

**Customs, Excise & Service Tax Appellate Tribunal**  
**West Zonal Bench At Ahmedabad**  
REGIONAL BENCH- COURT NO.3

**Excise Appeal No.13608 of 2013**

(Arising out of OIA--CCEA-SRT-II/SSP-145/2013-14/U/S35-3---FINALORDER- dated 31/07/2013 passed by Commissioner of Central Excise, Customs and Service Tax-SURAT-II)

**Chiron Behring Vaccines Pvt Ltd**

**.....Appellant**

Plot No. 3502, Gidc, Ankleshwar,  
Bharuch, Gujarat

*VERSUS*

**C.C.E. & S.T.-Surat-ii**

**.....Respondent**

New C.Ex Building...Opp. Gandhi Baug,  
Chowk Bazar,  
Surat, Gujarat-395001

**APPEARANCE:**

Shri Sanjeev Nair, Advocate for the Appellant  
Shri Sanjay Kumar, Superintendent (AR) for the Respondent

**CORAM:        HON'BLE MEMBER (JUDICIAL), MR. RAMESH NAIR**  
**HON'BLE MEMBER (TECHNICAL), MR. C.L. MAHAR**

**Final Order No. A/ 11107 /2023**

DATE OF HEARING: 20.03.2023  
DATE OF DECISION: 03.05.2023

**RAMESH NAIR**

The issue involved is whether the impugned order was correct in reversing the Order-In-Original dated 28.12.2010 and allowing the appeal filed by the revenue on the ground that sterile water for injection was captively consumed and hence ineligible for exemption in terms of notification no. 67/95-CE dated 16.03.1995 as amended by notification no. 16/2003-CE dated 01.03.2003.

02. The brief facts of the case are that since the appellant is engaged in the manufacture of "Rabipur vaccines", an anti-rabies vaccines falling under chapter heading no. 3002 of First Schedule to the Central Excise Tariff Act, 1985 attracting nil rate of duty. The said vaccine is sold in the domestic market in a combi pack and also exported out of India. The contents of the combi pack are as follows:-

- A) 1 vial of rabies virus strain in lyophilized powder form.
- B) 1 ampoule containing 1ml. of Sterile water for injection.
- C) 1 Sterile disposal syringe and needle.

2.1 In connection with the manufacture of vaccines, the appellant use to manufacture Sterile Water for Injection (SWFI) in the factory premises required for administering the vaccines. This activity of in house manufacture continued up to the month of April 2009. The SWFI so manufactured by the appellant was never cleared separately as it was always included to be used in administering and was accordingly cleared from the factory premises only in the combi pack. From the month of April 2001 onwards, the appellant had also started procuring SWFI from job workers namely Korten Pharmaceuticals Pvt. Ltd. and Soverign Pharma Pvt. Ltd. As per the audit objection, the first show cause was issued on 19.10.1998 wherein, the demand of Rs. 1,96,718/- was raised by the department alleging that the SWFI manufactured and cleared was a bulk drug under the Drugs And Cosmetics Act, 1940 and liable to duty at the rate of 16% ad valorem under Chapter sub heading 28510010 of Central Excise Tariff Act, 1985 as distilled water. Thereafter, 29 periodical show cause notices were issued to the appellant on the same grounds. The adjudicating authority vide Order-In-Original dated 28.12.2010 adjudicated all the 30 SCNs and dropped the demand hereby holding that no duty is payable by the appellant. The said Order-In-Original dated 28.12.2010 came to be reviewed by the department and appeal was filed against the said Order-In-Original on the ground that Sterile water for Injection captively consumed and hence ineligible for exemption in terms of Notification No. 67/95-CE dated 16.03.1995 as amended by notification no. 16/2003-CE dated 01.03.2003. In the first appeal proceedings, the Commissioner (Appeals) vide Order-In-Appeal dated 30.04.2012 allowed the appeal filed by the respondent. Being aggrieved by the said Order-in-Appeal dated 30.04.2012, the appellant preferred an appeal before the CESTAT, the CESTAT vide its order No. A/1727/WZB/AHD/2012 and Order No. S/2585/WZB/AHD/2012 dated 06.12.2012 remanded the case back to the Commissioner (Appeals) to decide the issues afresh on merit based on the evidence adduced by the appellant. In remand proceedings the Commissioner vide impugned order dated 31.04.2013 upheld the appeal filed by the revenue and interalia held that benefit of notification no. 3/2005-CE is inapplicable and directed to adjudicating authority to determine the quantum of penalty for each of the aforesaid show cause notices with interest quantifiable on the full duty amount covered by the aforesaid SCN's hence, the present appeal filed by the appellant.

03. Shri Sanjeev Nair, learned counsel appearing on behalf of the appellant reiterates the submissions made in the grounds of appeal in the appeal memorandum. He further submits that the review made by the department against the Order-In-Original and the Order of the Commissioner (Appeals) travels beyond the scope of show cause notice in as much as in the show cause notice the duty was demanded on the sterile water denying the exemption notification 3/2005-CE on the ground that the same is 'Bulk Drug' under Drugs & Cosmetics Act whereas, in the review the grounds in appeal of the revenue is that the notification no. 3/2005-CE is not applicable to the sterile water for the reason that the same was used captively in the manufacture of "Rabipur vaccines" hence, the captive consumption Notification No. 67/95-CE dated 16.03.1995 is not applicable therefore, on this ground itself the revenue's appeal was not maintainable before the Commissioner (Appeals) hence the order of the Commissioner (Appeals) is liable to be set aside. In this regard, he placed reliance on the following judgments:-

- CCE, Bhubaneswar-I Vs. Champdany Industries Ltd.- 2009 (241) ELT 481 (SC)
- CCE Vs. Gas Authority of India- 2008 (232) ELT 7 (SC)
- CCE Vs. Sunita Textiles Ltd.- 1993 (67) ELT 932 (Tribunal)

3.1 He further submits that even as regard the charge made in the show cause notice, it is settled that in the nature of the product in question the entire combi pack is treated as vaccine and correctly classifiable under Chapter 3002. In this regard, he placed reliance on the judgment in the case of VENTRI BIOLOGICALS Vs. COMMISSIONER OF CENTRAL EXCISE, PUNE-2000 (115) ELT 464 (Tri.) which was upheld by the Hon'ble Supreme Court. He further submits that the above decision was also relied upon by the tribunal in the case of INTERVET INDIA P. LTD. Vs. COMMISSIONER OF CENTRAL EXCISE, PUNE-III- 2010 (253) ELT 646 (Tri.-Mumbai).

3.2 He further submits that the impugned order contradicts the earlier judgment passed by the Commissioner (Appeals) and not considering the matter afresh as directed by Hon'ble CESTAT in its order dated 06.12.2012.

3.3 Without prejudice, he further submits that even if the sterile water is used as intermediate product, the same was exempted under notification no. 3/2005 and previous to that it was attracting only nil rate of duty as per the Central Excise Tariff Act therefore, for this reason also the demand on Sterile Water used for captive use is not liable to duty.

04. Shri Sanjay Kumar, learned Superintendent (AR) appearing on behalf of the revenue reiterates the finding of the impugned order.

05. We have carefully considered the submissions made by both the sides and perused the records. We find that in the show cause notice, the charge made by the revenue was the Sterile Water cleared in the combi pack along with "Rabipur vaccines" is classifiable under chapter heading no. CETH 28510010 as bulk drugs and the same was liable to duty. First we would like to deal with the classification of the goods disputed in the show cause notice, we find that the vaccine is cleared in combi pack in following manner:-

- A) 1 vial of rabies virus strain in lyophilized powder form.
- B) 1 ampoule containing 1ml. of Sterile water for injection.
- C) 1 Sterile disposal syringe and needle.

The Rabipur vaccine is administered as follows:-

- a) The vial containing the Rabies virus strain in a lyophilized powder is reconstituted with Sterile Water for Injection (SWFI).
- b) This reconstituted mixture is then administered by way of injection using the disposal syringe and needle.

From the above, it is clear that the vaccine cannot be administered without sterile water therefore the sterile water is also considered to be the vaccine which attracts only the nil rate of duty under CETH 3002. In this regard, it is necessary to go through the section notes of Section VI of Central Excise Tariff Act, 1985. The relevant note 3 is reproduced below:-

*3. Goods put up in sets consisting of two or more separate constituents, some or all of which fall in this Section and are intended to be mixed together to obtain a product of Section VI or VII, are to be classified in the heading appropriate to that product, provided that the constituents are :*

*(a) having regard to the manner in which they are put up, clearly identifiable as being intended to be used together without first being repacked;*

*(b) presented together and*

*(c) identifiable, whether by their nature or by the relative proportions in which they are present, as being complementary one to another.*

From the above Note 3, it is clear that when the goods are cleared in sets consisting of two or more separate constituents in that case if the product is included to be mixed whether to obtain a product of Section VI or Section VII are to be classified in the heading prior to that product. In the present

case, after mixing of the vaccine powder with sterile water, it is clearly intended to be administered as vaccine therefore, entire combi pack shall be correctly classified under the Central Excise Tariff Heading No. 3002 which is meant for vaccine. The condition from (a) to (c) given in Note 3 above is clearly satisfied in as much as all the constituents of combi pack are used altogether at the time of administering the vaccine to the human body. Being combi pack it is presented together and since the Rabipur vaccine powder cannot be used without mixing of sterile water, it is undoubtedly complementary to each other.

5.1 In view of the above Note 3 of Section VI there is absolutely no doubt that the sterile water cleared in a combi pack with vaccine and syringe will also fall under CETH 3002 which is a vaccine. When this be so, then the entire combi pack attracts nil rate of duty under CETH 3002. On this basis, the demand is not sustainable.

5.2 Without prejudice to our above findings, as regard the appellant's submission that the review as well as the Commissioner (Appeals) order is beyond the scope of show cause notice. We find that it is apparent from the show cause notice that the proposal is to demand duty on sterile water, considering the clearances of the same is finished goods for human consumption. However, in the review of the department as well as in the Commissioner (Appeals) order it was held that the sterile water was used as intermediate product for captive consumption therefore, exemption Notification No. 67/95-CE dated 16.03.1995 is not applicable to the appellant. This clearly shows that the review as well as Commissioner (Appeals) order travelled beyond the scope of show cause notice. On this basis also the impugned order is not sustainable.

5.3 Without prejudice to the above, we also find that even if it is assumed that the sterile water is used captively for manufacture of vaccine in such case also the sterile water is not liable to duty on the ground that from June 1998 till 24 February 2005, the distilled or conductivity water and water of similar purity used within the factory of production was attracting nil rate of duty and from 24<sup>th</sup> February 2005 to 30 December 2006, the said product was exempted under notification 3/2005-CE dated 24.02.2005 when used within the factory of production therefore even if the contention of the review order of the revenue is considered even then the product was not liable to duty.

06. As per our discussions and findings, the impugned order is not sustainable hence, the same is set aside. Appeal is allowed.

(Pronounced in the open court on 03.05.2023)

**(RAMESH NAIR)**  
**MEMBER (JUDICIAL)**

**(C.L. MAHAR)**  
**MEMBER (TECHNICAL)**

Mehul