

**Prem Pharmaceuticals Vs. Commissioner of Central Excise**

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**Court :** Customs Excise and Service Tax Appellate Tribunal CESTAT Delhi

**Decided On :** Jun-24-2004

**Reported in :** (2005)(98)ECC514

**Judge :** K Usha, N T C.N.B.

**Appellant :** Prem Pharmaceuticals

**Respondent :** Commissioner of Central Excise

**Judgement :**

1. Appellants are engaged in the manufacture of medicaments which include various variations of Intra Venus Fluids (IV Fluids) falling under Chapter 30 of the Central Excise Tariff Act, 1985.
2. A common issue, namely, whether appellants' claim for exemption under Notification No. 6/2000 as amended by Notification No. 36/2000, dated 4-5-2000 for IV Fluids in respect of their product is justified is raised in these appeals. Since identical issues are raised by the appellants, we propose to dispose of the appeals under this common order.
3. Appellants were manufacturing IV Fluids for the last so many years and from time to time they had been filing classification declarations under Rule 173B of the Central Excise Rules, 1944 along with the labels and the same were approved by the competent authority. After 1994, the appellants submitted classification declaration and paid central excise duty accordingly without any objection from the

Central Excise Department.

4. M/s. Prem appellants in E/487/03 filed a classification declaration under Rule 173B with effect from 4-5-2000 claiming exemption under Notification No. 6/2000 as amended by Notification No. 36/2000, dated 4-5-2000 for IV Fluids. In respect of the following IV Fluids the appellants claimed exemption: 5. Appellants were asked by the Central Excise Department to reverse total amount of Cenvat credit on the inputs used in the manufacture of finished goods covered under the said notification. Accordingly, the appellants debited an amount of Rs. 1,87,808. Therefore, according to the appellants the Department had accepted the view that the impugned products are exempted under Notification 36/2000, dated 4-5-2000.

Thereafter, by the DG, Central Excise Intelligence a show cause notice dated 28-5-2001 was issued proposing to demand duty on the intravenous fluids and injectible such as Mannitol Injection, Metronindazole Inj.

Ciprofloxacin Inj. etc. Duty demand under Section 11A was to the extent of Rs. 21,84,055/-, penalty under Section 11AC and Rule 173Q was also proposed. Appellant submitted detailed reply to the show cause notice denying the allegations in the show cause notice and contended that the goods are covered under the scope of IV Fluids exempted under notification referred to above and that the view taken by the Department that the scope of IV Fluids was restricted to IV Fluids used for sugar, electrolytes or fluid replenishment was incorrect. By order dated 7-2-2003 the Commissioner of Central Excise, Indore rejected the contentions raised by the appellant and confirmed the proposal made in the show cause notice.

6. M/s. IVES, appellants in E/488/03-NB(A), also submitted classification declaration from time to time raising their claim for exemption and they were being approved by the competent authority. They filed classification declaration under Rule 173B with effect from 4-5-2000 claiming such exemption in respect of the following IV Fluids : 7. As in the case of Prem Pharma this appellant was also directed to reverse the total amount of Cenvat credit on the inputs used in the manufacture of finished goods covered under the said notification lying in stock. Accordingly the appellants debited an amount of Rs. 8,14,316.

Thereafter a show cause notice dated 28-5-2001 was issued directing the appellant to show cause as to why the classification declaration with effect from 4-5-2000 should not be amended to the extent of denying the benefit of Notification 36/2000 to intravenous drugs and non intravenous electrolytes. There was a demand of duty to the extent of Rs. 20,19,777 under Section 11A and it was proposed to impose penalty under Section 11AC and Rule 173Q. Appellant submitted detailed reply denying the allegation and contending that the goods are covered under the scope of IV Fluids exempted under notification. Ultimately the Commissioner of Central Excise, Indore passed an order dated 31-10-2002 rejecting the contention taken by the appellant.

8. Under notification 6/2000, dated 1-3-2000 as amended by 36/2000, dated 4-5-2000 exemption from duty had been granted in respect of certain goods included in the list appended thereto. Item 47A was shown as Intravenous fluids coming under Chapter Heading 30 of the Schedule to Central Excise Tariff Act, 1985. Under subsequent notification, namely, 3/2001, dated 1-3-2001 similar exemption was being granted against Item No. 56 where it was shown "Intravenous fluids, which are used for sugar, electrolyte or fluid replenishment" coming under Chapter 30. Commissioner has taken the view in both the cases that IV Fluids for the purpose of exemption under Notification 6/2000 would be only those IV Fluids which are used for sugar electrolyte or fluid replenishment. The Commissioner comes to the above conclusion on the basis of the description of Intravenous Fluids in Notification 3/2001, dated 1-3-2001 appearing at Serial No. 56. He further took the view that in terms of definition of 'Intravenous Fluids' as given in Remington's Pharmaceutical Science intravenous fluids should not contain any added substance. Since the products of the appellants contained added substances they are not IV Fluids. According to the Commissioner the products in question are drugs and medicament, and, therefore, they cannot be considered as IV Fluids.

9. It is contended on behalf of the appellants that description given against Serial No. 56 in Notification 3/2001 which is effective from 1-3-2001 cannot be applied to interpret the scope of the term 'intravenous fluids' used in Notification 6/2000 with reference to Serial No. 47A. It is also submitted that Notification 3/2001 is not an

amendment or clarification to the Notification 6/2000. No retrospective effect could be given to the description against Item 56 in Notification 3/2001. It is also contended that Notification 6/2000-C.E. was rescinded by Notification 10/2001-C.E., dated 1-3-2001. Therefore, Notification 3/01 has to be treated as an independent notification and not an amendment of Notification 6/2000-C.E. Under these circumstances any action taken on the basis of Notification 6/2000 cannot be reversed. It is further contended that the product of the appellants would satisfy the definition of IV Fluid as given in Remington's Pharmaceutical Science relied on by the Commissioner.

10. Learned Counsel appearing on behalf of the appellants brought to our notice two decisions of this Tribunal where identical issues are considered. Misc. Order Nos. 18-21/NB(A), dated 22-1-2004 decided the issue in Appeal E/2497-98/2002/NB(A) filed by M/s. Albert David Ltd. & Ors., Appeal No. E/656/2003/NB(A) filed by M/s. Ahlcon Parenterals (I) Ltd. and Appeal No. E/956/2003/NB(A) filed by M/s. Wockhardt Life Sciences Ltd. Even though the order is shown as miscellaneous order for the reason that in respect of issue of Modvat there arose difference of opinion between the two Members, on the issue of the claim for exemption under Notification 6/2000, dated 1-3-2000, as amended by Notification 36/2000, dated 4-5-2000, both the Members have taken a concurrent view. The Bench has accepted the contention raised by the assessee that Notification 3/2001, dated 1-3-2001 is not an amending notification of Notification 6/2000 but an independent notification.

Notification 6/2000 was rescinded on 1-3-2001 by Notification 10/2001 itself. Therefore, the description of IV Fluid given under Entry 56 in Notification 3/2001 cannot be applied for interpreting the meaning of IV Fluids under Entry 47A of Notification 6/2000. Description under Entry 56 cannot be treated as clarification of Entry under 47A.11. Another issue considered by the Bench was whether the goods declared as IV fluids by Albert David and Ahlcon would conform to the specifications of IV fluids in terms of technical literature. The Revenue had contended that the products in question were meant for intravenous infusion for medicinal purposes and were not merely intended to be used as fluid replenishment in human body. It was also contended that the products were IV

fluids containing added substances.

On this ground also the products were sought to be excluded from the category of Intravenous Fluids coming under Entry No. 47A. The Bench took the view that the contention of the Revenue cannot be sustained.

Reliance was placed on technical literature such as Pharmacopoeia, encyclopedia etc. It was observed that all the literature on the subject invariably showed that intravenous fluids are large volume sterile solutions packed in containers holding 100 ml or more.

Reference was made to Chapter 8 of Sterile Dosage Forms (3rd Edition) by Salvatore Turco & Robert E. King which read as follows :- "The most common uses of intravenous fluids include the correction of serious disturbances in electrolyte and fluid balances in the body and a means of providing basic nutrition. In recent years, they have been used as vehicles for other drugs and as a method for providing parenteral hyperalimentation. " Reference was also made to Remington's Pharmaceutical Sciences where the common use of intravenous fluids was listed as under :- "Intravenous fluids commonly are used for a number of clinical conditions. These include.

The basis for the practice of providing TPN [Total Parenteral Nutrition], 12. The Bench noted that the British and Indian Pharmacopoeia also recognizes the above position. It was then held that the subject goods which were undisputedly cleared in unit volumes of 100 ml or more could not be anything other than intravenous fluids by the mere reason of the fact that they contained any drug whether Schedule 'H' drug (under the Drugs and Cosmetics Act) or not. Finally it was held that the exemption under 47A of the Notification No. 6/2000-C.E. as amended by Notification No. 26/2000-C.E., dated 4-5-2000 is not liable to be denied in respect of the IV fluids produced by the appellant therein.

13. In the second decision which is an order passed by the West Zonal Bench, Mumbai (C-II/733/WZB-2004), dated 27-2-2004 [2004 (171) E.L.T.259 (Tribunal)] it was held that S. No. (vi) of Notification No. 3/01, dated 1-3-2001 cannot mean that the exemption would be applicable to such IV fluids which had sugar,

electrolyte or fluid replenishment and used exclusively or alone for such purpose. In the above case, the Revenue had taken the view that IV fluids containing Ciprofloxacin I.P., or Metronidazole I.P., or PDZOLE.D, or Cirpodex, Tinipidi Isotonic infusion or Mannitol I.P. manufactured and cleared by the appellants were not eligible for the benefit of Notification 36/2000, not being intravenous fluids. The main grounds, for this stand, are enumerated as under :- (a) No additives or preservatives could be added in IV fluids, whereas the drugs contained in the disputed entities were in the nature of additives.

(b) IV fluids perform function of restoring sugar, fluid and electrolyte balance in the body. The drugs contained in them, on the other hand, were for treatment of specific ailments, having antamoebic or/and antibiotic properties, among others.

(c) In the 2001-2002 Budget, an explanation, was inserted in Notification 36/2000, clarifying that only such IV fluids which were used for sugar, electrolyte or fluid replenishment, were exempt from duty and not other IV fluids. (In actual fact, this was not a clarificatory explanation, but an entirely new dispensation, vide Notification 3/2001, dated 1-3-2001.

(d) The additives in question, if cleared in tablet/syrup form, were eligible to duty @ 16% ad valorem, under S.H. 3003.20. It would be anomalous, therefore, to hold that, if they were cleared as 'injections', as in this case, they would be wholly exempt from payment of duty under Notfn. 36/2000.

(e) The Pharmaceutical Form-Fill-Seal Association had, by its letter dated 12-3-2001, stated that IV infusions of Mannitol, Amino Acid, Ciprofloxacin and Metronidazole, were dutiable even after 2001-2002 Budget.

14. Reliance was also placed on the show cause notice on Remington's Practice of Pharmacy. The Bench took into consideration the relevant Chapter of Remington's Practice of Pharmacy and came to the conclusion that the finding of the Commissioner that the drugs of the appellant were only meant for use as vehicles for other drug substances and therefore, fall outside exemption provided under Notification No.3/2001, dated 1-3-2001 or exemption Notification No. 6/2002, dated 1-3-2002 was without any technical data or expert's opinion. The

Bench also took the view that the Commissioner had erred in discarding the view expressed by Deputy Director of Food and Drug Administration, Indore in the following manner :- "In this connection, it is informed that any I.V. Fluid does not lose its basic character of I. V. fluids simply by adding to it any medicament. In our case, adding of either ciprofloxacin with dextrose, ciprofloxacin with sodium chloride, met-ronidazole with dextrose, metronidazole with sodium chloride, tinidazole with sodium chloride and mannitol is covered under definition of intravenous fluids for which you have been given licence in Form No. 28-D. The route of administration of these products are through intravenous hence the said products come under intravenous infusion." [Emphasis supplied] 15. After referring to the expert opinion of the Deputy Director that IV fluids dextrose, sodium chloride or manitol would be serving the intending functions of use for sugar electrolyte fluid replenishment in the body of a patient and that the drugs e.g. ciprofloxacin, which are added, may serve an additional function of medicinal or therapeutic value to fluid replenishment functions the purpose and intent for which the IV fluids were being offered to patients, the Bench observed that no patient would be given a litre or more of a fluid the packing as in the present case with glucose etc. if the intent was only to inject a drug. The patients who do not need fluid replenishment cannot and will not be given such infusions to carry the drug. The Bench took the view that it is not permitted to add the word 'exclusive or alone' to a Notification, as proposed by the Revenue.

16. We are in respectful agreement with the view taken in the above decisions of this Tribunal in the matter of interpretation of the notifications granting exemption to IV fluids. Now coming to the facts of the present cases we find that in appeal by Prem Pharmaceuticals following are the details of clearances of IV fluids made without payment of duty during the period 4-5-2000 to 31-3-2001 :-  
 -----S. No. Description of the product Qty. Cleared Clearance value12.

|             |                                                                                                                                                     |   |    |    |    |       |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|---|----|----|----|-------|
| CPD         | Solution                                                                                                                                            | B | 42 | ml | IP | 260   |
| 59925.00    | -----                                                                                                                                               |   |    |    |    | Total |
| 13650344.20 | In respect of Sl. Nos. 1 to 8 the appellant will be entitled to exemption under the relevant notifications. As far as S. Nos. 9 to 12 are concerned |   |    |    |    |       |

no relief can be granted since the single-dose injection is of volume less than 100 ml., therefore, will not satisfy the definition of intravenous fluids. The duty demand in respect of S. Nos.

9 to 12 is sustained.

17. In Appeal of Ives Drugs (P) Ltd. the dispute relates to two categories. They are as follows:-----Sl. No.  
Name of the Product Category M. Litre15.

|     |          |      |      |
|-----|----------|------|------|
| 20% | Mannitol | (PP) | Drug |
| 100 | -----7.  |      |      |

Hemodilysis 10 Ltr.----- In respect of S. Nos. 1 to 15 the appellant will be entitled to the benefit of exemption notification. In respect of S. Nos. 1 to 8 in the second part of the above chart we are not inclined to accept the contention of the assessee that they are also to be treated as IV fluids entitled for exemption. Apart from the fact that the appellants themselves had mentioned on the label that these products are not for IV use, going by the literature made available to us we find that these products cannot be categorised as IV fluids. In Bailey & Love's Short Practice of Surgery Dictionary Fifteenth Edition process of Peritoneal Dialysis is explained as follows :- "Peritoneal Dialysis - This method has been used with success. The simplest method and the one least likely to give rise to peritonitis is to insert a polythene tube into the peritoneal cavity by means of trocar and canuula. Into the peritoneal cavity is gravitated moderately slowly a hypertonic solution (20 per cent dextrose solution with 6 G. sodium chloride per litre added). The liquid is retained by clipping the tube for two hours and then allowing it to flow out. The process is continued for up to forty-eight hours. Thus the peritoneum acts as a dialysing membrane".

The above would show how the Dextrose solution is used in peritoneal dialysis. In the same book kidney dialysis process is explained as below :- "The principle of the artificial kidney is that of dialysis across a membrane which is permeable to crystalloids and not to colloids, with the patient's blood on one side of the

membrane and a saline bath on the other; excessive crystalloids will leave the blood and enter the bath, which is constantly flowing." The above would show that these items are not pushed through veins and cannot be treated as IV fluids.

18. So also in the case of irrigation fluids we are not able to accept the contention of the appellant that they are to be treated as IV fluids. Irrigation fluid is used only at specific area and not pushed through veins. In the result, we hold that the appellant is not entitled to any exemption in respect of Sl. Nos. 1 to 8 in the second part of the chart and the duty demand in respect of the above items is upheld. In respect of the claim for Cenvat credit the learned DR would submit that there is no proposal in the show cause notice to deny such credit.

We make it clear that the appellants will be entitled to Cenvat credit on the inputs used in the manufacture of goods which are held dutiable.

It is also made clear that the appellants will be entitled to the benefit of ratio of the decision in CCE Delhi v. Maruti Udyog Ltd. - 2002 (141) E.L.T. 3 (S.C.) on the issue of cum duty prices.

19. In the facts of the case we are of the view that imposition of penalty is not justified. There is no suppression or misstatement of relevant facts by the appellant. The dispute relates to interpretation of the scope of the relevant notifications. Therefore, no penalty can be imposed under Section 11AC. We also take the view that penalty under Section 173Q is not justified the facts of this case. The demand of interest under Section 11AB is not maintainable.

20. Duty liability of the appellants will be recomputed in the light of the findings in this order and the appellants will satisfy such demand.

The appeals are partly allowed as above.

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