CUSTOMS, EXCISE & SERVICE TAX APPELLATE TRIBUNAL
CHENNAI

REGIONAL BENCH - COURT No. III

Customs Appeal No. 40106 of 2024

(Arising out of Order-in-Original No.104210/2023 dated 28.12.2023 passed by Commissioner of Customs (Audit), Custom House, 60, Rajaji Salai, Chennai 600 001.)

M/s. Biomerieux India Private Limited .... Appellant
B8, SIPCOT Industrial Park,
Irrungattukottai,
Sriperambudur,
Kanchipuram 602 105.

VERSUS

The Commissioner of Customs (Audit) ... Respondent
Custom House,
60, Rajaji Salai,
Chennai 600 001.

APPEARANCE :

Shri Lakshmi Kumaran V., Advocate
Shri D. Santhana Gopalan, Advocate
Shri S. Ganesh Aravindh, Advocate
For the Appellant

Shri Anoop Singh, Authorized Representative for the Respondent

CORAM :

HON'BLE MR. P. DINESHA, MEMBER (JUDICIAL)
HON'BLE MR. VASA SESHAGIRI RAO, MEMBER (TECHNICAL)

FINAL ORDER No. 40833/2026

DATE OF HEARING : 02.02.2026
DATE OF DECISION : 29.06.2026

Per: Shri P. Dinesha

M/s. Biomerieux India Private Limited (hereinafter referred to as "the Appellant") imported Diagnostic Test Kits bearing different product names, such as 'VIDAS TSH 60 TESTS' and 'VIDAS T3 60 TESTS' and filed Bill of Entry No. 8953535 dated 03.06.2022 declaring the imported goods as 'VIDAS Test Kits'. The said goods were classified under Customs Tariff Item 38221990 and were cleared on payment of Basic Customs Duty (BCD) at the concessional rate of 5% by availing the benefit under Sl. No. 166(A) read with List 3 of Notification No. 50/2017-Cus. dated 30.06.2017 along with applicable Social Welfare Surcharge (SWS) and Integrated Goods and Services Tax (IGST) at the concessional rate by availing the benefit under Sl. No. 1180 of IGST Notification No.01/2017-Integrated Tax (Rate) dated 30.06.2017.

2. According to the Appellant, the imported test kits are Enzyme-Linked Fluorescent Assay (ELFA) kits, which are the same as Enzyme-Linked Immunoabsorbent Assay (ELISA kits, and therefore they had rightly claimed exemption under

Sl. No. 166(A) read with List 3 of Notification No. 50/2017-Cus. dated 30.06.2017, wherein a concessional rate of duty is provided to Enzyme-Linked Immunosorbent Assay (ELISA) kits. Based on specific intelligence gathered by the officers of the Special Intelligence and Investigation Branch (SIIB), Customs House, Chennai regarding the alleged misdeclaration of the goods imported in Container No. SEGU 9709022 covered under Bill of Entry No. 8953535 dated 03.06.2022, an investigation was initiated. Upon scrutiny of the import documents, namely Invoice No. 2150006664 dated 28.04.2022 issued by the supplier M/s. Biomerieux, Singapore, it was observed that the goods consisted of different types of test kits bearing different names, such as 'VIDAS TSH 60 TESTS' and 'VIDAS T3 60 TESTS' imported in multiple quantities and having different assessable values.

3. The subject goods were examined by SIIB and it appeared to the Department that though the goods would merit classification under Customs Tariff Item 38221990, the exemption claimed by the Appellant was not admissible and the applicable duties would be BCD at 10% along with SWS @ 10% and IGST @ 12% under Sl. No. 80 of the relevant IGST Notification, on the ground that the imported goods

were not 'Enzyme-Linked Immunosorbent Assay (ELISA) kits'. The VIDAS Test Kits imported vide Bill of Entry No. 8953535 dated 03.06.2022 were seized under Section 110 of the Customs Act, 1962. The Appellant requested provisional release of the seized goods and paid the differential duty as determined by the Department under protest vide TR-6 Challan No. 1701 dated 06.07.2022 for an amount of Rs. 18,46,198/-. Thereafter, SIIB investigated the past imports of the Appellant for the purpose of issuance of a Show Cause Notice in respect of the earlier period as well. Show Cause Notice F. No. CUS/APR/SCN/30/2023-GR2 dated 01.02.2023 was issued proposing rejection and reassessment of the Bills of Entry annexed thereto and demanding differential Customs Duty amounting to Rs. 68,20,78,794/- along with applicable interest. The SCN also proposed confiscation of the imported goods under Sections 111(m) and 111(o) of the Customs Act, 1962 and imposition of penalties under Sections 112(a) and 114A of the Customs Act, 1962.

4. The allegation in the SCN is that the Appellant had imported ELFA kits and misdeclared the same as 'ELISA kits' and that the said kits were not entitled to the concessional

rate of duty under Sl. No. 166(A) of Notification No. 50/2017-Cus. dated 30.06.2017 and Sl. No. 180 of Schedule-l to Notification No. 01/2017-Integrated Tax (Rate) dated 30.06.2017. After following due process of adjudication, the Original Authority *vide* Order-in-Original No.104210/2023 dated 28.12.2023 confirmed the proposals contained in the SCN including confiscation of the goods, demand of interest and imposition of penalty under Section 114A of the Customs Act, 1962. However, the penalty proposed under Section 112(a) of the Customs Act was not imposed.

5. Aggrieved by the said Order-in-Original, the Appellant has filed the present appeal before the Tribunal.

6. Shri V. Lakshmi Kumaran, Learned Advocate arguing for the Appellant, contended that the subject goods fundamentally operate on the principle of ELISA (Enzyme-Linked Immunosorbent Assay) and that ELFA is only a technologically advanced variant or subset of ELISA wherein fluorescence detection is employed instead of chromogenic colour detection. It was therefore contended that the goods remain covered within the scope of 'ELISA Kits' specified in

the Exemption Notifications. Ld. Advocate also made elaborate contentions, which are summarized below:

- During the period from 07.02.2018 to 01.02.2022, the goods were classifiable under CTH 3002 and were eligible for exemption from Basic Customs Duty under Sl. No. 167(A) read with Sl. No. 32 of List 4 appended to Notification No. 50/2017-Cus.
- Consequent to tariff changes, the goods were classified under CTH 3822 with effect from 02.02.2022 and for the subsequent period up to 31.12.2022 the goods continued to remain eligible for concessional assessment under SI. No. 166(A) read with Sl. No. 125 of List 3 to Notification No. 50/2017-Cus. Insofar as the Integrated Tax is concerned, it was submitted that throughout the entire period in dispute, the subject goods were correctly assessed to IGST at the concessional rate of 5% under SI. No. 180 of Schedule-I read with Sl. No. 154 of List-l to Notification No. 01/2017-Integrated Tax (Rate), since the said entry specifically covered 'ELISA diagnostic kits' and the subject goods are nothing but ELISA-based diagnostic kits employing fluorescent detection

methodology. It was submitted that the Department had erroneously proceeded on the assumption that ELFA and ELISA are mutually exclusive technologies merely because the detection stage differs. According to the Appellant, such distinction is scientifically unsustainable, since both technologies admittedly employ the same immunoassay principle and differ only in the mode of signal detection.

- The subject goods are ELFA kits which primarily operate on the principle of sandwich ELISA. Explaining the principle involved, Learned Counsel submitted that the subject goods use the Sandwich ELISA principle using two antibodies which bind to two different sites on the antigen such as bacteria, viruses, etc. The clinical sample containing antigen is added to the well coated with the specific antibody for that antigen. The antigen is then allowed to react with the antibody attached to the well. The antigen thereafter gets bound to the antibody in the well, which is the bound antigen. After this step, a second enzyme-linked antibody is added to the well and then allowed to react with the bound antigen. Finally, a substrate is added, which is hydrolysed by

the enzyme to emit light. The development of colour indicates the presence of antigen in the clinical sample. The test is done using a solid surface to which the antibodies and other molecules stick.

- The ELISA type relevant for the present matter is 'sandwich ELISA', wherein two sets of antibodies are used to detect secreted products such as cytokines. It was submitted that in the first step, the ELISA plate is coated with a capture antibody and any excess unbound antibody is washed from the plate. The capture antibody is an antibody raised against the antigen of interest.
- Thereafter, the sample such as urine, serum, or cell supernatant is added. Any antigen found in the sample binds to capture antibody already coating the plate.
- Samples are usually added in duplicate or triplicate and in varying concentrations to guarantee that they fall within the levels of detection of the assay. Any excess sample is thereafter washed from the plate. In the next step, a detection antibody is added. This antibody is labelled with an enzyme, usually horseradish peroxidase or alkaline phosphatase. The

detection antibody binds to any target antigen already bound to the plate. Finally, substrate is added to the plate.

- ELISA assays are usually chromogenic using substrates such as Tetramethylbenzidine (TMB) or 2,2'-Azinobis [3-ethylbenzothiazoline-6-sulfonic acid]-diammonium salt (ABTS) using a reaction that converts the substrate into a coloured product which can be measured using a plate reader.
- Based upon the above explanation, it was submitted that sandwich ELISA is a principle used for the detection of antigens present in a sample by development of colour. Proceeding further, he submitted that the subject goods, namely ELFA kits, also operate on the principles of sandwich ELISA. According to him, the only difference between ELISA and ELFA is that in the case of ELFA there is fluorescence instead of a colour change.
- Instead of chromogenic substrates, a fluorogenic substrate such as 4-methylumbelliferyl phosphate (4MUP) is used at the detection stage.
- Further, instead of a spectrophotometer used for colour detection, a fluorometer is used for detection

of fluorescence. In any case, the principle involved continues to be ELISA only and therefore ELFA is merely a subset of ELISA. It was argued that ELFA is only an application of the ELISA principle inasmuch as it is also an enzyme-linked immunoassay with sensitivity to antigens during the detection phase. According to the Appellant, this by itself cannot be a basis to conclude that ELFA kits are different from ELISA kits.

- The entire case of the Department in the impugned order proceeds on the assumption that detection kits using the ELISA principle cannot use substrates other than chromogenic substrates and that the ELISA detection method detects antigen only on the basis of a change in the colour of the sample. According to the Appellant, the aforesaid assumption is incorrect since ELISA kits can detect antigens in multiple ways by using chromogenic, fluorogenic, or chemiluminescent.

7. In support of the above contention, reliance was placed upon '*The Immunoassay Handbook: Theory and Applications of Ligand Binding, ELISA and Related Techniques'* by David Wild, wherein it has been opined that different kinds of

substrates such as Chemiluminescent, Chromogenic, and Chemifluorescent substrates are used in ELISA kits and based on the sensitivity of the assays to the antigens the substrates are selected during detection using the ELISA method.

8. The Appellant particularly relied upon the discussion in the said publication, wherein it is stated that the purpose of the detection reagent is to bind the target antibody and allow a quantifiable signal to be measured and that enzyme is conjugated to the detection reagent and cleaves the appropriate substrates to generate a chromogenic, chemiluminescent, or chemifluorescent signals proportional to the amount of target antibody bound.

9. Shri Lakshmi Kumaran, learned Advocate also placed reliance upon the comparative table contained in the said publication indicating different ELISA detection methods namely Chromogenic, Chemifluorescent, and Chemiluminescent techniques together with corresponding sensitivity, equipment requirement, advantages, and disadvantages. Based on the aforesaid scientific literature, it is submitted that the ELISA detection method uses different kinds of substrates such as Chromogenic, Chemifluorescent, and Chemiluminescent substrates to detect antigens in the

samples and, therefore, the ELISA detection method is not limited only to detection of antigens through colour change using chromogenic substrates. It was therefore contended that merely because a fluorogenic substrate is used in ELFA kits, it cannot be stated that ELFA is not ELISA. ELFA kits operate on the ELISA principle with a fluorogenic substrate for detection. It was thus submitted that the Department's case that ELFA kits are a different technology from ELISA is incorrect and baseless. According to the Appellant, the terminology "ELFA" is used only to distinguish the usage of fluorescent detection instead of colour change.

10. Reference / Reliance was also placed upon the Letter dated 02.07.2015 issued by the National Institute of Biologicals (NIB) [page 401], to the Central Drugs Standard Control Organization (CDSCO) [page 402]; and the Letter dated 16.07.2015 issued by CDSCO to the Additional Commissioner of Customs (Import), New Delhi, wherein it was clarified that ELFA and ELISA are one and the same. The Appellant submitted that based on the said clarification the Commissioner of Customs, New Delhi, had ordered finalization of provisional assessments extending exemption

benefit under Notification No. 12/2012-Cus. *vide* Letter dated 17.08.2015. [page 403]

11. In view of the aforesaid submissions, it is contended that the ELFA method is only an application of the ELISA principle using a fluorogenic substrate and is therefore a subset of the ELISA method itself. Consequently, according to the Appellant, the finding in the impugned order that ELFA kits are not ELISA kits is unsustainable and the impugned order is liable to be set aside.

12. *Per contra*, Shri Anoop Singh, the learned Departmental Representative while explaining the significance of differences between ELFA and ELSA kits and its implications on proper classification of goods in question, took us through the findings of the Adjudicating Authority in the impugned order wherein, the Adjudicating Authority has after examining the records of the case, replies filed by the Appellant, explanations/submissions made during the personal hearing and the case laws relied upon by the Appellant, framed the following issues for determination:

(i) *Whether the impugned goods declared in the Bills of Entry as 'VIDAS TSH 60 TESTS, 'VIDAS T3 60*

TESTS, VIDAS FT4, VIDAS HCG, VIDAS 25 OH, VIDAS FT3, VIDAS AMH and VIDAS HAV IgM', which admittedly work on the principle of combining enzyme immunoassay competition method with final fluorescent detection, namely Enzyme-Linked Fluorescent Assay (ELFA) kits, could be considered as Enzyme-Linked Immuno Absorbent Assay (ELISA kits so as to extend the benefit of Notification No. 50/2017-Cus. dated 30.06.2017 claimed by the importer;

(ii) Whether the demand of differential duty invoking the extended period under Section 28 (4) of the Customs Act, 1962 was sustainable;

(iii) Whether the impugned goods were liable for confiscation and whether redemption fine could be imposed in lieu of confiscation; and

(iv) Whether penalties proposed under Sections 112 (a), 114A and 114AA of the Customs Act, 1962 were imposable.

13. Shri Anoop Singh would submit on the substantive issue regarding admissibility of Exemption under Sl. No. 166 (A) of Notification No. 50/2017-Cus. dated 30.06.2017 that though the importer repeatedly contended that ELISA kits and ELFA kits are one and the same, the Department had brought out material differences between the two technologies in the

SCN. He would invite our attention to para 17 of the Order-in-Original wherein the Adjudicating Authority tabulated the distinctions between ELISA and ELFA in the following manner:

ELFA	**ELISA**
Enzyme-Linked Immuno Absorbent Assay is used for detecting and measuring antigens or antibodies using chromogenic substrates.	Enzyme-Linked Fluorescent Assay where the enzyme catalyzes a fluorescence and not a colour reaction.
Uses chromogenic substrate such as p-nitrophenyl phosphate (PNPP)	Uses a fluorogenic substrate such as 4-methylumbelliferyl phosphate (4MUP).
Detects the development of colour on a solid phase	Detects the development of fluorescence on a solid phase
Substrate is chromogenic	Substrate is fluorogenic
Less sensitive	Approximately 100 times more sensitive
Longer window period	Five days shorter than ELISA

Based on the above distinctions, the core issue as to whether ELISA kits and ELFA kits were **'identical in all respects'** so as to permit extension of exemption specifically available to ELISA kits under the Notification was analyzed by the Adjudicating Authority, who has observed

that although both kits may perform similar functions and may belong to the same genus for classification purposes, the crucial question for the purpose of the Exemption Notification was whether the two kits could be treated as 'identical products capable of being substituted for one another'. In this regard, ld. Departmental Representative invited our attention to the findings of the Original Authority that the importer itself had admitted that ELFA technology is a more sophisticated technology and that the level of accuracy and speed of analysis differ remarkably from ELISA. Accordingly, this itself established that ELFA and ELISA were distinct technologies. It was observed that in ELISA colour difference constitutes the detection criteria whereas in ELFA, fluorescence emission constitutes the detection criteria. Therefore, it is his case that the differences extended beyond detection methodology and also involved differences in effectiveness, speed of diagnosis, and accuracy.

14. The ld. Departmental Representative while referring to the reliance placed by the Appellant/importer upon the clarifications issued by the National Institute of Biologicals (**NIB**) and the Central Drugs Standard Control Organization

(**CDSCO**) to the effect that ELFA and ELISA are similar, however, argued that although CDSCO is the Regulatory Authority in the field of Drugs and Diagnostics and its opinion may have persuasive value, such opinion cannot be treated as determinative for interpretation of the Customs Tariff Act or Exemption Notifications issued under Section 25 of the Customs Act, 1962.

15. Ld. D.R would refer to the observations of the Adjudicating Authority that classification and interpretation of Exemption Notifications fall within the domain of Customs authorities and, therefore, the opinion of CDSCO or NIB cannot be regarded as the final authority for determining eligibility to Exemption. It is a matter of record that the Original Authority has nevertheless acknowledged that the said authorities may have opined that ELFA and ELISA perform similar functions and has concluded that even those opinions do not establish that the two technologies are '*identical in all respects*.'

16. Ld. D.R. Shri Anoop Singh would then refer to the contentions of the Appellant as considered by the Adjudicating Authority regarding earlier assessments and decisions of the Commissioner of Customs, Delhi extending

Exemption benefit to ELFA kits. On this aspect, he would rely on the findings in the Order-in-Original wherein the Original Authority has observed that though uniformity in assessment is desirable, the same does not forbid examination of each assessment independently in the facts and circumstances of the case. Accordingly, earlier decisions or assessments cannot perpetuate an incorrect interpretation merely on the principle of precedent; while such earlier decisions may have persuasive value, they would not bind the Original Authority unless supported by decisions of superior judicial forums.

17. He would then refer and distinguish the reliance placed by the Appellant on clarifications issued by the Ministry of Health & Family Welfare and CBIC Circular No. 10/2022 dated 25.07.2022 relating to Electro CLIA kits by holding that the issues involved therein were different and not comparable with the present dispute.

18. With regard to the legal principles governing interpretation of Exemption Notifications, it was contended that while classification entries under the Customs Tariff may sometimes warrant liberal interpretation and application of

principles such as *ejusdem generis*, Exemption Notifications stand on a different footing and require strict interpretation. It was thus contended that merely because ELISA and ELFA may be classifiable under the same Tariff Heading, but the same does not automatically mean that exemption specifically granted to ELISA kits must also be extended to ELFA kits.

19. The Original Authority's emphasis was re-iterated by ld. D.R that Sl. Nos. 166(A) and 167(A) of Notification No. 50/2017-Cus. specifically describe the goods as 'Enzyme-Linked Immuno Absorbent Assay (ELISA) Kits' and, therefore, the benefit of Notification cannot be expanded to include ELFA kits by adopting a liberal interpretation. In support of strict interpretation of Exemption Notifications, reliance was placed upon the following judgments:

(i) **Novopan India Ltd. Vs CCE** Hyderabad [1994 (73) ELT 769 (SC)]

(ii) **Commissioner of Customs (Import), Mumbai Vs Dilip Kumar & Co & Ors..** [2018 (361) ELT 577 (SC)]

(iii) **Commissioner of Central Excise, Jaipur Vs Mewar Bartan Nirman Udyog** – [2008 (232) ELT 27 (SC)];

(iv) **Commissioner of Central Excise, Trichy Vs Rukmani Pakkwell Traders** [2004 (165) ELT 481 (SC)];

(v) **Rajasthan Spinning & Weaving Mills Ltd. Vs Collector of Central Excise** [1995 (77) ELT 474 (SC)];

(vi) **Commissioner of Central Excise, Kolkata-II Vs Lakho Engineering Works** [2000 (125) ELT 1097 (T)];

(vii) **Commissioner of Customs (Import), Sahar v. Wockhardt Hospital & Heart Institute** – [2006 (200) ELT 15 (Bom.)]

20. Relying upon the aforesaid judgments, particularly the decision of the Hon'ble Supreme Court in **Dilip Kumar & Co.,** (*supra*) our attention was drawn to the fact that the Adjudicating Authority has held that Exemption Notifications are required to be interpreted strictly and in the event of ambiguity, the benefit must go in favour of the Revenue and not the Assessee.

21. It was further contended by the ld. Departmental Representative that:

- The description contained in Column (3) of the Exemption Notification assumes primacy and therefore only those goods specifically described as ELISA kits

are entitled to the exemption. Based on the above reasoning, the Original Authority has concluded that 'ELFA kits' cannot be considered as 'ELISA kits' for the purpose of Notification No. 50/2017-Cus. and accordingly held that the importer was not entitled to the concessional rate of Basic Customs Duty and IGST.

- On the issue of limitation, the Adjudicating Authority examined whether the ingredients necessary for invoking the extended period under Section 28 (4) of the Customs Act were satisfied.
- The supplier invoices merely described the products as "VIDAS TEST KITS" of various types such as VIDAS T3, VIDAS HCG, VIDAS FT4 etc., whereas in the Bills of Entry the importer had declared the goods as 'ELISA kits'. The importer was fully aware that the imported goods worked on the ELFA principle and not the ELISA principle, as admitted in the statements recorded during investigation. It was further observed by the Adjudicating Authority that despite such knowledge, the importer deliberately declared the goods as 'ELISA kits' in the Bills of Entry for the purpose of availing exemption benefit under Notification No. 50/2017-Cus. and the corresponding IGST notification.

- The Adjudicating Authority also relied upon the statement of the Customs Broker, M/s. Arrow Shipping, wherein it was stated that the description 'ELISA kits' in the Bills of Entry was inserted based on instructions received from the importer. Based on the above the Adjudicating Authority concluded that the importer had intentionally mis-declared the goods with intent to evade payment of duty and, therefore, the ingredients of willful misstatement and suppression stood established.
- For the above reasons, the Original Authority upheld the invocation of the extended period under Section 28(4) of the Customs Act, 1962 and confirmed the differential duty demand amounting to Rs.68,20,78,794/- along with applicable interest under Section 28AA.
- The above reasons are, therefore, relevant since the importer had misdeclared 'ELFA kits' as 'ELISA kits' and had wrongly availed exemption notifications, the goods became liable to confiscation under Sections 111 (m) and 111(o) of the Customs Act.
- On the question whether redemption fine could be imposed despite non-availability of goods, reliance was

placed upon the judgment of the Hon'ble Madras High Court in **Visteon Automotive Systems India Ltd.** [2018 (9) GSTL 142 (Mad.)], wherein it was held that physical availability of goods is not necessary for imposition of redemption fine under Section 125 of the Customs Act. Reliance was also placed upon the decision in **Sri Janardhanan v. Commissioner of Customs, Chennai** [2002 (149) ELT 1029 (Tri.-Chennai)]. Accordingly, findings in the OIO by the adjudicating authority that the goods are liable to confiscation stands justified and hence, has imposed redemption fine *in lieu of* confiscation.

- The Original Authority has thus properly held that since the importer had rendered the goods liable to confiscation by deliberate misdeclaration and wrongful availment of exemption, penalty under Section 114A of the Customs Act was imposable. The observations of Adjudicating Authority that the importer had knowingly misdeclared ‘ELFA kits’ as ‘ELISA kits’ in the Bills of Entry despite supplier invoices not containing such description and thereby intentionally availed ineligible exemption resulting in short-payment of duty, are thus

justified. It was, therefore, held that the ingredients of wilful misstatement and suppression stood established and consequently penalty under Section 114A was imposable upon the importer.

22. We have carefully considered the submissions advanced by Shri V. Lakshmi Kumaran, learned Advocate for the Appellant and the arguments of Shri Anoop Singh, the learned Departmental Representative for the Revenue, the impugned Order-in-Original, the extensive technical literature placed on record and the judicial precedents relied upon by both sides during the course of arguments before us.

23. The principal issue arising for our consideration in the present Appeal is, 'whether the sixteen varieties of "VIDAS" Diagnostic Kits imported by the Appellant during the disputed period admittedly based on Enzyme-Linked Fluorescent Immunoassay ("ELFA") are eligible for exemption from BCD in terms of Sl.Nos.166 (A) and 167(A) of Notification No.50/2017-Cus. dated 30.06.2017 and corresponding concessional IGST entry under Notification No. 01/2017-Integrated Tax (Rate). The Revenue seeks to

deny the exemption primarily on the ground that the exemption entries specifically refer to "ELISA Kits", whereas the imported products are "ELFA Kits", which according to the Department constitutes a distinct and separate diagnostic technology. Proceeding on such basis, the Adjudicating Authority has concluded that Exemption Notifications must be construed strictly and, therefore, ELFA kits cannot be brought within the scope of ELISA kits. Upon careful scrutiny of the technical material and legal position, we are unable to agree with the aforesaid reasoning, for the following:

24. The evidence on record *prima facie* indicates that ELFA is not a distinct or unrelated scientific principle, but only an advanced technological application within the broader ELISA framework. The Appellant has demonstrated, through detailed technical literature and scientific explanations, that both ELISA and ELFA fundamentally operate on the same immunological principle of antigen-antibody interaction employing enzyme-linked immunoassay methodology.

25. The Appellant has explained the ‘sandwich ELISA’ principle in detail. Under this methodology, the antigen present in the clinical sample reacts with antibodies attached

to the well surface; a second enzyme-linked antibody is thereafter introduced, followed by addition of a substrate producing detectable signal. In conventional ELISA, chromogenic substrates generate colour change detectable through spectrophotometry. In ELFA, fluorogenic substrates such as 4-methylumbelliferyl phosphate (4MUP) generate fluorescence detectable through fluorometry. Thus, **the distinction lies only in the mode of signal detection at the terminal stage** and not in the underlying immunological or biochemical principle.

26. The technical extracts from *The Immunoassay Handbook: Theory and Applications of Ligand Binding, ELISA and Related Techniques* by David Wild, which was heavily relied upon by the Appellant, clearly show that ELISA methodologies themselves encompass Chromogenic, Chemifluorescent and Chemiluminescent detection systems. The literature specifically records that enzyme conjugates and may generate "chromogenic, chemiluminescent or chemifluorescent signal" depending upon the required sensitivity of the assay. The literature further notes that chemifluorescent and chemiluminescent systems merely

represent highly sensitive variants within ELISA-based assays.

27. Therefore, the very foundation of the Department's case that ELISA is confined only to colourimetric detection using chromogenic substrates stands scientifically disproved by authoritative technical literature. It is very significant that even the Adjudicating Authority has himself recorded at para 18 of the impugned Order-in-Original that ELFA is a *'much more sophisticated technology'* and that the level of speed and accuracy differs remarkably. Once this finding is accepted, the inevitable consequence is that ELFA represents a technological advancement or evolution of ELISA methodology and not an altogether different scientific species.

28. In our considered opinion, therefore, exemption entries concerning scientific instruments, medical diagnostics and biotechnology products cannot be interpreted in a rigid, frozen or static manner divorced from technological advancement. Scientific methodologies evolve continuously while retaining their essential foundational principles. Law cannot be interpreted in a manner that fossilizes scientific

understanding to the stage existing on the date when the Exemption Notification was originally drafted.

29. The Hon'ble Supreme Court in **Collector of Central Excise Vs Lekhraj Jessumal & Sons** [1996 (82) E.L.T. 162 (S.C.)] categorically recognized that interpretation of Tariff Entries and Exemption Notifications must keep pace with technological developments. Similar principles were reiterated recently, in **Hewlett Packard India Sales Pvt. Ltd. Vs Commissioner of Customs (Import), Nhava Sheva** [(2023) 2 Centax 236 (S.C.)]. The Tribunal in **Commissioner of Customs, Chennai Vs Novo Nordisk India Pvt. Ltd.** [2024 (12) TMI 365 (CESTAT Chennai)], applying the aforesaid principle, held that insulin manufactured through recombinant DNA technology would nevertheless qualify as "mono-component insulin" for exemption purposes, since technological advancement does not alter the essential character of the product. The ratio of the said decision squarely supports the Appellant. We further find direct support from the decision of the Tribunal in **Collector of Customs, New Delhi v. Ethnor Ltd.** [1996 (86) E.L.T. 558 (Tri.)] affirmed by the Hon'ble Supreme Court in 1997(96) E.L.T. A157 (S.C.). In that case also,

technologically advanced pregnancy diagnostic kits based on ELISA methodology were held entitled to exemption notwithstanding modification in the detection mechanism. Similarly, in **Cepheid India Pvt. Ltd. Vs Principal Commissioner of Customs, New Delhi** [2025 (6) TMI 1899 CESTAT New Delhi] relied upon by the Appellant, the Tribunal adopted purposive interpretation to extend exemption benefits to technologically advanced HIV diagnostic kits even though the notification referred to older forms of diagnostic kits. Likewise, in **Hemogenomics Pvt. Ltd. Vs Commissioner of Customs (Appeals), New Delhi** [2025 (10) TMI 820 (CESTAT New Delhi)], the Tribunal reiterated that diagnostic exemption entries must be interpreted keeping in view the technological progression and the underlying object of public healthcare. We also find considerable force in the Appellant's contention based on expert statutory clarifications issued by the Central Drugs Standard Control Organization (‘CDSCO’) and National Institute of Biologicals ("NIB"). The records reveal that the issue was not casually examined. The Customs authorities themselves had referred the dispute to the Drugs Controller General of India under CDSCO seeking clarification whether ‘ELFA kits’ could be treated as ‘ELISA kits’. CDSCO in turn

sought technical opinion from NIB, which is an apex autonomous scientific institution functioning under the Ministry of Health and Family Welfare and specializing in Biological and Diagnostic Standards. After detailed examination, NIB vide communication dated 02.07.2015 categorically clarified that ELISA and ELFA are one and the same. The said clarification was thereafter communicated by CDSCO to Customs authorities *vide* letter dated 16.07.2015. it is useful here, to reproduce the same :

"File No. 29/Misc./4/2015-DC(31) Date: 16.07.2015

To

Sh V.K. Gahlout,
Additional Commissioner,
Office of the Principal Commissioner of Customs (Import)
New Custom House, Near IGI Airport,
New Delhi-110 037.

SUB : Clarification on diagnostic kits based on ELFA technique in view of exemption claimed by the importer considering said kits as ELISA – regarding.

Sir,

Please refer to your office letter no. 2091 dated 12.05.2015 and subsequent letter 3775 dated 12/06/2015 on the subject matter.

In this connection, it is stated that matter has been taken up in consultation with NIB, Noida. It has been informed by the NIB that ELISA is a Enzyme-Linked Immunosorbent Assay and ELFA is a Enzyme-Linked Fluorescent Assay **which means that ELISA & ELFA**

are one & the same. (A copy of the same is attached for ready reference).

Yours faithfully,

Sd/-
(Aseem Sahu)
Deputy Drugs Controller (I)"

[emphasis added]

30. In the light of the above discussion, we are unable to appreciate the approach adopted in the impugned order in disregarding these expert opinions. In highly technical matters involving diagnostic science, immunology and biotechnology, opinions of statutory expert bodies deserve substantial weight and judicial deference. Adjudicating Authorities lacking equivalent scientific expertise ordinarily cannot substitute their own scientific understanding for that of Apex Regulatory Institutions unless the expert opinion is shown to be manifestly arbitrary or contrary to statutory provisions. **[Collector Customs & Central Excise Vs Lekjraj Jessumal & Sons** [1996 (82) ELT 162 (SC)]. No technical evidence of equivalent scientific value has been produced by Revenue to rebut the expert clarification issued by CDSCO and NIB. The Department itself having sought expert opinion cannot thereafter selectively discard the same

merely because the opinion does not support the proposed demand.

31. The Appellant has also rightly pointed out that based upon the very same CDSCO/NIB clarification, the Commissioner of Customs, New Delhi had earlier finalized provisional assessments extending exemption benefit to ELFA kits under Notification No. 12/2012-Cus., which is *pari materia* with Notification No. 50/2017-Cus. The principle of consistency in taxation is too well settled to require elaborate discussion. Identical goods imported under identical notifications cannot be subjected to contradictory treatment by different Commissionerates based on varying scientific interpretations. Such inconsistency undermines certainty and uniformity in tax administration. In **Comtrust Super Designer Tiles Pvt. Ltd. Vs CCE** [2010 (249) E.L.T. 41 (Tri.-Bang.)] and **Opal Exports Pvt. Ltd. Vs Collector of Customs** [1992 (60) E.L.T. 232 (Cal.), it has been held that different Commissionerates cannot adopt conflicting stands regarding identical products. Similar principles emerge from **Marsons Fan Industries Vs CCE Calcutta** [2008 (225) E.L.T. 334 (S.C.)], **CCE Mumbai Vs Bigen Industries Ltd**. [2006 (197) E.L.T. 305 (S.C.), **Indian Oil**

Corporation Ltd. Vs CCE Baroda [2006 (202) E.L.T. 37 (S.C.)] and other decisions relied upon by the Appellant.

32. The Commissioner has heavily relied upon the Constitution Bench judgment of the Hon'ble Supreme Court in **Commissioner of Customs (Import) Vs Dilip Kumar and Company & Ors.** [2018 (361) E.L.T. 577 (S.C.)] and the decision in **Novopan India Ltd. Vs CCE** [1994 Supp (3) SCC 606], to contend that exemption notifications must be interpreted strictly.

33. There can indeed be no dispute with the settled proposition that an Assessee claiming exemption must establish clear eligibility within the terms of the Notification. However, the principle of strict interpretation cannot be extended to justify a construction which ignores scientific realities or adopts an artificial distinction unsupported by technical evidence. The ratio of **Dilip Kumar** (*supra*) applies where genuine ambiguity exists regarding the scope or applicability of an exemption entry.

34. In the present case, upon cumulative consideration of the technical literature, expert clarifications issued by statutory Regulatory Authorities namely CDSCO and NIB, the

scientific material placed on record and the admitted functional characteristics of the imported goods, we find no ambiguity whatsoever that ELFA technology is fundamentally rooted in, and operates upon, the ELISA principle itself. Merely because technological advancement has introduced fluorescence-based detection in place of conventional colorimetric detection, the essential character of the diagnostic methodology does not undergo transformation so as to exclude the goods from the ELISA category. Equally important is the subsequent judgment of the Hon'ble Supreme Court in **Government of Kerala Vs Mother Superior Adoration Convent** [2021 (376) E.L.T. 242 (S.C.)], wherein the Court has clarified that the Constitution Bench decision in **Dilip Kumar & Company** (*supra*) did not impliedly do away with the established line of authorities governing beneficial exemptions intended to advance public welfare. The Hon'ble Supreme Court has in fact specifically held that exemption provisions having a beneficial object must receive purposive interpretation so as to advance the legislative intent rather than defeat it through narrow or overly formalistic construction. The exemption in the present case concerns diagnostic kits used in detection of infectious diseases and viruses. The evident legislative object is to

facilitate affordable healthcare and encourage availability of advanced diagnostic technologies. Denial of exemption merely because technology has progressed from colorimetric detection to fluorescence-based detection would defeat the very object underlying the notification.

35. We also find considerable merit in the Appellant's submission founded upon **Genus-Species** interpretation. The material placed on record establishes that ELISA represents the broader class of enzyme-linked immunoassay methodologies based upon antigen-antibody interaction, while ELFA constitutes a technologically evolved variation thereof employing fluorescence-based detection at the terminal stage. The underlying immunological principle and enzyme-linked assay mechanism admittedly remain the same. In **Standard Pencils (P) Ltd. Vs CCE Madras** [2002 (145) E.L.T. 280 (S.C.)], the Hon'ble Supreme Court held that once exemption is granted to a genus, its various forms and varieties would ordinarily remain covered unless specifically excluded. Similar views are expressed in **Alladi Venkateswarlu Vs Government of Andhra Pradesh**, [(1978) 2 SCC 552], **Jain Exports (P) Ltd. Vs Union of India** [1992 (61) E.L.T. 173 (S.C.)] and **Union of India Vs**

N.S. Rathnam & Sons [2015 (322) E.L.T. 353 (S.C.)]. Applying the aforesaid principles, we are unable to accept the Revenue's contention that adoption of fluorescence detection results in emergence of an altogether distinct diagnostic methodology outside the ELISA framework. Mere technological enhancement in the mode of detection cannot eclipse the foundational ELISA principle upon which the impugned kits admittedly operate.

36. We also find that the reliance placed upon CBIC Circular No.10/2022-Cus. dated 25.07.2022 issued in the context of CLIA and ECLIA diagnostic kits is apt. The said circular records that, based upon expert clarification furnished by the Ministry of Health & Family Welfare, ECLIA and CLIA operate on the same underlying principles notwithstanding differences in technological advancement or detection methodology. On the strength of such expert opinion, CBIC has clarified/advised the field formations to consider the clarification and make reasonable decision on the assessment of the CLIA and ECLIA kits. The underlying rationale of the said circular clearly supports the Appellant's case herein, namely that advancement or refinement in detection technology does not necessarily result in

emergence of an altogether distinct diagnostic methodology when the foundational scientific principle continues to remain the same.

37. In the light of the above, we also do not find any justification whatsoever for invocation of the extended period under Section 28 (4) of the Customs Act, 1962. The Adjudicating Authority has observed that in the Bills of Entry the importer described the goods as "VIDAS TEST KITS" and additionally mentioned in brackets "ENZYME IMMUNO ASSAY (ELISA) KIT", though such expression did not appear in the supplier's invoices. According to the Revenue, since the imported goods admittedly operate on the principle of ELFA, the Appellant intentionally described the goods as ELISA kits in order to wrongly avail the benefit of Exemption Notification. We are unable to accept the said contention for the purpose of invoking the extended period under Section 28 (4) of the Customs Act. It is not in dispute that the imported goods were 'VIDAS diagnostic kits' and that the identity and nature of the goods were fully available to the Department. The dispute essentially concerns the eligibility of ELFA-based kits to the exemption available to ELISA kits under the relevant Notification. The Appellant's consistent

stand throughout has been that ELFA technology operates on the ELISA principle and, therefore, the imported kits were eligible for exemption. Such understanding cannot be said to be *ex-facie* implausible or lacking in bona fides, particularly when the issue itself required examination by specialized expert bodies such as National Institute of Biologicals (NIB) and CDSCO.

38. The Appellant has also relied upon the earlier decision dated 17.08.2015 of the Commissioner of Customs, New Delhi accepting the Appellant's claim in respect of identical goods. In these circumstances, merely because the Appellant described the goods as "ELISA Kits" in the Bills of Entry while claiming exemption, it cannot automatically lead to the conclusion that there existed any deliberate intention to evade payment of duty. The present case is essentially one involving interpretation of the scope of the Exemption Notification in the context of evolving diagnostic technologies. It is well settled that where the dispute pertains to interpretation of exemption entries and all material particulars regarding the goods imported are available with the Department, the extended period cannot be invoked in the absence of clear evidence of willful

suppression, fraud or deliberate misstatement. In **Cosmic Dye Chemical v. CCE Bombay** [1995 (75) E.L.T. 721 (S.C.)] the Hon'ble Supreme Court held that 'misstatement or suppression of fact' must be willful and with an intent to evade duty. Applying the aforesaid principles, we are of the considered view that the ingredients necessary for invocation of Section 28 (4) are not proved in the facts of the present case.

39. We also find considerable force in the Appellant's contention regarding non-applicability of interest and penalty provisions in respect of IGST levied under Section 3 (7) of the Customs Tariff Act during the relevant period. The relevant period in the present case is February 2018 to December 2022. During substantial part of this period, Section 3 (12) of the Customs Tariff Act had not specifically incorporated the provisions relating to interest, penalty and confiscation from the Customs Act insofar as IGST was concerned. The legal position in this regard now stands settled by the judgment of the Hon'ble Bombay High Court in **Mahindra & Mahindra Ltd. Vs Union of India**, [2022 (10) TMI 212 (Bom.)] which is also affirmed by the Hon'ble Supreme Court *vide* **Union of India Vs Mahindra &**

Mahindra Ltd. [2023 (8) TMI 135 (S.C.)] and the Review Petition was also dismissed *vide* **2024 (1) TMI 1277 (S.C.).**

40. In the light of our discussion as above, we are of the clear view that the impugned Order-in-Original cannot sustain for which reason, the same is set aside; consequent demand of differential duty, interest, confiscation, redemption fine and penalties also would not survive. The Appeal is thus allowed with consequential benefits, if any, as per law.

(Order pronounced in open court on 29.06.2026)

sd/-
(VASA SESHAGIRI RAO)
Member (Technical)

sd/-
(P. DINESHA)
Member (Judicial)

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