IN THE HIGH COURT OF JUDICATURE AT BOMBAY
CIVIL APPELLATE JURISDICTION
WRIT PETITION NO. 326 OF 2025

Inspira Bio Pharma Pvt. Ltd. .. Petitioner
Versus
The Union of India & Ors. .. Respondents

***Mr. Rafique Dada, Senior Advocate**, with Mr. Jas Sanghavi, Vikas Poojary i/b PDS Legal, Advocates for the Petitioner.*

***Ms. Kavita Shukla**, with Ms. Neeta Masurkar, Advocates for the Respondents.*

ANJALI TUSHAR ASWALE Digitally signed by ANJALI TUSHAR ASWALE Date: 2025.02.10 19:07:40 +0530

CORAM: B. P. COLABAWALLA &
FIRDOSH P. POONIWALLA, JJ.

DATE: FEBRUARY 6, 2025

P. C.

1. Rule. Respondents waive service. With the consent of parties, Rule made returnable forthwith and heard finally.

2. The above Writ Petition is filed seeking a direction to the Respondents to forthwith assess the Bills of Entry Nos. 7058399, 7070581 and 7070003 dated 5th December 2024 with the benefit of partial exemption from customs duty under Sr. No. 166 (A) of Notification No.50/2017 dated 30th June 2017, read with Sr. No. 24 of List 3 thereof, and on payment of IGST (Integrated Goods and Services Tax) at 5% under Sr. No.180 of Schedule-I of Notification No.1/2017-IGST-Rate dated 28th June 2017, read

with Sr. No. 24 of List 1 thereof, permit clearance of Lactulose Solution USP / Lactulose Concentrate USP [for short hereinafter referred to as ***"Lactulose"***] covered therein.

3. The Petitioner imports Lactulose Solution USP/Lactulose Concentrate USP covered under Chapter 29 of the First Schedule to the Customs Tariffs Act, 1975.

4. Prior to the enactment of the Central Goods and Services Tax Act, 2017 ("***CGST Act, 2017***), the *Lactulose* imported by the Petitioner was eligible for partial exemption from customs duty in excess of 5% under Sr. No. 147 (A) of the Notification No.12/2012-CUS dated 17th March 2012 (for short the "***2012 Notification***") and additional customs duty in terms of Sr. No. 108 (A) of Notification No. 12/2012 dated 17th March 2012. This was prior to the GST regime. With effect from 1st July 2017 (i.e. after the GST regime came into force), according to the Petitioner, the *Lactulose* imported by the Petitioner is eligible for partial exemption from customs duty in excess of 5% under Sr. No. 166 (A) of Notification No.50/2017-customs, dated 30th June 2017 (***"2017 Notification"***), and eligible for making payment at 5% of IGST in terms of Sr. No. 180 of Schedule I of the Notification No. 1/2017-IGST dated 28th June 2017. The subject matter of the present Petition is only with reference to claiming partial exemption from customs duty. As far as

IGST is concerned, the same does not form the subject matter of the present dispute.

5. It appears that in the case of this very Petitioner, the Commissioner of Customs (NS-III) had issued a show cause notice on 4th May 2018 *inter alia* proposing to deny partial exemption claimed by the Petitioner under the *2012 Notification* in respect of *Lactulose* covered under 60 Bills of Entry. In the Show Cause Notice it was alleged that the *Lactulose* imported by the Petitioner did not fall within the purview of Sr No. 147 (A) of the *2012 Notification*. These imports were between May 2013 to June 2017 and hence covered under the *2012 Notification*.

6. The Commissioner of Customs (NS-I), by his order dated 31st January 2019 adjudicated the said Show Cause Notice and *inter alia* held that the *Lactulose* imported by the Petitioner was classifiable under Chapters 28, 29 and 30 of the Customs Tariffs Act, 1975 and since they form part of List 3 of the *2012 Notification*, they would be eligible for the exemption as provided under Sr No.147 (A) of the *2012 Notification*. What is important to note is that the Commissioner, in the said order, held that whether the *Lactulose* imported by the Petitioner were Bulk Drugs and not formulations, would have no effect on the eligibility for the benefit extended under the *2012 Notification*. It is not in dispute that the said order dated 31st January

2019 passed by the then Commissioner of Customs (NS-I) was accepted by the Review Committee and has attained finality.

7. Once again, for imports made between March 2018 to August 2019, the Petitioner filed 13 Bills of Entry and sought the benefit of partial exemption from duty under Sr. No.166 (A) of the *2017 Notification* and Sr. No. 180 of Schedule I under Notification No. 1/IGST-Rate dated 28th June 2017.

8. Once again, the Customs Authorities disputed the said claim of partial exemption from customs duty alleging that the *Lactulose* imported by the Petitioner were Bulk Drugs and hence not entitled to exemption under Sr. No.166 (A) of the *2017 Notification*. In these circumstances, the Petitioner deposited the higher amount of customs duty under protest and cleared the said *Lactulose*. Thereafter, the Petitioner requested the Proper Officer to re-assess the said 13 Bills of Entry. The Proper Officer re-assessed the 13 Bills of Entry on 20th August 2019 and allowed the partial benefit under Sr. No.166 (A) of the *2017 Notification*. What is important to note is that no further action was taken by the Customs Department in this regard and the said re-assessments have become final. In fact, since the Petitioner had paid excess duty, the Petitioner had filed a Refund Application, which was also ultimately

granted by the Assistant Commissioner of Customs (NS-III) by his order dated 7th August 2022.

9. Thereafter, the Petitioner, on 17th October 2024, filed another Bill of Entry No.6182247 seeking clearance of 100 MT of *Lactulose* imported by the Petitioner. The Proper Officer thereafter raised a query and upon the Petitioner filing a reply, the Proper Officer permitted clearance of the said *Lactulose* covered under the said Bill of Entry dated 17th October 2024.

10. It now transpires that once again when the Petitioner imported *Lactulose* through three Bills of Entry filed dated 5th December 2024, the same have not been cleared. The ground on which they have not been cleared is once again that they are “Bulk Drugs” and therefore do not qualify for partial exemption under Sr. No.166 (A) of the *2017 Notification*.

11. The Petitioner duly replied to these queries/contentions of the Customs Department vide its letter dated 18th December 2024, and in fact brought to their attention the favourable orders passed in the case of the Petitioner. The Petitioner, therefore, requested Respondent No. 3 to permit clearance of its goods as heavy demurrage was being incurred by them.

12. Since the Customs Department was doing nothing and the Petitioner was incurring heavy demurrage charges, vide its letter dated 24th December 2024, the Petitioner requested Respondent No.3 to allow warehousing of the imported *Lactulose*. Respondent No.4 vide his letter dated 30th December 2024 has accordingly permitted warehousing in a public bonded warehouse for the period of 30 days.

13. Be that as it may, since no reply was forthcoming, and neither were the Customs Authorities permitting clearance of the imported *Lactulose*, the advocate for the Petitioner once again requested Respondent No.3 to permit clearance of the *Lactulose* with the benefit of the exemption within 48 hours. Since there was no response to even this letter, the present Petition is filed seeking the reliefs set out above.

14. In this factual backdrop, Mr. Dada, the learned Senior Counsel appearing on behalf of the Petitioner, submitted that there is absolutely no reason why the Petitioner should not be allowed to clear the imported *Lactulose* by claiming exemption and giving a bond in the format required by the Customs Authorities that in the event any additional duty is payable by the Petitioner (after issuance of a show cause notice and adjudication thereof), the same would be paid by the Petitioner, subject to its right of Appeal.

15. Mr. Dada further submitted that considering there are favourable orders already passed in the case of the Petitioner inter alia holding that they are entitled to the partial exemption, there is absolutely no reason why the *Lactulose* imported by the Petitioner should be continued to be kept in the warehouse, and that too without issuing any Show Cause Notice to the Petitioner. He, therefore, submitted that necessary directions be passed as sought in prayer clause (a) of the Writ Petition.

16. On the other hand, the learned counsel appearing on behalf of the Department, in short, submitted that what is imported by the Petitioner is a Bulk Drug and not a finished product. According to the Department, the Drugs that are listed in List 3 of the *2017 Notification* are basically finished products and not "Bulk Drugs" used for making finished products. According to the Department, since what is imported by the Petitioner are Bulk Drugs, the Petitioner cannot claim partial exemption under Sr. No. 166 (A) of the *2017 Notification* but under Sr. No.166 (B) of the very same Notification. It is because of this mis-classification that the *Lactulose* has not been cleared, and the Department is in the process of issuing a Show Cause Notice to the Petitioner. She, therefore, submitted that the above Writ Petition holds no merit and the same ought to be dismissed.

17. We have heard the learned counsel for the parties, and we have also perused the papers and proceedings in the above Writ Petition. Initially, the Customs Department had issued the *2012 Notification* specifying effective rates of basic and additional duty for specified goods falling under Chapters 1 to 98 of the Customs Tariffs Act, 1975. The relevant portion of the Table of *2012 Notification* reads thus:-

S.No.	***Chapter or Heading or Sub-heading or tariff Item***	***Description of goods***	***Standard rate***	***Additional duty rate***	***Condition No.***
147	*28, 29, 30 or 38*	*The following goods, namely:* *(A) Drugs medicines, diagnostic kits or equipment* ***specified in List 3*** *(B) Bulk drugs used in the manufacture of drugs or medicines at (A)*	*5%* *5%*	*-* *-*	*-* *5*

"List 3 (See S. No.147 of Table)

(1) ……

(2) ……

(38) Isoflurane

(39) Ketamine

<u>(40) Lactulose</u>

(41) ……………

(42) Lomustine"

18. For the *Lactulose* imported by the Petitioner between May 2013 to June 2017, a Show Cause Notice was issued by the Commissioner of Customs (NS-III) on 4th May 2018 inter alia proposing to deny partial exemption to the Petitioner under the said *2012 Notification*. When this Show Cause Notice was adjudicated, the then Commissioner of Customs (NS-I) held that the *Lactulose* classifiable under Chapters 28, 29 and 30 of the Customs Tariffs Act 1975, if specified in List 3 of the *2012 Notification,* would be eligible for exemption as provided under Sr. No. 147 (A) set out by us above. The Commissioner was of the view that whether the *Lactulose* imported were Bulk Drugs and not formulations would have no effect on the eligibility for the benefit extended under the said Notification. This order of the Commissioner had attained finality.

19. After the GST regime came into force, a new Notification was issued, and which is the *2017 Notification*. The relevant portion of the Table of the *2017 Notification* is as under:-

S. No.	*Chapter or Heading or sub-heading or tariff item*	*Description of goods*	*Standard rate*	*Integrated Goods and Services Tax*	*Condition No.*
166	*28,29 or 30*	*The following goods, namely:-* *(A) Drugs, medicines,*			

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		diagnostic kits or equipment specified in List 3 *(B) Bulk drugs used in the manufacture of drugs or medicines at (A)*	*5%* *5%*	*-* *-*	*-* *9*

"List 3 S. No. 166 of Table

(1) ……

(2) ……

(22) Isoprenaline

(23) Isoflurane

(24) Lactulose

(25) Lomustine

20. When one compares Sr. No. 147 of the *2012 Notification* with Sr. No. 166 of the *2017 Notification*, we find that the same are identical, the only difference being that for Sr. No.147 (B) of the *2012 Notification* Condition No. 5 had to be complied with, and for Sr. No.166 (B) of the *2017 Notification* Condition No. 9 had to be complied. As far as Condition No. 9 is concerned, it is a condition that states that the Importer has to follow the procedure set out in the *Customs (Import of Goods at Concessional Rate of Duty or for Specified End Use) Rules, 2022*.

21. As mentioned earlier, it is the case of the Department that since the *Lactulose* imported by the Petitioner are Bulk Drugs, they cannot be

classified under Sr. No. 166 (A) but under Sr. No. 166 (B) of the *2017 Notification*. It is for this reason that the said *Lactulose* has not yet been cleared. When one examines Sr. No. 166 of the *2017 Notification*, we find that the standard rate of duty is the same whether the *Lactulose* [imported by the Petitioner] falls within Sr. No. 166 (A) or under Sr. No. 166 (B). The only difference between the two is that if they fall within Sr. No. 166 (B), the Petitioner has to comply with the *Customs (Import of Goods at Concessional Rate of Duty or for Specified End Use) Rules, 2022*. If those Rules are not complied with, the Petitioner would be liable for action.

22. In these circumstances, we are of the view that at this stage, and keeping all issues open, the *Lactulose* imported by the Petitioner can be released by allowing them the partial exemption as contemplated under Sr. No. 166 (A) of the *2017 Notification* subject to them furnishing a bond to the Customs Department in the format asked for by them. Thereafter, the Department is free to issue a Show Cause Notice, if it so chooses and take it to its logical conclusion. We have not opined whether the *Lactulose* imported by the Petitioner can be classified under Sr. No. 166 (A) or 166 (B) of the *2017 Notification*. This is an issue that would be decided in any Show Cause Notice that the Department may choose to issue to the Petitioner. We may also state here that we have taken this view of allowing release of the

Petitioner's goods on a bond because in the facts of this case, the Petitioner has already obtained favourable orders in the past for the very same goods and they were allowed to be cleared granting the Petitioner the exemption under the *2017 Notification* for Bill of Entry No. 6182247 dated 17th October 2024. We, therefore, see no reason that the present consignment [of *Lactulose*] imported by the Petitioner should be withheld and the Petitioner should incur costs of warehousing the same. In these circumstances, it would be unjust and inequitable that the *Lactulose* imported by the Petitioner, and which are in the nature of life saving drugs, continue to be in the warehouse pending the adjudication of a Show Cause Notice proposed to be issued to the Petitioner.

23. In view of the foregoing discussion, we allow the above Petition in terms of prayer clause (a) which reads thus:-

> *"(a) that this Hon'ble Court be pleased to issue a Writ of Mandamus or a writ in the nature of Mandamus or any other writ, order or direction under Article 226 of the Constitution of India ordering and directing the Respondents, their officers and subordinates to forthwith assess the Bills of Entry Nos. 7058399, 7070581 and 7070003 all dated 05-12-2024 with benefit of partial exemption from Customs duty under Sr. No. 166 (A) of Notification No. 50/2017 dated 30.06.2017 read with Sr. No. 24 of List 3 thereof and on payment of IGST at 5% under Sr. No. 180 of Schedule I of Notification No. 1/2017-IGST-Rate dated 28.06.2017 read*

> *with Sr. 24 of List I thereof and permit clearance of Lactulose Solution USP/Lactulose Concentrate USP covered therein.”*

24. We must immediately state that this is subject to the Petitioner furnishing a bond in the format as required by the Customs Department.

25. The Customs Department shall forward a copy of the format of the bond required from the Petitioner by 10th February 2025. Once the aforesaid bond is furnished to the Department, they shall permit the Petitioner to clear the *Lactulose* as per Sr. No. 166 (A) of the *2017 Notification* within a period of 5 days from the date of furnishing the said bond.

26. The Customs Authorities are free to issue a Show Cause Notice to the Petitioner, if they so choose to do. If such a Show Cause Notice is issued, the same shall be decided in accordance with law.

27. Rule is made absolute in the aforesaid terms and the Writ Petition is also disposed of in terms thereof. However, there shall be no order as to costs.

28. Though we have disposed of the Writ Petition, we place it on Board “for reporting compliance” on 20th February 2025.

29. This order will be digitally signed by the Private Secretary/ Personal Assistant of this Court. All concerned will act on production by fax or email of a digitally signed copy of this order.

[FIRDOSH P. POONIWALLA, J.] **[B. P. COLABAWALLA, J.]**