

**CUSTOMS, EXCISE & SERVICE TAX APPELLATE TRIBUNAL
BANGALORE**

Regional Bench COURT-2

Customs Appeal No. 20910 of 2014

[Arising out of the Order-in-Appeal No. 523 & 524/2013 dated
30.12.2013 passed by the Commissioner of Customs, Bangalore.]

M/s. Bharat Biotech Internal Ltd,

Survey No.230, 231 & 235,
Yadaram Turkapallu,
Shameerpet,
Hyderabad- 500 078.

.....Appellant

VERSUS

Commissioner of Customs,

C.R. Building, P.B.No.5400
Queens Road,
Bangalore - 560 001.

..... Respondent

Appearance:

Ms. Gayatri Priya, Advocate Appeared for Appellant

Mr.K.A.Jathin, Authorized Representative for Respondent

Coram:

Hon'ble Mr. P.A. Augustian, Member (Judicial)

Hon'ble Mr. Pullela Nageswara Rao, Member (Technical)

FINAL ORDER No. 20579 of 2024

Date of Hearing: 18.01.2024

Date of Decision: 16.07.2024

Per: Pullela Nageswara Rao

M/s. Bharat Biotech International Pvt Ltd, the appellant
imported "Montanide ISA 206 VG" vide two Bills of Entry No.
5434224 dated 12.12.2011 and 5629101 dated 02.01.2012 and
paid Customs duty of Rs. 6,72,425/- and Rs. 10,78,722/-,

respectively, classifying the imported goods under CTH 38249090, as residuary entry for chemical products not elsewhere mentioned, since the imported goods are chemical product and mineral based Adjuvant of vegetable origin and cleared the goods.

2. The Respondent, issued a Show Cause Notice proposing to classify the goods under CTH 30023000 as "Vaccine for Veterinary Medicines" alleging that the imported goods are animal vaccines. The Original Authority confirmed the demand of Rs. 2,16,447/- with interest and penalty was dropped. Aggrieved with the order, appellant filed an appeal before Commissioner (Appeals). Department has filed an appeal before Commissioner (Appeals) against the dropping of penalty. Commissioner (Appeals) confirmed the demand with interest and imposed penalty under Section 114A of the Customs Act, 1962. Aggrieved by the order of the Commissioner (Appeals) this appeal is filed before the Tribunal.

3. The appellant in the appeal contends that the Adjudicating Authority, held that; though the goods were only an "Adjuvant" and does not qualify to be called a vaccine either in terms of composition or function, since the imported item gets formulated with vaccine and it acquires the qualities of a vaccine when mixed with the vaccine, hence, it can be classified as a vaccine.

4. The Learned Counsel for the appellant contends that; on the sole ground on which the classification has been determined is that the 'Adjuvant' gets formulated with vaccine and enter into

body of the animal as vaccine and therefore the functional parameters are to act as a vaccine; Department has not disputed that the imported goods are Adjuvants and not vaccines and they are only added to the vaccines to increase the body's immune response to the Vaccine; the technical bulletin on the imported goods mentioned that the vaccine can be prepared by mixing the imported goods with an antigenic media, which produces anti bodies in the body; hence, the imported goods are merely raw materials/ingredients for certain vaccines and cannot be administrated as vaccines directly to any animal; Tariff item 30023000 under which revenue seeks classification of imported goods and Chapter heading 3002 does not include components or parts of raw materials that form part of the products mentioned in the CTH entry and no such inclusions are mentioned therein; hence, Tariff item 30023000, which reads as 'Vaccine for veterinary medicines' does not include elements in the vaccine and it is against the General Rules of interpretation of classification; giving the raw material a characteristic of final product for classification, when such raw material cannot be used directly as a product under Tariff item is improper and not sustainable in law. Further, the Learned Counsel submits that the difference between the Adjuvant and Vaccine is that Adjuvant is a carrier of the medicine for effective function of the vaccine, whereas the vaccine is administered for the immunity.

5. The Learned Counsel contends that; Commissioner (Appeals) classified the goods under CTH 3002 on the grounds that rule 3(b) of the general rules of interpretation is applicable.

This rule is applicable when the goods imported consists of mixture of composite goods; the imported goods being "Adjuvant" has no mixture or composite within it which is a vaccine; Commissioner (Appeals) finding that the predominant use of the product shall be considered for classification and since predominant use is in vaccine it has to be classified as a vaccine is highly erroneous; the imported goods without being processed any further cannot be used as a vaccine; the predominant use or end use for the product is not relevant criteria for classification as held in the case of **Glaxo Laboratories (India Ltd) Vs Union of India, 1985 (21) ELT 72 (Tri.-Bombay)**; the Hon'ble Court while placing reliance on the decisions of the Apex Court in the case of **Dunlop India Limited Vs Union of India AIR 1977 SC 571** held that;

14. *".....the end use of an article is absolutely irrelevant for the purpose of its classification under the tariff entry, where there is no reference to the end use of the article in the entry itself, it shall be judged on the basis of its nature at the time of its importation. Its ultimate use is not relevant."*

6. The Learned Counsel further submits that it is well settled principle of law that the classification of goods is a matter of chargeability and the burden to prove is clearly on the Revenue. In case the Department intends to classify the goods under a particular heading or sub-heading different from that claimed by the appellant, the Department is required to adduce proper

evidence for the discharge of the burden of proof. In the present case the department has failed to produce any documentary evidence to show that the product can be used as a vaccine as such for animals. The Learned Counsel relied on the following cases laws:-

- i. HPL Chemicals Ltd Vs. CCE, Chandigarh 2006 (197) ELT 324**
- ii. Hero Motorcorp Ltd Vs. CC (NS-1) Raigad 2022 (379) ELT 214 (Tri- Mumbai)**

7. Further the Learned Counsel contends that since the goods imported by no stretch of imagination can be directly placed under vaccines and the department itself admitted they are not vaccines by themselves, they are only "Adjuvant", where there is no specific entry for Adjuvants even under common parlance the importer does not treat the "Adjuvant" as vaccines and the department also does not treat the "Adjuvant" as vaccine, therefore allegation of wilful misdeclaration and suppression of facts is unsustainable.

8. The Learned Counsel contends that equal penalty alleging suppression and wilful misstatement is not warranted in cases involving classification disputes and this issue is no more res integra and they relied on the following case laws:-

- i. Abraham J Tarakan Vs. CCE, Cochin 2007 (210) ELT 112 (tri-Bang)**

**ii. CC Import Nhava Sheva Vs. Vodafone Essar
Gujarat Ltd 2020 (373) ELT 421 (Tri-Mum)**

9. The Learned Authorised Representative (AR) for the Revenue has reiterated the finding in the impugned order.

10. Heard both sides and perused the records. We find in this case the dispute is with the regard to the classification of the imported goods "Montanide ISA 206 (VG)". The importer has claimed classification under CTH 38249090, whereas department has proposed and classification under CTH 30023000 as "Vaccine for veterinary medicine". In this regard the purpose of Adjuvants and types are as below:

ADJUVANTS is an agent that modifies the effect of agents. Immunologic adjuvants are added to vaccines to stimulate the immune system's response to the target antigen, but do not in themselves confer immunity. Although immunological adjuvants have traditionally been viewed as substances that aid the immune response to antigen, adjuvants have also evolved as substances that can aid in stabilizing formulations of antigens, especially for vaccines administered for animal health.

Mechanisms of adjuvants:

Adjuvants are needed to improve the routing and adaptive immune responses to antigens. This reaction is mediated by two main types of lymphocytes, B and T cells. Adjuvants can apply their effects through different

mechanisms. Some adjuvants, such as alum, function as delivery systems by generating depots that trap antigens at the injection site, providing slow release in order to continue the stimulation of the immune system.

Types of adjuvants:

- *Inorganic compounds: alum, aluminum hydroxide, aluminum phosphate, calcium phosphate hydroxide*
- *Mineral oil: paraffin oil*
- *Bacterial products: killed bacteria Bordetella pertussis, Mycobacterium bovis, toxoids*
- *Nonbacterial organics: squalene, thimerosal*
- *Delivery systems: detergents (Quil A)*
- *Cytokines: IL-1, IL-2, IL-12*
- *Combination: Freund's complete adjuvant, Freund's incomplete adjuvant*

Alum is the most commonly used adjuvant in human vaccination. It is found in numerous vaccines, including diphtheria-tetanus-pertussis, human papillomavirus, and hepatitis vaccines

11. The above adjuvants are to be classified as per the material composition in the respective Tariff heading. The appellant imports different "Adjuvants", based on their composition, they are being classified, accordingly. We find that the item imported is "Immunological Adjuvant" used in the preparation of vaccines for human and animals. Immunological Adjuvant was classified by the Department under Tariff Item 30023000 as "Vaccine for veterinary medicine" as against the appellants declaration under Tariff Item 38249090 as chemical

products not elsewhere mentioned even though the imported goods are injectable mineral oil and emulsifier obtained from mannitol and purified oleic acid of vegetable origin. Further, we find the Adjuvants are of different types and they are used for the purpose of enhancing the immune response in the Immunological vaccines administered for humans and animals.

12. Considering the above, we find that to classify Adjuvant as a vaccine by the Department is incorrect and not legally tenable. Therefore, the confirmation of demand with interest is legally not sustainable, hence it needs to be set aside. Further we find that the imposition of penalty under Section 114A of the Customs Act. 1962 is also not sustainable as there is no misdeclaration or suppression of facts as all the details are submitted at the time of filing the bill of entry.

13. In view of the above discussion and in the facts and circumstances of the case, the appeal is allowed setting aside the impugned Order.

(Order Pronounced in Open court on 16.07.2024)

(P.A. Augustian)
Member (Judicial)

(Pullela Nageswara Rao)
Member (Technical)

Sasidhar