

**IN THE CUSTOMS, EXCISE AND SERVICE TAX APPELLATE TRIBUNAL
CHENNAI**

REGIONAL BENCH – COURT No. I

Customs Appeal No. 40367 of 2020

(Arising out of Order-in-Original No. 73076/2020 dated 06.01.2020 passed by the Commissioner of Customs - Audit, No. 60, Rajaji Salai, Custom House, Chennai – 600 001)

Commissioner of Customs

Chennai Import Commissionerate,
No. 60, Rajaji Salai,
Custom House,
Chennai – 600 001.

: Appellant

VERSUS

M/s. Novo Nordisk India Pvt. Ltd.

Plot No. 32, 47-50, EPIP Area,
Whitefield,
Bangalore – 560 066.

:Respondent

APPEARANCE:

Shri S. Subramanian, Special Counsel
For the Appellant

Shri G. Shivadass, Senior Advocate
For the Respondent

CORAM:

HON'BLE MR. P. DINESHA, MEMBER (JUDICIAL)

HON'BLE MR. M. AJIT KUMAR, MEMBER (TECHNICAL)

FINAL ORDER No. 41478 /2024

DATE OF HEARING : 11.09.2024

DATE OF DECISION: 22.11.2024

Order : [Per Hon'ble Mr. P. DINESHA]

This appeal is filed by the revenue, feeling aggrieved by the Order-in-Original No. 73076/2020 dated 06.01.2020 passed by the Commissioner of Customs – Audit, Custom House, Chennai.

2.1 Relevant facts, in brief, as could be gathered from the documents placed on record leading to the present *lis* are that the respondent claimed to be importing the products *viz.*, Insulatard, Mixtard and Actrapid which are human insulin and Novomix, NovoRapid, Levemir, Ryzodeg and Tresiba which are insulin analogues by classifying the same under HSN 30043110. The respondent has been filing Bills of Entry claiming exemption from payment of customs duty and CVD with SAD/IGST under Notification No. 12/2012 – Cus. dated 17.03.2012 [Sl. No. 148] and Sl. No. 167 r/w. entry No. 63 of List 4 of Notification No. 50/2017 – Cus. dated 30.06.2017, for the said goods.

2.2 It appears one consignment of insulin declared as monocomponent insulin vide Bill of Entry dated October 26, 2016 was intercepted by the SIIB, Custom House, Chennai. Respondent-assessee appears to have self-assessed the goods under Customs Tariff Item 3004 3110 to 'NIL' duty by way of claiming the above exemptions. Basis the investigation, the Respondent-assessee was issued with a SCN dated **February 23, 2018** wherein the main allegation was that the goods imported by the them did not qualify to be "monocomponent insulins". A demand of Rs. 1,67,43,49,227 was thus proposed for the period November 2014 to September 2017 invoking the extended period of limitation under the provisions of Section 28 of the Customs Act, 1962, as the benefit of Notification/s claimed by the respondent was allegedly not available to them.

2.3.1 It appears that the respondent filed its detailed reply, inter alia highlighting that;

- i. Insulin analogues imported by them are insulins and are "Monocomponent insulins". "Monocomponent insulins" are eligible for exemption under Notification No. 12/2012 Customs dated March 17, 2012, as they are lifesaving drugs.
- ii. In the absence of statutory definition for the term "Monocomponent insulins", the same will have to be determined by application of "trade or commercial parlance" rule.
- iii. The opinion rendered by technically qualified persons should not be neglected.
- iv. The goods are correctly classified under chapter heading 3004 31 10.

and thereby justifying its claim for exemption. Their claim appears to be supported by documentary evidences like opinion of the experts in the field, Scientific/Technical literatures on the subject, etc.

2.3.2 The Ld. Adjudicating Authority at Para 72(J) of page 50 of the Order-in-Original has concluded that there is no definition for "Monocomponent" either in HSN Explanatory Notes, Customs Tariff, or the Notification. As per expert opinion, the Impugned Goods are mono-component insulin and are hence, classifiable under tariff entry 30043110. The assessee has rightly availed benefit under Sl.No. 114 of Notification No. 12/2012-CE dated 17.03.2012. The products imported by assessee are developed

using r-DNA technology and hence devoid of High Molecular Weight Protein (HMWP). The non-mention of the term Mono-component in the product label or marketing literature in Nordic countries do not conclusively prove the case of the department and at Para 72(KK) of page 56 of the order, he concludes that the declaration contained in the bill of entry, packages and leaflets is correct.

2.3.3 In a nut-shell, the Ld. Adjudicating Authority / the Commissioner *vide* Order-in-Original No. 73076/2020 dated 06.01.2020 has held that goods imported by the Respondent-assessee *viz.*, 'Human Insulin' and 'Insulin Analogues' are "mono-component Insulin" covered by the Notifications *supra* and therefore, their claim for exemption was in order.

2.4 It is against this dropping of the demand by the AA/Commissioner, that the Revenue-Appellant has filed this Appeal before us.

3. We have heard Sri S. Subramanian, Ld. Special Standing Counsel for the Appellant – Revenue and Sri G. Shivadass, Ld. Senior Advocate for the Respondent, at length.

4.1 Submissions of Ld. Standing Counsel for the Appellant-Revenue are summarised below: –

- i. The term 'monocomponent insulin' refers to insulin extracted from animal pancreas that has been purified using Chromatographic techniques to reduce PRO-insulin. For this, he has placed reliance on the Oxford Dictionary of Biochemistry and Molecular Biology (1997 Edition), Gelanics of Insulin and European Pharmacopoeia.
- ii. Insulin from animal source and r-DNA source could be differentiated based on material, process of manufacture/purification and nature of precursor; and only the insulin obtained from animal source could be considered as 'monocomponent insulin'.
- iii. There is no specific 'monocomponent' in the insulin manufactured using r-DNA technology, the very phrase monocomponent has not been used uniformly in all countries by the respondent wherever their products were supplied, whereas the same was specifically indicated in the packaging of goods sold only in India, which only indicates that the mentioning of such an expression was merely to avail the benefit from payment of customs duty. Further, the said phrase was intended to cover insulin which had a single component, which would necessarily refer to purified porcine and bovine insulin and not to insulin manufactured using r-DNA technology.
- iv. On perusal of HSN Explanatory Notes, the insulin and insulin Analogue injections have different classifications; Insulin injections are covered under CTH 3004 3110 as insulin

injections, while the insulin Analogue injections are classifiable under the residual entry CTH 3004 3190 as 'Other', of the same Chapter.

- v. Insulin Analogue cannot be classified specifically as insulin and cannot be considered as mono-component insulin as opined by National Institute of Pharmaceutical Education and Research [NIPER]. They have indicated that insulin analogues cannot be considered as a substitute for insulin due to structural differences.
- vi. Expert opinions relied upon by the Respondent to establish their goods to be classified under as 'mono-component insulin' are hence liable to be rejected as the same have not categorically held the goods as mono component insulin.
- vii. Moreover, the report of National Institute of Biologicals also cannot be relied upon since they had approached the respondent and sought clarification on the product. So also, the report of Dr V Mohan is of no help since he has not commented on anything concerning the products under examination. For this reason, the same lacks evidentiary value to support the claim of the respondent that the imported goods are 'mono-component insulin'.
- viii. Conclusion drawn by the Commissioner that mono-component nature of modern insulin products is implicit based on the RP-

HPLC chromatograms and that insulin analogues are also a mono-component insulins, they are introduced with better kinetic profiles and better stability to mimic native insulin, is clearly without any basis.

- ix. The original authority has held that the term 'mono-component insulin' is faded in its application but, however, he has applied the common parlance test to hold that the said goods are mono-component insulin, which is clearly contradictory and hence, unsustainable.
- x. Respondent has claimed the benefit of Exemption notification and hence, the burden to prove its eligibility for the exemption is on the respondent, for which proposition, learned special counsel has relied upon the following decisions: –
- a. Commissioner of Customs (Import), Mumbai Vs. Dilip Kumar & Company [2018 (361) ELT 577 (SC)]*
 - b. Novopan India Ltd. Vs. Collector of Central Excise and Customs, Hyderabad [1994 (73) ELT 769 (SC)]*
 - c. Commissioner of Customs, Central Excise and Service Tax, Patna Vs. M/s. Shapoorji Pallanji and Company Pvt. Ltd. & Ors. [2023 LiveLaw (SC) 885]*
- xi. The European Medicines Agency, which is the Regulatory Authority for marketing of insulin products in the European countries, in its CHMA assessment report and European Pharmacopoeia has not described the

product under consideration as ‘monocomponent insulin’.

xii. Apart from the above, the information mentioned in the patient Leaflet information indicates that the goods in question are not marked as ‘mono-component insulin’.

4.2 He would thus request for setting aside the findings of the impugned order.

5.1 *Per contra*, Sri Shivadass, Ld. Senior Advocate appearing for the Respondent-Assessee submitted that the Respondent imports Insulin products from NNAS, Denmark by claiming Customs duty exemption. Details of the Insulin products imported along with the classification of products are provided in the table below: -

Nature	Products	HSN Classification
Human Insulin (whether in the form of vials, PENFILL® or FlexPen®)	Insulatard®	3004 3110
	Mixtard®	3004 3110
	Actrapid®	3004 3110
Insulin analogues (whether in the form of vials, PENFILL®, FlexPen® or FlexTouch®)	NovoMix®	3004 3110
	NovoRapid™	3004 3110
	Levemir®	3004 3110
	Ryzodeg™	3004 3110
	Tresiba®	3004 3110

His further submissions are summarised below: –

i. Term “monocomponent’ is used by the trade and industry to denote the insulin products of highest purity; the said term is not defined either in the Custom tariff or even in the Notifications in question.

- ii. The entry porcine and bovine insulin denote insulins derived out of these sources and the structure of the molecules is not relevant. The entry 'monocomponent insulin' would therefore cover all types of insulin which satisfies the definition of 'mono-component insulin' irrespective of the sources. An insulin made from yeast culture using r-DNA technology after repeated process of purification would thus be covered under this entry. The entry in the Exemption Notification is product oriented and not process oriented, as held by coordinate Mumbai bench in the case of *MJ Pharmaceuticals -Vs- Commissioner of Customs [2001 (6) TMI 490]*.
- iii. In fact, the case of the Revenue is based only on the inferences drawn from the books or articles, which are having no evidentiary value at all and hence, the same are not conclusive proof of evidence.
- iv. The entries under the Notification must be read in line with the technological advancements and hence, the development of mono-component insulin from yeast through the process of r-DNA technology and of 'Insulin Analogues' is which has resulted in ensuring a selectively increased action of regulating blood sugar levels in the human body would not exclude them from being covered under the head 'mono-component Insulins' as listed in the Exemption Notification. In this connection,

he placed reliance on the following decisions: –

- a. *Collector of Customs & Central Excise Vs. Lekhraj Jessumal & Sons [1996 (82) ELT 162 (SC)]*
- b. *Collector of Customs, New Delhi Vs. Ethnor Ltd. [1996 (7) TMI 212-CEGAT, New Delhi]*
- c. *Hewlett Packard India Sales Pvt. Ltd. Vs. Commissioner of Customs (Import), Nhava Sheva [2023 (2) CENTAX 236 (SC)]*

v. He also took us through the following expert opinions placed on record, to buttress his contention that the product under consideration is nothing but a 'mono-component insulin': -

- a. Expert opinion by Professor Utpal Tatu of the Indian Institute of Science (Page No. 1150, Volume 2) who, after testing the insulin products of the respondent, had opined that "*.....all the insulins being dealt by Novo Nordisk India Pvt Ltd are r-DNA technology based and the purity was tested by using highly sensitive mass spectroscopy method at Department of biological sciences, IISC under my supervision which re-confirms the purity; thereby insulin products listed below are mono-component in nature.*"
- b. Article titled "which insulin to use? Human or animal?" Authored by Dr. V. Mohan, wherein, (Page No. 1153, Volume 2) while discussing the purity of insulin, placing reliance on clinical studies Dr. Mohan observed that "*human insulin was shown to be indistinguishable from porcine insulin*

of comparable purity.” Based on numerous studies, he has concluded that there were no differences in ability to transport glucose between recombinant human insulin and porcine insulin and neither insulin is less reactive than the other insulin with antibodies.

- c. Clarification on the article by Dr V Mohan (Page No. 1157, Volume 2), *“recombinant insulins synthesized by the recombinant technology are highly pure which are free from proinsulin, thereby resulting in more than 99% pure form of insulin”* and *“it is rightly said that the term “Monocomponent Insulin refers to the purity of the insulin irrespective of its origin.”* He further observed that *“Bio synthetic Human Insulins and Insulin Analogues manufactured using recombinant DNA technology are correctly termed as “Monocomponent Insulins” as they both have no difference in its ability to bind to the receptors and their action of reducing blood glucose. Also, often these insulins can be used interchangeably in controlling blood sugar levels.”*

5.2 The HSN explanatory notes to chapter 29 states that analogue has a structure akin to the parent compound and are not considered derivatives.

5.3 Products sold in different countries are homogenous and of the same high-quality. The only difference is in nomenclature and packaging which is specific and in the instant case, the respondent has received approval from Drugs Controller General of India – DCGI for its insulin, which is the Expert Statutory Authority to assess and grant approvals.

6.1 Submissions of both the Ld. Counsels are taken on record. Before we delve into the submissions made by the rival parties, it would be relevant to list out the evidences relied upon by both the parties. The revenue has referred to the following evidences in the SCN : –

- i. expert opinion from National Institute of Biologicals **(letter dated 28.12.2016 Page No. 245, Volume 1)**;
- ii. expert opinion from NIPER **(letter dated 20.11.2012 Page No. 467, Volume 1 & letter dated 13.10.2017 Page No. 71, Para No. 90, finding at No.7 of OIO)**; and
- iii. expert opinion from DCGI **(letter dated 11.07.2017 Page No. 1117-1148, Volume 2)**.

6.2 The Respondent, on another hand has relied upon the following evidences in support: –

- i. expert opinion of Indian Institute of science **(Page No. 1150, Volume 2)**,
- ii. article titled which insulin to use? Human or animal? By Dr. V Mohan; and

iii. clarification issued by Dr. V Mohan.

6.3 In addition to the above, the Adjudicating authority has referred to the following evidence: –

- i. mail dated 05.12.2019 (Page No. 60, para 78, OIO dated 03.01.2020) from Mr. N. Manoj, Department of Biotechnology, IIT Madras; and
- ii. opinion of Dr. V Mohan, Chairman and chief diabetologist of Madras diabetes, research foundation, Chennai (Page No. 61, paras 79 & 80, OIO).

7. After hearing the rival contentions at length and after perusing the documents placed on record, we find that the only issue to be decided by us is, **“whether goods imported by the respondent which are impugned in the present appeal, could be considered as mono-component insulin, and thus are eligible for exemption from payment of customs duty?”**

8. We find that both the parties have referred to various scientific literature, wherein the definition of ‘monocomponent insulin’ are given as under: –

Sl. No.	Source	Definition
1.	Oxford Dictionary of Biochemistry and Molecular Biology (1997 edition)	<i>"a commercial preparation of natural insulin that has been highly purified by chromatography and is thus made essentially free of pro-insulin, intermediates in the conversion of pro-insulin to insulin, and breakdown products of insulin as well as any unrelated contaminants."</i>
2.	Gelanics of Insulin	Jens Brange in his literature on "Physio Chemical and Pharmaceutical Aspects of Insulin and Insulin Preparations" has described mono-component insulin as animal insulin purified by chromatography to reduce pro-insulin content to less than 1 ppm.
3.	Mosby's dictionary of medicine, nursing & health professions	<i>"Any highly purified insulin with less than 10 ppm of proinsulin."</i>
4.	Taber's cyclopaedic medical dictionary	<i>"Highly purified insulin that contains less than 10 parts per million of proinsulin, which is capable of inducing formation of anti-insulin antibodies".</i>

9. From the definition of the phrase 'mono-component' from various sources as referred to supra, it is clear that the same is used with reference to purity of insulin rather than the source. We also find that it is not the case of the department that the product under dispute have impurity level higher than 1PPM or that any test report has been relied upon by them, which is on record, to establish the same.

10. At this juncture, we find it is useful to refer briefly to the evolution of insulin as could be gathered from various literature provided by both the parties.

- a. Porcine and Bovine insulin – Insulin was initially supplied by extraction from pancreas of bovine and porcine insulin. These contained impurities which caused undesirable side-effects.
- b. Porcine and Bovine Insulin with modified amino acid sequence – After finding increased immunogenicity in humans while administering porcine and bovine insulin due to the difference between amino acid sequence in porcine/bovine insulin compared to the natural human insulin sequence, a method was developed to convert insulin into human insulin by modifying the amino acid which is different in the porcine insulin to be of the same as that of human insulin sequence.
- c. r – DNA technology insulin – With the advent of recombinant DNA technology (technology to produce human insulin by cloning), wherein the DNA sequence encoding human insulin (human insulin gene) was inserted into yeast to produce the human insulin peptide. One difference, however, was that the yeast cells could not make human proinsulin because the long C-peptide in insulin interfered with the folding and secretion so it could not produce fully processed human insulin like in the animal/human pancreatic beta cells. It was therefore necessary to modify the human insulin gene so that it was more conducive for production in yeast and hence, the long C-peptide was replaced by a short, synthetic C-peptide to give a molecule called '*mini-*

insulin'. Thereafter, a helper protein called '*Alpha-factor*' including a *pre-pro-peptide* was attached to the mini-insulin molecule to allow it to enter into the endoplasmic reticulum in the yeast for proper processing. This was referred to as pre-pro-mini-insulin, which was similar to pre-pro-insulin found in the pancreatic beta cells.

12. With the above short background, it would now be necessary for us to examine the issue in the light of the scientific literature/opinions/sources relied upon during the course of arguments before us.

13.1 During investigation, the Revenue sent a letter dated 29.11.2016 to the NIB wherein certain parameters were requested to be tested to ascertain the eligibility of the goods imported by the Respondent for the benefit of duty exemption. NIB was also asked to provide reasons in case they were unable to perform the test indicated in the letter. Vide another letter, the revenue also requested the NIB to test the samples of Mixtard 30 HM Penfill, NovoRapid Penfill, NovoMix, 30 Penfill and Actrapid HM Penfill imported by the respondent to ascertain (i) nature of compositions, (ii) source, (iii) presence of pro insulin as a percentage of weight or parts per million, (iv) presence of other non-insulin pancreatic hormones; and (v) molecular weight of the samples.

13.2 The NIB thereafter appears to have answered the queries of the Revenue per its letter dated

28.12.2016 indicating that as per the product pack insert: -

- i. the nature of composition is mono-component Biosynthetic recombinant DNA origin (r-DNA),
- ii. All the six samples were neither bovine insulin nor porcine insulin, but are of r-DNA origin; Novo Rapid Penfill, NovoMix 30 Penfill and Ryzodeg Flextouch were insulin analogues and Ryzodeg Flextouch was also a mixture of r-DNA origin and insulin analogues.
- iii. Insofar as third and fourth parameters which was to test the presence of pro insulin in weight percentage or PPM and other non-insulin pancreatic hormones, the NIB replied that the test specified were not required as the products were of r-DNA origin.
- iv. In response to the final parameter, which was to ascertain the molecular weight and structure, the NIB responded that the same was not required for finished drug product of insulin as per Indian Pharmacopoeia, 2014.

14. Not satisfied with the above opinion, the Revenue appears to have approached NIPER with a letter dated 25.07.2017 seeking opinion from the said authority on "correctness of Human insulins of r-DNA origin being claimed as mono-component insulin", along with supporting technical/scientific evidences. In its reply, the said authority through its director vide its letter dated 13.10.2017 has stated that mono-component insulin is traditionally referred to as purified from natural source and mono

component is used in the sense of single component, regardless of origin, and, in this regard the said authority has a relied upon the discussion made by European Medical Agency and an Order of National Pharmaceutical Pricing Authority – NPPA – in F.NO.8(1)/2006/DP/NPPA – Div II dated 29.03.2006 and NPPA's statement dated 09.07.2003.

15. Not satisfied again, it appears that the revenue approached the DCGI per letter dated 18.05.2017, requesting for the copies of Form 10 licenses issued for the import of insulin products by the Respondent from the year 2010 till that date, along with copies of documents furnished by the respondent-importer for obtaining approvals of labels for the products specified in the said letter. In response, that the DCGI per its letter dated 11.07.2017 furnished copy of Form 10 licenses along with the copy of application issued to the respondent for insulin products wherein it was indicated that the products imported were mono-component insulin. Strangely, however, all the above opinions/communications appear to be disregarded in the SCN itself.

16. In the expert opinion issued by the IISC, the following is the excerpt of the same – *"all the insulin being dealt by Novo Nordisk India Pvt. Ltd. are r-DNA technology based and the purity was tested by using highly sensitive mass spectroscopy method at Department of biological sciences, IISC under my supervision which re-confirms the purity; thereby insulin products listed below are mono-component in nature"*. Further, in the article of Dr. V. Mohan which

is also relied upon by the respondent, the observation of the said Dr. V. Mohan are "*....human insulin was shown to be indistinguishable from porcine insulin of comparable purity...*". Based on numerous studies, he has concluded that there were no differences in ability to transport glucose between recombinant human insulin and porcine insulin and neither insulin is less reactive than the other insulin with antibiotics.

17. During the adjudication proceedings, it is a fact borne on record that the Commissioner independently requested the Indian Institute of Technology, Chennai vide letter dated 29.11.2019 to examine whether human insulins and insulin analogue of biosynthetic origin could be referred to as 'mono-component insulin', in response to which the IIT through Shri N Manoj, Department of Biotechnology, per mail dated 05.12.2019 opined that "Biphasic Isophane Insulin" sold by the respondent was a two-component mixture of biosynthetic human insulin and protamine treated biosynthetic insulin. Protamine, a small protein/peptide is present as a second component and the two components together could not therefore be called as mono-component mixture. With the above opinion in hand, the AA countered the opinion of Dr. V. Mohan vide his letter dated 09.12.2019. The clarification issued by Dr. V. Mohan to his above article, while confirming that the opinion dated 25.12.2002 was issued by him (Page No. 61, para 80, OIO), clarified that: –

"mixture of biosynthetic human/analogue insulin and protamine can be treated as monocomponent

insulin and insulin analogues manufactured through the recombinant DNA technology are "Monocomponent Insulin."

Dr. V. Mohan's opinion confirmed that mixture of biosynthetic human/analogue insulin and protamine could be treated as monocomponent insulin and insulin analogues manufactured through the recombinant DNA technology are monocomponent insulin.

18. In the adjudication, the commissioner after considering various documents/evidences/experts' opinion made available/placed on record, has found as under: –

"6. From the above facts, it appears that the Term "Mono-component" is a misnomer for the Bio-synthesized Human Insulins (in single form /in combination) as well as Insulin Analogues (in Single form and Mixture). It appeared that the importer deliberately prefixed the term "Mono-component" to the Description of the goods in the import documents and also got the word "Mono-component" printed at some place on retail packing of the product, in understanding with their Parent Company, in order to avail duty exemption under Customs Notification No. 12/2012-SI No 148(A) List 4 Sl. No 71."

19. At this juncture, we find it relevant to refer to the order of **MJ Pharmaceuticals** (*supra*) relied upon by respondent. The coordinate bench has held that Monocomponent insulin in Serial 84 of Part A of schedule to the Notification 208/81 would include insulin in any form. Relevant extract is reproduced below: -

"The words used in the heading of schedule are 'life saving drugs and medicines.' We think it is erroneous to conclude that merely from the heading of the said schedule only finished medicaments are exempted in the list and not goods out of which these medicaments could be made. Heading itself is misleading. The list includes many goods which are obviously not drugs or medicaments at all – for example 'immunoassay kit for blood fibrinogen degradation product for direct estimation for diagnostic test in D.I.C.'- Entry 57, 'cesium tubes'-Entry 150, 'Elisa diagnostic tests'-Entry 155. These are neither drugs nor medicines but diagnostic chemicals. Even among the medicaments the list contains number of goods without specifying their form- Cyclosporine (Entry 137); Diphtheria anti-toxin serum (Entry 149); Lopamido (Entry 134); Pilacaprone (Entry 138); Bovine albumin (Entry 154); Flutamide (Entry 184) etc., are all examples of this. Therefore, Monocomponent insulin specified in Serial 84 would include insulin in any form. There was no basis for denial of exemption contained in Notification 208/80."

[Emphasis added by us]

20.1 It is also very useful to consider the other arguments advanced by the respondent namely that the interpretation of Notification must be made keeping in mind the technological development and that the DCGI being the authority on the subject matter, their opinion cannot be disregarded. It is judicially well settled that where the experts have clarified that the imported item is the result of an advancement in technology in the manufacture of a particular product, the improvement does not take away the item from the ambit of the description given in the exemption notification. Hence the development of Monocomponent insulin from yeast through the process of r-DNA technology and of "Insulin Analogues" which has resulted in ensuring a selectively increased action of regulating blood sugar levels in the human body would not exclude them from being covered under the head "Monocomponent insulins" as listed in the exemption notification. In

this regard, reliance has been placed on the decisions of the CESTAT in ***Collector of Customs, New Delhi versus Ethnor Ltd. 1996 (86) E.L.T. 558 (Tribunal)*** which was later on affirmed by the Apex court in ***Collector v. Ethnor Ltd. [1997 (96) E.L.T. A157 (S.C)]***.

20.2 Further, new process of production of highly purified human insulin directly from the DNA of the human insulin gene cannot be stifled by an over-rigid interpretation ignoring the development of r-DNA technology. In this regard, reliance is placed on the decision of the Hon'ble Supreme Court ***Collector of Customs & Central Ex. v. Lekhraj Jessumal & Sons [1996 (82) E.L.T. 162 (S.C.)***], wherein it was observed that static interpretation cannot be given ignoring the advancement of technology. Relevant extract is reproduced below: -

*"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.***

20.3 Also, in the case of ***Hewlett Packard India Sales Pvt. Ltd. Versus Commissioner of Customs (Import), Nhava Sheva [(2023) 2 Centax 236 (S.C.)]*** Apex Court highlighted the impact of technological advancement on law. Relevant portion of the decision is reproduced below: -

*"21. **Furthermore, we must also use this opportunity to highlight the impact of technological advancement on law. It's a matter of fact that at the time when the relevant entries of the First Schedule came into effect, weight was definitely an important criterion for deciding whether any ADPs was 'portable'. Scientific progress has greatly reduced the weight associated with high performance in the context of ADPs.** It is not surprising that the advent of LED technology, faster microchips, etc. has made it possible for mobile phones to have performance specifications which merely a decade ago was possible only on high end laptops. We must therefore be cognizant of such an impact on the consumer's understanding of any good or trade."*

[Emphasis added by us]

21. The binding ratio of the above judgements clearly is that interpretation is required to be drawn keeping in mind the development in the technology.

22. Insofar as the non-consideration of the opinion of the authority, namely DGCI is concerned, reliance on the decision of Bombay chemicals, Pvt Ltd. is very apt. Hon'ble High Court of Bombay in the case of ***Bombay Chemicals Pvt. Ltd. v. Appellate Collector of Customs [1975 (6) TMI 16]***, has held as follows: -

*"What is urged on behalf of the Respondents is that on a proper interpretation of Exh. A to the Petition, the exemption is only granted where such chemicals are used for what is termed in the affidavit in reply dated 10th July 1970 as 'chemical intermediates' for manufacture of insecticides, pesticides and fungicides, and that the certificates issued by the Director General of Technical Development, Government of India, are not conclusive. This argument on behalf of the Respondents is only to be sought to be rejected for the simple reason that the exemption Notification dated 1st March 1968, being Exh. A to the Petition, itself mentions the conditions upon which exemption is to be granted. **Those conditions are mandatory and it cannot therefore be argued that when the mandatory conditions are complied with they are not to be conclusive in so far as the granting of exemption is concerned or that the Customs authorities have a right to sit in Judgment over the certificates which are obligatory to be furnished to the Customs authorities for the purpose of obtaining the exemption. In my view, the Customs authorities have no jurisdiction whatsoever to sit in appeal over the certificates which have been granted by the Director General of Technical Development or the Director of Industries, as the case may be and come to their own conclusion. These certificates are binding and conclusive upon the Customs authorities save and except, when it can be contended that these certificates have been obtained by fraud or under some mistake.** In the present case, it is not the case of the Respondents that the certificates which have been obtained by the Petitioners and copies of which are annexed to the Petition and to the affidavit in rejoinder, have been obtained by fraud or under a mistake.*

23. On an overall appreciation of facts and the binding ratio in the decisions referred to supra insofar as the interpretation of notification is concerned, mono component insulin would undoubtedly cover the insulin developed using r-DNA

technology, which position has been accepted by the authority, namely DCGI, who is the Statutory authority approving the license for sale of insulin.

24. We also find that the Commissioner has also not laboured to even consider the common Parlance test and the observations of the original Authority at para 7 of the Order-in-Original which are quite relevant, with which we agree with in *toto*.

25. There was also an argument with regard to the issue raised in respect of insulin analogues. We find it would be pertinent to refer to HSN Explanatory Notes to chapter 29. It is specifically stated that an analogue has a structure akin to the parent compound and are not considered derivatives. The relevant portion reads as below:

"Analogue refers to chemicals having a close structural relationship to the parent compound, but which are not considered to be derivatives. It includes compounds which have a structural resemblance to the natural compounds, but which have one or more atoms in the structure replaced by others".

26. Sub-heading Note 1 of the HSN commentary volume 2, Sixth Edition (2017) for chapter 29 also states that the derivatives of a chemical compound are to be classified in the residuary entry. The relevant note reads thus: -

"Within any on heading of this Chapter derivatives of a chemical compound (or group of chemical compounds) are to be classified in the same subheading as that compound (or group of compounds) provided that they are not more specifically covered by any other subheading and that there is no residual subheading named "other in the series of subheadings concerned".

27. The aforesaid view is in sync with the opinion expressed by Dr V Mohan who had indicated that a mixture of biosynthetic human/analogue insulin and protamine could be treated as Mono component insulin. Therefore, Insulin would be classified under CTH 30043110. On the same basis, Insulin analogues would fall under CTH 30043110 as well.

28. In view of the above discussion and upon consideration of the evidences placed on record, including the opinion expressed by the experts in the field, we are of the view that the classification of the impugned goods as 'mono-component insulin' is a content based classification and certainly not a source based classification, as in the case of porcine and bovine insulin and hence, insulin manufactured using r-DNA technology would qualify as a mono component insulin, and hence, was entitled to the benefit of exemption under the Notification/s in question.

29. In the result, the impugned order does not call for any interference and hence, the Department's Appeal stands dismissed.

(Order pronounced in the open court on 22.11.2024)

Sd/-
(M. AJIT KUMAR)
MEMBER (TECHNICAL)

Sd/-
(P. DINESHA)
MEMBER (JUDICIAL)

MK