

IN THE SUPREME COURT OF INDIA

CIVIL APPELLATE JURISDICTION

CIVIL APPEAL NO. 4944 OF 2004

Commnr. of Central Excise & Customs, Indore

...Appellant(s)

Versus

M/s. Parenteral Drugs (I) Ltd.

...Respondent(s)

W I T H

**CIVIL APPEAL NOS.6519/2005, 1152/2006, 2127/2006,
2628/2006, 2630/2006 & 4059/2006**

O R D E R

Delay condoned.

In this batch of Civil Appeals, the main issue which arose for determination before the Adjudicating Authority was whether Intravenous Fluids having a therapeutic value stood covered under Exemption Notification No.3/2001.

In the lead matter – M/s. Parenteral Drugs (I) Ltd. - the respondents were engaged in the manufacture of various types of Intravenous Fluids. They were availing the benefits of Notification No.6/2000, dated 1.3.2000. The said Notification was amended by Notification No.36/2000, dated 4.5.2000, whereby Entry No.47-A was added thereby exempting “Intravenous Fluids” from payment of excise duty. However, from 1.3.2001, the earlier notifications were replaced by Notification No.3/2001 which defined “Intravenous Fluids” as those which are used for sugar, electrolyte or fluid replenishment. In other words, open-ended exemption stood restricted by the above three qualifications.

Accordingly, show cause notices were issued in which it was alleged that the respondents were engaged in the manufacture of intravenous infusions of various kinds which besides the fluids included certain medicines having anti-bacterial, antibiotic and antimicrobial properties. It was alleged in the show cause notice that by addition of the following items to the Intravenous Fluids, the product attained therapeutic value and, consequently, it fell outside Notification No.3/2001 which defined 'IV Fluids' as those used for sugar, electrolyte or fluid replenishment.

The items added to the fluids are as follows:

- (a) Ciprofloxacin I.P.
- (b) Metronidazole I.P.
- (c) PDZOLE-D
- (d) Ciprodex
- (e) Tinipidi Isotonic Infusion, and
- (f) Mannitol I.P.

The most important aspect to be noted is that in the 2001-2002 Budget, an explanation was inserted in Notification No.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. This provision in the Budget was relied upon by the Department in the show cause notice(s) to deny the benefit of exemption claimed by the respondents under Notification No.3/2001. Unfortunately, despite detailed analysis of the notification in question by the Commissioner, the Tribunal has not examined this aspect and, therefore, the matter needs to be remitted to the Tribunal to give its finding as to what is the effect of the 2001-2002 Budget which restricts the definition of 'IV Fluids' in terms of the above three qualifications.

There is one more aspect which the Tribunal is required to consider. In the

labels of the respondent-Company, there is a warning stating that IV fluid manufactured by the assessee is Schedule-H Drug. What is argued on behalf of the assessee(s) is that because of addition to the IV Fluid of one of the above-mentioned six items, the product manufactured is required to be sold as a Schedule-H drug. On the other hand, the Department has placed reliance on the Drugs and Cosmetics Rules, 1945 read with Schedule-H to indicate that when IV Fluid has dominant therapeutic value, it will not come within the exemption because it has to be treated as a Schedule-H drug. We do wish to express any opinion on this point. Suffice it to state that on the above two questions/issues, the matter needs to be remitted to the Tribunal for consideration in accordance with law.

We may add that exemption notifications have to be read strictly. We may also add that the burden is on the assessee to prove that the item falls within the four corners of the exemption notification.

Before concluding, we may state that if on the second issue, regarding Schedule-H Drug, as spelt out hereinabove, if the Tribunal feels that the matter requires further evidence, it may either itself decide that point after giving opportunity to the parties or it may remit the matter to the Adjudicating Authority for its decision on factual aspect in accordance with law.

Subject to what is stated above, the Department's Appeals are allowed, the impugned judgment is set aside and the matters are remitted to the Tribunal for fresh consideration in accordance with law. In the facts and circumstances, there will be no order as to costs.

.....J.

(S.H. KAPADIA)

.....J.

(AFTAB ALAM)

New Delhi,
March 31, 2009.