CUSTOMS, EXCISE & SERVICE TAX APPELLATE TRIBUNAL

NEW DELHI

PRINCIPAL BENCH- COURT NO. I

CUSTOMS APPEAL NO. 52186 OF 2022

[Arising out of Order-in-Original No. 02/2022-23/S.J/ Principal Commissioner dated 30.06.2022 passed by the Principal Commissioner of Customs, Air Cargo Complex, Import, New Delhi]

M/s Cepheid India Private Limited **....Appellant**
9th Floor, Paras Twin Towers, Tower B,
Golf Course, Sec-54, Gurugram,
Haryana, India, 122002

(Earlier situated at Unit No. DSM-214 &215,
Second Floor, DLF Tower,15, Shivaji Marg,
Najafgarh Road West, New Delhi-110037)

versus

The Principal Commissioner of Customs, **....Respondent**
New Customs House,
Near IGI Airport,
New Delhi- 110037

APPEARANCE:

Shri Rohan Shah,Senior Advocate, Shri Kumar Visalaksh, Ms. Tejas Pathak, Ms. Akansha Dikshit and Shri Mohd. Anajwala, Advocates for the Appellant

Shri S.K. Rahman, Authorised Representative for the Department

CORAM: HON'BLE MR. JUSTICE DILIP GUPTA, PRESIDENT
HON'BLE MR. P.V. SUBBA RAO, MEMBER (TECHNICAL)

Date of Hearing: 10.02.2025
Date of Decision: 25.06.2025

FINAL ORDER NO. 50929/2025

JUSTICE DILIP GUPTA:

M/s Cepheid India Private Limited[1] is aggrieved by the order dated 30.06.2022 passed by the Principal Commissioner of Customs, ACC Import, New Delhi[2]. The order rejects the declared assessable value of the goods imported through 85 Bills of Entry under rule 12 of the Customs Valuation (Determination of Value of Imported Goods) Rules,

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1. **the appellant**
2. **the Principal Commissioner**

2007[3] and re-determines the same. The exemption from basic customs duty[4] in respect of diagnostic kits imported under Notification (Cus.) dated 17.03.2012 (Serial No. 148) during the period up to 30.06.2017 and Notification (Cus.) dated 30.06.2017 (Serial No. 167) w.e.f 01.07.2017 has been denied to the appellant. Exemption from additional duty[5] equivalent to excise duty leviable under section 3(1) of the Customs Tariff Act, 1975 as provided for under Notification (C.E.) dated 17.03.2012 (Serial No. 108) for the period up to 30.06.2017 has also been denied to the appellant. Integrated Goods and Service Tax[6] with effect from 01.07.2017 @ 5% under IGST Rate Notification dated 28.06.2017[7] (Serial No. 180) of Schedule I has also been denied to the appellant. The order, therefore, confirms the proposed duty under section 28(4) of the Customs Act, 1962[8] with interest under section 28AA of the Customs Act. The order also confiscates the goods imported through 85 Bills of Entry under section 111(m) of the Customs Act, but as the goods were not available for confiscation, redemption fine has not been imposed. The order also imposes penalty upon the appellant under section 114A of the Customs Act.

2. The appellant is a part of the Cepheid Group, which is a Corporation based in California. It is mainly engaged in the business of trading of test cartridges, re-agents, molecular diagnostic testing equipments used for sampling and detection of different types of diseases. The products traded/sold by the appellant in India are imported from its related party suppliers named Cepheid Group

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3. the 2007 Valuation Rules
4. BCD
5. CVD
6. IGST
7. IGST Rate Notification
8. the Customs Act

Entities[9]. Such imported products can mainly be classified into three categories- **(a)** Test cartridges/kits, **(b)** Testing equipment/system and their standard accessories, and **(c)** Spares and assemblies for the equipment. These products shall collectively be referred to as **'subject goods'**. These equipment/ spares and test cartridges are sold under the trade name of 'GeneXpert®' and 'Xpert®', respectively and are owned by Cepheid, USA. These products are used for clinical tests in the areas of critical infectious diseases, healthcare-associated infections, sexual health, virology, and oncology, such as Tuberculosis, Hepatitis B, Hepatitis C, HIV and Influenza.

3. The issue involved in this appeal relates to the period from 16.08.2016 to 20.04.2021 during which the appellant had cleared consignments on finally assessed Bills of Entry. However, BCD, CVD and lower rate of IGST on HIV-VL Test Kits claimed by the appellant under various Exemption Notifications have been denied and the declared value has been rejected under rule 12 and re-determined under rules 4, 5 and 9 of the 2007 Valuation Rules.

4. The appellant initiated 'trading operations' in India from August 2016 when it imported and sold molecular diagnostic testing equipments, test cartridges, re-agents used for sampling and detection of different types of diseases in India, including HIV. These imports were made from related foreign suppliers of the appellant under a Purchase Requisition/ Purchase and Distribution Agreement dated 01.01.2019 entered with M/s Cepheid USA. In terms of the said agreement, the appellant was appointed on a non-exclusive basis to purchase, process, package, promote, sell and distribute the subject goods in India.

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9. the Foreign Suppliers

5. The present appeal involves two issues. The first relates to eligibility of exemption on import of HIV-1 viral load test kits and the second relates to determination of value of certain goods including HIV-1 Viral load test kits, cleared by the appellant on final assessment basis during the pendency of Special Valuation Branch[10] investigation. These two issues shall be dealt with separately.

A

Eligibility of Exemption Benefit to HIV-1 Viral Load Test Kits

6. On the basis of intelligence developed by Special Investigation and Intelligence Branch,[11] one consignment of HIV- viral load test kits imported by the appellant through a Bill of Entry dated 10.03.2021 was seized under section 110 of the Customs Act on the allegation that the appellant had wrongly availed exemption from BCD under Notification dated 30.06.2017 and lower rate of IGST under Notification dated 28.06.2017 by treating such goods as kits for detection of 'antibodies', though they were used for detection of 'viral load' for which no exemption from customs duty was available.

7. It would, therefore, be appropriate to refer to the relevant Notifications.

8. The relevant portion of Notification (Cus.) dated 17.03.2012 in report of BCD and CVD is reproduced below:

> *****
>
> **Notification: 12/2012-Cus. dated 17-Mar-2012**
>
> **the Central Government**, 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

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10. SVB
11. SIIB

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 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;

(b) **from so much of the additional duty** leviable thereon under sub-section (1) of section 3 of the 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 Sub-heading 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**	Nil	-	-
		(B) Bulk drugs used in the manufacture of life saving drugs or medicines at (A)	Nil	-	5
		(C) Other life saving drugs or medicines	Nil	Nil	10

(emphasis supplied)

9. The relevant portion of List 4 referred to at Serial No. 148(A) is reproduced below:

"**List 4 (See S. No. 148 and 516 of the Table)**

(32) Diagnostic kits for detection of HIV antibodies"

10. The relevant portion of Notification (C.E.) dated 17.03.2012 is reproduced below:

Notification: 12/2012-Cus. dated 17-Mar-2012

**** **the Central Government**, being satisfied that it is necessary in the public interest so to do, **hereby exempts the excisable goods of** the description specified in column (3) of the Table below read with relevant List appended hereto and falling within the Chapter, heading or sub-heading or tariff item of the First Schedule to the Central Excise Tariff Act, 1985 (5 of 1986) (hereinafter referred to as the Excise Tariff Act), as are given in the corresponding entry in column (2) of the said Table, **from so much of the duty of excise specified** thereon under the First Schedule to the Excise Tariff Act, as is in excess of the amount calculated at the rate specified in the corresponding entry in column (4) of the said Table and subject to the relevant conditions annexed to this notification, if any, specified in the corresponding entry in column (5) of the Table aforesaid:

Sl. No.	Chapter or Heading or Sub-heading or tariff item	Description of excisable goods	Rate	Condition No.
(1)	(2)	(3)	(4)	(5)
180	28,29,30 or 38	**The following goods, namely,** (A) Drugs or medicines including their salts and esters and **diagnostic test kits, specified in List 3 or List 4** appended to the notification of the Government of India in the erstwhile Ministry of Finance (Department of Revenue), No. 12/2012-Customs, dated the 17th March, 2012) (B) Bulk drugs used in the manufacture of the drugs or medicines at (A)	Nil Nil	- -

(emphasis supplied)

11. The relevant portion of the Notification (Cus.) dated 30.06.2017 dealing with BCD and IGST is reproduced below:

Notification: 50/2017-Cus. Dated 30-Jun-2017

****** **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, 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 integrated tax leviable** thereon under sub-section (7) of section 3 of said Customs Tariff Act, read with section 5 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017) as is in excess of the amount calculated at the 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 sub-heading or tariff item	Description of goods	Standard rate	Integrated Goods and Services 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 specirfied in List 4.**	Nil	-	-
		(B) Bulk drugs used in the manufacture of life saving drugs or medicines at (A)	Nil	-	9
		(C) Other life saving drugs or medicines	Nil	-	16

(emphasis supplied)

12. The relevant portion of List 4 is reproduced below:

> "**List 4 (See S.No. 167 and 607 of the Table)**
>
> (28) Diagnostic kits for detection of HIV antibodies"

13. The relevant portion of IGST Rate Notification dated 28.06.2017 is reproduced below:

> **Notification: 1/2017-Integrated Tax (Rate) dated 28-Jun-2017**
>
> **Rate of IGST on specified goods- Schedule I to VI**
>
> In exercise of the powers conferred by sub-section (1) of section 5 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017), **the Central Government,** on the recommendations of the Council, **hereby notifies the rate of the integrated tax of-**
>
> **(i) 5 per cent in respect of goods specified in Schedule I**
>
> *******
>
> appended to this notification (hereinafter referred to as the said schedules), that shall be levied on inter-State supplies of goods, the description of which is specified in the corresponding entry in column (3) of the said Schedules, falling under the tariff item, sub-heading, heading or Chapter, as the case may be, as specified in the corresponding entry in column (2) of the said Schedules.
>
> Schedule 1-5%

S.No.	**Chapter/Heading/Sub-heading/ Tariff item**	**Description of Goods**
(1)	(2)	(3)
180.	30 or any chapter	Drugs or medicines including their salts and esters and **diagnostic test kits, specified in List 1 appended to this Schedule**

14. The relevant portion of List I referred to above is reproduced below:

> "**List 1[See S. No. 180 of the Schedule I]**

(150) Diagnostic Kits for detection of HIV antibodies."

15. Coming back to the factual aspect, post the seizure of consignment of HIV- viral load test kits imported through Bill of Entry dated 10.03.2021, the appellant paid the differential customs duty and by order dated 16.04.2021 the seized goods were permitted to be provisionally released by the department, subject to submission of a bond and bank guarantee.

16. The SIIB also issued summons dated 13.04.2021 to the appellant for providing detailed justification on exemption claimed along with relevant details/documents with respect to previous clearances of HIV-viral load test kits. The appellant, thereafter, paid the differential customs duty under protest by a challan dated 06.05.2021 for the past clearances of HIV-viral load test kits for the 40 Bills of Entry, out of which 32 were provisional and the remaining 8 were finally assessed Bills of Entry.

17. During investigation, Manish Kumar Madhukar, Trade Compliance Analyst of the appellant appeared to provide reasoning and justification for claiming exemption and submitted information/documents.

B

Re-determination of value of goods cleared on final assessment basis.

18. Since the appellant and its foreign suppliers were related persons in terms of rule 2(2)(v) of the 2007 Valuation Rules, the case of the appellant was registered with SVB for examining as to whether the declared import prices had been influenced by the relationship between the parties. In view of the pendency of the investigation, all related

party imports since August 2016 were cleared on provisional assessment basis. During the course of the SVB proceedings, the appellant submitted various documents/ details to justify that the prices declared were at arm's length and, therefore, were required to be considered as transaction value under the Customs Act read with the 2007 Valuation Rules.

19. In the report dated 22.10.2019, the SVB suggested that the declared invoice value for the subject goods was influenced by the relationship and thus, the assessable value may have to be re-determined by loading of 93.93% on the declared value.

20. Accordingly, a show cause notice dated 13.01.2020 was issued to the appellant alleging that the imports made by the appellant from August 2016 from its related foreign suppliers were influenced by the relationship and were therefore, not at arm's length principle. The show cause notice, therefore, proposed a loading factor of 93.93% after allowing a discount at 20% to the appellant for importing goods in higher quantities. The appellant filed a reply dated 16.04.2021 but adjudication order has not been passed as yet.

21. After the filing of the reply, it was noticed that out of more than 900 Bills of Entries filed by the appellant during August 2016 to February 2021, 85 Bills of Entry were cleared on final assessment basis instead of provisional assessment. Therefore, another show cause notice dated 14.08.2021 was issued to the appellant with respect to such 85 finally assessed Bills of Entry. The adjudication of this show cause notice is the subject matter of this appeal.

22. The appellant filed a reply dated 14.01.2022 to the show cause notice and denied the allegations. The Principal Commissioner, however, confirmed the demand by the order dated 30.06.2022. The Principal

Commissioner denied the benefit of BCD and CVD, which the appellant had claimed. The Principal Commissioner also held that the appellant had wrongly paid IGST @ 5% under the IGST Rate Notification dated 30.06.2017. After rejecting the declared value of the imported goods, the Principal Commissioner re-determined the value of different types of goods under rules 4, 5 and 9 of the 2007 Valuation Rules. The goods can broadly be categorized under three classes- **(a)** test cartridges/ kits **(b)** testing equipments and standard accessories and **(c)** spares and assemblies for the equipment goods The details are as follows:

Particulars	**Issue I (HIV-VL Test Kits)**	**Issue II (Goods under 3 classes)**	**Total**
Duty u/s 28 (1)	Rs. 49,50,757	Rs. 3,06,05,411	Rs. 3,55,56,168
Interest u/s 28AA	Rs. 29,81,247	As applicable	As applicable
Penalty u/s 114A	Rs. 19,83,001	Rs. 3,06,05,411 + interest	Rs. 3,55,56,168 + interest
No. of BOEs	3 (unique) + 5 (common)	77 (unique) + 5 (common)	85

23. Shri Rohan Shah, learned senior counsel appearing for the appellant assisted by Shri Kumar Visalaksh, Ms. Tejas Pathak, Ms. Akhansha Dikshit and Shri Mohd. Anajwala made submissions broadly on the following four issues:

Jurisdictional issues

(i) The impugned order has re-determined the value cleared on final assessment basis even when the core issue of valuation and finalization of provisional assessment for related party imports of the appellant was pending before SVB, which had initiated proceedings by issue of a show cause notice dated 30.01.2020;

(ii) The impugned order, in the application of the 2007 Valuation Rules, has travelled beyond the show cause notice;

(iii) The show cause notice proposed a maximum loading of 93.93% but the percentage of loading imposed by the impugned order ranges between 0% to 822%. The impugned order offers no discount for quantity and commercial level difference and withdraws the discount of 20% offered in the show cause notice;

(iv) The impugned order relies upon an entirely different set of Bills of Entry than those referred to in the show cause notice; and

(v) The loading percentage for HIV-viral load test kits have been arrived at by relying on Bills of Entry not mentioned in the show cause notice.

Availability of Exemption to HIV-1 Viral Load Test Kits

(i) Exemption entry is of wide import to cover technologically advanced HIV testing kits such as HIV viral load test kits. While interpreting tariff and Exemption Notification, advancement of technology has to be taken into consideration. In this connection, learned counsel relied upon certain decisions to which reference shall be made at the appropriate stage;

(ii) It is not the case of the appellant that antibody test is based on an outdated technology which is no longer in use. Instead, since the initial development of antibody test, other tests capable of and used for detection and prognosis of HIV have also been introduced, which should be treated at par with antibody tests while extending benefit under the Exemption Notification;

(iii) The exemption benefit under the category of "life-saving drugs/medicines" has to be offered a purposive interpretation and hence the benefit should be extended to not only the diagnostic kits for detection of HIV antibodies but also to other diagnostic kits used for detection and prognosis of HIV, which serve the same purpose;

(iv) HIV-VL test kits are indeed "lifesaving diagnostic kits" and used for detection and prognosis of HIV virus in a human body. These kits not only detect the presence of HIV infection, but being more sensitive and accurate, are used for regular monitoring of the spread of HIV infection in the body and for identifying the failure of first course of treatment so as to change the course of treatment and thereby enable fighting the HIV epidemic, which was the sole intention behind introducing the exemption and extending it to diagnostic kits for HIV; and

(v) HIV-VL test kits are imported to support the larger public interest objective of the National AIDS Control Program aimed at halting and reversing the HIV epidemic in India and thus supplies of these kits to IPAQT laboratories and NGO institutions are at capped prices.

Redetermination of Value

(i) The Principal Commissioner committed an error in resorting to rules 4 and 5 of the 2007 Valuation Rules as these two rules are not applicable in the present case. This is for the reason that the goods have not been imported by the appellant and Labindia **"**at or about the same time**"** and so cannot be considered as contemporaneous imports; the goods imported by the

appellant and Labindia are not at the "same commercial level"; and goods imported by the appellant and Labindia are not at the "same quantity level";

(ii) No adjustment has been made for differences attributed to commercial and quantity level;

(iii) The "circumstances and sale" of imported goods indicate that the relationship did not influence the price;

(iv) The reasons for differences in the prices of spares is mainly due to the fact that imports by Labindia were on free of cost (FOC) basis under the warranty provided by the foreign suppliers. In such cases, higher value was declared "only for customs duty purposes", and thus there was no actual cost/ price incurred by Labindia towards such imports. Whereas, the supplies to the appellant are made for actual charges and hence the declared prices are actual cost borne by the appellant itself;

(v) Declared value of imported goods, mainly MTB test kits (with 90% import ratio) under valuation are close to the transaction value of identical goods when supplied directly to Central Government by the foreign suppliers after giving due account to the commercial level and quantity level differences; and

(vi) On application of rule 7 of the 2007 Valuation Rules to various product types including MTB test kits, which are supplied at a very low/negligible margin substantially to the Government bodies under HBDC program, it would be manifestly clear that by applying such deductive value principle also the import prices of the appellant

are appropriately valued and have not been influenced by the relationship.

Penalty and Interest

(i) Penalty under section 114A of the Customs is attracted only when short levy is caused by reason of collusion or willful misstatement or suppression of facts. In the present case, none of these circumstances exist to warrant the levy of penalty. Without prejudice to the fact that there has been no infraction of the law on the part of the appellant, in the event there has been any infraction, the same is completely unintended and bona fide and without any intent to evade duty;

(ii) Penalty is not imposable if the issue involved is one of interpretation;

(iii) Where the duty demand is itself not sustainable, no penalty can be leviable; and

(iv) Since demand itself is not sustainable, no interest can be demanded.

24. Shri S.K. Rahman, learned authorized representative appearing for the department, however, supported the impugned order and made the following submissions:

Jurisdictional issues

(i) The appellant is not justified in asserting that when the issue is pending before SVB, this adjudication which includes re-determination of value, should not have been undertaken. The related party issue has been examined by the Principal Commissioner in the order. The appellant, while filing Bills of Entries, should have requested for provisional assessment waiting for

finalization of the SVB issue but the appellant filed final Bills of Entry and also mis-declared the relationship as **"**not related**"**;

(ii) It is not correct that the impugned order relies upon entirely different Bills of Entries than those referred to in the show cause notice. On verification, it has been found that out of the 40 Bills of Entries mentioned in the show cause notice, 20 Bills of Entries have been relied upon in the order.

Denial of Exemption to HIV-VL Test Kits.

(i) The exemption under the Exemption Notification is restricted only to the diagnostic kits for "detection of HIV antibodies", whereas the appellant has imported the diagnostic kits for "detection of HIV Viral Load";

(ii) The benefits under an Exemption Notification have to be interpreted strictly. The technological advancement from "detection of HIV antibodies" to "detection of HIV Viral Load", cannot be considered unless the Notification is suitably amended;

(iii) There may be various methods of detecting HIV in infected persons. One method could be "detection of HIV antibodies" and another method could be "Detection of HIV viral load". The Government has specifically given benefit for "detection of HIV antibodies" method. It is not that Government was not aware about advancement in testing methods i.e. by "detection of HIV Viral Load". The Government did not want to give benefit to "detection of HIV Viral Load". Hence, the appellant is not eligible for benefit of Notification;

(iv) The impugned testing kit is for detection and quantification of HIV-1 viral RNA. In other words, the said testing is a viral load testing kit and it cannot detect HIV antibodies. The Viral Load testing and antibodies testing are two different Tests and hence, the benefit of Notification cannot be given to a testing method not mentioned in the Notification.

Re-determination of Value

(i) As per section 14 of Customs Act, the declared value of impugned goods shall be accepted as Transaction Value only when the foreign supplier and Indian importer of the goods are not related person. In the instant case, as the importer and the foreign supplier are related, the Transaction value cannot be accepted;

(ii) The relationship has influenced the Transaction Value. Hence, the declared Transaction Value cannot be accepted;

(iii) The foreign supplier has entered into "Purchase and Distribution Agreement effective 01.01.2019" between the importer and the Cepheid USA". The prices adopted for import of impugned goods is as per this agreement, which are different from Transaction Value between the same foreign supplier and unrelated buyer (importer) in India. As per Explanation (1)(iii)(c) of rule 12 of the 2007 Valutaion Rules, the Transaction Value can be rejected if sales invoices offer special discounts to exclusive Agents;

(iv) The reasons for rejection of Transaction Value have been communicated to the appellant in the show cause notice dated 14.08.2021;

(v) In the instant case, it appears that the same foreign supplier has supplied goods to the appellant importer (being related party) and to unrelated third party (Independent Importer) also. Hence, the Transaction Value between foreign supplier and unrelated third party (Independent Importer), would be adopted for re-determination of value between foreign supplier and the appellant importer (being related party);

(vi) After rejecting the declared Transaction Value, the Principal Commissioner has proceeded to sequentially apply rule 4 to rule 9 of the 2007 Valuation Rules; and

(vii) Wherever, identical goods are found, the enhancement of value has been done as per rule 4 of the 2007 Valuation Rules;

(viii) Wherever, identical goods are not found, the enhancement of value has been done on the value of similar goods under rule 5 of the 2007 Valuation Rules; and

(ix) Wherever, identical or similar goods are not found, the Principal Commissioner proceeded sequentially. In the instant case, data on valuation of goods sold in India could not be obtained. Hence, rule 7 could not be adopted for re-determination of value. Rule 8 requires information about cost of manufacturing, cost of labour and other expenses. In the instant case, data on value of raw materials, cost of manufacturing, overheads of impugned goods could also not be obtained. This

method under rule 8 could not be adopted for re-determination of value. Hence the only method by which re-determination of value could be done is under the residual rule 9.

Penalty and Interest

(i) The Principal Commissioner has correctly imposed penalty and demanded interest from the appellant.

25. The submissions advanced by the learned counsel for the appellant and the learned authorized representative appearing for the department have been considered.

26. The two basic issues namely, whether HIV-VL test kits imported by the appellant can be denied exemption from BCD and CVD and lower rate of IGST and whether the declared value could be rejected and re-determined shall be examined separately.

Denial of Exemption to HIV-1 Viral Load Test Kits

27. The first issue that arises for consideration is whether HIV-VL test kits imported by the appellant can be denied exemption from BCD and CVD and lower rate IGST merely because such exemption is restricted only to diagnostic kits for **'**detection of HIV antibodies**'** and not for **'**detection of HIV-viral load**'**.

28. To appreciate this issue, it would be necessary to examine the history of HIV epidemic. The HIV epidemic in India began in 1986-1987 following detection of the first HIV. Testing is integral to HIV prevention, treatment and care. Thus, knowledge of HIV status is important for preventing spread of disease. The appellant has elaborately described the aforesaid in the following manner:

(i) HIV is a lentivirus that infects and destroys cells in the immune system. There are two HIV types, HIV-1 and HIV-2. HIV-1 is the most prevalent type throughout the world. Early knowledge of HIV status is critical for linkage to medical care and treatment so that it can reduce mortality and improve quality of life. It is this critical clinical encounter that serves as the starting point for diagnosing and treating persons who are infected and delivering preventive services to those who are uninfected. **HIV diagnosis is made by either demonstrating the presence of virus or viral products in the host or alternatively by detecting host response to the virus.**

(ii) **Thus, over a period, different technologies have evolved with respect to HIV testing, as per which HIV diagnosis is commonly made through serological assays to detect HIV specific antibodies; or by Nucleic Acid Amplification Test (NAAT) to detect HIV nucleic acids as explained below:**

(a) <u>Serological Tests</u>: HIV antibody tests only look for antibodies to HIV in blood or oral fluid. Enzyme linked immunosorbent assays (ELISAs), rapid tests and western blots (WBs) are the common tests for detecting HIV antibodies. **Antibody tests can usually take 23 to 90 days to detect HIV infection after an exposure**.

A combination of both antigen and antibody test looks for both HIV antibodies and antigens. Antibodies are produced by immune system when one is exposed to

viruses like HIV. Antigens are foreign substances that cause immune system to activate. If one has HIV, an antigen called p24 is produced even before antibodies develop. **An antigen/antibody test performed on blood can usually detect HIV infection 18 to 45 days after an exposure.**

(b) **<u>Molecular Tests:</u>** **These are sensitive tests for diagnosis of HIV infections on the basis of PCR** (polymerase chain reaction) **or NASBA** (nucleic acid sequence-based amplification). **These tests look for the actual virus in the blood and involves drawing blood from a vein. The test can either tell if a person has HIV or tell how much virus is present in the blood (known as an HIV viral load test). A nucleic acid test (NAT) can usually detect HIV infection within 10 to 33 days after an exposure.** They use polymerase chain reactions (PCRs) or reverse transcription-polymerase chain reaction (RT-PCR) for the detecting various HIV structural genes. **These are test of choice in certain situations, such as early infant diagnosis and during window period. Diagnosis in a child less than 18 months cannot be done using antibody-based assays as maternal antibodies may be present in the infant's circulation. Therefore, up to the age of 18 months, the diagnosis of HIV infection can only be reliably made by DNA/RNA PCR.**

(iii) **Substantive and significant advances have been made in the last two decades in the characterization of human immunodeficiency**

> **virus (HIV) infections using molecular techniques.** These advances include the use of real-time measurements, isothermal amplification, the inclusion of internal quality assurance protocols, device miniaturization and the automation of specimen processing. The result has been a significant increase in the availability of results to a high level of accuracy and quality. Molecular assays are currently widely used for diagnostics, antiretroviral monitoring and drug resistance characterization in developed countries.
>
> **(emphasis supplied)**

29. It would also be useful to consider customs duty exemptions offered to life-saving drugs, medicines or equipment including HIV-test kits. As regard HIV test kits, the entry relating to "Diagnostic kits for detection of HIV antibodies" was added to the list of life saving drugs or medicines in 1989 when the HIV cases started increasing and attracted attention, both nationally and internationally. A tabular summary of Customs duty exemptions awarded to "life-saving drugs, medicines or equipment" including 'HIV test kits' is contained in the following Chart:

S.N.	**Year**	**Notification Number**	**Relevant Entry**	**Description of list covering HIV kits**
1.	1981	Notification No. 208/81-Cus. dated 22.09.1981	Life-saving drugs or medicines	-
2.	**1989**	**Notification No. 209/89-Cus. dated 17.07.1989**	**Life-saving drugs or medicines**	**218. Diagnostic kits for detection of HIV antibodies**
3.	**1995 till date**	Various notifications	Life Saving drugs or medicines including diagnostic test Kits	Specific List Number under different notifications included Diagnostic kits for detection of HIV antibodies.

30. Having considered the aforesaid facts, it would be appropriate to examine the case of the appellant.

31. An Import License dated 17.02.2020 was issued to the appellant for the product 'Xpert HIV-1 Viral Load' under the provisions of the Medical Device Rules 2017. Paragraph 6 of the License is as follows:

> "**Central Drugs Standard Control Organisation**
>
> **Sub:- Import License under the Medical Device Rules, 2017 thereunder- regarding.**
>
> ******
>
> 6. **This license is being issued on the condition that the firm needs to submit performance evaluation report for the proposed product i.e. Xpert HIV-1 Viral load within 90 days from the issue of the license.**"
>
> **(emphasis supplied)**

32. Form MD-15 deals with License to Import Medical Device. The relevant portion of the Form is reproduced below:

> Licence No.: IMP/MD/2018/000250
>
> Endorsement No. 13
>
> 1. M/s Cepheid India Pvt. Ltd., DSM 214 & 215, 2nd Floor DLF Towers, Shivaji Marg, New Delhi, Delhi (India)- 110015 Telephone No.: 11 48353001 Fax: 11 48353000 is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

S.No.	Medical Device Details

1	**1. Generic Name: Xpert HIV-1 Viral load** 2. Brand Name(if registered under the Trade Marks Act, 1999): Xpert HIV-1 Viral load 3. Class of Medical Device: Class C 4. Shell Life: 18 months 5. Sterile/ Non-sterile: Non-Sterilized 6. **Intended Use: The Xpert HIV-1 VL assay is an in vitro reverse transcriptase polymerase chain reaction (RT-PCR) assay for the detection and quantification of Human Immunodeficiency Virus type 1 (HIV-1) RNA in human plasma from HIV-1 infected individuals, using the automated GeneXpert Instrument Systems**. The assay can quantify HIV-1 RNA over the range of 40 to 10,000,000 copies/mL. The Xpert HIV-1 VL assay is validated for quantification of RNA from HIV-1 Group M (subtypes A, B, C, D, F, G, H, J, K, CRF01_AE, CRF02_AG, and CRF03_AB), Group N, and Group O. The Xpert HIV-1 VL assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in plasma HIV-1 RNA levels. The assay is intended to be used by laboratory professionals or specifically-trained healthcare workers. The Xpert HIV-1 VL assay is not intended to be used as a donor screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.

(emphasis supplied)

33. It would also be useful to refer to the Product Catalogue published by the appellant and the relevant portion is reproduced below:

> "**3. Intended Use**
>
> **The Xpert HIV-1 VL assay is an in vitro reverse transcriptase polymerase chain reaction (RT-PCR) assay for the detection and quantification of Human Immunodeficiency Virus type 1 (HIV-1) RNA in human plasma from HIV-I infected individuals, using the automated GeneXpert**

> **Instrument Systems.** The assay can quantify HIV-1 RNA over the range of 40 to 10,000,000 copies/mL.
>
> The Xpert HIV-1 VL assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in plasma HIV-1 RNA levels. The assay is intended to be used by laboratory professionals or specifically-trained healthcare workers."
>
> **(emphasis supplied)**

34. It would also be useful to examine the National Guidelines for HIV Testing containing information regarding different types of tests for HIV published in July, 2015.

35. The relevant portions of the Guidelines contained in Chapter I are reproduced below:

> " **Diagnosis of HIV Infection**
>
> **Like other infectious diseases, HIV diagnosis is made by either demonstrating the presence of virus or viral products in the host, alternatively by detecting host response to the virus. An HIV diagnosis is commonly made through serological assays to detect HIV specific antibodies or by Nucleic Acid Amplification Test (NAAT) to detect HIV nucleic acids.**
>
> **Serological Tests: Enzyme linked immunosorbent assays (ELISAs), rapid tests and western blots (WBs) are the common tests for detecting HIV antibodies.** To accurately diagnose an HIV infection, these tests are used in a specific sequence or algorithm. Additionally, Chemiluminescence Immunoassays (CIA), Immuno Floresent Assays and Line Immunoassays are also available for specific HIV antibody detection. Commercial assays are also available for P24 antigen detection.

> **NAAT: These are sensitive tests for diagnosis of HIV infections. They use polymerase chain reactions (PCRs) for the detecting various HIV** structural genes (usually gag, pol and env). PCRs are the test of choice in certain situations, such as early infant diagnosis and during window period. Branch DNA (bDNA) assays based on signal amplifications are also used.
>
> **Diagnosis in a child less than 18 months cannot be done using antibody based assays as maternal antibodies may be present in the infant's circulation. Therefore, up to the age of 18 months, the diagnosis of HIV infection can only be made by DNA PCR."**
>
> **(emphasis supplied)**

36. Chapter 3 of the Guidelines deals with Serological Diagnosis of HIV Infection and the portions dealing with Limitations of Antibody Assays is reproduced below:

> "**Limitations of Antibody Assays**
>
> **Antibodies are not detectable in the window period. Therefore, antibody detection tests are of no use during this period. Diagnostic tests based on antibody detection are also not useful in the diagnosis of infection in children below 18 months of age.** Babies born to HIV positive mothers may have passively acquired maternal antibodies. **In this situation, tests that detect the viral genome may be done for early diagnosis (see Chapter4).** NACO is now promoting the use of the DBS technique for early infant diagnosis, based on the detection of HIV 1 DNA viral nucleic acid. The test is discussed in detail in chapter four."
>
> **(emphasis supplied)**

37. Chapter 4 of the Guidelines deal with Molecular and Other Assays for the Diagnosis of HIV Infection and the relevant portion is reproduced below:

> "**Introduction**

Serological assays for the diagnosis of HIV infections. In certain situations, such as patients in the window period and infants born to HIV positive mothers antibody detection assays cannot be relied upon. In these situations, the diagnosis of HIV infections is established using molecular assays to detect viral genomes. **This chapter describes molecular assays, assays for virus isolation, and detection of virus core proteins (p24).**

Diagnosis of Paediatric HIV Infection (<18 months)

The standard diagnostic method for HIV infection in adults (i.e., testing for antibodies) has limited utility in newborns, infants, and children less than 18 months of age. This is due to the transplacental transfer of maternal IgG (including HIV-specific antibodies) from infected mothers to their babies during pregnancy. **HIV antibody tests are reactive in most infants born to HIV positive mothers, though the infection is transmitted to less than half of such infants (even in the absence of ART). HIV antibodies may persist in an infant's blood until 18 months after birth, and are difficult to differentiate from those produced by an infected infant. Therefore, antibody tests cannot produce a definitive diagnosis of HIV infection until 18 months of age. Waiting until this time delays specific treatment. In this situation, Nucleic Acid Testing (NAT) can facilitate early infant diagnosis. NACO recommends the use of a qualitative HIV-1 DNA PCR.**

Further Reading: Laboratory Guidelines for HIV Diagnosis in infants and children<18 months, NACO 2010

Detection of Acute HIV Infection

Virological tests can be used for the detection of acute HIV infection during the "window period," before HIV antibodies become detectable. Though positive NAT

> **results confirm the HIV diagnosis, the NAT result may turn out negative if tested within 7 to 10 days of exposure. NAT tests may be successfully employed for the detection of HIV infection if appropriate infrastructure and technical expertise is available.** At present, NACO does not recommend the use of NAT for the diagnosis of acute HIV infection.
>
> NATs include tests for the qualitative detection of HIV-1 DNA or RNA, as well as the quantitative detection of HIV-1 RNA (viral load determination) through various assays."
>
> **(emphasis supplied)**

38. What transpires from the aforesaid is that there are two types of HIV out of which HIV-1 is most prevalent and early knowledge of HIV status is critical for medical care and treatment. The first HIV antibody test was developed in 1985. HIV antibody test only look for antibodies to HIV in blood or oral flood. HIV infection is detected after an exposure between 23-90 days. With passage of time, HIV testing improved and on account of technological advancements different types of test methods have also evolved. These tests have not only reduced the detection window period considerably, but have also enabled ascertainment of virus load to determine whether the patient has an acute infection. These tests detect HIV infection even before HIV antibodies become detectable.

39. Thus, over a period of time, different technologies have evolved with respect to HIV testing. HIV diagnosis is commonly made through serological assays to detect HIV specific antibodies. On the other hand, NAAT looks for actual virus in the blood. This test can not only determine whether a person has HIV but can also determine how much virus is present in the blood. HIV-viral load test can detect HIV infection within 10 to 33 days after exposure. Diagnosis in a child less than 18

months cannot be done by using antibody assays. Therefore, up to the age of 18 months, the diagnosis of HIV infection can only be done by NAAT test. Further, mere detection of HIV is not enough for treatment of HIV infection in a body. It is equally important to continuously monitor the spread of HIV infection in the body for determining the course of treatment. It is for this reason that the use of immunologic tests and virological tests and viral load test kits have assumed importance. These kits not only detect the presence of HIV infection, but being more sensitive and accurate, are used for regular monitoring of the spread of HIV infection in the body. Thus, these kits are required for identifying the course of treatment of HIV and thereby fighting the epidemic of HIV, which is the sole intention behind introducing the exemption benefit to life saving drugs/medicines and diagnostic kits for HIV.

40. As noted above, Customs Notification dated 17.03.2012 exempted customs duty and additional duty leviable under section 3(1) of the Customs Tariff Act to diagnostic test and test kits specified in List 4, which list refers to **"**diagnostic kits for detection of HIV antibodies**"**. The subsequent Customs Notification dated 30.06.2017 also exempted duty of customs and integrated tax to diagnostic tests and kits specified in List 4, which list again referred to diagnostic kits for detection of HIV antibodies. The IGST Rate Notification dated 28.06.2017 also exempted diagnostic test kits specified in List 1, which list referred to **"**diagnostic kits for detection of HIV antibodies**"**. The diagnostic kits that were imported by the appellant were sold under a trade name "GenXperts®" and are called HIV-viral load test kits. The reason why exemption has not been granted to the appellant by the impugned order is that these

HIV-viral load test kits are not diagnostic kits for detection of HIV antibodies.

41. The contention of the learned senior counsel appearing for the appellant is that the Exemption Notifications under consideration in this appeal should be widely construed to cover diagnostic kits imported by the appellant, which kits provide an essential diagnostic tool for detection and prognosis of HIV. The contention, therefore, is that there is no rationale for exclusion of this diagnostic kits when the kits for detectable antibodies are included. Learned senior counsel for the appellant, therefore, submitted that the said entry should be interpreted in a broad manner to include kits working on technologically advanced methodology. Learned senior counsel also submitted that technical progress and development must not be overlooked and the new products/innovations serving the same objective should be considered as part and parcel of the same entry. To support this contention, learned senior counsel placed reliance upon the following decisions:

(a) Collector of Customs & Central Ex. Vs. **Lekhraj Jessumal & Sons**[12];

(b) Collector of Customs, New Delhi Vs. **Ethnor Ltd.**[13]

42. Learned authorized representative appearing for the department, however, submitted that the exemption under Exemption Notifications is restricted only to diagnostic kits for **'**detection of HIV antibodies**'**, whereas the appellant has imported diagnostic kits for **'**detection of HIV viral load**'.** Such an exemption has to be interpreted strictly and technological advancements cannot be considered unless the

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12. 1996(82) E.L.T. 162 (S.C.)
13. 1996 (86) E.L.T. 558 (Tribunal)

Notifications are suitably amended. Learned authorized representative, therefore, submitted that when various methods of detecting HIV are present, it is only the method of detection of HIV antibodies that has been exempted and no other method has been exempted.

43. The submissions advanced by the learned senior counsel for the appellant and the learned authorized representative appearing for the department on this issue have been considered.

44. As noticed above, the first HIV antibody test was developed in 1985. Since then, on account of technological breakthroughs, different types of testing methods have evolved over a period of time and the subsequent generation tests have not only reduced the detection window period considerably, but have also enabled ascertainment of virus load to determine whether the patient has an acute infection. Earlier, HIV diagnosis was made through serological tests only to detect HIV specific antibodies, but these HIV antibody tests only look for antibodies and it takes about 23-90 days to detect HIV infection after an exposure. On the other hand, molecular tests look for the actual virus in the blood and the test can tell whether a person has HIV and if so, how much virus is present in the blood. Such tests can have a very reduced window period for detecting of HIV infection. The antibodies tests, therefore, have inherent limitations. The antibodies are not detectable up to a certain window period and they cannot also diagnose infection in children below 18 months of age. Nucleic Acid Amplification Test, however, can be used for the detection of acute HIV infection during a much lesser window period even before HIV antibodies become detectable. This test includes qualitative detection of HIV as well as quantitative detection of HIV (viral load determination). This test can also diagnose HIV in children below the age of 18 months. It is not that

the test based on advanced technology has replaced the antibody test. Both the tests can be undertaken.

45. It is correct that the Notification (cus.) dated 17.03.2012 and Notification (cus.) dated 30.06.2017 at Serial No's. 148 and 167 refer to diagnostic test kits specified in List 4 and List 4 mentions 'diagnostic kits for detection of HIV antibodies' and what is imported by the appellant is HIV- viral load test kits, but the issue that arises for consideration is whether these entries should be interpreted in a restricted sense or in a broad manner so as to include kits working on technologically advanced methodology.

46. This issue was examined by the Supreme Court in **Lekhraj Jessumal**. Lekhraj Juessmal had imported miniaturized switches for use in electronic hearing aids which it manufactured. The two types of switches were the conventional one called water switches and the newly innovated, reed switches. The appellant imported reed switches. The department believed that reed switches were not entitled to concessional rate of import duty. The contention of the department was that the words 'switches, miniaturized' as component parts of hearing aid should be understood to mean only those types of switches which were generally used in the manufacture of hearing aids at the time of publication of the import policy. This understanding of the department was not accepted by the Supreme Court and the relevant paragraphs of the judgment are reproduced below:

> "**2.** The respondent had imported miniaturised switches for use in electronic hearing aids which it manufactured. It appears that there are two types of such switches, the conventional one then being wafer switches and the other, newly innovated, being reed switches. It was the latter type of switch which was imported. The Customs authorities took the view that

the respondents' import licence did not cover reed switches and they were not entitled to the concessional rate of import duty. The stand of the Customs authorities was, ultimately, assailed in the writ petition filed by the respondent before the High Court. The Writ petition was allowed. An appeal was preferred and it is the judgment in appeal which is under challenge before us.

3. The High Court in the impugned order noted that the stand of the Customs authorities was that the words "switches, miniaturised" as component parts of hearing aids should be understood to mean only those types of switches which were generally used in the manufacture of hearing aids at the time of publication of the Import Policy for the relevant year, namely 1977, and that these words could not be said to include any other type of switch even if such other type of switch could be used in the manufacture of hearing aids. **The Division Bench observed, in our view, very rightly, that such an interpretation overlooked that industry was not static and that there was continuous technical progress therein. New processes and new methods developed from time to time and new material and components or types of components superseded others. It was unreasonable to give a static interpretation to words used in a tariff schedule ignoring the rapid march of technology. Having regard to the technical opinion that reed switches would improve the performance of hearing aids, the High Court held that reed switches were covered by the tariff entry.** The High Court also noted that it was not the case of the Customs authorities that the respondent was trying to divert the imported reed switches from the manufacture of hearing aids to another purpose.

4. We do not think that we can put it better. Progress cannot be stifled by an over-rigid interpretation of Import Policy or Customs Tariff. Both must be read as they stand on the date of importation and whatever is reasonably covered thereby must be allowed to be

> **imported regardless of the fact that it was not in existence or even contemplated when the policy or tariff was formulated**."
>
> **(emphasis supplied)**

47. In **Ethnor**, it was noticed that it had imported one consignment of pregnancy detection kits and declared them to be **'**Elisa diagnostic test**'** and claimed benefit of a Notification. The department, on a scrutiny of technical literature, found that the goods were immunoassay kits based on menoclonal antibodies for qualitative detection of HCG. It is in this context, that the Tribunal observed that improvement in the testing methods have to be also granted the benefit. The observations of the Tribunal are as follows:

> "9. **The point which is required to be considered is as to whether any advancement made in scientific field to bring out a new innovation and same having been recognised both in medical field and by licencing controller, will these factors negative the conclusion that absence of enzyme in the item by replacing it by a colour conjugate system, will be itself take away the item from the ambit of the description in the notification namely,** "Elisa Diagnostic Tests". The answer has to be given clearly in the negative. The reason being that "Elisa Test" refers to pregnancy test carried out on the urine of a pregnant woman. **The improvement has been made to make the test more clear and to make the results more positive. The experts have clarified and amplified that the imported item is an advancement in technology of "Elisa Test". This factor has been recognised by the Drug Controller, as noted by us and the Drug Licence itself clearly states that the item is a "Elisa Test".** There has been a clarification also from Dr. S.K. Das, Asstt. Commissioner (BHS) Ministry of Health & Family Welfare to the effect that "Cards ± O.S.HVG - urine from Pacific Biotech INC" is an immunoassay and works on the principle of Elisa.

> Thus it is a Rapid Elisa Diagnostic Test for Pregnancy Test."
>
> **(emphasis supplied)**

48. It is not in dispute that the kit imported by the appellant also detects HIV and is based on an advanced technology. When the intention of the Exemption Notification was to grant exemption to diagnostic kits for HIV antibodies, there is no good reason why the test kits imported by the appellant for detection of HIV should be denied exemption.

49. Learned authorized representative appearing for the department however, submitted that in view of the judgment of the Supreme Court in **Commissioner of Cus. (Import), Mumbai** Vs. **Dilip Kumar & Company**[14], the Exemption Notification has to be strictly construed, and if a person claiming exemption does not fall strictly within the description indicated in the Notification, he cannot claim exemption.The Supreme Court, after considering number of decisions, ultimately held:

> "52. To sum up, we answer the reference holding as under-
>
> (1) Exemption notification should be interpreted strictly; the burden of proving applicability would be on the assessee to show that his case comes within the parameters of the exemption clause or exemption notification.
>
> (2) When there is ambiguity in exemption notification which is subject to strict interpretation, the benefit of such ambiguity cannot be claimed by the subject/assessee and it must be interpreted in favour of the revenue.
>
> (3) The ratio in Sun Export case (supra) is not correct and all the decisions which took similar view as in Sun Export case (supra) stands overruled."

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14. 2018 (361) E.L.T. 577 (S.C.)

50. Learned senior counsel for the appellant, however, relied upon a subsequent decision of the Supreme Court in **Government of Kerala** Vs. **Mother Superior Adoration Convent**[15] to contend that the beneficial purpose of an Exemption Notification has to be given full effect.

51. In **Mother Superior**, the Supreme Court observed that there was a line of authority which stated that even in tax statues, an exemption provision should be liberally construed in terms of the object sought to be achieved and if such a provision grants incentive for promoting economic growth or otherwise has some beneficial reason behind it, then the legislative intent is not to burden the subject with tax. The Supreme Court also noticed that constitution bench judgment of the Supreme Court in **Dilip Kumar** did not refer to the line of authority which made a distinction between exemption provisions generally and exemption provisions which have a beneficial purpose. The relevant portions of the judgment of the Supreme Court in **Mother Superior** are reproduced below:

> ″**23. It may be noticed that the 5-Judge Bench judgment did not refer to the line of authority which made a distinction between exemption provisions generally and exemption provisions which have a beneficial purpose.** We cannot agree with Shri Gupta's contention that sub-silentio the line of judgments qua beneficial exemptions has been done away with by this 5-Judge Bench. It is well settled that a decision is only an authority for what it decides and not what may logically follow from it [see Quinn v. Leathem - [1901] AC 495 as followed in State of Orissa v. Sudhansu Sekhar Misra - (1968) 2 SCR 154 at 162, 163].
>
> **24. This being the case, it is obvious that the beneficial purpose of the exemption contained in Section 3(1)(b) must be given full effect to,**

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15. 2021 (376) E.L.T. 242 (S.C.)

> **the line of authority being applicable to the facts of these cases being the line of authority which deals with beneficial exemptions as opposed to exemptions generally in tax statutes. This being the case, a literal formalistic interpretation of the statute at hand is to be eschewed. We must first ask ourselves what is the object sought to be achieved by the provision, and construe the statute in accord with such object. And on the assumption that any ambiguity arises in such construction, such ambiguity must be in favour of that which is exempted.** Consequently, for the reasons given by us, we agree with the conclusions reached by the impugned judgments of the Division Bench and the Full Bench."
>
> **(emphasis supplied)**

52. It is seen that in **Mother Superior** the Supreme Court held that the beneficial purpose of an exemption must be given full effect to and the question that is needed to be asked is what is the objective sought to be achieved by the provision and then the exemption has to be construed in terms of such an object.

53. In the present case, the HIV-VL test kits are life-saving diagnostic kits used for detection and prognosis of HIV virus in human body. Thus, a purposive interpretation has to be extended to the entries in the Notifications so as to give the benefit of duty not only diagnostic kits for detection of HIV antibodies but to also other technologically advanced diagnostic kits used for detection and prognosis of HIV, as they serve the same purpose. The object and purpose behind the introduction of exemption to HIV kits was in public interest to support the high demand of healthcare at affordable prices and to curb the spread of HIV virus in India. The HIV-VL test kits are 'life-saving diagnostic kits' used for detection and prognosis of HIV-virus in a human body. These kits not

only detect the presence of HIV infection, but being more sensitive and accurate are used for regular monitoring of the spread of HIV infection in the body and for identifying the failure of the first course of treatment. They also serve the same purpose. Infact, the HIV-VL test kits imported by the appellant support the larger public interest objective of the National Aids Control Programme aimed at halting and reversing the HIV epidemic in India.

54. What follows from the aforesaid discussion is that the HIV-VL test kits imported by the appellant would be entitled for exemption from BCD and CVD, and only 5% integrated tax as provided for in List 1 of the IGST Rate Notification would be payable by the appellant.

Re-determination of Value

55. The Principal Commissioner first examined whether the appellant and the foreign suppliers were related persons in terms of section 14 of the Customs Act and the 2007 Valuation Rules and then examined whether the invoice values of the goods imported by the appellant from the foreign suppliers were influenced by such relationship.

56. Since the appellant and its foreign suppliers were related persons, the case of the appellant was registered with the SVB for examining as to whether the declared import prices had been influenced by the relationship between the parties. In the report dated 22.10.2019, the SVB suggested that the declared invoice value was influenced by the relationship and, therefore, the assessable value was required to be determined by loading 93.93% on the declared value. Accordingly, a show cause notice dated 13.01.2020 was issued to the appellant alleging that the imports made by the appellant from August 2016 from its related foreign suppliers were influenced by the relationship. The show cause notice, therefore, proposed a loading factor of 93.93%,

after allowing a discount of 20% to the appellant for importing goods in higher quantities. The appellant claims that though, it filed a reply to the show cause notice on 16.04.2021 but the matter has not been adjudicated upon as yet.

57. Learned senior counsel for the appellant contended that the present show cause notice and the impugned order passed by the Principal Commissioner have placed much reliance on the SVB report dated 22.10.2019 submitted to the department but the SVB report was not supplied to the appellant and, therefore, the principles of natural justice have been violated since the impugned order is based on the SVB report.

58. Learned authorized representative appearing for the department, however, submitted that the contents of the SVB report were referred in the show cause notice and, therefore, the appellant cannot allege that it was not aware of the SVB report. Learned authorized representative appearing for the department, therefore, submitted that principles of natural justice have not been violated.

59. There is substance in the submission advanced by the learned senior counsel for the appellant. The show cause notice merely picks up some portions of the SVB report dated 13.01.2020. As the appellant was required to file a reply to the allegations made in the show cause notice, it was imperative for the department to have made the SVB report a relied upon document to the show cause notice, and in any case a copy of the same should have been supplied to the appellant. It is only after perusal of the entire report that the appellant would have been in a position to respond to the allegations made in the show cause notice. Denial of a copy of the SVB report has caused prejudice to the appellant and has resulted in gross violation of the principles of natural

justice. The impugned order, therefore, deserves to be set aside on this ground.

60. What is also important to notice is that the declared import values have been enhanced by the Principal Commissioner by applying different load percentages ranging from 0 to 822% on three different types of goods which can broadly be categorized under three classes namely, **(a)** Test cartridges/kits, **(b)** Testing equipment and their standard accessories, and **(c)** Spares and assemblies for the equipment. The details of the category, the particular 2007 Valuation Rules applied, and the loading percentage are reproduced below:

Categories	**Rule**	**Loading Percentage**
Imported item for which identical goods are available as per the Respondent	Rule 4	**Table IA:** Test cartridges/ kits- 11% to 822% ○ MTB-50-11% ○ MTB-10-56% ○ HIV-VL test kits-75% ○ Others- 11% to 822% **Table IIA:** Equipment – 66% to 95% **Table IIIA:** Spares/ assemblies- 8% to 136%
Imported item for which similar goods are available as per the Respondent	Rule 5	**Table IB:** Test Kits- 15% to 25% ○ MTB-IN-50- 15-17% ○ MTB-IN-10- 0%-25% **Table IIB:** Equipment-322%
For remaining items, for which identical or similar goods are not available as per the Respondent	Rule 9	**Table IC:** Test Kits- 56.10% **Table IIC:** Equipment-85.78% **Table IIIB:** Spares/ assemblies- 111.99%

61. The contention that has been advanced by the learned senior counsel for the appellant is that though the show cause notice had proposed a loading factor of 93.93% after allowing a discount of 20% to the appellant for importing goods in higher quantities, the impugned order passed by the Principal Commissioner has applied different loading percentages ranging from 0 to 822%. It has, therefore, been submitted that the impugned order has travelled beyond the show cause notice.

62. Learned authorized representative appearing for the department, however, contended that good and cogent reasons have been given by the Principal Commissioner for applying various loading percentages and there is no good reason to take a contrary view.

63. There is substance in this submission also that has been advanced by the learned senior counsel for the appellant. The show cause notice is the basis on which an assessee is called upon to submit a reply. The adjudication can take place only on the basis of the allegations made in the show cause notice and not beyond the allegations made in the show cause notice.

64. Learned senior counsel for the appellant also submitted that the Principal Commissioner has relied upon entirely different sets of Bills of Entries than those mentioned in the show cause notice. Elaborating this submission, learned senior counsel pointed out the 50 Bills of Entries filed by Labindia and certain Government bodies that were relied in the show cause notice for re-determination of the assessable value, the impugned order placed reliance upon 21 different Bills of Entries filed by Labindia for re-determing the assessable value without providing any opportunity to the appellant to examine such Bills of Entries and make submissions.

65. Learned authorized representative appearing for the department stated that though some of the Bills of Entries may not have been referred to in the show cause notice, but the other Bills of Entry were referred to and, therefore, no prejudice has been caused to the appellant.

66. It is not possible to accept the contention advanced by the learned authorized representative appearing for the department. The Principal Commissioner could not have taken into consideration any Bill of Entry

which was not referred to in the show cause notice as no opportunity was provided to the appellant to rebut such Bills of Entries.

67. Learned senior counsel for the appellant also submitted that though the show cause notice proposed that the value of the goods could not be determined under rule 4 in the absence of identical goods, but as bills of similar goods supplied by foreign suppliers to unrelated buyers was available, the invoice value was proposed to be re-determined under rule 5 of the 2007 Valuation Rules, but the impugned order passed by the Principal Commissioner has invoked not only rule 5 but also rule 4 for determination of the assessable value in respect of such goods which were identical and rule 9 in respect of such goods where rules 4 and 5 could not be applied.

68. Learned authorized representative appearing for the department, however, submitted that the Principal Commissioner has very meticulously applied rules 4 in cases where identical goods were available, rule 5 where similar goods were available and rule 9 when rules 4 and 5 were not available.

69. The Principal Commissioner was obliged to re-determine the value only in accordance with the allegations made in the show cause notice and in case the show cause notice referred to rule 5 of the 2007 Valuation Rules, it was imperative for the Principal Commissioner to have confined the order only to rule 5 of the 2007 Valuation Rules.

70. The result of the aforesaid discussion on this issue is that it will not be possible to sustain the re-determination of the value of the imported goods undertaken by the Principal Commissioner under the 2007 Valuation Rules. The matter would, therefore, have to be remitted to the adjudicating authority to examine this issue afresh after

supplying a copy of the SVB report to the appellant and in terms of the allegations made in the show cause notice dated 14.08.2021.

CONCLUSION

71. What follows from the aforesaid discussion is that the HIV-VL test kits imported by the appellant would be entitled for exemption from BCD and CVD, and IGST would be payable @ 5% as provided for in List 1 of the IGST Rate Notification. The impugned order dated 30.06.2022 denying exemption from BCD and CVD, and 5% IGST to the appellant would, therefore, have to be set aside. The re-determination of the value of the goods imported by the appellant is, accordingly, set aside, but the matter is remitted to the adjudicating authority to determine the value afresh in the light of the observations made above.

ORDER

72. The impugned order dated 30.06.2022 passed by the Principal Commissioner is, accordingly, set aside. The appellant is held entitled to benefit of BCD and CVD in terms of the Notifications. The appellant is also justified in paying IGST @ 5% in terms of the Integrated Rate Notification. The re-determination of value of the imported goods is also set aside but the matter is remitted to the adjudicating authority to pass a fresh order in accordance with law and in the light of the observations made above. The appeal is, accordingly, allowed to the extent indicated above.

(Order pronounced on **25.06.2025**)

(JUSTICE DILIP GUPTA)
PRESIDENT

(P.V. SUBBA RAO)
MEMBER (TECHNICAL)

Kritika