



IN THE HIGH COURT OF JUDICATURE OF BOMBAY
BENCH AT AURANGABAD

**CIVIL APPLICATION NO. 3756 OF 2024 IN
WRIT PETITION NO. 9735 OF 2023**

Siddarth Carbochem Products Ltd. .. Applicant

versus

The Union of India & others .. Respondents

Ms. P. S. Talekar, Advocate holding for Mr. S. S. Bora, Advocate for the Applicant.

Mr. P. K. Lakhotiya, AGP for the State.

Mr. S. W. Munde, Advocate for Respondent Nos. 1 to 3.

Mr. D. S. Ladda, Advocate for Respondent No. 4.

**CORAM : RAVINDRA V. GHUGE AND
R. M. JOSHI, JJ.**

DATE : 22nd APRIL, 2024.

PER COURT : (Per Ravindra V. Ghuge, J.)

1. This Application dated 10.04.2024 is filed by the Petitioner in Writ Petition No. 9735/2023, which is decided by judgment and order dated 22.03.2024, for seeking a clarification.

2. The Applicant is seeking clarification to the extent that no NOC is required under Drugs and Cosmetics Act, 1940 (for short 'Act of 1940) for import of salicylic acid industrial/technical grade, since it is not covered under the definition of "drug" under the Act of

1940. The Applicant also asks for liberty to seek damages against the concerned persons for the loss caused in view of the high-handed action of the authorities.

3. According to the Applicant, it is a company involved in manufacturing of several chemical products including Salicylic Acid IP/BP/EP/USP as well as Methyl Salicylate, Octisalate and Homosalate and holding licenses for carrying out manufacturing activities. It is claimed that the Salicylic Acid has many variants, whereas the Salicylic Acid industrial/technical grade is laden with impurities and cannot be used for medical purposes and, therefore, it is not covered under the definition of drugs under the Act of 1940.

4. It is further canvassed that consequently, it's manufacture, sale, purchase and imports are not regulated under the said Act. It is further claimed that the communication dated 24.11.2023, received from the department under Right to Information Act, clearly indicates that the manufacturing and sale of technical and industrial grade of salicylic acid used for making APIs, is not regulated by SLA (Maharashtra FDA) since it does not fall under Section 3(b) of the Act of 1940.

5. It is also claimed that the Applicant is importing Salicylic Acid for more than 25 years and no objection certificate was ever required for the same, since this product is not classified as a Drug under the Act of 1940. It is alleged that in the recent past, more particularly, when the post of Drugs Controller General was filled in, by a person who was anti-pathetic towards the Applicant, there have been several instances of harassment of the Applicant at the hands of the authorities. The authorities have been blocking the import consignment of the Applicant under the guise of NOC under Rule 43 of the Act of 1940. As a consequence, the Applicant has faced many instances of paying hefty demurrage and detentions in this period. It is further claimed that the custom authorities have refused to clear the goods except on receipt of NOC from the Drugs Controller General and on the plea that the custom authorities have no power to waive the said requirement.

6. Though the Respondents have appeared, inspite of there being several allegations against the Drugs Controller General, except for Respondent No. 4, the other Respondents failed to file say to the Application. Pertinently, inspite of the fact that there are specific

allegations made against Drug Controller General and department, no reply has been filed to counter the same.

7. In the affidavit-in-reply, Jay Manoj Shah, the Deputy Commissioner of Customs at Jawaharlal Nehru Custom House, on merits of the case, has claimed that the Assistant Director Controller is the proper authority to issue NOC of the goods covered under the Act of 1940. As per the procedure followed by the custom authorities, in case of consignment of Salicylic Acid which has been imported by the Applicant, it is for the Assistant Director Controller to determine that the consignment is not a drug and unless the NOC is given, the consignment cannot be cleared. It is also claimed that the order passed by this Court dated 22.03.2024, is required to be complied with by the authorities under the Act of 1940 and not by Respondent No. 4 – Customs.

8. We have extensively heard the submissions made by the learned Advocates for both the sides. The learned Advocate for the Applicant makes a grievance that inspite of the order dated 22.03.2024, passed by this Court recording the statement of the Applicant herein that the Salicylic Acid imported would not be used

for manufacturing medical drugs, the authorities concerned are refusing to release the consignment of the Applicant which has resulted into causing huge losses to the Applicant. She has even drawn the attention of the Court to the instances occurred in the past in respect of arrest of the Drugs officials/authorities, by the CBI on the allegation of graft. It is claimed that a clarification is required since the authorities concerned are refusing to comply with the order of this Court.

9. The learned Advocate for the Customs, in candid terms, has stated that this department is not concerned with the controversy. However, it is not open for the Customs to clear the Applicant's consignment in the absence of NOC from the Drugs Controller i.e. the Assistant Drug Controller in the present case.

10. The learned Standing Counsel for Union of India, on instructions from an officer of the department present in the Court, opposed the Application on the ground that it is within the authority of the Central Drugs Standard Control Organization (CDSCO) to decide as to whether any particular drug is covered by the provisions of the Act of 1940, or not. It is his submission that irrespective of

any order being passed by the State Authority, it would be only the decision of this authority which would prevail. It is submitted that NOC is mandatory for the purpose of releasing the Salicylic Acid in order to ensure that the same is not used for medical purpose.

11. We had dealt with the submissions of the rival parties in details, while passing the order dated 22.03.2024. It is clearly recorded therein that the Drugs Consultative Committee and Drugs Technical Advisory Board had taken a decision in the light of Rule 43 of Drugs and Cosmetics Rules, 1945 and Schedule D and opined that the legal position is very clear and therefore, substances intended to be used as drugs after further purification or rendering them sterile, are not exempted under Rule 43 under the provisions of Chapter III of the Act of 1940 and the rules made thereunder.

12. This Court, after taking into consideration Rules 43, 43-A and 43-B of the Drugs Rules, 1945, has further taken into account the order passed by the Ministry for Food and Medical Administration, State of Maharashtra, under Rule 85(3) of the Drugs Rules, 1945 framed under the Act of 1940. The said order clearly held that the chemical imported as industrial/technical would not fall

within the definition of 'drugs' and as such, the law does not impose any condition on the Petitioner-company while importing Salicylic Acid industrial grade. The said order clearly held that the chemical imported as industrial/technical would not fall within the definition of 'drugs' and as such, law does not impose any condition on the Petitioner while importing salicylic acid industrial grade, which is not to be used for manufacture of drug.

13. In the light of these facts, the Petitioner/Applicant had made a solemn statement before this Court that the imported Salicylic Acid would be used for industrial purpose and shall not be used for manufacturing of drugs. On considering overall facts and the undertaking of Petitioner, it was held as under :-

"14. In view of the statement made by the Petitioner that the chemical would not be used for medicinal purpose, the goods/consignment of the Petitioner which is not being cleared by the authorities on account of their demand of 'No Objection' Certificate, need not be detained and deserve to be released expeditiously, by following the procedure in vogue."

14. In spite of such a specific order by this Court, the concerned authorities, more particularly, the Central Authorities

under the Act of 1940, are creating an uncalled for impediment in the release of consignment of the Applicant. We find it relevant to note that even during the hearing of this Application, the said Authority was unable to cite any provision or circular before us in order to substantiate the demand of an NOC, despite of the undertaking by the Applicant before this Court to the effect that the imported Salicylic Acid Industrial grade would not be used for manufacturing of drugs. We find that there remains no reason or justification in detaining of the consignment of the Applicant, by the concerned authorities.

15. From the affidavit-in-reply filed by Customs, it is apparent that the custom authorities are not in a position to release the consignment for want of NOC from the concerned Authorities. We are conscious of the fact that this Court always allows concerned Statutory Authorities to arrive at independent decisions. However, certain situations require passing of extra ordinary orders. More particularly, when this Court *prima facie* finds merit in the grievance made by Petitioner, against the Central Authorities under the Act, 1940, that the consignment of the Petitioner is sought to be withheld

for no justified reasons. We do not wish to add anything more in this regard, at this stage.

16. We, therefore, find it appropriate to issue the following directions :-

a) The Assistant Drugs Controller is hereby directed to issue NOC for release of the consignment (of the Applicant) of Salicylic Acid industrial/technical, within a period of 15 days from today.

b) The customs authorities shall release the consignment, forthwith.

c) The Applicant/Petitioner shall be bound by the undertaking tendered to this Court, as recorded in our order dated 22.03.2024.

17. **The Civil Application is disposed off in the above terms.**

(R. M. JOSHI)
JUDGE

(RAVINDRA V. GHUGE)
JUDGE

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