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

Appeal No. : E/2026/2005-EX[DB]

Dated: **03/10/2012**

Assistant Registrar
C.E.S.T.A.T. New Delhi
To,
J.MITRA & CO LTD
A-180, Okhla Industrial Area, Phase-I,
New Delhi

J.MITRA & CO LTD (Appellant)

VS

C.C.E. DELHI II (Respondent)

I am directed to transmit herewith a certified copy of Final Order No. **A/1182/2012-EX[DB]** dated **26/09/2012** passed by the Tribunal under section **35-C(1) of the Central Excise and Salt Act, 1944.**

Assistant Registrar
EXCISE Appeal Branch

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Assistant Registrar
EXCISE Appeal Branch

IN THE CUSTOMS, EXCISE & SERVICE TAX
APPELLATE TRIBUNAL
West Block No. 2, R.K. Puram, New Delhi – 110 066.
Principal Bench, New Delhi

COURT NO. I

DATE OF HEARING : 15/06/2012.
DATE OF DECISION : 27/7/2012.

Excise Appeal No. 2026 of 2005

[Arising out of the Order-in-Original No. 17 to 18/2005 dated 16/03/2005 passed by The Commissioner of Central Excise, New Delhi.]

Hon'ble Shri Justice Ajit Bharihoke, President
Hon'ble Shri Rakesh Kumar, Member (Technical)

1.	Whether Press Reporters may be allowed to see the Order for publication as per Rule 27 of the CESTAT (Procedure) Rules, 1982?	:
2.	Whether it would be released under Rule 27 of the CESTAT (Procedure) Rules, 1982 for publication in any authoritative report or not?	:
3.	Whether their Lordships wish to see the fair copy of the order?	:
4.	Whether order is to be circulated to the Department Authorities?	:

M/s J. Mitra & Co. Ltd. — Appellant

Versus

CCE, Delhi – II — Respondent

Appearance

Shri B.L. Narasimhan, Advocate – for the Appellant.

Shri Bharat Bhushan, Authorized Representative (DR) – for the Respondent.

CORAM : **Hon'ble Shri Justice Ajit Bharihoke, President**
Hon'ble Shri Rakesh Kumar, Member (Technical)

FINAL Order No. A/1182/2012-EX(BR)

Per. Shri Rakesh Kumar :-

The appellant manufacture Blood Grouping Reagents and Diagnostics and Laboratory Reagents falling under Chapter 30 and 38 of the Central Excise Tariff. The period of dispute in this case is from March 2002 to February 2003. The dispute is about the classification of AIDS (HIV I and II) Diagnostic Kits and Hepatitis B and Hepatitis C test kits. The appellant were classifying these diagnostic kits under heading 30.02 of the Central Excise Tariff which covered "Antisera and other blood fractions; vaccines, Toxins, Cultures of Micro-organisms (including ferments but excluding yeasts) and similar products" and were not paying any duty as the tariff rate of duty for the products of this sub-heading is nil. According to the department, however, these products are correctly classifiable under heading 38.22 which covers "diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents, whether or not on a backing, other than those of Chapter 30".

1.1 The HIV kits work on the principle based on antigen and anti body reaction. The antigen (Recombinant Antigens) used in the kit are obtained from the cultures of Micro-organism which are immobilised on a porous immuno-filteration membrane. A colour conjugate (Protein A), also obtained from the cultures of Micro-organism is also used with HIV Antigen to obtain distinct colour. As the patient's sample passes through the membrane, HIV antibodies, if present in the sample, react with the immobilised Antigen and produce a distinct colour.

1.2 Main ingredient of Hepatitis B detecting kit is a combination of monoclonal and polyclonal antibodies. Monoclonal antibodies obtained from the cultures of Micro-organism are conjugated to colloidal gold. The monoclonal antibodies conjugated to colloidal gold and polyclonal antibodies are immobilised on a nitrocellulolse strip. When the test sample comes in contact with this strip and if the test sample contains the HbsAg Antigen, it binds with the monoclonal and polyclonal antibodies immobilised on the strips producing a distinct colour, due to formation of an antibody-antigen-antibody colloidal gold complex.

1.3 For making Hepatitis C detection kit the main ingredients is HCV antigen obtained from micro organism culture which is immobilised on a porous immuno-filtration membrane, alongwith a colour conjugate (Protein A), also obtained from the culture of micro organism. When the sample comes in contact with the test membrane and if the sample contains the HCV antibodies, the same combines to HCV antigen and produces a distinct colour.

1.4 The department being of the view that the above test kits are not classifiable under 3202 but are classifiable under heading 3832, issued two show cause notices dated 28/3/03 and 5/2/04 for classification of the above products under heading 38.22 and demand of differential duty amounting to Rs. 77,57,189/- and Rs. 19,81,194/- alongwith interest and also for imposition of penalty on the appellant under Rule 25 of the Central Excise Rules.

1.5 These show cause notices were adjudicated by the Commissioner vide order-in-original dated 16/3/05 by which the Commissioner –

(a) held that the diagnostic kits, in question, are correctly classifiable under sub-heading 3822.00 of the Tariff and ;

(b) confirmed the total duty demand of Rs. 93,63,830/- alongwith interest on it under Section 11AB.

He, however, did not impose any penalty on the appellant on the ground that the dispute in this case is purely of classification.

1.6 Against this order of the Commissioner, this appeal has been filed.

2. Heard both the sides.

3. Shri B.L. Narasimhan, Advocate, the learned Counsel for the appellant, pleaded that the main ingredients of the diagnostic kit are antigen and monoclonal antibodies obtained from cultures of micro-organism, that polyclonal antibodies are nothing but Antisera/blood fraction, that in terms of HSN explanatory notes of heading 30.02, the product group – "vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products", also covers the diagnostic reagents of microbial origin other than those covered by Note 3 (d) to Chapter 30 which are covered under HSN heading 30.06 (corresponding to heading 30.05 of Central Excise Tariff), that the products, in question, being based

on the diagnostic reagents obtained from cultures of micro-organism and being not of the type covered under chapter Note 3 (d) of Chapter 30 of HSN, would be correctly classifiable under heading 30.02, that heading 3822 covers only those diagnostic/laboratory reagents whether or not on a backing which are classifiable under Chapter 30, that in view of this, if the product is classifiable under Chapter 30, its classification under heading 3822 would be Ruled out, that according to WCO Ruling dated 23rd September 1997, the HIV infection detecting kit is classifiable under heading 30.02, that the Apex Court in the case of **Span Diagnostics Ltd. vs. CCE, Surat** reported in **2007 (211) E.L.T. 521 (S.C.)** has held that the blood grouping reagents based on monoclonal antibodies are correctly classifiable under heading 30.02, as the reagents are derived from cultures of micro-organism, and not under heading 30.05, that in this judgment, the Apex Court also held that even though the HSN mentions "Antisera, blood fractions and modified immunological products (MIP) including monoclonal antibodies" as one class, there is no contradiction between the Chapter Heading 30.02 of Central Excise Tariff and HSN heading 30.02, that the judgment of the Apex Court in the case of **Span Diagnostics Ltd. vs. CCE, Surat** (supra) is squarely applicable to the facts of this case, that in this case there is no dispute that the main ingredients are obtained from cultures of micro-organism and, therefore, in terms of HSN Explanatory notes to heading 30.02, the same would be covered by the heading 30.02 and once the goods, in question, are covered under this heading,

their classification under heading 3822 would be ruled out. He, therefore, pleaded that the impugned order is not correct.

4. Shri Bharat Bhushan, learned Departmental Representative, defended the impugned order by reiterating the findings of the Commissioner in it and emphasised that –

> 'if the appellant claims that they are not covered by heading 38.22, it is for the appellant to produce the evidence that the products, in question, are covered by heading 30.02, that the kits contain antigen or antibodies obtained from micro organism culture, that the extracts of the culture of micro-organism cannot be treated as micro-organism, that the Tribunal in the case of **Metropolis Laboratory vs. CC (Appeals), Airport, Mumbai** reported in **2006 (193) E.L.T. 117 (Tri. - Mumbai)**, has held that the diagnostic kits for detection of HIV antibodies fall under Chapter 38 of Customs Tariff, which during the period of dispute was aligned with the Central Excise Duty, and that in view of this, there is no infirmity in the impugned order'.

5. We have considered the rival submissions and perused the records.

6. There is no dispute about the facts that –

> "(a) the main ingredient of AIDS (HIV I & II) diagnostic kit is HIV antigen (recombinant antigens) obtained from cultures of micro-organism which is used alongwith colour conjugate (Protein A) also obtained from cultures of micro-organism,
>
> (b) the main ingredient of the kit for detection of Hepatitis B is a combination of monoclonal antibody

obtained from cultures of micro organism and polyclonal antibodies which is nothing but Antisera/Blood fraction, which is conjugated to colloidal gold ; and

(c) the main ingredient of kit for detection of Hepatitis C is antigen (recombinant) obtained from culture of micro-organism alongwith the colour conjugate (Protein A) also obtained from cultures of micro organism.

The strip is nothing but a porous immuno-filtration membrane on which the antigen or monoclonal antibodies and polyclonal antibodies have been immobilised. All the three types of diagnostic kit work on the principle of antigen antibody reaction. The point of dispute is as to whether these kits are classifiable under heading 30.02 or 38.22.

7. The competing entries for the product, in question, as the same stood during the period of dispute are reproduced below :-

"30.02 Antisera and other blood fractions ; vaccines, toxins, cultures of micro-organisms (including ferments but excluding yeasts) and similar products".

"38.22 Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, other than those of Chapter 30".

7.1 The HSN headings 30.02 and 3822 during the period of dispute were as under :-

"30.02 Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions and modified immunological products,

whether or not obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products. "

" 38.22 Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading 30.02 or 30.06; certified reference materials."

7.2 A comparison of HSN heading 38.22 and Central Excise Tariff heading 38.22 would show that except for product group "certified reference materials", which is there is HSN heading 38.22 but is not there in Central Excise Tariff heading 38.22, the Central Excise Tariff heading 38.22 and HSN Heading 38.22 are identical. From a plain reading of Central Excise Tariff heading 38.22 it will be seen that it covers those diagnostic or laboratory reagents whether or not on a backing, which are not covered by 30.02. Since the goods, in question, are diagnostic reagents on a backing, for their classification under 38.22, their classification under heading 30.02 has to be ruled out.

8. During the period of dispute, while Central Excise Tariff heading 30.02 covered two product groups, namely -

(i) Antisera and other blood fractions ; and

(ii) Vaccines, toxins, cultures of micro-organism (including ferments but excluding yeasts) and similar products ;

HSN heading 30.02 covered four product groups namely –

(i) Human blood ;

(ii) Animal blood prepared for therapeutic, prophylactic or diagnostic uses ;

(iii) Antisera and other blood fractions and modified immunological products whether or not obtained by means of biotechnological processes ; and

(iv) Vaccines, toxins, cultures of micro-organism (excluding yeasts) and similar products.

8.1 Thus product group (ii) of Central Excise Tariff heading 30.02 is identical with product group (iv) of HSN heading 30.02 and therefore the scope of – "Vaccines, toxins, culture of micro-organics (including ferments but excluding yeasts) and similar products" in heading 30.02 of Central Excise Tariff would be the same as the scope of this expression in HSN heading 30.02. In terms of Apex Court's judgment in case of **Span Diagnostics Ltd. vs. CCE, Surat** (supra) (para 14 of the judgment) the product group "Antisera and other blood fractions" in Central Excise Tariff 30.02 would also include modified immunological products, whether or not obtained by biotechnological process.

9. The Revenue's plea is that the diagnostic kits, in question, being based on antigens or monoclonal antibodies derived from culture of micro-organism are not covered by heading 30.02 and this heading covers only the "cultures of micro-organism", not the reagents derived from micro-organism cultures. This contention of the Revenue is not correct as in terms of HSN Explanatory Notes to heading 30.02 -

(a) the product group "Vaccines, toxins, cultures of micro-organism (excluding yeasts) and similar products" includes the diagnostic reagents of microbial origin, other than those provided for in Note 4 (d) to HSN Chapter 30 (corresponding to Note 3 (d) of Central Excise Tariff Chapter 30) ;

(b) Diagnostic kits are classified in this Chapter of the essential character of the kit is given by any of the products of this heading and common reactions occurring in the use of such kits include agglutination, precipitation, neutralisation, binding of complement, haemagglutination, Enzyme Linked Immuno Sorbent Assay (ELISA) etc. ; and

(c) monoclonal antibodies which are specific immunoglobulin from selected and cloned hybridoma cells cultured in a culture medium are also covered by this heading under the product group – "modified immunological products, whether or not obtained by means of biotechnological process", which according to Apex Court's judgment in case of **Span Diagnostic Ltd.** (supra) is also covered by the product group – "antisera and other blood fractions".

9.1 HIV detection kits and Hepatitis C detection kits containing antigens obtained from micro-organism cultures, immobilised on a ~~porous~~ immuno-filtration membrane and which were on antigen – antibody reaction (neutralisation) would be covered by heading 30.02 as in view of the above-mentioned HSN explanatory notes, this heading includes the diagnostic reagents of microbial origin other than those covered by Chapter note 4 (d) [corresponding to Chapter note 3 (d) of Central Excise Tariff Chapter 30], which covers –

"Opacifying preparations for X-ray examination and diagnostic reagents designed to be administered to patients, being unmixed products put up in measured doses or products consisting of two or more ingredients which have been mixed for such uses and the products, in question, are not covered by Chapter note 4 (d) of Chapter 30 of HSN [Chapter note 3 (d) of Central Excise Tariff Chapter 30] as these products are not the products meant for being administered to patients for diagnostic purposes and are diagnostic reagents of microbial origin. For the same reason, Hepatitis B detection kit which consists of monoclonal antibodies (a reagent of microbial origin) conjugated with colloidal gold and polyclonal antibodies on a nitrocellulose strip and which also work as the principle of antigen – antibody reaction would be covered by heading 30.02. Since the goods, in question, are correctly classifiable under heading 30.02, their classification under heading 38.22 is ruled out.

10. In view of the above discussion, the impugned order is not sustainable. The same is set aside. The appeal is allowed.

(Pronounced in the open court on 26/9/2014)

(Justice Ajit Bharihoke)
President

(Rakesh Kumar)
Member (Technical)

PK