IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 06.11.2024

CORAM

THE HONOURABLE MRS.JUSTICE T.V.THAMILSELVI

Crl.O.P.No.4629 of 2022
and
Crl.M.P.No.2400 of 2022

1.M/s.Ajanta Pharma Ltd.,
Represented by its Directors
Central Ware House- Domestic
Gut No.378, Plot No.9, 10 & 11 Km Stone,
Aurangabad - Oune High Way, Village - Walul (BK)
Tal - Ganagapur, Aurangabad, Maharashtra - 431 133.

2.Madhusudhan
3.Purushottam Agarwal ... Petitioners 3, 4 & 5

Vs.

The Union of India,
Represented by the Drugs Inspector
Office of the Deputy Drugs Controller (India)
Central Drugs Standard Control Organization,
South Zone, 2nd Floor,
Shastri Bhawan Annex, Nungambakkam,
Chennai-600 006. ... Respondent

Prayer: Criminal Original Petition filed under Section 482 of Cr.P.C., praying to call for the records relating to the proceedings in C.C.No.2 of

2021 on the file of the Principal and District Judge, Puducherry, based on the private complaint of the respondent dated 26.03.2021, in so far as it relates to the petitioners and quash the same.

For P1 : Mr.P.S.Raman, Senior Counsel
for Mr.T.D.Selvan Babu
For P2 & P3 : Ms.AL.Gandhimathi, Senior Counsel
for Ms.M.Meenarukmani
For Respondent : Mr.N.Ramesh,
Senior Panel Counsel (Govt. of India).

O R D E R

This petition has been filed to quash C.C. No. 2 of 2021 on the file of the Principal District Judge, Puducherry, where cognizance was taken for the alleged offence punishable under Section 27(d) of the Drugs and Cosmetics Act, 1940 ("the Act") based on a complaint given by the respondent under Section 200 of the Cr.P.C. The complaint alleges commission of offences under Section 18(c), punishable under Section 27(b)(iii), and Section 18(b), punishable under Sections 27(b)(ii) and 27(d) of the Act. The complaint is against M/s. Safetab Life Sciences (A1), Mrs. R. Meenakshi, Managing Partner of M/s. Safetab Life Sciences (A2), along with two other persons who are petitioners ranked as A3 to A5.

2. The petitioners / A3 to A5 have filed this petition to quash the proceedings in C.C. No. 2 of 2021 pending before the Principal District Judge, Puducherry.

3. A1, M/s. Safetab Life Sciences, is a Public Limited Multinational Company, registered under the Companies Act, 1956, and operates in India as well as over 30 other countries. The second and third petitioners are members of the Board of Directors of the first petitioner company.

4. The prosecution's case is that, on 06.07.2018, the Drugs Controller General (India) (DCGI), Central Drugs Standard Control Organization (CDSCO), directed an investigation into an unapproved drug: the Fixed Dose Combination of Voglibose and Repaglinide, reportedly manufactured in and around Chennai. Subsequently, officials were deputed for this purpose. A joint investigation between officials from CDSCO-HQ, CDSCO-South Zone, Chennai, was conducted at the premises of the first accused company, M/s. Safetab Life Sciences, on 09.07.2018 and 10.07.2018.

5. During the investigation, it was found that the first accused company, despite requests, allegedly failed to produce a product endorsement for manufacturing the Fixed Dose Combination of Voglibose and Repaglinide tablets (referred to as "Volga-R Tablets") as required by Conditions No. 1 and 3 of the Form 25 License, as well as other manufacturing-related documents. The inspection allegedly revealed that all six Volga-R batches manufactured by the first accused company were sold under invoices to the first petitioner company.

6. According to the respondent, the State Licensing Authority, Puducherry, in a letter dated 10.07.2018, stated that permission for the Volga-R tablets had not been granted as of the renewal date, 23.03.2017, for the first accused. Since the first accused company could not produce manufacturing permission for the product, they were allegedly in violation of Section 18(c) of the Act. Following this, various records and materials were seized under Section 22(1)(cc) of the Act and submitted to the learned Principal District and Sessions Judge for safe custody as per the Act.

7. On 16.07.2018, the Deputy Drugs Controller (I), CDSCO, South

Zone, requested the CDSCO West Zone, Mumbai, to take further action against the first petitioner company and asked the State Licensing Authority, Puducherry, to recall the Volga-R tablets that had been sold to the first petitioner company. Consequently, the State Licensing Authority directed the first accused company to recall the tablets sold to the first petitioner company. The Drugs Inspector from CDSCO West Zone, Mumbai, conducted a joint inspection at the central warehouse of the first petitioner company and found various strengths of Volga-R tablets available for sale and distribution under Form 20B issued by the State Licensing Authority, Maharashtra.

8. Subsequently, show-cause notices were issued to the directors of the first accused company and the directors (petitioners 2 and 3) of the first petitioner company. However, instead of a direct response from the petitioners, a reply was sent on 04.10.2018 by the AVP-Legal & Company Secretary of the first petitioner company, stating that the drugs in question were purchased under valid Form 20B and Form 21B licenses issued by the State Licensing Authority, Maharashtra, and marketed within the country. As per Condition 3(i) of the Form 20-B license, no drug should be sold

unless purchased under a cash or credit memo from a licensed dealer or manufacturer. The first petitioner company allegedly violated this condition by, in collusion with the first accused, purchasing and marketing the unlicensed drug within the country.

9. The second and third petitioners were directors of the first petitioner company on the date of the sale and distribution of the unlicensed Volga-R tablets. Based on these findings, the current complaint was lodged.

10. The learned counsel for the petitioners submitted that their implication in the present complaint is entirely unsustainable, and they have not acted in contravention of the law in force. The 1st petitioner company is a large multinational organization with operations worldwide and is known for responsibly undertaking strict compliance with the law in its business transactions. The 1st petitioner company has lawfully procured the drugs and marketed them only under a valid license. Therefore, the entire prosecution against the petitioners is illegal and liable to be quashed, based on the following grounds:

"i). Admittedly, the 1st petitioner company has obtained a valid

licence under Form 20B and Form 21B issued by the State Licensing Authority, Maharashtra on the basis of the information provided by the manufacturer for the marketing of the drug Volga-R and therefore, the alleged actus reus of 1st petitioner compnay is entirely lawful.

ii). The allegation that the 1st petitioner company violated condition No.3(i) of the Form 20B licence which requires that no drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licenced dealer or a manufacturer is baseless and is made without an impartial and a proper enquiry. The 1st petitioner company has adhered to due compliance while procuring the said drug from the manufacturer, in the manner prescribed by law and under the representation from the manufacturer that the drug is approved and is validly licensed. As such, the 1st petitioner company has not contravened the law and no prosecution against the company or its representatives can be lawfully sustained under the Act.

iii). The main allegation in the complaint that the 1st petitioner comapny had manufactured and marketed the drug Volga-R, in connivance with the manufacturer 1st accused company is vague, presumptuous and is not supported with a single piece of oral or documentary evidence despite two years of investigation. In the absence of material to establish such an alleged conspiracy between the 1st petitioner company and the 1st accused manufacturer company, a prosecution cannot be allowed to proceed on the

basis of a mere presumption.

iv). In any case, assuming without admitting such a conspiracy existed in the circumstances of the complaint, there is no material to justify the prosecution of the 2nd and 3rd petitioners.

v). The complaint and the evidence miserably fail to make out a case against the 2nd and 3rd petitioners. The '2nd and 3rd petitioners were not in charge of the day to day affairs of the 1st petitioner company. The complaint and the evidence produced is bereft of any specific allegation to attribute any overt act on part of the 2nd and 3rd petitioner, in their capacity as Directors is even present in the complaint and therefore their prosecution is not sustainable under Section 34 of the Act thereby calling for threshold interference by this Court to quash the proceedings under Section 482 of Cr.P.C.

vi). The prosecution of the petitioners, fails to serve any remotely fruitful purpose especially in light of the report dated 19.10.2018 of the Government Analyst who has certified that the Drug Volga-R is a drug of standard quality.

vii). In any view of the matter, the prosecution is illegitimate and is liable to be quashed."

11. To support his contention the learned counsel for the petitioners

relied on the proportion laid down in the following cases.

(i) Order of this Court, in the case of M/s.Lupin Limited vs. State Rep. by on 23 January, 2018, in which it was stated as follows:

> *" 6. I am unable to comprehend as to how such an averment made in the complaint can be maintainable, in view of the specific provisions under Section 19(3) of the said Act. As observed earlier, the petitioners herein possess valid license for drug distribution and purchased the drugs through a valid invoices. there is no material before the respondent herein evidencing that the petitioners herein were either the manufacturer or the agent of the manufacturer. A mere statement in the complaint that the first petitioner was the agent may not be sufficient to implicate the petitioners herein for contravention of the provision of the Drugs and Cosmetics Act.*

(ii) ***Order of this Court, reported in 2020 SCC online Mad 4666,*** in the case of ***M.Sujatha Vs. State of Tamil Nadu Represented by Drugs Inspector,*** in which it was stated as follows:

> *"8. Point for consideration is that whether the petitioner can be rescued from prosecution under Section 19(3)(a) of the drugs and Cosmetics act, 1940. It is relevant to extract the provision under Section 19(3) of the said Act as follows:*
>
> *"19(3) A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of Section 18 if he proves-*
>
> *(a) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer*

> *thereof;*
> *(b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that Section; and*
> *(c) that the drug or cosmetic, while in his possession was properly stored and remained in the same state as when he acquired it."*
>
> *9. The provision says that the manufacturer alone is liable for prosecution and the retailer ought not to have been prosecuted under the provision under Section 19(3)(a) of the Drugs and Cosmetics Act. admittedly the petitioner had purchased the subject drug from the licensed distributor, namely the second accused herein under valid invoice dated 09.10.2017 / 26.02.2017. Invoice, copy of the bill, purchased written bill, have been produced by the petitioner to the respondent herein."*

12. In response, the learned Senior Panel counsel (Govt. of India) submitted that on the 9th and 10th of July, 2018, a Joint Investigation was conducted at the premises of M/s. Safetab Life Sciences at Plot No. A67 & A68, PIPDC, Electronic Park, Thirubuvanai, Puducherry-605107. At that time, the 1st accused was represented by its Managing Partner, 2nd accused, namely Mrs. R. Menakshi. The investigation team found the batch manufacturing records, control samples, and printed primary and secondary packing materials used for manufacturing Volga-R tablets, as well as sales

invoices for batch numbers S17010130K, S17010131K, S180130C, S180131D, and S180230D, which represented various strengths of the fixed-dose combination of Voglibose and Repaglinide tablets (Volga-R tablets). Purchase invoices and Repaglinide, the pharmaceutical substance used for manufacturing Volga-R tablets, were also found on the manufacturing premises of the 1st accused.

13. Accordingly, all six batches of Volga-R tablets (S17010130K, S17010131K, S180130C, S180131D, and S180230D) were manufactured by the 1st accused company and sold via invoice numbers SLS/1718/519, SLS/1718/534, SLS/1718/520, SLS/1819/16, SLS/1819/106, and SLS/1819/153 to the 1st petitioner, M/s. Ajanta Pharma Ltd.

14. During the investigation, the 1st accused failed to provide the product endorsement for manufacturing the fixed-dose combination of Voglibose and Repaglinide tablets (Volga-R tablets) as required by Condition Nos. 1 and 3 of the Form 25 license. Furthermore, as per information submitted by the State Licensing Authority, Puducherry, no product permission for Voglibose and Repaglinide tablets (Volga-R tablets) was granted at the time of renewal dated 23.03.2017 for M/s. Safetab Life

Sciences (1st accused), indicating that the 1st accused did not hold a valid license for the manufacture of Voglibose and Repaglinide tablets. This action contravened the principles laid down under Section 18(c) and is punishable under Section 27(b)(ii) of the Drugs and Cosmetics Act, 1940. The seized materials were produced before the learned Principal District and Sessions Judge, Puducherry.

15. The learned Senior Panel Counsel (Government of India) further submitted that on the 16th of July, 2018, a Drug Inspector from the CDSCO, West Zone, Mumbai, conducted a Joint Investigation at M/s. Ajanta Pharma Ltd., the 1st petitioner. Various strengths of Volga-R tablets bearing batch numbers S17010130K, S17010131K, S180130C, S180131D, and S180230D were found to have been purchased from the 1st accused, M/s. Safetab Life Sciences, Puducherry, and distributed to various parts of the country for sale or distribution under Form 20B issued by the State Licensing Authority, Maharashtra.

16. The Senior Panel Counsel pointed out that according to Condition 3(i) of the Form 20B license, no drug shall be sold unless it is purchased

under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer. However, in the present case, the 1st petitioner procured various strengths of Volga-R tablets from M/s. Safetab Life Sciences, Puducherry (the 1st accused), which did not have a valid license to manufacture and sell such drugs. By doing so, the 1st petitioner violated Condition No. 3(i) of the Form 20B license. He further noted that the agreement made with the 1st accused for the exclusive manufacturing and supply of Volga-R tablets to the 1st petitioner (M/s. Ajanta Pharma Ltd.) included supplying the active raw material, Repaglinide, to the 1st accused, M/s. Safetab Life Sciences, which lacked a valid manufacturing license to produce drugs containing Repaglinide.

17. The learned Senior Panel Counsel submitted that the petition is not maintainable because the petitioners have committed an offense by failing to procure the drug Volga-R, a Fixed Dose Combination (FDC) of Metformin and Repaglinide, from a duly licensed manufacturer. Furthermore, they did not exercise reasonable diligence to ascertain whether the drug contravened any provisions under Section 18 of the Drugs and Cosmetics Act, 1940. The petitioners supplied the active raw material,

Repaglinide, to the 1st accused, M/s Safetab Lifescience, for manufacturing Volga-R and entered into an agreement with them to distribute the drug.

18. Upon reviewing the submissions from both sides, it is evident that the 1st accused, M/s Safetab Lifescience, Puducherry, was engaged in the manufacturing of Volga-R tablets without a valid license at the time of the alleged search on 9th and 10th July 2018. The unapproved drugs were also purchased by the 1st petitioner via invoice. At the time of the alleged purchase by the 1st petitioner, no authorization had been granted to manufacture the Volga-R tablets, and the license had not been verified as genuine on 23.03.2017. Therefore, the 1st accused did not hold a valid license to manufacture Volga-R tablets, which is a contravention of Section 18(c) of the Drugs and Cosmetics Act, 1940, punishable under Section 27(b)(ii).

19. Moreover, the Senior Panel Counsel (Government of India) submitted that M/s Ajanta Pharma Ltd. / 1st petitioner had entered into an agreement with the 1st accused, M/s Safetab Lifescience, for the exclusive manufacturing and supply of Volga-R tablets. They also supplied the active raw material to the 1st accused, who lacked the manufacturing license

required to produce these tablets.

20. The learned counsel for the petitioners argued that a license had initially been granted to the 1st accused on 02.03.2007, with the product list, including Volga-R tablets. This license was renewed by the Department of Drugs Control, Government of Puducherry, under Form 26, effective from 02.03.2017 to 01.03.2022. A certified copy of this renewed license, dated 23.03.2017, was submitted by the petitioners. However, as rightly noted by the Senior Panel Counsel, the product list was not attached to this renewal, indicating a lack of prima facie evidence supporting that the 1st accused's license was renewed to include permission for manufacturing Volga-R tablets during the investigation period.

21. The petitioners' counsel relied on aforesaid case laws and contended that the petitioners were not the manufacturers of the alleged drug. They merely procured the drug from the 1st accused, who lacked a valid license at the time, although the original license had permitted manufacturing. The counsel argued that the petitioners had been falsely implicated and prayed the proceedings against them be quashed.

22. The Senior Panel Counsel's submission highlights that the

petitioners not only procured Volga-R tablets from the 1st accused, who lacked a valid manufacturing license, but also supplied the raw materials to the 1st accused and had an agreement for exclusive distribution. As such, the precedent cited by the petitioners does not apply in this context. There is no evidence from the petitioners demonstrating that the 1st accused held a valid license. On the contrary, the prosecution has established that, according to the investigation, the 1st accused did not have a valid license to manufacture Volga-R tablets.

23. The petitioners, having engaged in supplying raw materials and forming an agreement with the 1st accused, were obligated to exercise due diligence in verifying whether the 1st accused was licensed to manufacture the drug. Thus, the petitioners must establish their innocence through evidence in the trial court, as mere allegations are insufficient.

24. In conclusion, I find no merit in this petition. Accordingly, this Criminal Original Petition is dismissed as devoid of merit. Considering the ages of the 2nd and 3rd petitioners, their personal appearance before the trial court is waived except when their presence is required. The trial judge

is directed to conduct the trial expeditiously, avoiding unnecessary adjournments. Consequently, the connected miscellaneous petition is closed.

06.11.2024

Index: Yes/ No
Neutral Citation: Yes/No
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To
1.The Principal and District Judge, Puducherry.
2.The Public Prosecutor, High Court of Madras.

T.V.THAMILSELVI, J.

Crl.O.P.No.4629 of 2022
and
Crl.M.P.No.2400 of 2022

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