



IN THE HIGH COURT OF JUDICATURE OF BOMBAY  
BENCH AT AURANGABAD

**WRIT PETITION NO. 9735 OF 2023**

Siddarth Carbochem Products Ltd. .. Petitioner

versus

Union of India & others .. Respondents

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

Mr. P. K. Lakhotiya, AGP for Respondent Nos. 5 and 6.

Mr. B.M. Dhanure, Advocate for Respondent Nos. 1 to 4.

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

**DATE : 22<sup>nd</sup> MARCH, 2024.**

**PER COURT :**

1. On 10<sup>th</sup> August, 2023, we had passed an extensive order which reads thus :-

1. Notice in this matter was issued yesterday after the Petitioner moved a motion expressing extreme urgency and sought orders in the light of such urgency.

2. The learned Standing Counsel for the Union of India and the learned AGP are instructed to address the Court.

3. The Petitioner has put forth prayer clauses b, c, d and e as under:-

*“b. That, by issuing appropriate writ, order or direction under Article 226 of the Constitution of India, this Hon’ble Court declare that Salicylic acid (Industrial / Technical grade) and other Industrial Raw Materials meant for industrial purpose (and not for medicinal purpose) do not fall within the purview of Drug as defined in the Drugs and Cosmetics Act 1940.*

*c. Pending hearing and final disposal of the present Writ Petition, the Respondent Nos.2 and 4 be directed not to insist on NOC from the respondent No 2 or his officers for the import clearance of Salicylic Acid (Industrial / Technical grade)*

*d. That, by issuing appropriate writ, order or direction under Article 226 of the Constitution of India, the impugned Order / communication dated 28.07.2023 issued by Deputy Drugs Controller (India), Central Drugs Standard Control Organization, West Zone, Mumbai and the annexed report may kindly be quashed and set aside.*

*e. Pending hearing and final disposal of the present Writ Petition, the effect, operation and implementation of the impugned Order / communication dated 28.07.2023 issued by Deputy Drugs Controller (India), Central Drugs Standard Control Organization, West Zone, Mumbai, the annexed report and all directions therein may kindly be stayed.”*

*4. The averments sufficient for us to pass an ad-interim order are that the Petitioner is an ISO company*

*having been bestowed with ISO 9001, 14001, 45001 and 22001 certification. The Petitioner is registered under the Registration, Evaluation, Authorisation and Restriction of Chemical (REACH) for exports to the European Union. There are many other certifications received by the Company, which is registered with the USA-FDA, as a manufacturer of drugs and food facility.*

5. *The allegation against the Petitioner is that Salicylic Acid (industrial/technical) has been used by the Petitioner for manufacturing three drugs as set out in paragraphs 3(a) and 3(b). The material imported has been used for manufacture of Salicylic Acid IP/BP/EP/USP. In a surprise check, it is alleged that the Petitioner has misused the bulk drugs, which were imported for the said purpose, under Rule 43 of the Drugs and Cosmetic Rules, 1945.*

6. *The Government of India through the Deputy Drugs Controller (India), CDSCO, West Zone, Mumbai issued the communication dated 28.07.2023 to the Joint Commissioner (Nashik Division), Food and Drug Administration, Nashik, thereby, ordering initiation of action against the Petitioner. He has directed the Joint Commissioner, Nashik to get the GMP compliance of the Petitioner verified from the inspectorate staff and take action as deemed fit under the provisions of the Drugs and Cosmetic Act, 1940 such as issuance of show cause notice, stop production activity for the affected products and*

*suspension or cancellation of the product permission, etc. due to systemic failure of maintaining GMP.*

7.           *The inspection report dated 10.07.2023 of the Assistant Drugs Controller (I), CDSCO, West Zone, Mumbai, is attached to the said communication wherein, it is recommended that the State Licensing Authority (SLA) shall be informed to revisit the site to verify the GMP compliance through their inspectorate staff and to take action under the provisions of the Drugs and Cosmetic Act, 1940 such as issuance of show cause notice, stop production activity for the product methyl salicylate and suspension or cancellation of the product permission, etc. due to systemic failure of maintaining GMP or non compliance with respect to observations as specified in part-B of the said inspection report.*

8.           *On 03.08.2023, which is the date on which the present petition was filed, the Petitioner was handed over the order from the Assistant Commissioner (Drugs), Nashik Division Maharashtra State, Nashik, dated 03.08.2023 by which, the Petitioner has been directed to stop the manufacturing of Salicylic Acid IP/BP/EP/USP, forthwith. There is no show cause notice issued to the Petitioner vide this order dated 03.08.2023.*

9.           *Hence, liberty to add prayer clause and place on record the order dated 03.08.2023.*

10. *Reliance is placed by the Respondents on Rule 85 of the Drugs and Cosmetics Rules, 1945, which reads as under:-*

*“85. Cancellation and suspension of licences:-*

*(1) The Central Licence Approving Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons. therefor, cancel a licence issued under this Part, or suspend it for such period as he thinks fit either wholly or in respect of any of the drugs to which it relates for direct the licensee to stop manufacture, sale or distribution of the said drugs and [thereupon order the destruction of drugs and] the stock thereof in the presence of an Inspector), if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or rules made thereunder.*

*(2) The Licensing Authority may, for such licences granted or renewed by him, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit either wholly or in respect of any of the drugs to which it relates [for direct the licensee to stop manufacture, sale or distribution of the said drugs and [thereupon order the destruction of drugs and] the stocks thereof in the presence of an Inspector], if in his opinion, the licensee has failed to comply with any of the conditions of*

*the licence or with any provisions of the Act or rules made thereunder.]*

*[(3) A licensee whose licence has been suspended or cancelled by the Central Licence Approving Authority or Licensing Authority under sub-rule (1) or sub-rule (2), as the case may be, may within ninety days of the receipt of a copy of the order by him prefer an appeal to the Central Government or the State Government, as the case may be, and the Central Government or the State Government may after giving the licensee an opportunity of being heard, confirm, reverse or modify such order.]”*

11. *Prima facie, the learned Advocate for the Petitioner is right in contending that clause (1) of Rule 85 opens with giving a licensee an opportunity to show cause why such an order should not be passed.*

12. *The learned Advocates for the Respondents have vehemently tried to canvass that an action can be taken first and a show cause notice can be issued later. To us, this is like putting the horse in front of the cart. If the law mandates that a show cause notice should be issued before passing "such an order", the Respondents did not have any other option but to follow the Rules. The Deputy Drugs Controller (India), New Delhi, has also directed the Authorities to follow the procedure of issuance of show cause notice vide the communication dated 28.07.2023. The report of the Assistant Drugs Controller (I), Mumbai, also mentions*

*in his report that the State Licensing Authority shall revisit the site to verify GMP compliance and to take action as deemed fit under the provisions of the Drugs and Cosmetics Act, 1940.*

13. *Prima facie, Rule 85 does not contain any ambiguity. A show cause notice has not been issued in the present case. The order of stoppage of manufacturing activity has been passed. Such an action, prima facie, cannot be sustained.*

14. *The learned Advocates for the Respondents have vehemently submitted that the drugs manufactured by the Petitioner by using the component, which is not permitted, is likely to be hazardous to the health of the society. They are, however, unable to explain as to the inaction/loss of days from 10.07.2023 till 03.08.2023 (24 days).*

15. *In view of the above, we are of the opinion that an equitable order could be passed since the order of stopping the manufacturing activity is without issuance of any show cause notice. The workers deployed in the said activity are likely to be without work.*

16. *Therefore, while staying the order dated 03.08.2023 as an ad-interim measure, we direct that though the Petitioner may resort to the manufacturing of the said*

*drug at issue, at it's own risk, it shall not resort to dispatching the said drug either for sale, for export or for consumption in any manner. Batches of the manufactured drugs would be packed and preserved separately with proper markings and the manufacturing that may be resorted to from tomorrow, shall be accounted in the records of the Petitioner. Without the leave of the Court, the said drug would not be utilized in any manner whatsoever.*

17. *Insofar as the notice dated 03.08.2023, which is separately issued by the Joint Commissioner (Drugs) calling upon the Petitioner to show cause as to why an action should not be initiated against it, the Petitioner shall tender a reply to the concerned Authorities by tomorrow, which is the last date for filing of such reply. Thereafter, the Authorities would be at liberty to follow the due procedure laid down for passing appropriate orders, as are permissible.*

18. *List this petition for passing further orders on 25.08.2023."*

2. After the pleadings were completed, an issue was raised by the Respondents that the Petitioner has to obtain a 'No Objection' Certificate from Respondent No. 2, if the Petitioner desires to import Salicylic Acid for industrial use and subject it to certain procedures for purification, as may be legally permissible, to convert it into an

ingredient known as Salicylic Acid IP BP USP and EP, to be used for manufacturing of medicines/drugs. The learned Advocate for the Petitioner has been consistently submitting that such 'No Objection' Certificate is not required and in the last 35 years, no such certificate was ever demanded.

3. On 9<sup>th</sup> November, 2023, we had recorded the submissions of the parties in the following order :-

*1. The learned AGP has pointed out an affidavit undertaking by the petitioner filed at page Nos. 97 and 98 of the Petition paper book. Relevant portion reads as under :*

*That we are the importer of SALICYLIC ACID (TECHNICAL GRADE) from M/s ZHEJIANG CHEMICALS IMPORT AND EXPORT CORPORATION Address : No. 37 QINGCHUN ROAD HANGZHOU, CHINA of Sales Contract No. HC23C271097 Dated 17.05.2023.*

***1. That we undertake to use 810000 KG of above said drug for Non-Medicinal purpose only.***

*2. That we undertake to maintain books and records of transaction of above said drug for which NOC will be granted.*

3. *That we undertake to allow the Drug Inspectors from the CDSCO to inspect the books and records as well as the actual usage of SALICYLIC ACID (TECHNICAL GRADE) as and when required.*
4. *We state that consignment document like Certificate of analysis, Bill of Entry, Invoice etc. clearly mentions -**Not for Medicinal Use.***
5. *That the bags/ containers carrying SALICYLIC ACID (TECHNICAL GRADE) along with other requirements of labeling and packaging also mentions For Medicinal Use. **Not For Medical Use.***
2. *By consent of the parties, we list this matter for hearing on 28<sup>th</sup> November, 2023, first day after vacation, to be called out after the fresh admissions board is over.*
4. It is thus apparent from the record that the Petitioner had executed an undertaking which is re-produced below paragraph No. 1 in the order dated 9<sup>th</sup> November, 2023.
5. On 8<sup>th</sup> January, 2024, as a similar matter was being heard by this Court at the Principal Seat in Writ Petition (L)No. 33182/2023 (Ms/ Rishabh Metals & Chemicals Pvt. Ltd. vs. the

Union of India & others), we were informed that a committee has been directed to take a decision by this Court vide order dated 13<sup>th</sup> December, 2023. We, therefore, recorded in paragraph No. 2 of our order dated 8<sup>th</sup> January, 2024 as under :-

*2. We are informed by the Standing counsel that the matter is under consideration of the Legal Cell, Central Drugs Standard Control Organization, CDSCO, Head Quarter, New Delhi and it is informed on 18.12.2023 that the issue of technical/industrial grade Salicylic acid will be tabled before the Drugs Consultative Committee and Drugs Technical Advisory Board, which are statutory bodies under Chapter II of Drugs and Cosmetics Act, 1940 in deciding the policy matters. It is further informed that the use of technical/industrial grade Salicylic acid for non medical purposes is not objected to. The matter before the Principal Seat is posted on 10.01.2024.*

6. Since the Central Drugs Standard Control Organization (CDSCO) New Delhi did not take any decision, we recorded in our order dated 14<sup>th</sup> February, 2024 as under :-

*1. In our order dated 8.1.2024, we have noted the observations of this Court recorded in the order dated 13.12.2023 passed at the Principal seat in (M/s Rishab Metals and Chemicals Pvt. Ltd., Vs. The Union of India and others) in WP(L) No. 33182 of 2023. We have*

*also noted that the Legal Cell, Central Drugs Standard Control Organization, CDSCO, Head Quarter, New Delhi has to deal with the issue and the subject was to be tabled before the Drugs Consultative Committee and Drugs Technical Advisory Board, which are statutory bodies under Chapter II of the Drugs and Cosmetics Act, 1940. No decision has been taken on whether Industrial Grade Salicylic Acid which is used for non-medical purposes could also be used for medicinal purposes without requiring the 'no objection' of the competent authority.*

*2. The learned advocate for the Petitioner submits that the Petitioner has suffered enough since August, 2023. The Petitioner is awaiting orders of this Court, which are not being passed on the issue taken up in this Petition since the Union of India is seeking adjournments on one pretext or the other.*

*3. We are listing this Petition on 28<sup>th</sup> February, 2024 in the same category. If the Drugs Consultative Committee and Drugs Technical Advisory Board, do not take any decision as is appraised to this Court at it's Principal Seat, as is also informed to us, we would be constrained to direct the Respondent no. 3 – Drugs Controller (India), Central Drugs Standard Control Organization, New Delhi to remain present in the Court on 28<sup>th</sup> February, 2024.*

7. On 28<sup>th</sup> February, 2024, the learned Advocate Mr. Dhanure brought to our notice that the Drugs Consultative Committee and Drugs Technical Advisory Board, had taken a decision. The decision taken by the said authority is as under :-

CONSIDERATION OF THE PROPOSAL FOR IMPORT  
OF INDUSTRIAL / TECHNICAL GRADE API OR DRUG  
SUBSTANCES THROUGH DUAL USE NOC FOR NON  
MEDICINAL USE

DCC was apprised regarding the issue and essentially of Dual Use NOC for Industrial/technical grade API or Drug Substances to be imported for Non Medicinal Use to be treated as chemicals and exempted from Schedule D to be read with Rule 43 of Drugs and Cosmetics Rules, 1945 and uniform regulation under Chapter III and IV of Drugs and Cosmetics Act and Rules thereunder. There are concerns as well as court cases related to import of Salicylic Acid (industrial/technical grade) in this regard.

The matter was deliberated by DCC in detailed in light of Schedule D to be read with Rules 43 of Drugs Rules, 1945. The committee opined that the rule position is very clear and therefore substances intended to be used as drugs after further purification or rendering them sterile is not exempted under Rule 43 from the provision of Chapter III or the Drugs and Cosmetics Act, 1940 and rules made thereunder.

Further, DCC also opined that any substance imported in a chemical name irrespective of any grade or containing higher amount of impurities intended to be used as a drug is also not exempted under Rule 43 and Schedule D.

8. We deem it apposite to refer to Rules 43, 43A and 43B of the Drugs Rules 1945, which reads as under :-

**Rule 43.** The drugs specified in Schedule D shall be exempt from the provisions of Chapter III of the Act and of the Rules made thereunder to the extent, and subject to the conditions specified in that Schedule.

**43-A.** No drug shall be imported into India except through one of the following places, namely: -  
Ferozepur Cantonment and Amritsar Railway Stations: in respect of drugs imported by rail across the frontier with Pakistan.

Ranaghat, Bongaon and Mohiassan Railway Stations: In respect of drugs imported by rail across the frontier with Bangladesh.

Petrapole Road in West Bengal, Sutarkandi in Assam, Old Raghna Bazar and Agartala in Tripura : in

respect of drugs imported by Road from Bangladesh.

Raxual: In respect of drugs imported by road and railway lines connecting Raxual in India and Birganj in Nepal.

Chennai, Kolkatta, Mumbai, Cochin, Nhava Sheva, Kandla and Inland Container Depots at Tuglakabad and Patparganj in Delhi and Tuticorin in Tamil Nadu and Marmugao port in Goa: in respect of drugs imported by sea into India.

Chennai, Kolkata, Mumbai, Delhi, Ahmedabad, Hyderabad, Goa and Bengaluru: in respect of drugs imported by air into India.

**43-B.** Drugs, consignments of which are in transit through India to foreign countries and which shall not be sold or distributed in India shall be exempted from the requirements of Chapter III of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made thereunder:

Provided that if the Government of the countries to which the drugs are consigned regulate their import by the grant of import licences, the importer shall at the time of import into India, produce such import licences.

9. We are informed that the Minister for Food and Medical Administration, State of Maharashtra has delivered an order under Rule 85(3) of the 1945 Rules framed under the Drugs and Cosmetics Act, 1940. The said order refers to the visit by the Assistant Drug Controller and Assistant Drug Inspector. While drawing conclusion, the concerned authority has concluded that the chemical imported as 'industrial/technical' would not fall within the definition of drugs and that the law does not impose any condition or terms on the Petitioner/company while importing Salicylic Acid since there is no provision which deals with the grade of domestic technical Salicylic Acid which should be used in the manufacturing of drugs. It is specifically recorded as under :-

संस्थेने Technical/Industrial grade चे chemical आयात करून प्रशासनाने मंजूर केलेल्या औषधी पाठांचे उत्पादन केल्याचे निदर्शनास येते. अपिलार्थी कंपनीस मंजूर अनुज्ञाप्रीमध्ये अपिलार्थी यांनी त्यांचे औषध उत्पादनासाठी कोणत्या ग्रेडचे डोमॅस्टीक टेक्नीकल Salicylic Acid चा वापर करावा याबाबत काही मर्यादा, अटी व शर्ती दिसून येत नाही. त्यामुळे अपिलार्थी यांनी आयात केलेल्या Technical Salicylic Acid या chemical चा वापर वापरून मंजूर अनुज्ञाप्रीतील औषधी पाठांचे उत्पादन केल्याने कोणत्याही अटी व शर्तीचा भंग होत नाही. Industrial Salicylic Acid or any chemical हे औषध व सौंदर्य प्रसाधने कायदा १९४० मधील कलम 3(b) अन्वये औषध या संज्ञेत येत नाही व प्रतिवादी मार्फत त्याचे नियंत्रण ठेवले जात नाही. त्यामुळे केवळ CDSCO यांचे पत्रावरून अपिलार्थी यांचेवर कारवाई करणे उचित होणार नाही. त्यामुळे कोणतीही तपासणी व अभिलेखाचे अवलोकन न करता केवळ CDSCO यांचे पत्रावरून अपिलार्थी यांस दिनांक

२८.०७.२०२३ रोजी दिलेले स्टॉपवर्कचे आदेश हे चुकीचे असल्याच्या निष्कर्षाप्रत मी आलेलो आहे. अपिलार्थी यांनी वादी यांच्या “Stop Production” च्या आदेशानुसार कारखाना सात दिवसांकरीता बंद ठेवला होता व मा. उच्च न्यायालयाने त्यास स स्थगिती दिली आहे. यावरून अपिलार्थी यांनी यापूर्वीच सात दिवसांची शिक्षा उपभोगली आहे. अपिलार्थी यांनी औषधांचे उत्पादन करताना मंजूर परवाना अंतर्गत नमूद अटीचे पालन करणे अभिप्रेत आहे. तथापि आढळलेले दोष/त्रुटी व घेतलेली कारवाई ही कायद्याच्या दृष्टीने सुसंगत नाही असे माझे मत झाले आहे.

10. In view of the above conclusion, the grievance of the Petitioner is redressed and prayer clause ‘B’ is satisfied. No orders are required on this count.

11. In prayer clause ‘C’, the Petitioner has prayed as under :-

c. pending hearing and final disposal of the present Writ Petition, the Respondent Nos. 2 and 4 be directed not to insist on NOC from the respondent No. 2 or his officers for the import clearance of Salicylic Acid (Industrial / Technical grade)

12. The learned Advocate for Petitioner submits on instructions that the Petitioner has taken a decision not to use the Salicylic Acid imported for industrial use, for preparing any ingredient which would be used for manufacturing of drugs.

13. The learned Advocate Mr. Dhanure submits that in the light of the above statement, no cause of action survives in the Petition.

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.

15. In view of the above, **this Writ Petition is disposed off.**

**( R. M. JOSHI )**  
**JUDGE**

**( RAVINDRA V. GHUGE )**  
**JUDGE**

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