

CUSTOMS, EXCISE & SERVICE TAX APPELLATE TRIBUNAL
PRINCIPAL BENCH, WEST BLOCK No.2, R.K.PURAM, NEW DELHI - 110066
EXCISE APPEAL BRANCH

Appeal No. E/2752,3110/2003,3519/04,3249/03,837/05,4688/04,4739/04,4860/04,6075/04 -EX[DB] Date 03/11/2010
EM/58/10,E/M/15,80,303/10,E/M/35/10,E/M/70/10,E/M/902/09 & E/CROSS/47/05-EX

Assistant Registrar
C.E.S.T.A.T, New Delhi

To :
IVES DRUGS (INDIA)PVT.LTD.
405, CHETAK CENTRE, 12/2,
R.N.T. MARG, INDORE - 452001 (MP)
IVES DRUGS (INDIA)PVT.LTD.

Appellant

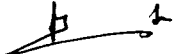
Vs
Respondent

C.C.E. INDORE

MISC ORDER NO.614-620/2010-EX

2010 EX[DB] dated 29-10-10

I am directed to transmit herewith a certified copy of Final order No. 759-767/
passed by the Tribunal under Section 35-C(1) of Central Excises Act, 1944


Assistant Registrar
(Excise Appeal Branch)

Copy to :

1. Respondent

C.C.E. INDORE

MANIK BAGH PALACE, POST BOX NO. 10, INDORE 452001 (M.P.)

2. Adv. / Consult

MR.RAMESH NAIR

LAKSHMI VIHAR, AG- 192, SCHEME NO. 54, VIJAYNAGAR, INDORE(MP)

3 C.D.R

~~4 J.C.D.R.~~

5 Bar association, CESTAT, New Delhi

6 Director Publications, Customs, Excise. I.P. Estate, New Delhi

7 M/s Centax Publications Pvt Ltd., 1512-B, Bhishm Pitamah marg, Opp. ICICI Bank of Defence Colony, New Delhi - 3

8 Company Law Institute of India Pvt Ltd., No.2(Old No. 36), Vaithyaram Street, T. Nagar, Chennai -17

9 M/s. Deeparchie Publications, M-93, Marg. 46, Saket, New Delhi 110017

10 Taxmann Allied Service Pvt Ltd., 59/32, New Rohtak Road, New Delhi - 110005

11 Easy Service Tax Online Dot Com Pvt.Ltd.407A.Iscon Mall.Above Star India Bazar.Satellite Road.Ahmedabad-15

12 LAWCRUX Advisors Pvt Ltd. LAW House.1-8.Sector - 10. Faridabad 121003 (Harvana)

13 TaxIndiaOnline.com Pvt Ltd., Unit No.1, 2nd Floor, Vasant Arcade, Nelson Mandela Road, Vasant Kunj, New Delhi - 110070

14 Office Copy

15 Guard file

16.HON'BLE PRESIDENT.


Assistant Registrar
(Excise Appeal Branch)

17. M/S. VENUS REMEDIES LTD,
51-52, INDL. AREA, PHASE-1, PANCHKULA
18. M/S. PREM PHARMACEUTICALS,
501, ALANKAR POINT,
GEETA BHAWAN SQUARE,
A.B. ROAD, INDORE (MP)
19. M/S. INVEN PHARMACEUTICALS (P) LTD,
27/1, PATEL NAGAR, MAIN ROAD, INDORE (MP)
20. M/S. BERYL DRUGS LTD.
PLOT NO. 123, INDL. AREA, SECTOR-1,
PITHAMPUR DISTT. DHAR (MP)
21. M/S. DUJOHN LABORATORIES LTD,
A-3, SECTOR-E, SANWER ROAD, INDORE
22. M/S. INVEN PHARMACEUTICALS (P) LTD,
NEW HILL, KALSADA KHURD,
GHATABILLOD, DISTT. DHAR (MP)
23. MS. ASMITA NAYAK, ADV.,
SH. K. K. ANAND, ADV.,
A-5, BASEMENT,
LATPAT NAGAR-III,
N. DELHI-24
24. M/S. K. S. JOHN & CO.
428, M. C. SETALVAD LAWYERS CHAMBERS,
OPP. SUPREME COURT OF INDIA,
BHAGWAN DASS ROAD, N. DELHI-
25. CCE, PANCHKULA
26. Sh. Sanjay Grover
Law offices, E-500
Greater Kailash II N. Delhi-48.
27. Sh. A. K. Raha, J-1967, Flat No 4, Chhitronjan Park N.D-19,

**IN THE CUSTOMS, EXCISE AND SERVICE TAX
APPELLATE TRIBUNAL, NEW DELHI, PRINCIPAL
BENCH NEW DELHI**

Date of Hearing: 29.04.2010

Date of Decision: 29.10.2010

For approval and signature:

Hon'ble Shri Justice R.M. S. Khandeparkar, President

Hon'ble Shri Rakesh Kumar, Member (Technical)

1. Whether Press Reporters may be allowed to see
CESTAT (Procedure) Rules, 1982.

Yes

2. Whether it should be released under Rule 27 of the
CESTAT (Procedure) Rules, 1982 for publication
in any authoritative report or not?

Yes :

3. Whether Their Lordships wish to see the fair copy
of the Order?

: Seen

4. Whether Order is to be circulated to the Departmental
authorities?

Yes

(1) * Excise Appeal No.E/2752/03-Excise

with Misc. Application No.E/58/2010-Excise

(Arising out of Order-in-Appeal No.77-78/COMMR/CEX/IND/2003
dated 28.07.2003 passed by the Commissioner of Central Excise, Indore
(M.P.)

M/s. Ives Drugs (India) Pvt. Ltd.

..Appellant

Rep. by Shri Ramesh Nair, Advocate
Vs.

CCE, Indore

...Respondent

Rep. by Shri A.K. Raha, Special Counsel

AND

(2) Excise Appeals Nos.E/3110/03 with Misc.

Applications Nos.E/M/15, 80 & 303/2010

& Appeal No.E/3519 of 2004-Excise

(Arising out of common Order-in-Original No.23/Comm./PKL/03 dated
5.08.2003 passed by the Commissioner of Central Excise, Panchkula in
both the appeals).

M/s. Venus Remedies Ltd.

....Appellant

Rep. by Ms. Asmita Nayak, Advocate
Vs.

CCE, Panchkula

....Respondent

Rep. by Shri A.K. Raha, Special Counsel

**IN THE CUSTOMS, EXCISE AND SERVICE TAX
APPELLATE TRIBUNAL, NEW DELHI, PRINCIPAL
BENCH NEW DELHI**

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| 1. Whether Press Reporters may be allowed to see
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| 2. Whether it should be released under Rule 27 of the
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in any authoritative report or not? | Yes : |
| 3. Whether Their Lordships wish to see the fair copy
of the Order? | : Seen |
| 4. Whether Order is to be circulated to the Departmental
authorities? | : Yes |
-

**(1) Excise Appeal No.E/2752/03-Excise
with Misc. Application No.E/58/2010-Excise**
(Arising out of Order-in-Appeal No.77-78/COMMR/CEX/IND/2003
dated 28.07.2003 passed by the Commissioner of Central Excise, Indore
(M.P.)

M/s. Ives Drugs (India) Pvt. Ltd.		..Appellant
	Rep. by Shri Ramesh Nair, Advocate	
	Vs.	
CCE, Indore		...Respondent
	Rep. by Shri A.K. Raha, Special Counsel	

AND

**(2) Excise Appeals Nos.E/3110/03 with Misc.
Applications Nos.E/M/15, 80 & 303/2010
& Appeal No.E/3519 of 2004-Excise**
(Arising out of common Order-in-Original No.23/Comm./PKL/03 dated
5.08.2003 passed by the Commissioner of Central Excise, Panchkula in
both the appeals).

M/s. Venus Remedies Ltd.		Appellant
	Rep. by Ms. Asmita Nayak, Advocate	
	Vs.	
CCE, Panchkula		Respondent
	Rep. by Shri A.K. Raha, Special Counsel	

Vice Versa

AND

- (3) **Excise Appeals Nos. E/3249 of 2003 & E/837 of 2003- Excise with Misc.Application No.E/M/35/10-Excise**

[Arising out of Order-in-Original No. 81/COMMR/CEX/2003 dated 18.08.2003 in Appeal No.E/3249 of 2003 & Order-in-Original No.10/COMMR/CEX/IND/2003 dated 31.10.2002 in Appeal No. E/837 of 2005, both passed by the Commissioner of Central Excise, Indore (M.P.)].

(1) M/s. Prem Pharmaceuticals Appellants
Rep. by Shri S.K. Bagaria, Sr. Advocate with
Shri Sardesai and Shri P.K. Jha, Advocates

Vs.

CCE, Indore

Respondent
Rep. by Shri A.K. Raha, Special Counsel

AND

- (4) **Excise Appeal No.E/4688 of 2004 with Misc. Application No.E/M/70/10-Excise**

(Arising out of Order-in-Appeal No.IND-I/215/2004 dated 14.06.2004 passed by the Commissioner of Central Excise (Appeals-I), Indore and Order-in-Original No.47/ADC/CEX/IND/02-03 dated 23.12.2002 passed by the Addl. Commissioner of Central Excise, Indore).

CCE, Indore ...Appellant
Rep. by Shri A.K. Raha, Special Counsel

Vs.

M/s. Inven Pharmaceuticals Pvt. Ltd. ...Respondent
Rep. by Shri Ramesh Nair, Advocate

AND

- (5) **Excise Appeal No.E/4739 of 2004 with Misc. Application No.E/M/902/09-Excise**

[Arising out of common Order-in-Appeal No.IND-I/214/2004 dated 14.06.2004 passed by the Commissioner of Central Excise (Appeals-I), Indore & Order-in-Original No.118/JC/CEX/IND/02-03 dated 29.04.2003 passed by the Joint Commissioner of Central Excise, Indore]

CCE, Indore

....Appellant
Rep. by Shri A.K. Raha, Special Counsel

Vs.

M/s. Beryl Drugs Ltd.

....Respondent
Rep. by Shri S.K. Bagaria, Sr. Advocate
with Shri Sanjay Grover, Advocate & Shri S.K. Pawar, Advocate

AND

(6) Excise Appeal No.4860 of 2004-Excise

(Arising out of Order-in-Appeal No.285-CE/IND/APPL-II/04 dated 30.06.2004 passed by the Commissioner of Central excise (Appeals-II), Indore & Order-in-Original No.99/JC/CEX/IND/03-04 dated 16.04.2003 passed by the Joint Commissioner of Central Excise, Indore).

CCE, Indore

....Appellant
Rep. by Shri A.K. Raha, Special Counsel

Vs.

M/s. Dujohn Laboratories Ltd .

...Respondent
Rep. by Shri S.K. Bagaria, Sr. Advocate
with Shri Sanjay Grover, Advocate

AND

(7) Excise Appeal No.6075 of 2004-Excise with E/Cross/47/05-Excise

(Arising out of Order-in-Appeal No.IND-I/309/2004 dated 21.07.2004 passed by the Commissioner of Central Excise (Appeals-I), Indore & Order-in-Original No.4-5/JC/CEX/IND/04-05 dated 15.04.2004 passed by the Joint Commissioner of Central Excise, Indore)

CCE, Indore

....Appellant
Rep. by Shri A.K. Raha, Special Counsel

Vs.

M/s. Inven Pharmaceuticals Pvt. Ltd.

...Respondent
Rep. by Ms. Asmita, Nayak, Advocate

CORAM: **Hon'ble Shri Justice R.M.S. Khandeparkar, President**
Hon'ble Shri Rakesh Kumar, Member (Technical)

FINAL Order No. 759-767/10-EX Dated: 28.04.2010

Misc order No 614-620/10-EX

Per Shri Justice R.M.S. Khandeparkar:

Since common questions of law and facts arise in all these appeals and applications, they were heard together and are being disposed of by this common order.

2. The appeals by the assessee arise from the orders passed by the lower authority demanding duty with interest and imposition of penalty while denying the benefit of Notification No.6/2000-CE dated 1.3.2000, as amended by Notification No.36/2000-CE dated 4.5.2000 for the period prior to 28.02.2001 and of the Notification No.3/2001-CE dated 1.3.2001 for the period from 1.3.2001 onwards. The assessee is engaged in the manufacture of various types of intravenous fluids. They had been claiming benefit under Notification No.6/2000-CE dated 1.3.2000 as amended by the Notification No.36/2000-CE dated 4.5.2000 whereby the intravenous fluids were exempted from payment of excise duty. With effect from 1.3.2001, the same was replaced by Notification No.3/2001-CE dated 1.3.2001, whereby the exemption from payment of duty was provided in relation to intravenous fluids, which are used for sugar, electrolyte and fluid replenishment. The appeals by the department are against the orders granting such benefits under the said notifications.

3. Since the Department sought to deny the benefit of the said notifications on the ground that the benefit under those notifications was restricted to those intravenous fluids, which are used for sugar, electrolyte and fluid replenishment, the benefit thereunder being not available for those intravenous fluids which are used for other purposes

also, the proceedings were started against the assesseees by issuing show cause notices which culminated in the orders passed by the adjudicating authority adverse to the interest of the assesseees. Before the Commissioner (Appeals), the orders of the adjudicating authority were either set aside or partially modified. When the matters were carried in appeals before the Tribunal, the issue was answered in favour of the assesseees and against the Revenue. The matters thereupon were carried in appeals before the Hon'ble Supreme Court.

4. By Order dated 31.03.2009, the Hon'ble Supreme Court set aside the orders passed by the Tribunal and remanded the matter to the Tribunal. The remand order reads thus:-

“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, the 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, anti-biotic and antimicrobial properties. It was alleged in the show cause notice that by addition of the following items to be 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
- (d) 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 judgement 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.”

5. Plain reading of the said remand order discloses that the Hon’ble Supreme Court has made it abundantly clear that the earlier Notification No.6/2000 dated 1.3.2000 as amended by the Notification No.36/2000 dated 4.5.2000 was replaced by new notification with different provision under Notification No.3/2001-CE dated 1.3.2001 and secondly that the earlier notification was open ended exemption while the latter one is restricted by three qualifications. The Hon’ble Supreme Court has clarified that in 2001-2002 Budget, explanation was inserted in Notification No.36/2000 clarifying that only such IV Fluids which are used for sugar, electrolyte or fluid replenishment would be exempt from duty and not other IV Fluids. Further that, the Commissioner had analysed this aspect in detail, which was ignored by the Tribunal in its order, which has been set aside by the Hon’ble Supreme Court.
6. The Hon’ble Supreme Court has also observed that the Tribunal has to consider the point relating to the label affixed to the containers of their products stating that IV fluids manufactured by the assesseees are scheduled H Drugs. Findings are expected on both these issues and therefore both the questions/issues need to be considered by the Tribunal in accordance with law, and hence the matter has been remanded.
7. The Hon’ble Supreme Court has also reminded that the exemption notifications are to be read strictly and that burden lies upon the assesseees to prove that the item falls within the four corners of the

exemption notification. The Hon'ble Supreme Court also observed that as regards the issue regarding Schedule H drug is concerned, if the Tribunal feels it necessary, may permit the parties to lead further evidence in relation to the said issue.

8. The matter has been remanded essentially to decide the two issues specified by the Hon'ble Supreme Court in the remand order. The issues are, firstly, the effect of 2001-2002 Budget, which describes the product of IV fluids with three qualifications viz. that IV fluids which are used for sugar, electrolyte or fluid replenishment and secondly, the effect of label affixed to the container of the product disclosing warning that IV fluid is Schedule H drug. Needless to say that on consideration of the said points, the claim of the assesseees for exemption benefit to IV fluids manufactured by them under Notification No.6/2000, as amended from time to time, for the period prior to 1st March, 2001 and under Notification No.3/2001 for the period from 1.3.2001 onwards has to be decided.

9. Evidently, the remand order discloses that it is not an open remand but a limited remand. It was held by the Calcutta High Court in **Scientific Instruments Co. Ltd. Vs. Collector of Customs & Excise** reported in 1980 (6) ELT 89 that when the order of the lower authority is set aside and the matter is remanded with specific directions then the power and jurisdiction of the lower authority is confined to the limits prescribed by the remand order. In such cases, the entire matter is not at large before the lower authority, nor the authority is free to decide the

case in its own way. Similar was the ruling by the Apex Court in **Mohan Lal Vs. Anandi Bai & Ors.** reported in AIR 1971 SC 2177 and reiterated in **Paper Products Ltd. Vs. Commissioner of Central Excise, Mumbai** reported in 2007 (214) ELT 161.

10. The restrictive nature of remand is further clear from the last para of the order of the Hon'ble Supreme Court wherein it has been specifically held that the appeals by the Department were allowed and the order of the Tribunal was set aside and the matters were remanded for fresh consideration in accordance with provisions of law "subject to what is stated above". The expression "subject to what is stated above" clearly brings out the restrictions imposed upon the scope of inquiry and adjudication of the matter by the Tribunal while deciding the appeals afresh in accordance with the law.

11. The Excise Appeal No.E/2752 of 2003 is filed by M/s. Ives Drugs (India) Pvt. Ltd. arises out of Order dated 24.07.2003 passed by the Commissioner of Central Excise, Indore. The said order was passed in relation to show cause notice dated 25.06.2003, which related to the period from 1st April, 2001 to 31st March, 2002. The products involved were Intravenous Fluids mixed with Mannitol, Metronidazole, Ciprafloracin, Icodex, Icolyte, Isodex 5% Invert Sugar, Iccocel, Icoamin, Isodex M & P, Glydex. The Commissioner had confirmed the demand to the tune of Rs.34,16,637/- with interest and had imposed penalty of Rs.2 Lakh under Rule 173Q read with Rule 25 of the Central Excise Rules. It also related to the show cause notice dated 24.04.2003, which pertained

to the period from April, 2002 to 31/12/2002 and the Commissioner confirmed the demand to the tune of Rs.37,48,361/- along with interest thereon and imposed penalty of Rs.2 Lakh under Rule 25 of the Central Excise Rules.

12. The Excise Appeal No.E/3110 of 2003 and Appeal No.E/3519 of 2004 have been filed by M/s. Venus Remedies Ltd. Therein the show cause notice was issued on 29th October, 2002 and the period involved was from March, 2001 to April, 2002. The products involved were Renaid, Metronidazole, Mannitol, Metrinidazole, Cipro, Mical, Vefloxin, Metro-Vet, Atropine Sulphate, Calcia, Ofloxin, Glycin Irrigation Solution and Detox. The Commissioner has confirmed the demand of Rs.18,12,240/- along with interest and imposed equal amount of penalty. Besides, he has also confirmed the demand of Modvat credit of Rs.22,046/- along with interest thereon and has appropriated credit of Rs.22,046/-, which has already been debited. In this matter, in fact, under show cause notice, the duty demanded was Rs.21,74,498/-. However, the Commissioner has held that Atropine Sulphate (brand name - Detox) was entitled for benefit of nil rate of duty under Notification No.3/2001-CE dated 1.3.2002 and the same being valued at Rs.4,51,867/-, the total value of the product in that regard was required to be reduced accordingly and that is how the demand has been confirmed only to the tune of Rs.18,12,240/-.

13. The Excise Appeal No.3249 of 2003 has been filed by M/s. Prem Pharmaceuticals against the order of the Commissioner of Central Excise,

Indore dated 13.08.2003. The period involved therein was 1st April, 2002 to 31st December, 2002 and the show cause notice was issued on 19.03.2003. The products involved were Ciprofloxacin, Mannitol, Anticoagulent Citrate Dextrose Solution, Anticoagulent Citrate Phosphate Dextrose Solution, Metronidazole, CPO Solution, Sodium Chloride Irrigation, D-Flox, Tinidex and Qulox. The Commissioner confirmed the duty amounting to Rs.23,27,116/- along with interest thereon and had imposed penalty of Rs.5 Lakhs under Ruled 25 of the Central Excise Rules.

14. The Excise Appeal No.E/837 of 2005 has been filed by M/s. Prem Pharmaceuticals against the order passed by the Commissioner, Indore on 29.01.2003. The period involved was from April, 2001 to March, 2002 and a show cause notice was issued on 29th April, 2002. The products involved were Ciprofloxacin, Mannitol, Anticoagulent Citrate Dextrose Solution, Anticoagulent Citrate Phosphate Dextrose Solution, Metronidazole, CPO Solution, Sodium Chloride Irrigation, D-Flox, Tinidex and Qulox. The Commissioner confirmed demand of duty to the tune of Rs.33,14,549/- along with interest thereon and also imposed penalty of Rs.5 Lakh under Rule 173 Q of the Central Excise Rules, 1944 and Rule 25 of the Central Excise Rules, 2001/2002.

15. The Excise Appeal No.4688 of 2004 has been filed by the Department against the order passed by the Commissioner of Central Excise (Appeals), Indore on 14.06.2004. The period involved therein was from 4.5.2000 to 31.03.2001 and a show cause notice was issued on

25.05.2001. The products involved therein were Mannitol, Glydex, Entigyl, Mezodex, Elcip, Metranidazole, Mezodex, Ciprofloxacin, Entigyl, Glycine Irrigation and Sodium Chloride Irrigation. The Adjudicating Authority therein had confirmed the demand of duty to the tune of Rs.10,59,490/- along with interest and equal amount of penalty. The Commissioner (Appeals) set aside the order to the extent of Rs.9,64,998/- and confirmed demand only to the tune of Rs.94,498/- while holding that there was no suppression of any facts and therefore the penalty was set aside.

16. The Excise Appeal No.E/4739 of 2004 has been filed by the Department against the order passed by the Commissioner of Central Excise (Appeals), Indore on 14.06.2004. The period involved was from May, 2000 to March, 2001 and a show cause notice was issued on 30.06.2001. The products involved therein were Ciprofloxacin, Mannitol, Metronidazole and Berrizole Injections. The Adjudicating Authority therein had confirmed the demand to the tune of Rs.3,27,190/- with interest and had imposed equal amount of penalty. The Commissioner (Appeals) has set aside the entire order of the adjudicating authority.

17. The Excise Appeal No.4860 of 2004 has been filed by the Department against the order passed by the Commissioner of Central Excise (Appeals), Indore on 13.06.2004. The period involved therein is from 5 of May, 2000 to 31st March, 2002 and a show cause notice was issued. The products involved therein were Mannitol, Ciprofloxacin, Typhocip, Anticoagulent Citrate Dextrose, Anticoagulent Citrate

Phosphate Dextrose, Metronidazole, Sodium Chloride Irrigation and Glycine Irrigation. The Adjudicating Authority had confirmed the demand to the tune of Rs.4,73,289/- with interest and equal amount of penalty was imposed. The Commissioner of Central Excise (Appeals), Indore held that the products viz. Mannitol Irrigation, Ciprofloxacin Irrigation, Typhocip Irrigation and Metronidazole Irrigation were eligible for exemption and, therefore, the total liability was directed to be re-computed. It was also held that the assesseees were entitled for Cenvat Credit. The entire penalty was set aside.

18. The Excise Appeal No.6075 of 2004 has been filed by the Department against the order passed by the Commissioner (Appeals), Indore on 21.07.2004. The period involved in the matter is from April, 2001 to March, 2003. Two show cause notices came to be issued, one dated 25.06.2002 and the other dated 7.7.2002. The products involved therein were Mannitol, Glydex, Entigyl, Mezodex, Elcip, Metranidazole, Mezodex, Ciprofloxacin, Entigyl, Glycine Irrigation and Sodium Chloride Irrigation. The Adjudicating Authority therein had confirmed the demand to the tune of Rs.1,68,989/- with interest and had imposed penalty of Rs.1 Lakh in relation to the show cause notice dated 25.06.2002 whereas had confirmed the duty demand to the tune of Rs.8,371/- with interest and penalty of Rs.10,000/- in relation to the show cause notice dated 7.7.2002. The Commissioner (Appeals) has set aside the entire demand and the penalty.

19. The applications filed in the said appeals are either relating to leave for production of additional evidence or are in the nature of submissions in response to the opposite side's case.

20. The product manufactured by the assesseees comprises of the intravenous fluids mixed with different medicaments like Mannitol, Metranidazole, Ciprofloxacin, Metronidazole, Tinidex, Ciprofloxacin, Ofloxacin, etc. The controversy relates to the claim for benefit of notification No.6/2000 read with Notification No.36/2000-CE dated 4.5.2000 for the period upto 28.02.2001 as well as of Notification No.3/2001-CE dated 1.3.2001 for the period from 1.3.2001 onwards in respect of the products in question. It is in relation to the said controversy that we have to find out the effect of 2001-2002 Budget which describes the product namely IV fluids with three qualifications and the effect of the warning disclosed in the labels on the containers of the products in question.

21. During the pendency of the proceedings, after remand, the assesseees filed applications for production of additional evidence in terms of Rule 23 of CESTAT Procedure Rule 1982. The Rule 23 (1) of CESTAT (Procedure) Rules provides that "the parties to the appeal shall not be entitled to produce any additional evidence either oral or documentary, before the Tribunal, but if the Tribunal is of the opinion that any document should be produced or any witness should be examined or affidavit should be filed to enable it to pass orders or for any sufficient cause, or if adjudicating authority or the appellate or

revisional authority has decided the case without giving sufficient opportunity to any party to adduce the evidence on the points specified by them or not specified by them, the Tribunal may, for the reasons to be recorded, allow such documents to be produced or witnesses to be examined or affidavits to be filed or such evidence to be adduced.”

22. Evidently, therefore, no party to the appeal is entitled, as a matter of right, to produce any additional evidence either oral or documentary before the Tribunal. Undoubtedly, if the Tribunal is of the opinion, that for sufficient cause, such opportunity should be given, and then the parties can be permitted to produce such evidence.

23. In the case in hand, as already observed above, the Hon’ble Supreme Court after hearing the parties while passing the remand order has specifically observed that the parties would be at liberty to produce evidence in relation to the issue relating to the Schedule H drug. In fact, the Hon’ble Supreme Court’s order is very clear on the point that the liberty so granted is only in relation to the issue pertaining to the warning comprised under label affixed to the container of the product manufactured by the assesseees. The remand order nowhere refers to such liberty in relation to other issue.

24. The applications filed by the assesseees for additional evidence is not in consonance with the said liberty. The same clearly travel beyond the scope of the liberty granted by the Hon’ble Supreme Court in the remand order.

25. It is pertinent to note that in case of claim for exemption from payment of duty on the basis of a notification, it is always for the assessee to establish his claim by producing sufficient evidence in support of such claim. In fact, this elementary principle of law relating to the burden to prove was clearly reminded by the Hon'ble Supreme Court in the remand order itself; however, no leave or liberty was sought for by the assessees from the Hon'ble Supreme Court to produce further evidence on the said issue. In other words, in spite of knowing well the said elementary principle of law and in spite of reminding about the same by the Hon'ble Supreme Court in the remand order itself, and further that the liberty to produce the evidence was restricted only in relation to the issue pertaining to Schedule H drug, no efforts were ever made by the assessees to seek liberty and/or leave from the Hon'ble Supreme Court to produce additional evidence on the said issue. The Hon'ble Supreme Court having restricted such liberty only in relation to the issue pertaining to the warning about Schedule H Drug, the question of allowing the parties to produce additional evidence in relation to any other issue does not arise, unless the Tribunal itself is of the opinion that such evidence is necessary to meet the ends of justice as provided under Rule 23 (4) of the CESTAT (Procedure) Rules.

26. Bare perusal of the applications seeking leave to produce additional evidence filed by the assessees discloses that the same are sought to be produced in answer to the question relating to the effect of addition of various medicaments and drugs to the IV fluids and whether

the mixture of anti-biotics and such fluids would justify the denial of exemption under the said notification. This is apparent from para-11 of the applications filed by the assesseees.

27. It is settled law, and the assesseees are very well knew that the matters relate to the claim of exemption benefit and therefore the burden in that regard squarely lies upon the assesseees to establish the claim and therefore it was necessary for the assesseees to produce all the materials in support of their claim before the adjudicating authority. This was necessary not only to establish the claim of the assesseees but also to give fair opportunity to the department to respond to the said claim.

28. Undoubtedly, additional evidence can be allowed by the Tribunal on sufficient cause being shown for the same by the party seeking to adduce such evidence. That would be in a normal appeal. In case of proceedings on remand, the authority dealing with the same has to confine itself to the limits of the adjudication earmarked by the appellate or remanding authority. As already observed above, the Hon'ble Supreme Court while remanding the matter has restricted the liberty to produce the additional evidence and the same has been confined to the issue relating to the warning about Schedule H drug, and even though the Tribunal has reminded of the burden to prove the claim of the exemption lies upon the assesseees yet no liberty has been given to the assesseees to produce further evidence in that regard. Being so, the question of Tribunal permitting the assesseees to lead further evidence on any other issue does not arise.

29. Even otherwise, a party to an appeal seeking to produce additional evidence has to make out a sufficient cause for production thereof. The sufficient cause would necessarily imply that such party should disclose the cause for non-production of such evidence before the adjudicating authority and the cause for production thereof only at the appellate stage before the Tribunal. When we speak of cause for such delay, the same must be convincing and justifiable.

30. Perusal of the applications filed by the assessee nowhere discloses any cause for non-production of proposed material before the adjudicating authority. Rather the liberty granted under the remand order to the assessee to lead further evidence is sought to be misconstrued to include the liberty relating to the evidence pertaining to the issues other than the warning about Schedule H drug also. The material sought to be produced do not relate to the issues under consideration in the matter at this stage.

31. For the reasons stated above, therefore, the question of allowing the parties to lead further evidence on any other issue does not arise at all. The applications are, therefore, liable to be dismissed and are dismissed.

32. Reverting to the facts of the case, as far as the period up to 28th February 2001 is concerned, the relevant notifications apparently disclose that the benefit thereunder was assured to "intravenous fluids" without any prefix or suffix and without any restriction or qualification. Both notifications merely referred to intravenous fluids classifiable under Chapter 30 of the Central Excise Tariff Act without any reference to and

without being qualified by any word or expression either as condition relating to the use of such products, or relating to the composition thereof.

33. Though all throughout the proceedings before the lower authorities, it was sought to be contended that the Notification No. 3/2001 will have retrospective effect, the learned Advocate appearing for the department has fairly conceded that it is difficult to support the said contention. Even otherwise, under the remand order itself, the point stands concluded as the Hon'ble Supreme Court has in the remand order itself clearly held that the earlier notifications were without any qualifications in contradiction to those prescribed under the changes brought about in the new notification.

34. As regards the said Notification No. 3/2001, the same specifically speaks of intravenous fluids which are used for sugar, electrolyte or fluid replenishment classifiable under Chapter 30 of the Tariff Act. In other words, the notification apparently does not apply to all the intravenous fluids but the benefit is restricted to those intravenous fluids which are used for sugar, electrolyte or fluid replenishment. This has been done not by mere clarification or any explanation being added to the old notification nor by way of amendment to the old notification but as has been held by the Hon'ble Supreme Court in the remand order, by way of replacement of the old notification, which was an open-ended exemption, by specifying three qualifications under the new notification.

35. The contention on behalf of the assessee, however, is that the said notification cannot be construed as restricted to those intravenous fluids

which are used exclusively for sugar or electrolyte or fluid replenishment. Irrespective of the fact that a medicament is mixed up or assimilated with the other contents in the intravenous fluids used for sugar or electrolyte or fluid replenishment, such products would also be entitled for benefit under the said notification. According to the assesseees unless the notification is so read, it would amount to reading down the notification with the addition of the expression like “exclusively” which would defeat the very purpose of the notification. That apart, it would be contrary to the law laid down by the Apex Court as regards the scope and rules of interpretation of an exemption notification.

36. The Id. Advocates appearing for the assessee have strenuously argued that once the condition specifically stated in the notification stands satisfied, the product would be eligible for availing the benefit thereunder. The fact that intravenous fluids, apart from being used for sugar, electrolyte or fluid replenishment, also carry some other drugs/medicaments, do not in any way make the notification inapplicable. It has been further submitted that the notification does not contain any restriction or prohibition in that regard nor it uses the expressions like “solely” or “only” or “exclusively” with reference to the three qualifications. According to the Id. Advocates addition of other drugs or medicaments in intravenous fluids used for sugar, electrolyte, or fluid replenishment would not prohibit or bar the applicability of the notification. Reliance is sought to be placed in the decisions in the matter of **Union of India Vs. Tata Iron and Steel Co. Ltd.**, reported in

1977 (1) ELT 61, **Gujarat State Fertilizers Co. Vs. Collector of Central Excise** reported in 1997 (91) ELT 3, **Compack Pvt. Ltd. Vs. Commissioner of Central Excise, Vadodara** reported in 2005 (189) ELT 3 and **Commissioner of Customs, Kolkata Vs. Rupa & Co. Ltd.** reported in (2004) 6 Supreme Court Cases 408. According to the Id. Advocates if the primary function of the intravenous fluid continues to be one for the use of sugar, electrolyte or fluid replenishment and the same simultaneously carries with it other drug or medicament as incidental to its main function, the product then would not change its identity or character as the intravenous fluid. Bearing in mind this fundamental concept, the product in question merely because it contains drugs and medicaments cannot be denied the benefit assured under the said notification.

37. It is also sought to be argued on behalf of the assesseees that there is a complete fallacy in the Revenue's assumption that the intravenous fluids in question are used merely as a carrier for vehicle for other drugs. Intravenous fluids for sugar, electrolyte or fluid replenishment are themselves drugs classifiable under Chapter 30. Intravenous fluids are administered when a patient is bed- ridden, mostly in hospitals. In normal course and depending upon the condition, the bed ridden patient is required to be given replenishment for sugar, electrolyte or fluid deficit in the body and it is for taking care of this medical requirement that intravenous fluid is administered in the body. Simultaneously, the patient may also need some other drug such as ciprofloxacin, metronidazole etc.

and their extent is hardly about 5 ml to 10 ml which comes to less than even 0.5%. Since large doses of intravenous fluids to the extent of 100 ml or more are to be administered in the body of the patient as per his medical requirements for sugar, electrolyte or fluid replenishment, such other drugs or medicaments whose extent is comparatively much smaller, are mixed in the intravenous fluid at the manufacturing stage itself so that the doctor will not have to bother about administering such other drugs separately. Apart from being convenient, this also takes care of the concept of aseptic conditions and reduces irritation potential of the drug. The IV fluid continues to perform its primary function of being used for sugar, for replenishment and simultaneously carries other drugs and medicaments as incidental to its main function and does not in any manner change the identity or the character of IV fluids.

38. It is further contention on behalf of the assessee that the aforesaid position is fully recognised in the book viz. 'Remington's Science and Practice of Pharmacy'. It has clearly been stated that it has become common practice to add other drugs to certain intravenous fluids to meet the clinical needs of the patient. Using intravenous fluids as vehicles offers the advantage of convenience, the means of reducing the irritation potential of the drug, and a method for continuous drug therapy. The intravenous fluids even with a small extent of antibiotics are nothing else but intravenous fluids for fluid replenishment. The intravenous fluids comprising of medicaments and drugs are administered in human body by

injecting the same and even intravenous fluids for sugar, electrolyte or fluid replenishment etc. are also intravenous injections.

39. The Id. Advocates for the assesseees have also referred to a report by Prof. Ms. A.R. Jubekar, extracts from Remington's Science and Practice of Pharmacy, and affidavit of Dr. Ram Irani, in support of their submissions. All these materials, however, are sought to be produced along with the applications seeking leave to adduce additional evidence.

40. As regards the issue relating to the Schedule H drugs, it is sought to be contended on behalf of the assesseees that the notification grants exemption in respect of all intravenous fluids used for sugar, electrolyte or fluid replenishment and it makes no reference nor provides any restriction with regard to Schedule H drug. The effect of the warning about Schedule H drug is that the goods have to be sold by retailer only on prescription of a registered medical practitioner and it does not speak of use or pharmacological category of the medicine and this is evident from the certificate dated 28.08.2009 issued by the licensing authority.

41. The Id. Advocate appearing for the department, on the other hand, has submitted that the notification restricts the benefit to those intravenous fluids which are used for specified purposes. It does not include any other purpose. To assume that the notification does not bar simultaneous use of intravenous fluids for other purposes also, either as incidental or otherwise, would amount to enlarge the scope of the notification. According to the department, the law on the point that the exemption notification ought to be interpreted strictly is well settled. To

presume that the notification also takes into its sweep the products which are used for any purpose, other than sugar, or electrolyte or fluid replenishment, would render the specific expression used regarding the qualifications attached to the product to be eligible to avail the benefit thereunder to be otios.

42. He further submitted that it is true that the notification does not use the expressions like 'solely', 'only' or 'exclusively'. But at the same time, the notification also does not use the expressions like "along with" or "exclusively or otherwise" nor it gives any indication that the exemption thereunder can be extended to the product which is used for any purpose other than those specified therein or for any other purpose along with the purpose specified therein. According to the Id. Advocate for the department, if we accept the interpretation sought to be given by the assessee, it would automatically enlarge the scope of the notification and defeat the very purpose behind the notification.

43. The Advocate for the department has submitted that the essential character of the impugned drugs mixed with intravenous fluids is that of the injections by which nomenclature those products are known in the market. Even in common parlance intravenous fluids are distinguished from IV injections and that is apparent from the tender document placed on record. It is settled law that to understand a product for the purpose of classification, the twin tests, which include the common parlance theory, have to be applied as has been held by the Apex Court in **Commissioner of Central Excise, Nagpur Vs. Shree Baidyanath Ayurved Bhawan**

Ltd. reported in 2009 (237) ELT 225. Even the Drugs and Cosmetic Act clearly distinguishes the impugned injection, which are covered as prescription drugs in Schedule H from intravenous fluids which are covered by Schedule C. The injection known as irrigation are meant to clean the veins only and not for pushing through veins or for replenishing body fluids. The injections which are less than 100 ml quantity did not qualify to be called intravenous fluids.

44. It is further contention on behalf of the department that the budget Explanatory note of 2000-01 clearly clarified that intravenous fluids exempted under Notification No. 36/2000 are those meant to be used for sugar, electrolyte or fluid replenishment. Attention is drawn to the decision of the Supreme Court in the matter of **Collector of Central Excise Vs. Parle Exports (P) Ltd.** reported in 1988 (38) ELT 741 (SC), while contending that a notification is to be treated as if it is enacted in the Act itself.

45. While contending that the term intravenous fluids has distinct connotation in medical parlance, it is further submitted on behalf of the department that under Chapter 30 of the Tariff Act, no distinction has been made between oral antibiotics and intravenous antibiotic injection. Obviously, it could not be assumed that the intention of the legislature was to make a special dispensation by exempting intravenous antibiotic injections from duty while levying duty on oral antibiotics in the absence of specific and clear notification in that regard. If that was the intention, it would have clearly reflected in the notification itself. Even assuming that

there is any ambiguity or doubt regarding the scope of exemption notification issued under a fiscal statute, it is settled law that the same should be resolved in favour of Revenue and in that regard our attention has been drawn to the decision of the Apex Court in the matter of **Liberty Oil Mills (P) Ltd. Vs. Collector of Central Excise, Bombay** reported in 1995 (75) ELT 13.

46. After the conclusion of the arguments in the above matter and while the same was reserved for the judgment, the Advocate for the assessee forwarded a copy of order passed by the West Zonal Bench of CESTAT at Mumbai on 5th May, 2010 in Appeal No. C/9 to 13 of 2002 in the matter of **Fresenius Kabi India Pvt. Ltd. Vs. CC (Import), Mumbai** which is reported in 2010 (256) ELT 257. The said decision apparently appears to have been forwarded in support of the contention that the notification in the absence of use of the words like 'exclusively', 'only' or 'solely' could not deny the benefit to the product in question.

47. The Departmental Representative has also referred to the opinion by the Director, Shri G.S. Institute of Technology and Science, Indore, extracts from Ramington's Science and Practice of Pharmacy, Tender documents of BHU, websites' definitions in support of his contentions. All these materials were produced in answer to the applications by the assessee seeking leave to produce further evidence.

48. Before dealing with the rival contentions on the points in issue, it will be necessary to scan through the decision by the Co-ordinate Bench

of the Tribunal in **Fresenius Kabi India Pvt. Ltd.** case and to ascertain whether the same is relevant for the decision in the matters in hand.

49. In **Fresenius Kabi India Pvt. Ltd.** case, the question for determination was whether the goods imported by the assessee in the year 1999 and 2000 and described in the Bills of Entry as “Intravenous Amino Acid” were entitled for the benefit of Notification No. 20/99-Cus dated 28th February 1999 and No. 16/2000-Cus dated 1st March 2000. The relevant entry under both the notifications reads thus : “life saving drugs/medicines including their salts and esters and diagnostic text kits specified in List 2”. In List 2 annexed to each of the notification Item No. 100 reads thus : “Intravenous Amino acids”. The goods which were imported under brand name “Vamin-G” and under the brand name “Aminomix”, the product composed of a mixture of Amino acid, glucose (Carbohydrates) and electrolytes. The Tribunal while observing that, admittedly, the goods were composed of “Intravenous Amino acid” along with glucose and a variety of electrolyte and that they were life saving drugs and that such life saving drugs were covered under Sr. No. 50 (A) of Notification No. 20/99 and under Sr. No. 80 (A) of Notification No. 16/2000 and further taking note of scientific literature has observed that, the Amino acid would optimally benefit patients in the presence of carbohydrates, electrolytes etc. Further, it has been held that the functional ingredient being Intravenous amino acid, the benefit of the notification would be available to the product. Reliance has been placed in the decision of the Tribunal in the matter of **Commissioner of**

Customs, Chennai Vs. Tablets (India) Ltd. reported in 2005 (191) ELT 280, further order by the Apex Court in the same matter reported in 2006 (198) ELT 36 and **Tata Iron and Steel Co. Ltd.** (supra), while observing that, the Supreme Court took the view that the benefit was not available “exclusively” or “only” to duty paid pig iron inasmuch as the expressions like “exclusively” or “only” were not used in the notification.

50. At the outset, it is to be noted that the decision of West Zonal Bench in **Fresenius Kabi India Pvt. Ltd.** case was not in relation to the notifications in question. The said decision was in relation to notifications under the Customs Act. Besides the phraseology used in the notification was not similar to the one used in the notifications in question. The exemption available under the notification which was subject matter of the decision in **Fresenius Kabi India Pvt. Ltd.** case was essentially to “life saving drugs/medicines including”. Apparently, the definition of the products, which were made eligible to avail the benefit of notification, was of inclusive nature. That is not the case in relation to the notifications in question. Being so, the decision is clearly distinguishable. The decision which is delivered in relation to a notification, the phraseology of which is totally different, the definition of the product under the notification being of inclusive nature, and the notification being under totally different statute, the said decision cannot be of any help to the assessee in the matters in hand.

51. It is true that the Division Bench had relied upon the decision of the Apex Court in **Tata Iron and Steel Co. Ltd.**, hereinafter referred to as **TISCO Ltd.** case. In that case, the Apex Court was dealing with a matter relating to an exemption Notification No. 30/60-CE dated 1st March 1960 under which steel ingots, in which duty paid pig iron was used, were exempted from so much of duty leviable thereon as is in excess of Rs.30 per ton. By Notification No. 120/60 dated 1st October 1960, the said Notification No. 30/60 was amended by substituting the figures and words “29.35 per metric tone” for the words and figures “30 per ton”. Further, under Notification No. 75/62 dated 24th April 1962, steel ingots falling under Item 26 of the First Schedule to the Central Excise Tariff Act and specified in Column 2 of the Table appended to the notification were exempted from so much of duty of excise leviable thereon as is in excess of duty specified in the corresponding entry in Column 2 of the said Table. According to the description of the product and the duty payable as specified in Column 2 of the Table appended to the said notification, if it was produced out of scrap obtained from duty paid pig iron, the duty payable was Rs.30 PMT and if produced out of old iron or steel or scrap obtained from duty paid steel ingots or products, the duty payable was Nil. The said rates were further amended under Notification No. 22/64 dated 1st March 1964 whereby the words and figures “Rs.29.35 per metric ton” were substituted which by “Rs.20 per ton” in relation to the rates specified in Notification No. 30/60 dated 1st March 1960.

52. The facts of the TISCO's case as revealed from the judgment of the Apex Court are that the duty was realised from the assessee on steel ingots in the making of which duty paid pig iron of rejected ingot moulds and bottom stools were used along with non-duty paid materials. The assessee had claimed exemption in respect of duty paid pig iron on rejected moulds and bottom stools used in the manufacture of steel ingots. The claim was rejected by the revenue authorities. When the matter was challenged before the High Court the orders of the Revenue authorities were quashed, while observing that the notification did not use the words like 'entirely', 'exclusively' or 'only' but only exempted steel ingots manufactured out of the use of the duty paid pig iron. When the matter was carried before the Apex Court, it was held thus :

" Counsel for the respondent is right in the contention that the only question here is whether duty-paid pig-iron is used along with non-duty paid materials. There is no dispute that there are materials and data to find out the quantity of duty-paid pig iron used. Pig iron is made out of iron ore plus limestone plus coke. Pig iron is melted and processed into ingot moulds and bottom stools. Nothing is added to pig iron. When ingot moulds and bottom stools become unserviceable they are broken. This becomes scrap and is melted and used in the manufacture of steel ingots. The respondent rightly contends that all the time it is duty-paid pig iron which is processed into ingot moulds and bottom stools and again broken into scrap and melted in the making of steel ingots.

The High Court rightly held that the contention of the Revenue fails on two broad grounds. First, there cannot be double taxation on the same article. Counsel for the Revenue gave the example of excise duty on motor car, in spite of the fact that there was duty on tyres and duty on metal sheets. The analogy is misplaced. In such cases the duty is on the end product of motor cars as a whole. The duty on tyres and the duty on metal sheets do not enter the area of duty on motor car. Second, Notification No. 30/60 grants exemption to duty-paid pig iron. The High Court rightly said that the Notification does not say that exemption is

granted only when duty paid pig iron is used and that the exemption would not be available if duty paid pig iron is mixed with other non-duty paid materials. If the intention of the Government were to exclude the exemption to duty paid pig iron when mixed with other materials then the notification would have used the expression "only" or "exclusively" or "entirely" in regard to duty paid pig iron. The object of the notification was to grant relief by exempting duty paid pig iron."

53. The said decision of the Apex Court in TISCO's case relates to the exemption granted to a product manufactured with the use of certain inputs in terms of notification which clearly provided that the produce with the use of identified inputs would be entitled for exemption as per the notification which was under consideration before the Apex Court. The description of the produce related to the utilisation of an input while manufacturing the final product which would be entitled to take the benefit of exemption. It is common knowledge that the final product of the nature described in the notification could not have been manufactured with the use of sole input described in the notification. In those circumstances, the High Court and Apex Court came to the conclusion that in the absence of the words like 'entirely', 'exclusively' or 'only', the benefit of notification cannot be restricted to a product with the exclusion of use of other inputs along with the inputs identified under the notification. It is so because the final product could not have been manufactured without utilisation of other inputs alongwith the one identified under the notification. Certainly the absence of words like 'exclusively', 'only' or 'entirely' restricting the benefit would have resulted in defeating the very purpose of the notification. The reasonings narrated by the Apex Court in para-22 quoted above clearly disclose the

justification for the view taken in the facts and circumstances of the case wherein the notification does not permit any such restriction for the grant of benefit thereunder. The said ruling cannot be applied to the facts of the case in hand. It cannot be said, nor it is the case of the assessee that the intravenous fluids used for sugar, electrolyte or fluid replenishment cannot be manufactured without the mixture of the drugs in question.

54. Similarly, the decision of the Tribunal in **Tablets (India) Ltd. case** reported in 2005 (191) ELT 280 (Tribunal-Chennai) was relating to the claim of exemption benefit in respect of bulk drugs imported for the use in manufacture of Intravenous Amino Acid and it was under Notification No.17/2001-Cus and the said benefit was sought to be denied solely on the basis of Board's Circular No.45/2000-Cus dated 16.05.2000 under which it was sought to be decided not to extend the benefit of the said notification to Intravenous Amino Acid containing Carbo Hydrates and Electrolyte. It was observed that the goods under import were not Intravenous Amino Acid but the bulk drugs for their use in the manufacture of Intravenous Amino Acid. It was not the case that the branded medicines manufactured by the assessee from the imported bulk drugs were not Intravenous Amino Acids and, therefore, the additional presence of Sorbitol or Glucose would not make the manufactured drugs other than Intravenous Amino Acids. In those circumstances, the Apex Court also did not interfere in the said order of the Tribunal. Apparently the decision, apart from being relating to a different notification under a different statute, it is clearly distinguishable on facts. That was in a case

where it related to the product used for manufacture of some other products and the exemption notification did not provide that the final product was required to be exclusively the one, which was specified and, nor it provided that such final product should not be accompanied by any other component, either expressly or impliedly. The notification related to a product to be used as intermediate product in the manufacture of a final product. In the case in hand, the exemption notification is under Excise Act relating to the final product with specific qualifications regarding the use thereof.

55. Before proceeding to deal with the issue in the matter, it would be necessary to address to the point canvassed relating to the scope of interpretation of exemption notification under a fiscal statute. While it has been argued on behalf of the department that exemption notification ought to be interpreted strictly and the burden is upon the assesseees to establish that their products are entitled to avail the exemption, on the other hand, on behalf of the assessee, the Tribunal has been repeatedly reminded that under the guise of interpretation it is neither permissible to add something to the notification nor to subtract therefrom.

56. Undoubtedly, law on the point that the exemption notification has to be understood on the basis of the grammatical meaning of the words used in such notification unless context otherwise requires is well settled. It is well settled law that in a taxing statute there is no room for any intendment but regard must be had to the clear meaning of the words. The entire matter is to be governed wholly by the language used in a

notification. If the tax-payer is within the plain terms of the exemption, it cannot be denied its benefit by calling in aid any supposed intention of the exempting authority. If such intention can be gathered from the construction of the words of the notification or by necessary implication therefrom, the matter could be different. What the law makers intended to be done or not to be done can only be legitimately ascertained from that which it has chosen to enact, either in express words or by reasonable and necessary implication. It should not be forgotten that primacy is to be given to the words in which the intention of the law-giver has been expressed. The decisions of the Apex Court in **Hemraj Gordhandas Vs. H.H. Dave Assistant Collector of Central Excise & Customs** reported in 1978 (2) ELT 350 and **Collector of Central Excise Vs. Parle Exports (P) Ltd.** reported in 1988 (38) ELT 741 are very clear in this regard.

57. In **Parle Exports (P) Ltd.** (supra), it was held thus:-

“The expressions in the Schedule and in the notification for exemption should be understood by the language employed therein bearing in mind the context in which the expressions occur. The words used in the provision, imposing taxes or granting exemption should be understood in the same way in which these are understood in ordinary parlance in the area in which the law is in force or by the people who ordinarily deal with them. It is, however, necessary to bear in mind certain principles. The notification in this case was issued under Rule 8 of the Central Excise Rules and should be read along with the Act. The notification must be read as a whole in the context of the other relevant products. When a notification is issued in

accordance with power conferred by the statute, it has statutory force and validity and, therefore, the exemption under the notification is, as if it were contained in the Act itself. So in this connection the observations of this Court in **Orient Weaving Mills (P) Ltd. v. The Union of India** 1978 (2) ELT (J311) (SC) (1962 Supp. 3 SCR 481). See also *Kailash Nath vs. State of U.P.* (Air 1957 SC 790). The principle is well-settled that when two views of a notification are possible, it should be construed in favour of the subject as notification is part of a fiscal enactment. But in this connection, it is well to remember the observations of the Judicial Committee in *Coroline M. Armytage Others v. Frederick Wilkinson* [1978 (3JA.C. 355 at 370)] that it is only, however, in the event of there being a real difficulty in ascertaining the meaning of a particular enactment that the question of strictness or of liberality of construction arises. The Judicial Committee reiterated in the said decision at page 369 of the report that in a taxing Act provisions establishing an exception to the general rule of taxation are to be construed strictly against those who invoke its benefit. While interpreting an exemption clause, liberal interpretation should be imparted to the language thereof, provided no violence is done to the language employed. It must, however, be borne in mind that absurd results of construction should be avoided”.

58. In **Hemraj Gordhandas** (supra), the Apex Court had held that in a taxing statute, there is no room for any intendment but regards must be had to the clear meaning of the words. The entire matter should be governed wholly by the language of the notification.

59. The Apex Court in **CCE, Hyderabad Vs. Sunder Steels Ltd.** reported in 2005 (181) ELT 154 had clearly ruled that the notification has

to be interpreted on its wordings and no words, not used in the notification can be added.

60. **Bombay Oil Industries Pvt. Ltd., vs. Union of India** reported in 1995 (77) ELT 32 (SC) it was held that it is trite to say that in order to earn the exemption, the person claiming the exemption must satisfy that his imported item has fulfilled all the conditions of exemption notification as such exemptions are granted in public interest.

61. In **Indo-International Industries vs. Commissioner of Sales Tax**, reported in 1981 (8) ELT 325 (S.C.) the Bench of three Hon'ble Judges of the Apex Court had ruled that in interpreting items in statutes like the Excise, Customs, Sales Tax Acts, whose primary object is to raise revenue for which purpose they classify diverse products, articles and substances, resort should be had not to the scientific and technical meaning of the terms or expressions used but to their popular meaning, that is to say, the meaning attached to them by those dealing in goods. If any term or expression has been defined in the enactment, then it must be understood in the sense in which it is defined but in the absence of any definition being given in the enactment the meaning of the term in common parlance or commercial parlance has to be adopted.

62. In **Liberty Oil Mills (P) Ltd. Vs. Collector of Central Excise, Bombay** reported in 1995 (75) ELT 13, the Apex court has held that in case of an ambiguity or doubt regarding an exemption provision in a fiscal statute, the ambiguity or doubt will have to be resolved in favour of the Revenue and not in favour of the assessee. It was observed that the

said issue stood concluded by the decision of the three Judges Bench of the Apex Court in **M/s Novapan India Limited, Hyderabad vs. CCE & Customs, Hyderabad** reported in 1994 (73) ELT 769.

63. **In Commissioner of Central Excise, Hyderabad Vs. Sunder Steels Ltd.** reported in 2005 (181) ELT 154 (SC), the Apex Court had held that a notification has to be interpreted on its wording and no words not used in the notification can be added.

64. **In Parle Biscuits (P) Ltd. Vs. State of Bihar & Ors.** reported in 2005 (9) SCC 669, it was ruled that a statutory notification should not be extended so as to meet a casus omissus, while relying upon the decision in the case of **Privy Council in Crawford Vs. Spooner** reported in 1846 6 Moo PC 1, wherein it was held that “we cannot aid the legislature’s defective phrasing of the Act, we cannot add, and mend, and, by construction, make up deficiencies which are left there”.

65. **In Union of India Vs. Inter Continental (India)** reported in 2008 (226) ELT 16 (SC), it was held that the department by issuing a circular subsequent to the notification could not add new condition to the notification thereby restricting the scope of exemption notification or whittling it down.

66. **In Gujarat State Fertilizers Co.** (supra), it was clearly held that by catena of decisions, it is now well settled that for deciding whether an exemption notification gets attracted on the facts of a given case, the expressed language of the exemption notification has to be given its due effect, and due emphasis are to be given to the clear language of the

condition mentioned in the exemption notification. It was further held that it must be kept in view that the object and the purpose of the exemption has to be culled out from the expressed language of the notification. If the express language of the notification does not indicate a contrary intention conveyed by the wide words employed by the notification, full effect has to be given to the wide terminology employed by the notification otherwise the result would be that in trying to search for the supposed intention underlying the notification, the intention flowing from the expressed language of the notification would get stultified or truncated.

67. While understanding the scope of a notification it is not sufficient to apprehend the phraseology used in the provision of law but it is also necessary to take note of the words which are specifically omitted to be used therein. The scope of statutory provision, whether primary or subordinate, can be well understood and appreciated by taking stock of both the aspects in that regard. Merely because the extension of such benefit to the product used for sugar, electrolyte or fluid replenishment along with other medicament may even appear to be appropriate, that would not be justification for extension of such benefit to all such products. It is not permissible to enlarge the meaning of a notification as it will amount to encroachment over the jurisdiction of the legislature and executive. It is not the function of the Tribunal to make the law. It has to understand the law as it exists and to make others to understand it whenever any doubt arises relating thereto. A notification is to be

understood as has been explicitly stated, and at the most, what is necessarily implicit, and nothing less, nothing more.

68. While being cautious of the basic dictums of interpretation of exemption notifications issued under taxing statutes as propounded by the plethora of judicial pronouncements, our dialectic analysis in the matter in hand can not traverse the peripheral limits prescribed under the remand order passed by the Apex Court.

69. The first issue relates to the effect of the budget of 2001-2002 relating to the exemption from payment of duty on IV Fluids. It has two aspects, first relates to retrospectivity and second relates to three qualifications – whether the same disclose restrictive nature or not. The Explanatory Note in the Budget 2001-2002 in respect of Chapter 30 of the Schedule to the Central Excise Tariff Act reads thus :-

“Medicaments (Chapter 30) – The description of Intravenous Fluids (IV Fluids) has been changed to IV Fluids, for sugar, electrolyte or fluid replenishment. This change is clarificatory in nature. The reference to brand name E Mal, in the exemption relating to ARTEETHER has been deleted. The description now reads as ‘ARTEETHER’ or formulations of ‘ARTEMI SININ’.”

70. According to the Department, this clarification would disclose the retrospective applicability of three qualifications in relation to the use of the product to be eligible to claim the exemption benefit, whereas the assessees contend that the same cannot be enforced retrospectively. Reliance is placed in the decision in the matter of **Collector of Central**

Excise, Shillong Vs. Wood Craft Product Ltd. reported in 1995 (77) ELT 23 on behalf of the department whereas on behalf of the assessee, reliance is placed in the decision in the matter of **The Cannanore SPG & WVG. Mills Ltd. Vs. CCE** reported in 1978 (2) ELT J 375 (SC), **Bombay Oil Industries Pvt. Ltd. Vs. Union of India** reported in 1995 (77) ELT 32 and **P. Mahendran & Ors Vs. State of Karnataka & Ors.** reported in 1990 (1) SCC 411.

71. At the outset, it is to be noted that the Explanatory Note never formed part of any notification including the Notification No.36/2000 as is apparent from the said notification itself. It was in relation to the budget for the year 2001-2002 while referring to the exemption in the changed form incorporated under the new Notification No.3/2001 dated 1.3.2001, which came into force from the said date. The said changes were clarified under the explanatory note to the budget. What is stated in the Note is that the change, which has been brought about, is clarificatory in nature. However, the clarification was introduced by replacement of the old notification by new notification and the new notification was made enforceable from 1.3.2001. Even the said Notification No.3/2001 on the face of it states that it “hereby” exempts the excise goods referred thereunder.

72. It is to be noted that prior to 4.5.2000, there was no exemption to IV Fluids. It was introduced for the first time from 4.5.2000 under Notification No.36/2000. However, no material has been placed before us relating to contemporaneous period which could reveal the mind of the

law makers that the exemption to the products qualified by three things as specified under the Notification No.3/2001 was to apply retrospectively.

73. The decision in **Wood Craft Product Ltd.** case was in a totally different facts situation. It was a case of amendment to Chapter Note 5 in Chapter 44. Considering the same, it was held that the amendment merely clarified and made explicit that which was implicit in the heading throughout. That is not the case in the matter in hand. The law makers have not merely added any Explanatory Note either to the Chapter 30 or to the Notification itself, but Explanatory Note is under a budget which relates to the subsequent year and effect of note was not merely to amend the Notification No.6/2000 or Notification No.36/2000 but to introduce a totally new notification in place of old one.

74. As far as the decision in the matter of **Cannanore SPG & WVG Mills Ltd.** is concerned, the same was on the basis of concession made by the department's counsel. The decision in **Bombay Oil Industries Pvt. Ltd. case** was to the effect that the latter notification, which is a fresh notification laying down fresh conditions deleting the earlier conditions about the colour specifications could not be said to be a clarificatory notification nor it can have any retrospective effect. In **P. Mahendran's case**, it was held that unless there were words in a statute or rules showing the intention to affect the existing rights, the rule must be held to be prospective. Being so, it is difficult to accept that the Explanatory Note to the Budget 2001-2-2 would disclose retrospectivity of the changed provision in respect of exemption granted to IV Fluids.

The changes brought about are essentially under Notification No.3/2001, which came into force w.e.f. 1.3.2001 and not prior thereto. This covers first part of the said issue.

75. The second part of the issue relates to three qualifications. It is to be noted that we are dealing with the matter relating to the claim for exemption to the product manufactured by the assessee. This is not a matter relating to the dispute pertaining to classification. The notification *ex facie* describes the product, which is eligible to claim the exemption benefit thereunder. A person claiming the benefit of exemption under a notification in relation to a product which does not correspond to the description given in the notification, by applying the theory of implied inclusion of such product under the notification, has to establish the same by cogent evidence. As already observed above, the burden in that regard rests exclusively upon such claimant. This has also been reiterated by the Apex Court in the remand order itself.

76. The notification in question specifically refers to the expression “intravenous fluids which are used for sugar, electrolyte or fluid replenishment” with effect from 1st March 2001 and prior to that the same used the expression “intravenous fluids”. Apparently, there was conscious decision by the law makers to identify the intravenous fluids which would be entitled to avail the benefit under the said notification to be those which are used for sugar, electrolyte or fluid replenishment.

77. The notification apparently relates to the product which is entitled for exemption while specifying the use thereof. The law makers have

identified the use of intravenous fluids for sugar, electrolyte and fluid replenishment for the purpose of grant of exemption. It is true that it does not use the word “exclusively” or “only”. At the same time the description also does not use the words like “along with” or “etc”. Besides, prefix like “all” is conspicuously absent before the expression “intravenous fluids”. If one peruses item No.58 in the very said notification, the law makers have used the expression “all” before the word “goods” to signify that it refers to all the goods covered by Chapter 30. That is not the case in relation to intravenous fluids classifiable under Chapter 30. It has restricted to those intravenous fluids which are used for sugar, electrolyte or fluid replenishment. In such circumstances, can it be said that the absence of the words like ‘exclusive’, ‘only’ or ‘entirely’ would make any difference?

78. The Chapter 30 of the Central Excise Tariff Act refers to various medicaments. If the benefit under the said notification is meant for all such drugs, which are introduced in the human body through intravenous then the law makers would not have qualified the intravenous fluids as being those used for specified purposes while referring to the goods classifiable under Chapter 30 for the purpose of availability of exemption from payment of duty.

79. The contention that the product remains the same even after addition of drugs like ciprofloxacin, metronidazole etc. is neither acceptable, nor even relevant. It is the case of the appellants themselves that some times patient may need some other drugs such as ciprofloxacin,

metronidazole etc. and the same instead of administering separately, in order to facilitate the medical practitioners these drugs are mixed with the fluid used for sugar, electrolyte or fluid replenishment so that the doctors need not bother about administering such drugs separately. Apart from being convenient, it also takes care of the concept of aseptic conditions and reduces irritation potential of the drug. The very fact that the product having such mixture of drugs are meant for totally different function, purpose and effect, apparently discloses that pursuant to such mixture of drugs, the product does not remain merely to be intravenous fluids used for sugar, electrolyte or fluid replenishment. The product acquires a totally different character. It has different purpose and use.

80. The contention that notification grants the exemption in respect of all the intravenous fluids for sugar, electrolyte or fluid replenishment is totally devoid of substance. As already pointed out above, the expression referring to the exempted product is not prefixed by the word "all", rather it specifically restricts to those intravenous fluids which are used for specified purposes and no other intravenous fluids.

81. Perusal of the report on intravenous fluids by the Institute of Chemical Technology, Mumbai, affidavit of doctor, Remington's Science and Practice of Pharmacy does not render any assistance to the appellant's case. The contention that additions of drugs do not change the basic character of the product i.e. intravenous fluids used for replenishment of sugar or electrolyte or fluid in the human body system is also devoid of substance. As it is apparent that the addition of the drugs

or medicaments in such fluid is certainly for a totally different function and on mixture of such drugs or medicaments, the product is not known by the same name.

82. It is to be borne in mind that in the cases in hand prior to 1.3.2001, and w.e.f 4.5.2000 onwards, the exemption was available to Intravenous Fluids without there being any restriction or qualifying words being appended to the said entry. With effect from 1.3.2001, the law makers introduced three qualifying words so that the IV Fluids, in order to be eligible to claim exemption, should be those which are used for sugar, electrolyte or fluid replenishment. The law makers, therefore, consciously imposed the condition which clearly speaks of restrictions and limitation prescribed to the product to be eligible to claim the exemption benefit. If one peruses the Explanatory Note in the Budget, it clearly speaks of “changes” having been brought about by introducing the above qualifications for the product to be eligible to claim the benefit. Had it been the intention of the law makers to allow IV Fluids with any sort of composition to be eligible for the benefit of exemption then the notification itself would not have qualified the entry with those three words, nor the Explanatory Note would have specifically referred to “the changes” having been brought about.

83. The contention that even after mixture of anti-biotics with the Intravenous Fluids the latter continues to replenish sugar, electrolyte or fluid in the body and that, therefore, the product does not change its basic character and, therefore, would be eligible for exemption benefit is also

totally devoid of substances. Basically the eligibility criteria in relation to the exemption notification nowhere speaks of mixture of Intravenous Fluids with any component which can be used for therapeutic purposes. By way of interpretation of the notification, inclusion of product with such mixture in the eligibility criteria would amount to read down the notification by expanding its scope beyond the description of the product for which the exemption has been granted. It is not the pharmacopical view that can decide the classification of the product. It has to be on application of common parlance theory. The contention that the character of the IV Fluids would not change pursuant to the mixture of anti-biotics with such product cannot be accepted. In order to be eligible to claim the benefit under the said notification, the product has to satisfy the description of the product given under the notification. Mixture of anti-biotics with IV Fluids cannot be construed as included in the product named and identified for exemption benefit under the said notification.

84. In **Dabur (India) Ltd., vs. Commissioner of Central Excise, Jamshedpur** reported in 2005 (182) ELT 290 (SC) a Bench of three Hon'ble Judges of the Supreme Court held that in classifying a product the scientific and technical meaning is not to be resorted to. The product must be classifiable according to the popular meaning attached to it by those using the product. Referring to the facts of the case before the Apex Court, it was held that the assessee had shown that all the ingredients in the product were those which were mentioned in the Ayurvedic Text Books. That by itself would not have been sufficient,

however, the assessee had shown that they had a Drug Controller's Licence for the product and they had also produced evidence by way of prescriptions of Ayurvedic Doctors, who had prescribed those for treatment of rickets. As against that the revenue had not made any effort nor had produced any evidence.

85. In **Commr. of C. Ex. Nagpur vs. Shree Baidyanath Ayurved Bhawan Ltd.**, reported in 2009 (237) ELT 225 (SC) the Apex Court disapproved the approach of the Tribunal in overlooking and ignoring common parlance test which is one of the well recognized tests to determine whether the product is classifiable as medicament or cosmetic. It was held that it is well settled legal proposition that without a change in the nature or a change in the use of the product and in the absence of a statutory definition, the product will not change its character. It was also held that the definition of one statute having different object, purpose and scheme cannot be applied mechanically to another statute.

86. In **Rupa & Co.** (supra), the Apex Court was dealing with a matter related to the claim of exemption from the customs duty and additional duty under Notification No.29/97-Cus dated 1.4.97. Thereunder the capital goods imported under EPCG Scheme were exempted from payment of customs duty and so much of additional duty as was in excess of 10% of the value of the goods. Under the proviso, if the capital goods were imported for manufacture of the items mentioned therein then they were exempted from payment of whole of the additional duty. Thus, if the capital goods were imported for manufacture of textile garments then

under the said notification, the importer was exempted from payment of customs and additional duty. The said exemption was sought to be denied to the assessee on the ground that the machines imported by them were not required for the purpose of manufacture of textile garments. But they were the machines for knitting and dyeing fabrics or for processing of fabric/ yarn. The Notification No.29/97-Cus itself define the term 'capital goods' under the explanation clause thereto. It provided thus:-

“Explanation-- In this notification—

(1) ‘Capital goods’ means,---

- (i) any plant, machinery, equipment and accessories required for –
 - (a) manufacture or production of other goods Including packaging machinery and equipments, refractories, refrigeration equipment, power-generating sets, machine tools, catalysts for initial charge, and equipments and instruments for testing, research and development, quality and pollution control;
 - (b) use in manufacturing, mining, agriculture, aquaculture, animal husbandry, floriculture, horticulture, pisciculture, poultry, viticulture and sericulture; and

X X X X X X X X X X X “

Taking into consideration the meaning of the term ‘capital goods’ under the said notification, which clearly included the goods specified as well as other related goods, it was held thus:-

“8. Further, in our view, this notification is very clear. The 100% exemption is given to capital goods required for manufacture of, amongst others, “textile garments”. The term ‘capital goods’ has been defined in the notification. The term “capital goods” means

which are used in the manufacture of that product and also goods which would be required for manufacture or production of other goods including packaging machinery and equipments. The term also includes instruments for testing, research and development. The term includes machines for pollution control, refrigeration, power-generating sets, etc. Thus, for example, if after manufacturing of textile garments the same have to be packed, the machinery required for packing would be capital goods required for manufacture of textile garments. Similarly, refrigeration machinery for refrigerating the plant would also fall within the term capital goods required for manufacture of textile garments. If such sort of equipments and machinery get covered by the term 'capital goods', we fail to understand as to how the machinery required for knitting, dyeing, compacting are not covered."

Apparently, the decision was with reference to the definition of 'capital goods' as defined in the notification itself. That is not the case in the matter in hand.

87. One should not forget the basic and elementary principle of law that a judgement of court is not to be read and understood as a statute. The Apex Court in **Escorts Ltd.Vs. Commissioner of Central Excise, Delhi-II** reported in 2004 (173) ELT 113 has clearly ruled that:-

"8. Courts should not place reliance on decisions without discussing as to how the factual situation fits in with the fact situation of the decision on which reliance is placed. Observations of Courts are neither to be read as Euclid's theorems nor as provisions of the statute and that too taken out of their context. These observations must be read in the context in which they appear to have been stated. Judgments of Courts are not to be construed as statutes. To interpret words, phrases and provisions of a statute, it may become necessary for judges to embark into lengthy discussions

but the discussion is meant to explain and not to define. Judges interpret statutes, they do not interpret judgments. They interpret words of statutes; their words are not to be interpreted as statutes. In *London Graving Dock Co. Ltd. v. Horton* (1951 AC 737 at p. 761), Lord Mac Dermot observed :

“The matter cannot, of course, be settled merely by treating the ipsissima verba of Willes, J. as though they were part of an Act of Parliament and applying the rules of interpretation appropriate thereto. This is not to detract from the great weight to be given to the language actually used by that most distinguished judge.”

9. In *Home Office v. Dorset Yacht Co.* [1970 (2) All ER 294] Lord Reid said, “Lord Atkin’s speech..... is not to be treated as if it was a statutory definition It will require qualification in new circumstances,” Megarry, J. in (1971) 1 WLR 1062 observed : “One must not, of course, construe even a reserved judgment of Russell L.J. as if it were an Act of Parliament.” And, in *Herrington v. British Railways Board* [1972 (2) WLR 537] Lord Morris said :

“There is always peril in treating the words of a speech or judgment as though they are words in a legislative enactment, and it is to be remembered that judicial utterances made in the setting of the facts of a particular case.”

10. Circumstantial flexibility, one additional or different fact may make a world of difference between conclusions in two cases. Disposal of cases by blindly placing reliance on a decision is not proper”.

88. That brings us to the second issue, which relates to the effect of the warning about Schedule H drug. It is the contention of the advocates for the assesseees that the notifications make no reference nor prescribes restrictions with reference to the Schedule H or any other provision of the Drugs and Cosmetics Act, 1940 or the rules framed thereunder. Only

effect of the coverage by Schedule H drug would be that the goods are to be sold by the retailer only on the prescription of a registered medical practitioner. The warning does not speak of use of pharmacological category of the medicine. On the other hand, it is the contention on behalf of the department that the anti-biotics are covered under the Schedule H whereas dextrose/saline are not covered by the said Schedule. The pharmacopeia of dextrose/sodium chloride clearly reflects those substances to be in the category of fluid replenishment/electrolyte replenishment. The substances like Ciprofloxacin, Metronidazole, etc. injections are covered under the category of anti-biotics and anti-bacterial whereas Mannitol falls in the category of Osmotic Diuretic, Diagnostic aid and it cannot be equated with sugar inasmuch as that it is an alcohol having $C_6H_{14}O_6$ Molecular formula. The product literature published by the assessee itself reveals that the Mannitol with Glycerine or the Mannitol itself is to be prescribed for the relief in case of symptoms of cerebral edema. It is their further contention that the decision in **Miaami Pharma**, 1999 (108) ELT – 788 in fact, supports the case of the Respondent as it specifically recognises in para 6 that Sodium Chloride is used as a fluid and electrolyte replenisher which is the language of the present notification; it deals with a product different from the products in issue in the present case; it interprets a notification which is worded totally different from the present notification; the decision in **May and Baker** ex facie does not apply to the issue arising in the present case and, therefore, reliance on the same is sans any basis.

89. The fact that IV Fluids are covered by Schedule 'C' whereas the various injections sought to be assimilated with the IV Fluids are covered by the Schedule H of the Drug and Cosmetics Act is not, nor can be, in dispute. The IV Fluids used for sugar, electrolyte and fluid replenishment do not contain any warning, except when the product is essentially comprised of therapeutic medicines, is also clear from the records. In order to buy a product having Schedule H Drug warning, one has to carry the prescription issued by the registered medical practitioner and this fact is also not in dispute. It is not the case that the medicines like Ciprofloxacin or Metromadazole etc. cannot be administered independently and without being mixed with IV Fluids and that they are mixed with the IV Fluids essentially for the purpose of convenience to the doctors, who may not have to bother about administering those drugs separately. It is a matter of convenience. In other words, those medicines aren't essentially components of IV Fluids meant for sugar, electrolyte and fluid replenishment. Secondly, even in common parlance, the IV Fluids with such drugs are neither known as fluid replenishment nor are administered otherwise than on prescription by the registered medical practitioner. The two products – one meant for sugar, electrolyte and fluid replenishment and another meant for therapeutic functions are clearly distinct and distinguishable from one another and a warning about the Schedule H Drugs on the products having therapeutic prospective is the identifying mark for such differentiation. Besides, undisputedly, the fact that the Sodium Chloride and Dextros are used either to restore or to keep in

balance the fluid and electrolyte in the human body, whereas the anti-biotics are procured to treat various infections in the body. The materials on record also clearly establish these facts. The warning about Schedule H drug as the contents of the products clearly brings out distinguishing factor in the IV fluids make all the more clear. This clearly establishes that the product of Intravenous Fluids used for sugar, electrolyte or fluid replenishment fall in the category of fluid replenishment whereas the products manufactured by the appellant fall in the category of anti-biotics or anti-bacterial. The two products being clearly classifiable in two different categories, the product of the appellant cannot be said to be entitled for benefit under the said notification. The Apex Court in **Bombay Chemical Pvt. Ltd. Vs. Collector of Central Excise, Bombay** reported in 1995 (77) ELT 3 (SC) had clearly held that :-

“When a question arises whether a particular goods is covered in any category or not, it has to be examined if it satisfies the characteristic which go to make it a goods of that category and whether in trade circle it is understood as such and if it is a good of technical nature, then whether technically it falls in one or other category. Once it is found that a particular good satisfies the test, then issue which arises for consideration is whether it should be construed broadly or narrowly. One of the settled principles of construction of an exemption notification is that it should be construed strictly, but once a good is found to satisfy the test by which it falls in the exemption notification it cannot be exempt from it by resorting to applying or construing such notification narrowly.”

90. The evidence in the form of affidavit by Dr. Ram Irani and other literature, which is sought to be produced cannot be considered as the same has not been produced in relation to the issue regarding the warning of Schedule H drug. Even otherwise and even assuming that the

evidence has been produced in relation to the said issue, perusal of the said material nowhere discloses any relation to the said issue either directly or indirectly.

91. **In Compack Pvt. Ltd. (supra)**, the Apex Court was dealing with the matter in relation to the interpretation of exemption notification No.67/82-CE dated 28.02.1982. The matter related to the rate of excise duty payable on paper and paper board contained in Chapter 48. Item 48.02 referred to un-coated paper whereas Item 48.07 referred to plastic coated paper. As per the said notification, the only requirement for availing the benefit thereunder was payment of excise duty on base paper or base paper board where for a legal fiction had been raised in explanation appended to the said notification. The assessee therein had taken a stand that the three layers of the carton consisted of base paper and only one layer thereof consisted of plastic coated paper. The Tribunal had denied the benefit to the assessee, without considering the import of the notification. In those background, the Apex Court had observed that the eligibility clause in relation to an exemption notification has to be given strict meaning and the notification has to be interpreted in terms of its language. It has to be given effect to.

92. The fall out of the above discussion is that with effect from 1.3.2001 the exemption benefit, which is available to the Intravenous Fluid for sugar, electrolyte and fluid replenishment, does not extend to the Intravenous Fluid comprising of medicines and drugs like, anti-bacterial, anti-biotic and anti-microbial, having therapeutic properties or

functions but is restricted strictly to those meant for the sugar, electrolyte and fluid replenishment only. However, there was no such restriction as far as the period prior to 1.3.2001 and since 4.5.2000 is concerned. The impugned order relating to the period from 1.3.2001, thus call for no interference. They can not, however, be sustained as far as they relate to the period prior from 4.5.2000 to 1.3.2001 and that the notification dated 1.3.2001 has no retrospective effect.

93. In the facts and circumstances of the case and applying the law thereto, we find that the authorities below were justified in denying the benefit of the Notification No.3/2001-CE to the products in question with effect from 1.3.2001 but were not justified in denying the same for the period prior that to in terms of Notification No.6/2000-CE read with Notification No.36/2000-CE.

94. The assessees are, therefore, entitled for the benefit claimed by them in relation to the product in question under Notification No.6/2000-CE dated 1.3.2000 read with Notification No.36/2000-CE dated 4.5.2000. However, no such benefit is available to the product in question with effect from 1.3.2001 under Notification No.3/2001-CE dated 1.3.2001.

95. As far as the issue of penalty is concerned, question of imposition of penalty does not arise as matters involve interpretation of notification. Being so, the orders of imposing penalty cannot be sustained.

96. The appeals filed by the Department are, therefore, to be allowed except in relation to the imposition of penalty. The appeals filed by the assessees are to be partly allowed to the extent they relate to the

imposition of penalty and the orders imposing the penalty are to be set aside while confirming the remaining part of the orders, which relates to confirmation of the demand of duty and interest thereon.

97. The appeals filed by the Department against the grant of benefit of Notification No.3/2001-CE dated 1.3.2001 are hereby allowed. The challenge to grant of such benefit under Notification No.6/2000-CE dated 1.3.2000 read with Notification No.36/2000-CE dated 4.5.2000 is rejected.

98. The appeals filed by the assesseees rejecting the benefit of Notification No.3/2001-CE dated 1.3.2001 are dismissed. The assesseees are entitled for the benefit only in relation to Notification No.6/2000-CE dated 1.3.2000 read with Notification No.36/2000-CE dated 4.5.2000 upto 28.02.2001.

99. In view of what is stated above, all the appeals and the applications filed in the above appeals stand disposed of in above terms.

(Justice R.M.S. Khandeparkar)
President

(Rakesh Kumar)
Member (Technical)

ckp.