BLE MR. JUSTICE HARPREET SINGH BRAR

Present: Mr. Akshay Jain, Advocate
for the petitioners.

Ms. Divya Sharma, Senior Panel Counsel, UOI
for the respondent.

HARPREET SINGH BRAR, J.

1. The petitioners have approached this Court by the filing present petition under Section 482 of the Code of Criminal Procedure seeking quashing of criminal complaint bearing no. 06 dated 22.08.2023 titled as ***'Union of India v. M/s Zee Laboratories and Ors.'*** filed under Section 18(a)(i) and 18(a)(vi) of the Drugs and Cosmetics Act, 1940 (hereinafter 'the Act') pending in the Court of learned Additional Sessions Judge, SAS Nagar and all subsequent proceedings arising therefrom.

FACTUAL BACKGROUND

2. The brief facts of the present case are that the respondent-complainant which is being represented by the Drug Inspector, Central Drug Standard Control Organisation, India (CDSCO), duly appointed under the Act

has brought the present complaint before the learned Additional Sessions Judge, SAS Nagar. The respondent is empowered under Section 21 of the Act to institute such complaints. Petitioner no. 1- accused is a firm (hereinafter 'the firm') i.e., 'Zee Laboratories' Ltd.' licenced by the Licencing Authority to manufacture and produce various drugs and medicines. The licence of the firm has been issued up till 25.02.2025. Petitioner no.2-co-accused is the Managing Director of the firm, while petitioners 3 to 5 are the Directors of the said firm, responsible for its net profit and losses. The petitioner no. 6 was the Technical Director-cum-Person In-charge of manufacturing the alleged deficient drugs in question. Lastly, petitioner no. 7 was responsible for overseeing and implementing quality control as well as testing the drugs manufactured by the firm before their release in the market.

3. A sample of Atenolol and Amlodipine tablets (50 mg and 5 mg respectively, bearing Batch no. Z20-660, month of manufacture: May 2020, and month of expiry: April 2022) manufactured by the firm, was drawn by Mr. Sanjay Kumar Agrawal, the then Drug Inspector deputed at CDSCO, sub-zone Baddi, on 10.09.2021, to test and analyse the same, as per Sections 22 and 23 of the Act. The said drugs were obtained from the premises of Ms. Veenu Kumari Singh, Proprietor of M/s Janaushadhi Kendra, Dera Bassi, Punjab, along with two other samples, details of which were filled out in Form-17 of the Act.

4. As per the procedure prescribed in Section 23 of the Act, the samples of drugs obtained by the Drug Inspector were divided into four equal portions which were sealed and marked with brass seal and wax, in presence of Ms. Veenu Kumari. All the samples were duly signed by both the Drug Inspector and the Ms. Veenu Kumari. Further, the receipt on Form 17-A and a

copy each of Form 17 and 17-A were handed over to Ms. Veenu Kumari, Proprietor of M/s Janaushadhi Kendra, Dera Bassi, Punjab.

5. In compliance with Section 23 of the Act, one portion of the sample (LS/SA/BDI/2021/223) was sent to the Government Analyst, Regional Drug Testing Laboratory, Sector 39-C, Chandigarh on 10.09.2021. The said sample (LS/SA/BDI/2021/223) was declared as "Not of Standard Quality" by the Government Analyst vide Test Report bearing no. LSD/RDTL/0583/21-22 dated 15.11.2011 under Form 13 for the reason that the "sample does not conform to claim as per Patent and Proprietary in respect of Assay of Amlodipine Besilate calculated as Amlodipine found 75.40% against the limit of 90.10%".

6. Thereafter a copy of the report was delivered to Ms. Veenu Kumari, Proprietor of M/s Janaushadhi Kendra, Dera Bassi, Punjab, as per Section 25(2) of the Act, and a link from the Janaushadhi Kendra to the firm was established. Once the chain was established and it was discovered that the firm is the manufacturer of the drugs under scrutiny, a copy of the Test Report and one portion of the sealed sample were supplied to it. Two letters were sent to the firm to give it a chance to challenge the Report under Sections 25(4) and 25(5) of the Act, however, the firm chose not to challenge the Test Report of the Government Analyst.

7. On 01.02.2022, a joint investigation was conducted by the officer of the CDSCO, sub-zone, Baddi along with the State Licensing Authority, Himachal Pradesh, into the manufacturing practices of the firm at the firm's facility, on the basis of which appropriate action as per the provisions of the Act was recommended. Hence, the impugned complaint before the learned Additional Sessions Judge, SAS Nagar.

CONTENTIONS

8. Learned counsel for the petitioners contends that the complaint was filed after expiry of the shelf life of the drug, which is not maintainable in terms of **Medicamen Biotech Ltd. v. Drug Inspector (2008) 7 SCC 196**. Further, the Drug Inspector is appointed by the Central Government who is not competent to draw samples and file a compliant in view of Chapter IV of the Act. Learned counsel relies upon the affidavit dated 03.05.2019 (Annexure P-17) filed by the Deputy Drug Controller (I), CDSCO, Baddi, Ministry of Health and Family Welfare to contend that the Central Government exercises regulatory control over imported drugs in terms of Chapter III of the Act, whereas manufacture, sale and distribution of drugs are regulated by the Licensing Authorities appointed by the State Government. A bare reading of Articles 73, 172 and 256 of the Constitution of India which deals with administration of executive functions between Union and State, along with Chapter III and IV of the Act would indicate that the power to file the instant complaint rests solely with the State government and not the respondent. Moreover, the alleged offence was triable by the Court of Judicial Magistrate Ist Class, however the instant complaint has been directly filed before the Court of Sessions. Finally, no specific averments have been made to invoke vicarious liability against the petitioners.

9. *Per contra*, learned standing counsel for the Union of India submits that on 10.09.2021 a sample of tablets of Atenolol and Amplodipine (50/5 mg), which belongs to a class of anti-hypertensive medication primarily used to treat hypertension, were drawn by Drug Inspector for testing and analysis in accordance with the provisions of Sections 22 and 23 of the Act. A portion of the sample was sent to the Government Analyst Regional Drug

Testing Laboratory, Chandigarh on 10.09.2021 itself. Petitioner no. 1 was asked to provide a method of analysis of the said drug vide letter dated 10.11.2021. However, petitioner no. 1 provided the information vide letter dated 26.11.2021 which was after receiving the report of the Government Analyst dated 15.11.2021, which was duly supplied to them vide letter dated 17.12.2021 along with a portion of the sealed sample. Thereafter, petitioner no. 1, vide letter dated 11.01.2022, informed the respondent that the in-house test results were contradictory to that of the Government Analyst. In view of the same, the respondent gave the petitioners an opportunity to challenge the report of the Government Analyst vide letter dated 13.01.2022, however, the petitioners refused the same vide letter dated 14.01.2022 specifically stating that they have no intention for doing the same.

10. Further, learned counsel submits that the Durg Inspector was duly appointed in accordance with Gazette Notification F. No. A. 12025/03/2012-D dated 30.08.2013 under Section 21 of the Act and therefore, he was authorised to seize sub-standard drugs and lodge the complaint after carrying out the said activities in Derabassi, SAS Nagar on 10.09.2021. Moreover, Section 32 of the Act categorically provides that offences punishable under this Chapter shall not be triable by a court inferior to the Court of Sessions and as such, the respondent has committed no irregularity by filing the instant complaint before learned Additional Sessions Judge, SAS Nagar, which is further affirmed by Section 36-AB of the Act and notification No. S.O. 45/C.A.23/1940/S.36AB/2011 dated 26.05.2011 issued by the Governor of Punjab.

OBSERVATIONS AND ANALYSIS

11. Having heard the learned counsel for the parties and perusing the record of the case, it transpires that the respondent-Drug Inspector was appointed under Section 21 of the Act by the Central Government. On 10.09.2021, the respondent inspected the premises of Janaushadhi Kendra, Derabassi and drew samples of Atenolol(50 mg) and Amoldipine (5mg) bearing batch no. Z-20-660 manufacturing dated May 2020 and expiry dated April 2022.

12. The argument of the petitioners regarding incompetence of the respondent to filed the instant complaint cannot be accepted as the authority of the Central Government cannot be ousted since the affidavit dated 03.05.2019 (Annexure P-17) relied upon by the petitioner clearly states that as far as a new drug is concerned, the application is required to obtain permission from the Licensing Authority appointed by the Central Government in view of Rule 21(b) and Rule 68A of the Drugs and Cosmetics Rules, 1945. Moreover, in view of Gazette Notification F. No. A. 12025/03/2012-D dated 30.08.2013 with respect to Section 21 of the Act and the fact that the respondent was a duly appointed Drug Inspector, CDSCO for the Sub Zone of Baddi, Himachal Pradesh, the argument regarding distribution of executive functions under Articles 73, 172 and 256 is liable to be rejected. Section 21 of the Act reads as follows:

> ***"Section 21. Inspectors***.—
>
> *(1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or State Government, as the case may be.*

> *(2) The powers which may be exercised by an Inspector and the duties which may be performed by him, the drugs or 9 [classes of drugs or cosmetics or classes of cosmetics] in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.*
> *(3) No person who has any financial interest 1 [in the import, manufacture or sale of drugs or cosmetics] shall be appointed to be an Inspector under this section.*
> *(4) Every Inspector shall be deemed to be public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860), and shall be officially subordinate to such authority 2 [having the prescribed qualifications,] as the Government appointing him may specify in this behalf.]"*

Furthermore, validity of the Gazette notification cannot be examined by this Court under Section 482 of the Cr.P.C. As such, the respondent was competent to conducted the seizure on 10.09.2021 and lodge a complaint in pursuance of the same.

13. Further, the petitioners given the opportunity to challenge the Government Analyst Test Report bearing no. LSD/RDTL/0583/21-22 dated 15.11.2011, under Sections 25(4) and 25(5) of the Act vide letter dated 13.01.2022 and again within 14 days. However, vide letter dated 14.01.2022, the petitioners specifically stated that they do not intend to challenge the same. Moreover, as far as the argument regarding expiry of shelf life is concerned, since the petitioners had accepted the report of the Government Analyst dated 15.11.2021 and categorically stated their intention not to challenge it in spite of two opportunities to do the same, they cannot be allowed to take shelter of the complaint being lodged at a belated stage. Reliance in this regard can be placed on the judgment rendered by a two Judge bench of the Hon'ble Supreme Court in **Glaxo Smith Kline Pharmaceuticals Ltd. And another v. State of**

Madhya Pradesh 2011(3)R.C.R.(Criminal) 736, wherein speaking through Justice B.S. Chauhan, the following was observed:

> *"8. In view of the fact that the appellants did not express an intention to adduce evidence to controvert the analyst report within the statutory limitation period of 28 days, further delay in filing the complaint becomes immaterial. Even otherwise, expiry date of the medicine was March 1998 i.e. only after 4 months of submission of the reply by the appellants, and they did not fulfill their burden of expressing intention to adduce evidence in contravention of the report. Therefore, they cannot raise the grievance that the complaint had been lodged at a much belated stage. So far as the application of I.P. 1985 or I.P. 1996 is concerned, such an issue can be agitated at the time of trial.*
>
> *xxx xxx xxx*
>
> *10. We agree with Ms. Makhija that the case is squarely covered by the judgment of this Court in* ***State of Haryana v. Brij Lal Mittal & Ors., 1998(2) RCR (Criminal) 608 : (1998)5 SCC 343*** *wherein this Court has held as under :*
>
> > *"....Sub-section (4) also makes it abundantly clear that the right to get the sample tested by the Central Government Laboratory (so as to make its report override the report of the Analyst) through the court accrues to a person accused in the case only if he had earlier notified in accordance with sub-section (3) his intention of adducing evidence in controversion of the report of the Government Analyst. To put it differently, unless requirement of sub-section (3) is complied with by the person concerned he cannot avail of his right under sub-section (4)."*
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> *In the said case, like the present case, the manufacturer did not notify the Inspector within the prescribed period that he intended to adduce evidence in contravention of the report. Also, akin to the case at hand, the manufacturer's right under section (3) of Section 25 expired few months before expiry of shelf life. Holding for the directors of the manufacturing company on different grounds, the court opined that the right to get drugs tested by Central Drugs Laboratory does not arise unless requirement of sub-section (3) is complied with."*

14. The argument of the petitioner that the alleged offence was not triable by the learned Additional Sessions Judge, SAS Nagar, is also unfounded as Section 32(2) of the Act specifically states that no court inferior to that of Court of Sessions shall take cognizance of an offence committed under this Chapter. Section 32 of the Act reads as follows:

> ***"32. Cognizance of offence.—***
> *(1) No prosecution under this Chapter shall be instituted except by*

> *(a) an Inspector, or*
> *(b) any gazetted Officer of the Central Government or a State Government authorized in writing in this behalf by the Central Government or a State Government by a general or special order made in this behalf by that Government; or*
> *(c) the person aggrieved; or*
> *(d) a recognised consumer association whether such person is a member of that association or not.*
>
> *(2) Save as otherwise provided in this Act,* ***no court inferior to that of a Court of Sessions shall try an offence punishable under this Chapter.***
>
> *(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence against this Chapter."*

Further, in view of Section 36-AB of the Act, notification No. S.O. 45/C.A.23/1940/S.36AB/2011 dated 26.05.2011 was issued by the Governor of Punjab whereby Court of Additional Sessions Judge was was allowed to try offences relating to adulterated drugs.

15. Finally, establishment of vicarious liability is a matter of evidence which can't be delved into by this Court. A two Judge bench of the Hon'ble Supreme Court in **HMT Watches Limited vs M.A. Abida (2015) 11 SCC 776** has held that inherent powers under Section 482 of the Cr.P.C. cannot be extended to determining disputed question of facts. It is only for the trial Court to determine the disputed questions of fact after examining the evidence on record and interference by this Court with regards to factual questions is impermissible in law.

16. A two Judge bench of the Hon'ble Supreme Court in **Rathish Babu Unnikrishnan Vs. State (Govt. of NCT) 2022 SCC Online SC 513,** speaking through Justice Hrishikesh Roy, observed as under:

> *"17. The consequences of scuttling the criminal process at a pre-trial stage can be grave and irreparable. Quashing proceedings at preliminary stages will result in finality without the parties having had an opportunity to adduce evidence and the consequence then is that the proper forum i.e., the trial Court is ousted from weighing the material*

evidence. If this is allowed, the accused may be given an un-merited advantage in the criminal process. Also because of the legal presumption, when the cheque and the signature are not disputed by the appellant, the balance of convenience at this stage is in favour of the complainant/prosecution, as the accused will have due opportunity to adduce defence evidence during the trial, to rebut the presumption."

CONCLUSION

17. In view of the discussion above, the present petition stands dismissed.

18. Pending miscellaneous application(s), if any, shall also stand disposed of.

(HARPREET SINGH BRAR)
JUDGE

22.02.2024
Neha

Whether speaking/reasoned : Yes/No
Whether reportable : Yes/No