(2024) 11 CESTAT CK 1292

In the Customs, Excise And Service Tax Appellate, New Delhi

Case No : Customs Appeal No. 51743, 51744 of 2023

Commissioner of Customs @APPELLANT @Hash M/s Rapid Diagnostics Pvt Ltd and Anr. @RESPONDENT

Date of Decision : 19-11-2024

Acts Referred:
Customs Act, 1962 — Section 25(1), 28(4), 28AA, 111(m), 112, 114A, 114AA
Customs Tariff Act, 1975 — Section 3(1)

Citation : (2024) 11 CESTAT CK 1292

Hon'ble Judges : Dilip Gupta, President (J);P. V. Subba Rao, Member (T)

Bench : Division Bench

Advocate : S.K. Rahman, B.L. Narasimhan, Anurag Kapur, Shubham Jaiswal, Kaushal Jaisalmeia

Final Decision : Dismissed

Judgement

Dilip Gupta, J

1. Customs Appeal No. 51743 of 2023 and Customs Appeal No. 51744 of 2023 have been filed by the department to assail the order dated 21.11.2022 passed by the Commissioner of Customs, ICD Tughlakabad, New Delhi, the Commissioner by which the proceedings initiated by show cause notices dated 31.08.2021, 25.11.2021 and 03.09.2022 issued to M/s Rapid Diagnostics Pvt. Ltd, Delhi, Rapid Diagnostics and to its Director Bharat Bhushan Jindal have been dropped.

2. The issue that arises for consideration in the appeals is whether the "hCG Pregnancy Rapid Test Strip" and "hCG Pregnancy Rapid Test Cassette" imported by Rapid Diagnostics would be eligible for exemption provided at Serial No. 148 of the Notification No. 12/2012-Cus dated 17.03.2012 and Serial No. 167 of Notification No. 50/2017-Cus dated 30.06.2017, the Exemption Notifications. Under these two Notifications, exemption from duty of customs is provided to "diagnostics test kits specified in List , CTH".

3. Rapid Diagnostics is a Private Limited Company engaged in the import and

trading of comprehensive range of disposable items, laboratory, patient care, ICU & surgical equipments, and diagnostic test kits (serology kits, biochemistry and rapid test kits) since the year 1995. During the period from 31.08.2016 to 07.07.2021, it claims to have imported "hCG Pregnancy Rapid Test Strip" and "hCG Pregnancy Rapid Test Cassette" through Bills of Entry and classified them under Custom Tariff Heading4 3002 of the First Schedule to the Customs Tariff Act, 1975, the Customs Tariff Act.

4. According to Rapid Diagnostics, the technical nature of the disputed goods, the description, components and the working principle are as follows:

(i) The disputed goods are rapid chromatographic immunoassays for detection of Human Chorionic Gonadotropin, hCG in urine to aid in the early detection of pregnancy. hCG is glycoprotein hormone produced by the developing placenta shortly after fertilization. The test utilizes monoclonal antibodies to selectively detect elevated levels of hCG in urine;

(ii) The disputed goods are made up of the following components:

(a) Agglutinating sera containing monoclonal antibodies for hCG;

(b) Membrane Sheet;

(c) Plastic Cassette; and

(d) Absorbent.

(iii) The test uses two lines, C and T to indicate results. The test line (T) is coated with anti hCG antibodies (monoclonal antibodies). The monoclonal antibody is purified agglutinating sera for making the test more reliable and accurate. The control line (C) is coated with antibodies and colloidal gold particles. The assay is conducted by adding urine specimen to the specimen wall of the test device and observing the formation of red colored line(s). The specimen migrates via capillary action along the membrane to react with the antibodies at C and T lines. When positive specimen containing hCG (Antigen) passes through the membrane, it reacts with the anti hCG antibody (Antigen-Antibody reaction) at test line. Positive reaction is made visible by colored conjugate. Absence of this colored line suggests a negative result.

5. At the time of import of the disputed goods, Rapid Diagnostics classified the goods under CTH 3002 and so basic customs duty was required to be paid @ Nil rate under the Exemption Notifications.

6. However, proceedings were initiated against Rapid Diagnostics in respect of Bill of Entry No. 2874642 dated 23.02.2021. The Customs Officers examined the disputed goods under the cover of panchnama dated 23.07.2021. During the examination of disputed goods, a view was entertained by the Department that Rapid Diagnostics camouflaged the actual description of the disputed goods by adding the term "agglutinating sera" with an intent to avail the benefit under the Exemption Notifications.

7. Further investigation was initiated against the imports made by Rapid Diagnostics. During the investigation, various statements were recorded and samples of disputed goods were sent to AIIMS Biochemistry Department, New Delhi, and National Institute of Immunology, Delhi for testing purposes. The Test Reports from AIIMS Biochemistry Lab were received on 03.04.2021 and 15.04.2021. The Test report from the National Institute of Immunology was received on 14.06.2021.

8. During the investigation, Rapid Diagnostics, also deposited Rs. 70,00,000/- towards duty and interest, without prejudice to its right to contest the proposal of duty.

9. Show cause notices dated 25.11.2021 and 03.09.2021 for the period 31.08.2016 to 07.07.2021 were issued to Rapid Diagnostics alleging that the disputed goods were not "agglutinating sera", but complete pregnancy test kits in ready to use condition and, therefore, the benefit of exemption under the Exemption Notifications would not be available to Rapid Diagnostics. Consequently, it was proposed to reject the exemption claimed by Rapid Diagnostics and a demand for differential duty under section 28(4) of the Customs Act, 1962, the Customs Act along with interest under section 28AA of the Customs Act was proposed. Proposal for confiscation under section 111(m) and imposition of penalty under sections 112/114A and 114AA of the Customs Act were also made. Penalty on Bharat Bhushan Jindal, Director of Rapid Diagnostics was also proposed under sections 112 and 114AA of the Customs Act.

10. Rapid Diagnostics filed a detailed reply dated 09.11.2022 and submitted that the disputed goods are based on agglutinating sera and, therefore, the same are correctly classifiable under CTH 3002 attracting basic customs duty @ nil rate under the Exemption Notifications.

11. The Commissioner held that the disputed goods deserve classification under CTH 3002 and so basic customs duty would have to paid @ Nil under the Exemption Notifications since the essential character of the disputed goods comes from the agglutinating sera. The demands proposed in the show cause notices were, accordingly, dropped. The relevant portions of the order passed by the Commissioner are reproduced below:

"40.2 After going through the case file, I find that there is no dispute regarding the description of the imported goods, namely, "HCG Pregnancy Rapid Test Strip" and "HCG Pregnancy Rapid Test Cassette". It is also not in dispute that the impugned goods are classifiable under Customs Tariff Head No. 3002 of the Customs Tariff Act, 1975, *****

40.3 Further, there is no dispute regarding the contention of the department that the impugned goods described as "HCG Pregnancy Rapid Test Strip" and "HCG Pregnancy Rapid Test Cassette" are complete pregnancy test kits and not "Agglutinating Sera" per se. *****

40.4 However, there is equally no dispute that the impugned goods, namely "HCG Pregnancy Rapid Test Strip" and "HCG Pregnancy Rapid Test Cassette" are based on "Agglutinating Sera", the chief component of the test kit that produces the result regarding pregnancy. At this juncture, I may mention that the initiation of the investigation arises from the fact that the importer has included reference to "Agglutinating Sera", which has not been found on inspection of the product package or literature. This contention of the department in the SCN has not been controverted. Nonetheless, it is absolutely not in dispute that the impugned goods, namely "HCG Pregnancy Rapid Test Strip" and "HCG Pregnancy Rapid Test Cassette" do contain "Agglutinating Sera", albeit not simply that and contain other items as well.

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40.7 The impugned goods, as per investigation and submissions of the Noticee, primarily consists of membrane sheet, plastic cassette and absorbent. The basic function of these components is to provide longer shelf life and stability to the impugned goods. However, it is observed that the essential component of these goods is agglutinating sera, which is the only active component on which test reaction is based. As such, the same is the only active component of impugned goods and rest are passive components. As such, the impugned goods (pregnancy detection kits) have their essential character defined by agglutinating sera only. The agglutinating sera is essential and inseparable part of the impugned goods is also part of the findings of the test report dated 03.04.2021 issued by Biochemistry Department, AIIMS, New Delhi and test report dated 14.06.2021 issued by the National Institute of Immunology Delhi."

(emphasis supplied)

12. After referring to the judgment of the Supreme Court in M/s. Span Diagnostics Ltd. vs. Commissioner of Central Excise, 2007 (211) E.L.T. 521 (S.C.) and the decision of the Tribunal in Inter Care Ltd. vs. Collector of Customs, New Delhi, 1997 (89) E.L.T. 545 (Tribunal), the Commissioner concluded as follows:

"4.10. In view of the above, I hold that the impugned goods are diagnostic test kits, which attain their essential character from 'agglutinating sera' and, therefore, the same are squarely covered under S. No. 148 (S.No. 4 of list 4) of Notification number 12/2012 dated 17.03.2012 before 30.06.2017 and under S.No. 167 (list 4) of Notification No. 50/2017 dated 30.06.2017 after 30.06.2017, making them eligible for the 100% exemption claimed by the noticee."

(emphasis supplied)

13. These appeals have been filed by the Department to assail the order dated 21.11.2022 passed by the Commissioner.

14. Shri S.K. Rahman, learned authorized representative appearing for the Department made the following submissions:

(i) The imported hCG pregnancy rapid test strip cassette and agglutinating sera are not same, even though the latter is the main reactive agent or active ingredient of the test kit;

(ii) The benefit of the Exemption Notifications is available only to agglutinating sera and not to pregnancy rapid test strip cassette; and

(iii) Other manufacturers, namely Medi Force Healthcare, Pvt Ltd having similar product with brand name "Prega News" import agglutinating sera as a raw material, and rightly claim benefit of the Exemption Notifications. This shows that the products test kit and agglutinating sera are distinct, and the latter is the raw material of the former. Raw material and finished products cannot be equated for availing exemption benefit.

15. Shri B.L. Narasimhan, learned counsel appearing for the Rapid Diagnostics assisted by Shri Anurag Kapur, Shri Shubham Jaiswal ans Shri Kaushal Jaisalmeia, however, made the following submissions:

(i) Rapid Diagnostics correctly availed the benefit of exemption under the Exemption Notifications;

(ii) The disputed goods are classifiable under CTH 3002 of the Customs Tariff Act;

(iii) The disputed goods are diagnostic test kits based on agglutinating sera; and

(iv) To support the contentions, learned counsel placed reliance upon the decision of the Tribunal in Inter Care, wherein the benefit of Notification dated 22.09.1981 was allowed to the pregnancy test kits which were based on agglutinating sera. The said decision of the Tribunal was subsequently followed by the Tribunal in Inter Care Ltd. vs. Commissioner of Customs, New Delhi, 2001 (128) E.L.T. 203 (Tri-Del.), wherein the benefit of Notification dated 16.03.1995 was allowed to the "agglutinating sera" in freeze dried form.

16. The submissions advanced by the learned authorized representative appearing for the department and the learned counsel for the respondent Rapid Diagnostics have been considered.

17. The question that arises for consideration in these appeals is as to whether the "hCG Pregnancy Rapid Test Strip" and "hCG Pregnancy Rapid Test Cassette" deserve classification under CTH 3002 and whether basic customs duty @ Nil rate as required to be paid under the Exemption Notifications. The description of goods under CTH 3002 is as follows:

Chapter 30

Pharmaceutical Products
983

Tariff Item

Description of goods

Unit

Rate of duty

Standard

Preferential

(1)

(2)

(3)

(4)

(5)

3002

Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera, other blood factions and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products

18. The relevant portion of the Exemption Notification dated 17.03.2012 is as follows:

19. EFFECTIVE RATES OF DUTY FOR GOODS OF VARIOUS CHAPTERS/HEADINGS

Exemption and Effective rates of basic and additional duty for specified goods of Chapters 1 to 98. – In exercise of the powers conferred by sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962) ***** the Central Government, on being satisfied that it is necessary in the public interest so to do, hereby exempts the goods of the description specified in column (3) of the Table below or column (3) of the said Table read with the relevant List appended hereto, as the case may be, and falling within the Chapter, heading, sub-heading or tariff item of the First Schedule to the said Customs Tariff Act, 1975 (51 of 1975) as are specified in the corresponding entry in column (2) of the said Table, when imported into India,-

(a) from so much of the duty of customs leviable thereon under the said First Schedule as is in excess of the amount calculated at the standard rate specified in the corresponding entry in column (4) of the said Table; and

(b) from so much of the additional duty leviable thereon under sub-section (1) of section 3 of said Customs Tariff Act, 1975, (51 of 1975) as is in excess of the additional duty rate specified in the corresponding entry in column (5) of the said Table, subject to any of the conditions, specified in the Annexure to this notification, the condition number of which is mentioned in the corresponding entry in column (6) of the said Table:

S. No.

Chapter or Heading or Subheading or tariff item

Description of goods

Standard rate

Additional duty rate

Condition No.

(1)

(2)

(3)

(4)

(5)

(6)

148.

28, 29, 30 or 38

The following goods, namely:- (A) Life saving drugs/medicines including their salts and esters and diagnostic test kits specified in List 4.

(B) Bulk drugs used in the manufacture of life saving drugs or medicines at (A)

(C) Other life saving drugs or medicines

Nil

Nil

Nil

-

-

Nil

-

5

10

(emphasis supplied)

19. This Notification was subsequently superseded by Notification dated 30.06.2017 and the relevant portion of the Table contained in said Notification is reproduced below:

S. No.

Chapter or Heading or Subheading or tariff item

Description of goods

Standard rate

Integrated Goods and Service Tax

Condition No.

(1)

(2)

(3)

(4)

(5)

(6)

167.

28, 29, 30 or 38

The following goods, namely:- (A) Lifesaving drugs/medicines including their salts and esters and diagnostic test kits specified in List 4.

(B) Bulk drugs used in the manufacture of life saving drugs or medicines at (A)

(C) Other life saving drugs or medicines

Nil

Nil

Nil

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-

-

-

9

16

20. It would be seen that the aforesaid two Exemption Notifications provide exemption to goods contained in Chapter 30 to the following goods specified in List 4 falling in Chapter 28, 29, 30 or 38:

(i) Life saving drugs/medicines;

(ii) Salts and esters of (i); and

(iii) Diagnostic test Kits.

21. The appellant claims that the disputed goods are prepared using agglutinating serum/antisera and the essential character of the kit is provided by monoclonal antibody (hCG antibody). The disputed goods would, therefore, be classifiable under CTH 3002. There is no dispute with regard to the classification of the disputed goods. Therefore, the condition mentioned in Column (2) of Serial No's. 148 and 167 of the Exemption Notifications stands satisfied.

22. According to Rapid Diagnostics, the disputed goods are rapid chromatographic immunoassay for detection of hCG in urine to aid in the early detection of pregnancy. hCG is glycoprotein hormone produced by the developing placenta shortly after fertilization. The test utilizes monoclonal antibodies to selectively detect elevated levels of hCG in urine. There is no dispute that the disputed goods are prepared using agglutinating serum/sera.

23. "Serum/sera" is the fluid fraction separated from blood after clotting. When an antigen is introduced in an animal, antibodies are produced in the serum. The "antibody" is an immunoglobin molecule having specific amino acid sequence that gives each antibody the ability to adhere to and interact only with the antigen that induced its synthesis. This antigen specific property of the antibody is the basis of the antigen-antibody reaction that is essential to an immune response.

24. When a woman becomes pregnant, the placenta produces high quantity hCG. This hCG is excreted through the urine. Detection of the presence of hCG in the urine is one of the indications to confirm that a woman is pregnant. Therefore, when urine contains hCG and if that is brought into contact with an agglutinating serum/sera which contains antibody to the hCG, it will agglutinate or clump.

25. It can, therefore, be said that the agglutinating sera used in the preparation of the disputed goods provide the essential character to the disputed goods. Further, agglutinating sera is the most essential and only active component on which test reaction is based. The other components like membrane sheet, plastic cassette and absorbent are passive components which provide longer shelf life and stability to the kit. As the disputed goods are based on agglutinating sera, the benefit of the Exemption Notifications would be available to Rapid Diagnostics.

26. The decision of the Tribunal in Inter Care, wherein the benefit of the Exemption Notifications was allowed to the pregnancy test kits which were based on agglutinating sera, supports the aforesaid view. The relevant portions of the decision of the Tribunal are reproduced below:

"5. Regarding import in kit form, we are satisfied from what has been narrated above that, since at the time of use, antiserum is used in liquid form only, it has to be liquified with a special buffer solution and is hence imported in the form of a kit consisting of two components, viz. (a) agglutinating sera in solid form and

(b) buffer solution and the two are mixed together for reconversion or reconstitution of agglutinating sera in liquid form for use. Hence the third reason of the adjudicating authority for holding that the imported item is not agglutinating sera also cannot be sustained.

6. We further find that the adjudicating authority has emphasised the point that agglutinating sera are not covered within the ambit of sub-title of the notification which reads as "life saving drugs or medicines", as they are used in pathological laboratories for conducting routine tests of pregnancy detection. This reasoning is not correct for the reason that the title of a notification gives only a broad indication of the goods covered therein and cannot be used as characteristic or a yard-stick for determining the exact scope of the specific entry therein and factually the imported item is life saving in nature it is used for detecting life threatening conditions like Hydatidiform mole, choriocarcinoma, etc. The main stay of early diagnosis of both the above diseases is ultrasonic examination supported by serum HCG estimation. Further, when early detection of pregnancy is necessary to carry out medical termination of pregnancy, agglutinating sera which detects the presence of HCG in urine is certainly life saving. Moreover, it is medically recognised that, before the insertion of Intra Uterine Devices or before prescribing oral contraceptives, it is necessary to rule out pregnancy, otherwise if the woman is already pregnant and by mistake the IUD is inserted or any oral contraceptive is prescribed it could prove highly detrimental to the woman and the unborn foetus. The notification also covers certain diagnostic tests e.g. Sl. No. 155 of Notification No. 208/81 covers Elisa Diagnostic Tests and this is a test that can be used for detecting pregnancy by determining HCG levels. In a recent decision of the Tribunal in the case of Collector of Customs, New Delhi v. Ethnor Ltd. reported in 1996 (86) E.L.T. 558 (Tribunal) = 1996 (16) RLT 166 (CEGAT), pregnancy detection kits bearing trade name of "Clear View HCG" have been held to be covered by the description "Elisa Diagnostic Tests" mentioned at Sl. No. 155 of Notification No. 208/81. The list of life saving drugs or medicines stipulated in the notification covers a number of other tests e.g. blood group sera (Sl. No. 215), Enzyme linked Immunoabsorbent Assay Kits Elisa Kits (Sl. No. 186). This clearly indicates that the list appended to the notification covers diagnostic kits also. It is relevant to note at this juncture that the HSN Explanatory Notes to Heading 30.02 states that antisera are used against dysentery, pneumonia, snake bite, allergic diseases, etc. and are also used for diagnostic purposes, including in vitro tests and specific immunoglobulins are purified preparations of antisera.

7. ***** The basic character of the product depends upon the nature of the product and not upon the brand name. If the brand name of agglutinating sera was different, the basic characteristics would still remain the same and even the label `Preg color' is removed, the product would still remain agglutinating sera.

7.1 The Collector has relied upon two letters dated 30-3-1993 and 23-11-1993 of the National Institute of Immunology, New Delhi. The letter of March 30, 1993

states that although Preg color - pregnancy detection diagnostic kit used as antibody which is agglutinating in nature, the kit itself does not fall into the category of "agglutinating sera". This letter does not contain any reason or basis for holding that the kit does not fall into the category of agglutinating sera. The Collector has also referred to the opinion dated 29-3-1993 of the Institute of Research in Reproduction which states that "Preg color" cannot be referred as agglutinating sera. The monoclonal `antibody sera' referred is a diagnostic reagent wherein antibodies (monoclonal) are coated to a gold SOL particles. Sera do cause agglutination in a final reaction but in our opinion it is a value added product and not merely a simple derivative of sera. It is that the product is obtained from sera and has agglutinating properties; however, classification as agglutinating sera has been ruled out apparently because it is in kit form. We have already held earlier that the import of the product is in kit form is not detrimental to the claim of the appellants that what they imported was agglutinating sera. The criterion for value addition is not also relevant for the purpose of this case. On the other hand, the appellants have produced opinion from the Department of Biotechnology, Ministry of Science and Technology, which is the administrative department to give technical clarification on pharmaceuticals diagnostic based on bio-technology techniques. In this letter dated 23-8-1993 (page 196 of the paper book) it is certified that the item Preg color as presently marked is agglutinating sera."

27. The aforesaid decision was subsequently followed by the Tribunal in Inter Care Ltd. decided on 24.11.2000.

28. The Commissioner, in the impugned order, has dropped the demands proposed in the show cause notices for the reason that the disputed goods are classifiable under CTH 3002 and so basic customs duty would have to be paid at Nil rate of duty. To arrive at this conclusion, the Commissioner held that the disputed goods are based on "agglutinating sera" which is the chief component of the test kit that produces the result regarding the pregnancy. Thus, as agglutinating sera is the only active component and the rest of the components are passive, the pregnancy detection kits have their essential character defined by agglutinating sera only. Thus, the imported goods would be covered under the Exemption Notifications. The aforesaid findings recorded by the Commissioner are based on an earlier decision of the Tribunal in Inter Care and do not suffer from any infirmity.

29. The two appeals filed by the department, therefore, deserve to be dismissed and are dismissed.

(Order Pronounced on 19.11.2024)

