

प्रधान आयुक्त का कार्यालय, सीमा शुल्क, अहमदाबाद

"सीमा शुल्क भवन", पहली मंजिल, पुराने हाई कोर्ट के सामने, नवरंगपुरा, अहमदाबाद - 380 009.

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PREAMBLE

A	फाइलसंख्या File No.	:	GEN/ADJ/ADC/1563/2023-TECH
B	कारणबताओनोटिससंख्या-तारीख/ Show Cause Notice No. and Date	:	GEN/ADJ/ADC/1563/2023-TECH DATED 07.08.2023
C	मूलआदेशसंख्या Order-In-Original No.	:	01/ADC/VM/TECH/2024-25
D	आदेशतिथि Date of Order-In-Original	:	01.07.2024
E	जारीकरनेकीतारीख Date of Issue	:	01.07.2024
F	द्वारापारित Passed By	:	Vishal Malani, Additional Commissioner, Customs, Ahmedabad.
G	आयातक का नाम और पता/ Name and Address of Importer / Noticee	:	M/s. Mylan Laboratories Limited, Zydus-Pharmaceutical SEZ, Plot No. 20 and 21, Village - Matoda, Sanand, Ahmedabad, Gujarat, 382213.
(1)	यह प्रति व्यक्ति के उपयोग के लिए निशुल्क प्रदान किया जाता है जिन्हें यह जारी किया जाता है।		
(2)	कोई भी व्यक्ति इस आदेश से स्वयं को असंतुष्ट पाता है तो वह इस आदेश के विरुद्ध अपील इस आदेश की प्राप्ति की तारीख के 60 दिनों के भीतर आयुक्त का कार्यालय, सीमा शुल्क (अपील), 4वीं मंजिल, हुडको भवन, ईश्वर भुवन मार्ग, नवरंगपुरा, अहमदाबाद - 380014 में कर सकता है।		
(3)	अपील के साथ केवल पाँच रुपये (5.00 रुपये) के न्यायालय शुल्क टिकट लगा होना चाहिए, और इसके साथ होना चाहिए:		
(i)	अपील की एक प्रति और		
(ii)	इस प्रति या इस आदेश की कोई प्रति के साथ केवल पाँच रुपये (5.00 रुपये) के न्यायालय शुल्क टिकट लगा होना चाहिए।		
(4)	इस आदेश के विरुद्ध अपील करने के इच्छुक व्यक्तिको) %7.5अधिकतम करोड़ 10 रुपयेशुल्क (जमा करना होगा, जहां शुल्क या ड्यूटी और जुर्माना विवाद में हैं, याजुर्माना, जहां इस तरहकी दंड विवाद में है और अपील के साथ इस तरह के भुगतान का प्रमाण पेशकरने में असफल रहने पर, सीमाशुल्क अधिनियम, के 1962 धारा के 129 प्रावधानों का अनुपालन न करने के लिए अपीलको खारिज कर दिया जाएगा।		

Sub: Adjudication of Show Cause Notice No. GEN/ADJ/COMM/1563/2023-TECH dated 07.08.2023 issued by the Commissioner (in-situ), Customs, Ahmedabad to M/s.Mylan Laboratories Limited. Pharma SEZ, Plot No.20 and 21, Matoda Village, Matoda, Sanand, Ahmedabad, Gujarat, India-382213 & Other.

Brief facts of the Case:

M/s. Mylan Laboratories Limited (hereinafter referred to as "MLL-SEZ", for the sake of brevity) (GSTIN: 24AADCM3491M2Z6), Zydus-Pharmaceutical SEZ, Plot No. 20 and 21, Village - Matoda, Sanand, Ahmedabad, Gujarat, 382213, is engaged in the manufacturing of Oral Contraceptive Pills falling under Chapter 30 of the First Schedule to the Customs Tariff Act, 1975, as per LOA No. KASEZ/P&C/6/44/07-08/4232 dated 19.07.2007, as amended from time to time.

2. M/s. MLL-SEZ filed DTA Sale-Bills of Entry for Home Consumption on behalf of Domestic Tariff Area buyer unit namely M/s. PSI India Private Limited (hereinafter referred to as "PIPL-DTA", for the sake of brevity) (GSTIN 09AAICP4297R1ZB), E-119, Transport Nagar, Kanpur Road, Lucknow, Uttar Pradesh - 226012, in terms of proviso to Sub- Rule 1 of Rule 48 of the Special Economic Zones Rules, 2006 (herein after referred to as the "SEZ Rules, 2006") and Rule 47(1) of the SEZ Rules, 2006 read with Section 30 of the Special Economic Zones Act, 2006, for clearing goods.

3. Customs Receipt Audit (CRA) Objection Details (Audit Observation reference : 1, OBS-649386) :- During the check of records of the office of the Specified Officer, Zydus Pharma SEZ, Ahmedabad for the period from 2018-19 to 2021-22, it was noticed from the data analysis of DTA sales that M/s MLL-SEZ had cleared the manufactured goods "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" in DTA by classifying under Tariff Item 3006 60 10 and paid NIL duty. Literature of the said product furnished and available online suggest that "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" is used for the treatment of 'Androgen-dependent diseases in women, such as Acne, Alopecia and mild forms of Hirsutism'. Further, it is stated in FAQ available on "<https://www.1mg.com/drugs/frewil-2mg-0.035mg-tablet-323190?wpsrc=Google+Organic+Search>" that "Frewil 2mg / 0.035 mg Tablet" is a combination of two hormonal medicines : Cyproterone and Ethinylestradiol. It treats PCOS symptoms (Polycystic Ovary Syndrome) such as Acne, excessive hair growth (Hirsutism) and irregular periods. Cyproterone works by blocking the overproduction of androgens (male hormones) in the ovaries, thereby reducing unwanted hair growth and acne. Ethinylestradiol enhances the effect of Cyproterone by reducing the amount of androgens in the blood circulation." Thus, it is clear from above facts that "Cyproterone and Ethinylestradiol Tablet (2 mg/0.035 mg) (Frewil)" is primarily used for treatment of 'Androgen-dependent diseases in women, such as acne, alopecia and mild forms of hirsutism' and should have been classified under CTH 30049099 and applicable duty @ 24.32% (BCD-10% and IGST-12%) should have been paid on it. Therefore, incorrect classification of goods has resulted in non levy of duty of Rs.12,17,625/-.

3.1 The SEZ Office, vide letter dated 13.04.2023, referred the matter to M/s. MLL-SEZ and sought their reply on the observations made by the CRA. M/s. MLL-SEZ, vide letter dated 20.04.2023 (received by the SEZ Office on 24.04.2023) submitted "literature based scientific justification / dosage regimen recommendation" for the fixed dose combination drug dosage regimen Cyproterone and Ethinylestradiol Tablets – 2 mg. / 0.035 mg (Brand Name – Frewil). In the said letter, it has *inter-alia* been submitted as follows –

"Both active drugs which are considered for fixed dosage formulation are classified as hormones and as per the fixed dosage product information study, Frewil 2 mg /0.035 mg Tablet is a combination of two hormonal active drug medicines used to treat symptoms of polycystic ovary syndrome (PCOS) such as

excessive hair growth (hirsutism), acne, and irregular periods which also has contraceptive properties.

3.2 M/s. MLL-SEZ, vide letter dated 20.04.2023 has also submitted copy of 'Fixed Dose Combinations Approved by DCG (I) since 1961 till 12th July, 2018'. The product under reference has been described at Sr. No. 383 of the said list as follows :-

#	Name of Drug	Indication	Date of Approval
383	Combipack of 28 Tablets of Cyproterone Acetate 2 mg. and 7 Tablets of Ethinyl Estradiol 0.035 mg.	Androgen dependent disease in women such as acne, alopecia & mild of hirsution	20.02.2003

4. The relevant chapter heading / Sub-heading mentioned in Audit Observation are as under:

3004	<i>Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale</i>
3004 90	- Other
3004 90 99	---- Other
3006	<i>Pharmaceutical goods specified in Note 4 to this Chapter</i>
3006 60	- Chemical contraceptive preparations based on hormones, on other products of heading 2937 or on spermicides :
3006 60 10	--- Based on hormones

5. It appears that Sub-Heading 3006 60 applies to 'Chemical contraceptive preparations based on hormones, on other products of heading 2937 or on spermicides'. However, M/s. MLL-SEZ has *inter-alia* submitted vide letter dated 20.4.2023 that both active drugs which are considered for fixed dosage formulation are classified as hormones and as per the fixed dosage product information study, Frewil 2 mg /0.035 mg Tablet is a combination of two hormonal active drug medicines used to treat symptoms of polycystic ovary syndrome (PCOS) such as excessive hair growth (hirsutism), acne, and irregular periods which also has contraceptive properties. Thus, from the submissions made by M/s. MLL-SEZ as well as the literature, it appears that Cyproterone works by blocking the overproduction of androgens (male hormones) in the ovaries, thereby reducing unwanted hair growth and acne as well as Ethinyl Estradiol enhances the effect of Cyproterone by reducing the amount of androgens in the blood circulation. Thus, it is clear from above facts that Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" is primarily used for treatment of 'Androgen dependent diseases in women, such as acne, alopecia and mild forms of hirsutism'.

5.1 It is also apparent from Sr. No. 383 of the list of 'Fixed Dose Combinations Approved by DCG (I) since 1961 till 12th July, 2018" that the product is indicated for "Androgen dependent disease in women such as acne, alopecia & mild of hirsution". The

content and/or dosage of product is not indicated to be used as "Contraceptive". M/s. MLL-SEZ has also submitted in its letter dated 20.04.2023 that Frewil is not primarily registered in India as a contraceptive.

5.2 It, therefore, appears that the product "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" is not classifiable under Tariff Item 3006 60 10 of the First Schedule to the Customs Tariff Act, 1975.

6. As per the General Rules for Interpretation of the Harmonized System, the classification of goods in the Nomenclature shall be governed by certain principles. As per Rule 1 of the General Rules for the Interpretation *'the titles of Sections, Chapters and sub-chapters are provided for ease of reference only; for legal purposes, classification shall be determined according to the terms of the headings and any relative Section or Chapter Notes and, provided such headings or Notes do not otherwise require, according to the following provisions.'*

6.1 Chapter Heading 3004 of the First Schedule to the Customs Tariff Act, 1975 covers Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale.

6.2 The product "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" is indicated for use in Androgen dependent disease in women such as acne, alopecia & mild of hirsution. Thus, the said product is medicament consisting of mixed products for therapeutic or prophylactic use. Further, the said product is put up in measured doses or in forms or packings for retail sale.

6.3 In view of the aforesaid position, "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" is classified under Chapter 30 of the CTH system, which is for pharmaceutical products. The subject goods appear to be appropriately classifiable under Customs Tariff Heading 3004, as the Chapter Heading 3004 of Chapter-30 of the First Schedule to the Customs Tariff Act, 1975 categorically specifies "Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packing for retail sale". The Chapter heading 3004 of the First Schedule to the Customs Tariff Act, 1975 covers mixed or unmixed products for therapeutic or prophylactic use, put up in measured doses for retail sale. The product under reference is a medicine consisting of mix product of cyproterone and ethinylestradiol in measured dose i.e. 2mg/0.035mg, for therapeutic or prophylactic use. Therefore, it is classifiable under subheading 3004. The subject goods is further classifiable under subheading 300490 for other medicaments. As the product is not specified in any other subheading, the same is appropriately classifiable under Tariff Item 3004 90 99 of the First Schedule to the Customs Tariff Act, 1975.

7. The Customs Duty structure for the aforesaid chapter heading / Sub-heading has been as under:

DTA Clearance CTH wise Duty Rate		
CTH	30066010	30049099
Effective BCD Rate	0 %	10%

Social Welfare Surcharge	0 %	10%
IGST	0 %	12%
TOTAL DUTY RATE	0 %	24.32%

7.1 From the above duty structure, it emerges that, the import items, when classified under Tariff Item – 30066010 as “Contraceptive” attract Nil Duty (Basic Customs Duty (BCD) @ 0% of the Assessable value, Social Welfare Surcharge @ 10 % of BCD & IGST rate @ 0%). However, if the import item is classified under Customs Tariff Heading (CTH) 30049099, it attracts BCD @ 10% of Assessable Value along with Social welfare Surcharge @10 % of BCD and IGST @ 12.00%. Thus, the item classified under CTH 30049099 attracts total duty @ 24.32%.

7.2 In view of the above, it appears that ‘Cyproterone and Ethinylestradiol Tablets 2 mg / 0.035 mg Frewil-35’ cleared into DTA by M/s MLL-SEZ was not correctly classified and thus appropriate duty @ 24.32% of the assessable value has not been paid on clearance of the said goods. It is evident from the submission of M/s. MLL-SEZ that the said product in dosage form is also not registered in India as contraceptive by Drug Controller General of India (DCGI). Though their submission indicates the dual use of the dosage form / combination of the said goods, the same is registered for the treatment of “androgen dependent diseases in women such as Acne, Alopecia and mild of hirsution” but not as contraceptive. It, therefore appears that the said product is appropriately classifiable under Tariff Item 30049099 of the First Schedule to the Customs Tariff Act, 1975 and attracts total duty @ 24.32%.

8. RELEVANT LEGAL PROVISIONS

I. Special Economic Zones Act, 2005

Section 30. Domestic clearance by Units. - Subject to the conditions specified in the rules made by the Central Government in this behalf,-

- (a) any goods removed from a Special Economic Zone to the Domestic Tariff Area shall be chargeable to duties of customs including anti-dumping, countervailing and safeguard duties under the Customs Tariff Act, 1975 (51 of 1975), where applicable, as leviable on such goods when imported; and
- (b) the rate of duty and tariff valuation, if any, applicable to goods removed from a Special Economic Zone shall be at the rate and tariff valuation in force as on the date of such removal, and where such date is not ascertainable, on the date of payment of duty.

II. SEZ Rules, 2006:

RULE 47. Sales in Domestic Tariff Area — (1) A Unit may sell goods and services including rejects or wastes or scraps or remnants or broken diamonds or by-products arising during the manufacturing process or in connection therewith, in the Domestic Tariff Area on payment of customs duties under section 30, subject to the following conditions, namely, -

- (a)
- (b)
- (2)
- (3)

(4) *Valuation and assessment of the goods cleared into Domestic Tariff Area shall be made in accordance with Customs Act and rules made thereunder.*

(5) *Refund, Demand, Adjudication, Review and Appeal with regard to matters relating to authorized operations under Special Economic Zones Act, 2005, transactions, and goods and services related thereto, shall be made by the Jurisdictional Customs and Central Excise Authorities in accordance with the relevant provisions contained in the Customs Act, 1962, the Central Excise Act, 1944, and the Finance Act, 1994 and the rules made thereunder or the notifications issued there under.*

RULE 48. *Procedure for Sale in Domestic Tariff Area. – (1) Domestic Tariff Area buyer shall file Bill of Entry for home consumption giving therein complete description of the goods and/or services namely, make and model number and serial number and specification along with invoice and packing list with the Authorised Officers :*

Provided that the Bill of Entry for home consumption may also be filed by a Unit on the basis of authorization from a Domestic Tariff Area buyer.

(2) *Valuation of the goods cleared into Domestic Tariff Area shall be determined in accordance with provisions of Customs Act and rules made thereunder as applicable to goods when imported into India.*

(3) *.....*

III. Customs Act, 1962

SECTION 28. *Recovery of duties not levied or not paid or short-levied or short-paid or erroneously refunded. –*

(1) to (3) *.....*

(4) *Where any duty has not been levied or not paid or has been short-levied or short-paid or erroneously refunded, or interest payable has not been paid, part-paid or erroneously refunded, by reason of:-*

(a) collusion; or

(b) any wilful mis-statement; or

(c) suppression of facts,

by the importer or the exporter or the agent or employee of the importer or exporter, the proper officer shall, within five years from the relevant date, serve notice on the person chargeable with duty or interest which has not been so levied or not paid or which has been so short-levied or short-paid or to whom the refund has erroneously been made, requiring him to show cause why he should not pay the amount specified in the notice.

(5) to (11) *.....*

Explanation 1. *- For the purposes of this section, "relevant date" means,-*

(a) in a case where duty is not levied or not paid or short-levied or short-paid, or interest is not charged, the date on which the proper officer makes an order for the clearance of goods;

(b) in a case where duty is provisionally assessed under section 18, the date of adjustment of duty after the final assessment thereof or re-assessment, as the case may be;

(c) in a case where duty or interest has been erroneously refunded, the date of refund;

(d) in any other case, the date of payment of duty or interest.

Explanation 2 to 4. *.....*

SECTION 28AA. Interest on delayed payment of duty. –

(1) Notwithstanding anything contained in any judgment, decree, order or direction of any court, Appellate Tribunal or any authority or in any other provision of this Act or the rules made thereunder, the person, who is liable to pay duty in accordance with the provisions of section 28, shall, in addition to such duty, be liable to pay interest, if any, at the rate fixed under sub-section (2), whether such payment is made voluntarily or after determination of the duty under that section.

(2) Interest at such rate not below ten per cent. and not exceeding thirty-six per cent. per annum, as the Central Government may, by notification in the Official Gazette, fix, shall be paid by the person liable to pay duty in terms of section 28 and such interest shall be calculated from the first day of the month succeeding the month in which the duty ought to have been paid or from the date of such erroneous refund, as the case may be, up to the date of payment of such duty.

(3) -----

SECTION 111– Confiscation of improperly imported goods, etc.- The following goods brought from a place outside India shall be liable to confiscation :-

(a) to (l)

(m) any goods which do not correspond in respect of value or in any other particular with the entry made under this Act or in the case of baggage with the declaration made under Section 77 in respect thereof, or in the case of goods under transshipment, with the declaration for transshipment referred to in the proviso to sub-section (1) of Section 54.

(n) to (q) ...

SECTION 112. Penalty for improper importation of goods, etc. – Any person –

(a) who, in relation to any goods, does or omits to do any act which act or omission would render such goods liable to confiscation under section 111, or abets the doing or omission of such an act, or

(b) who acquires possession of or is in any way concerned in carrying, removing, depositing, harboring, keeping, concealing, selling or purchasing or in any other manner dealing with any goods which he knows or has reason to believe are liable to confiscation under Section 111,

shall be liable, -

(i) in the case of goods in respect of which any prohibition is in force under this Act or any other law for the time being in force, to a penalty not exceeding the value of the goods or five thousand rupees, whichever is the greater;

(ii) in the case of dutiable goods, other than prohibited goods, subject to the provisions of section 114A, to a penalty not exceeding ten per cent. of the duty sought to be evaded or five thousand rupees, whichever is higher:

Provided that where such duty as determined under sub-section (8) of section 28 and the interest payable thereon under section 28AA is paid within thirty days from the date of communication of the order of the proper officer determining such duty, the amount of penalty liable to be paid by such person under this section shall be twenty-five per cent. of the penalty so determined;

(ii) in the case of goods in respect of which the value stated in the entry made under this Act or in the case of baggage, in the declaration made under section 77 (in either case hereafter in this section referred to as the declared value) is higher than the value thereof, to a penalty not exceeding the

difference between the declared value and the value thereof or five thousand rupees, whichever is the greater;

- (iv) in the case of goods falling both under clauses (i) and (iii), to a penalty not exceeding the value of the goods or the difference between the declared value and the value thereof or five thousand rupees, whichever is the highest;*
- (v) in the case of goods falling both under clauses (ii) and (iii), to a penalty not exceeding the duty sought to be evaded on such goods or the difference between the declared value and the value thereof or five thousand rupees, whichever is the highest.*

SECTION 114A - Penalty for short levy or non levy of duty in certain cases.-

Where the duty has not been levied or has been short-levied or the interest has not been charged or paid or has been part paid or the duty or interest has been erroneously refunded by reason of collusion or any wilful mis-statement or suppression of facts, the person who is liable to pay the duty or interest, as the case may be, as determined under sub-section (8) of section 28 shall also be liable to pay a penalty equal to the duty or interest so determined :

Provided,.....

9. Vide Finance Act, 2011 w.e.f. 08.04.2011 "Self Assessment" has been introduced under the Customs Act, 1962. Section 17 of the said Act provides for self-assessment of duty on import and export goods by the importer or exporter himself by filing a bill of entry or shipping bill as the case may be, in the electronic form, as per Section 46 or 50 respectively. Thus, under self-assessment, it is the importer or exporter who will ensure that he declares the correct classification, applicable rate of duty, value, and benefit or exemption notification claimed, if any, in respect of the imported / exported goods while presenting Bill of Entry or Shipping Bill. In the present case, it is evident that the actual facts about the product were only known to M/s. MLL-SEZ and M/s. PIPL-DTA and aforesaid facts came to light only subsequent to the in-depth investigation during the course of Audit by the CRA - Audit Party. Therefore, it appears that M/s MLL-SEZ has deliberately contravened the above said provisions with an intention to evade payment of Customs Duty leviable and payable on the DTA Sale from SEZ to DTA of "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" as specified in the first schedule under Section 2 of Customs Tariff Act, 1975. It appears that M/s MLL-SEZ had contravened the provisions of Section 46(4A) of the Customs Act, 1962 in as much as M/s. MLL-SEZ, while filing DTA Sale - Bill of Entry had to ensure the accuracy and completeness of the information given therein for assessment of Customs duty, whereas in the instant case, M/s. MLL-SEZ had failed to fulfil this legal obligation in respect of DTA Sale of "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil) " for its correct and accurate classification.

10. In view of the above discussion and evidences, it appears that M/s. MLL-SEZ, while clearing the subject goods into DTA, had entered into a conspiracy to evade payment of Customs duty by intentionally wrongly classifying the goods with an intent to evade payment of Customs duties on the DTA clearance of subject goods from their SEZ unit. In fact, these DTA Sale - Bills of entry were filed by M/s. MLL-SEZ on behalf of M/s. PIPL-DTA in terms of proviso to Rule 48(1) of the SEZ Rules, 2006, therefore, it was expected from M/s. MLL-SEZ to classify the product under proper HSN Code. Hence, it appears that M/s. MLL-SEZ knowingly and deliberately indulged in misclassification of the said goods and thereby contravened the provisions of Rule 47(4) of the SEZ Rules, 2006 read with Section 46(4) of the Customs Act, 1962 in as much as they had filed DTA sale Bills of

Entry with incorrect information in regard to classification of the said goods cleared by them by wrongly classifying the said goods in duty free Tariff Item (HSN code), sold by them to M/s. PIPL-DTA. These were cleared on the strength of invoices submitted along with the respective DTA Sale Bills of Entry, which did not reflect the actual HSN code of the goods on which duty of Customs was payable. The usage of the said product as well as the fact that the said product is not registered with the Drug Controller General of India (DCGI) to be used as contraceptives was never informed by M/s. MLL-SEZ. The complete details of the product for its proper classification were thus suppressed from the Department with an intent to evade payment of duty. M/s. MLL-SEZ has wilfully suppressed the actual HSN code. M/s. MLL-SEZ has engaged in mis-declaration & suppression of facts with an intent to evade payment of Customs duties on the clearance of subject goods into DTA from their SEZ unit. It further appears that M/s. MLL-SEZ has not correctly classified the product under actual HSN code of the subject goods as required in terms of Rule 1 of the General Rules for Interpretation read with section 46(4) the Customs Act, 1962. Thus, the provisions of extended period for demand of duty as contained in Section 28 (4) of the Customs Act, 1962 appears applicable in the instant case.

10.1 Further, it appears that M/s. MLL-SEZ was well aware of the duty structure under CTH 30049099 and CTH 30066010. However, they wrongly claimed classification under CTH 30066010 with a *mala-fide* intention of evading Customs duty. M/s. MLL-SEZ, with the intent to evade payment of Customs Duty had consciously and intentionally mis-declared the goods under CTH 30066010 in the DTA Sale Bills of Entry by suppressing the fact that, 'Cyproterone and Ethinylestradiol Tablets (2 mg / 0.035 mg) (Frewil)' is neither used primarily as contraceptive nor registered in India as contraceptive, but it is a mixed product for therapeutic use in measured dose for treating the symptoms / diseases of androgen sensitivity. The above wilful suppression and wilful mis-statement was done by them with the intention to evade payment of Customs Duty leviable and payable on DTA sale of "Cyproterone and Ethinylestradiol Tablets (2 mg/ 0.035 mg) (Frewil) " as specified in the first Schedule under Section 2 of the Customs Tariff Act, 1975. Hence, it appears that the importer had knowingly involved themselves in the suppression of the material facts and also indulged in mis-statement of facts.

10.2 From the facts and evidences discussed in the foregoing paras, it appears that the goods 'Cyproterone and Ethinylestradiol Tablets (2 mg/ 0.035 mg) (Frewil)' cleared from SEZ into DTA by M/s. MLL-SEZ should have been appropriately classified under CTH 30049099 and accordingly should have been assessed to higher rate of Customs duty as applicable for CTH 30049099 during relevant period.

10.3 The differential amount of Customs duty of **Rs.12,17,625/-**, as worked out in **Annexure-A** to the Show Cause Notice under adjudication is required to be recovered from M/s. MLL-SEZ under the provisions of Section 28(4) of the Customs Act, 1962 read with Section 30 of the SEZ Act, 2005, along with interest at the prescribed rate on Customs duty evaded in terms of Section 28AA of Customs Act, 1962.

10.4 From the above, it appears that the MLL-SEZ while clearing the goods in DTA to M/s. PIPL had knowingly and deliberately indulged in suppression of facts in respect of their imported product and had wilfully misrepresented / mis-stated the material facts regarding the goods cleared in DTA (imported in DTA from SEZ) in the declarations made in the import documents including Check lists presented for DTA Sale- Bills of Entry presented before the Customs at the time of DTA Sale – Bills of Entry for assessment and clearance, with an intent to evade payment of applicable Customs Duty. Therefore, extended period of limitation, as provided under Section 28(4) of the Customs Act, 1962

appears applicable in the present case. The differential Customs duty amounting to **Rs.12,17,625/-** in respect of the DTA Sale-BOE cleared at Pharmez (INZIP6), as indicated in Annexure-A to the SCN, is liable to be recovered from M/s. MLL-SEZ under Section 28(4) of the Customs Act, 1962 along with applicable interest under Section 28 AA *ibid*.

11. The said act of mis-declaration and suppression of facts on the part of M/s. MLL-SEZ, as discussed in the foregoing paras constitute an offence of the nature described in Section 111(m) of the Customs Act, 1962 and thereby render the said goods *viz.* "Cyproterone and Ethinylestradiol Tablets (2 mg / 0.035 mg) (Frewil)" cleared in DTA to M/s. PIPL-DTA, valued at Rs. 50,06,680/-, liable for confiscation under **Section 111(m) of the Customs Act, 1962**. However, as the said goods are not available for confiscation, hence the fine in lieu of confiscation is liable to be imposed.

11.1 M/s. MLL-SEZ had made DTA clearance of 'Cyproterone and Ethinylestradiol Tablets (2 mg / 0.035 mg) (Frewil)' valued at **Rs.50,06,680/-**, by deliberately suppressing the material fact and by way of wilful mis-statement in contravention of the provisions of Section 46 (4) of the Customs Act, 1962, by classifying the same under CTH 30066010. In terms of Section 46(4) of the Customs Act, 1962, the importer was required to make a declaration as to truth of the contents of the DTA sale-Bills of Entry submitted for assessment of Customs duty, which in the instant case, M/s MLL-SEZ had failed to fulfil in respect of DTA clearance of 'Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil) cleared through PHARMEZ (INZIP6). For these contraventions and violations, the goods fall under the ambit of 'smuggled goods' within the meaning of Section 2(39) of the Customs Act, 1962, and are liable for confiscation under the provisions of Section 111(m) of the Customs Act, 1962.

12. The aforesaid acts of non-payment of duty of **Rs.12,17,625/-** on the part of M/s. MLL-SEZ by suppression of facts and wilful mis-statement appears to have rendered them liable for penalty under Section 114A of the Customs Act, 1962, inasmuch as the duty amounting to **Rs.12,17,625/-** was not levied by reason of wilful mis-statement and suppression of facts with a *mala fide* intention of evasion of Customs duty. All the aforesaid acts of omission and commission on the part of M/s MLL-SEZ have rendered the subject DTA clearance of goods totally valued at Rs. 50,06,680/- (as detailed in Annexure-A of this SCN) liable for confiscation under Section 111(m) of the Customs Act, 1962. M/s MLL-SEZ are therefore liable to penalty under Section 112(a) of the Customs Act, 1962. In the present case, it is also evident that the actual facts were only known to the M/s. MLL-SEZ and M/s. PIPL-DTA about the product, its usage and its actual classification.

12.1 The aforesaid act of mis-declaration and suppression of fact and evasion of duty of **Rs.12,17,625/-** on the part of M/s. MLL-SEZ constitute an offence of the nature described under Section 112 (a) of the Customs Act, 1962 and thereby rendering them liable for penalty under Section 112(a) of the Customs Act, 1962.

13. It further appears that M/s. PIPL-DTA, while clearing subject goods from SEZ into DTA had entered into conspiracy in collusion with M/s. MLL-SEZ in the said acts of mis-declaration of correct classification of the subject goods and suppression of facts on the part of M/s. MLL-SEZ as discussed in the foregoing paras. M/s. PIPL-DTA purchased the subject goods, acquired possession and / or dealt with the subject goods which they knew or had reason to believe were liable to confiscation under Section 111 (m) of the Customs Act, 1962 and thereby rendered themselves liable to penalty as provided under Section 112(b) of the Customs Act, 1962.

14. Accordingly, a Show Cause Notice dated 07.08.2023 was issued from GEN/ADJ/ADC/1563/2023-TECH to:

(A) M/s. Mylan Laboratories Limited (GSTIN: 24AADCM3491M2Z6), located at Zydus-Pharma SEZ, Plot No. 20 and 21, Matoda Village, Matoda, Sanand, Ahmedabad, Gujarat, 382213, calling upon to show cause to the Commissioner (*in-situ*) / Additional Commissioner of Customs, Ahmedabad, as to why:-

- (i) The goods i.e. "Cyproterone and Ethinylestradiol Tablets (2 mg / 0.035 mg) (Frewil)" should not be held appropriately classifiable under Customs Tariff Head 30049099 of the first Schedule to the Customs Tariff Act, 1975;
- (ii) The goods i.e. "Cyproterone and Ethinylestradiol Tablets (2 mg / 0.035 mg) (Frewil)" cleared in DTA to M/s. PSI India Private Limited, totally valued at **Rs.50,06,680/- (Rupees Fifty Lakh Six Thousand Six Hundred Eighty Only)** as detailed in **Annexure-A to the SCN** should not be confiscated under Section 111(m) of the Customs Act, 1962. However, as the said goods are not available for confiscation, why redemption fine in lieu of confiscation should not be imposed under Section 125 of the Customs Act, 1962;
- (iii) Differential Customs duty amounting to **Rs.12,17,625/- (Rupees Twelve Lakh Seventeen Thousand Six Hundred Twenty Five only)**, as detailed in **Annexure-A to SCN**, evaded by them on the said goods, should not be demanded and recovered from them under Section 28(4) of the Customs Act, 1962 read with Section 30 of the Special Economic Zones Act, 2005, by invoking extended period of limitation;
- (iv) Interest should not be recovered from them on the said differential Customs duty as mentioned at (iii) above, under Section 28AA of the Customs Act, 1962;
- (v) Penalty should not be imposed on them under Sections 114A and / or 112 (a) of the Customs Act, 1962.

(B) M/s. PSI India Private Limited (GSTIN 09AAICP4297R1ZB) located at E-119, Transport Nagar, Kanpur road, Lucknow, Uttarpradesh, India-226012, calling upon to show cause to the Commissioner (*in-situ*) / Additional Commissioner of Customs, Ahmedabad, as to why penalty should not be imposed on them under Section 112(b) of the Customs Act, 1962.

DEFENCE REPLY /WRITTEN SUBMISSION:

15. Written submissions to the Show Cause Notice / defence reply submitted by the noticees is summarised herein as under:

15.1 M/s.Mylan Laboratories Limited vide letter dated dated 04.09.2023 submitted that prior to issuance of Show Cause Notice and on the basis of SEZ Customs Letter dated 13.07.2023 and CRA letter CRA/LAR-22-/2022-23 dated 02.06.2023, they had paid "Under Protest" customs duties of Rs.12,17,628/- alongwith interest of Rs.5,45,485/- on 24.07.2023 under Challan No.SEZ/ZIPL/094/22-23 dated 24.07.2023. Copy of TR-6 Challan submitted;

15.1.1 M/s.Mylan Laboratories Limited vide letter dated dated 17.11.2023 inter-alia submitted that:

- they are a unit operating in the Zydus Pharmaceutical Special Economic Zone, Sanand, Ahmedabad and are engaged in the manufacture of Oral Contraceptive Pills falling under Chapter 30 of the First Schedule to the Customs Tariff Act as per

LOA No KASEZ/P&C/6/44/07-08/ Dated 19-07-2007 as amended from time to time;

- They had sold certain products to PSI India Private Limited and appropriate DTA Sale Bills of Entry have been filed in terms of the Customs / SEZ provisions and the subject goods have been cleared under Chapter Sub Heading 3006 60 10 with Nil Customs Duty;
- With regard to the classification of goods that was contested during the CRA, they have submitted their response on April 20, 2023, wherein we have mentioned the following:
"We are herewith submitting " literature based scientific justification/ dosage regimen recommendation" for the fixed dose combination drug dosage regimen Cyproterone Acetate and Ethinylestradiol Tablets -2 mg/0.035 mg (Brand name - Frewil) "
- Both active drugs which are considered for fixed dosage formulation are classified as hormones and as per the fixed dosage product information study, Frewil 2mg/0.035mg Tablet is a combination of two hormonal active drug medicines used to treat symptoms of polycystic ovary syndrome (PCOS) such as excessive hair growth (hirsutism), acne, and irregular periods which also has contraceptive properties;
- Though Frewil is not primarily registered in India as a contraceptive, it is to be taken regularly in order to achieve the therapeutic efficacy and required contraceptive protection since previously used contraception used by the woman if any, should be discontinued which is also specified in the product literature guidance. The dose of Frewil is similar to the usual regimen of most of the combined oral contraceptives and thus, the same administration rules are to be considered;
- the drug indication may vary as per the therapy recommended by the Doctor/Pharmacist country to country. The said finished product has dual indications and the prescribed dose is recommended for treatment of PCOS as well as an oral contraceptive. They had clarified that their finished product is falling under HSN Code 3006 60, not in 3004. As per Chapter 30, Heading 3006 includes "Chemical contraceptive preparations based on hormones on other products of heading 2937 or on spermicides-. However, detailed scientific justification regarding active drugs and finished product are evaluated based on the approved indications and based on the classification the product should be executed at an approved -sex hormone facility" according to the manufacturing/export license issued by the Gujarat State FDA considering the contraceptive indication of the product;
- Despite the above submission, the SCN has merely concluded that Cyproterone works by blocking the overproduction of androgens (male hormones) in the ovaries, thereby reducing the unwanted hair growth and acne as well as Ethinyl Estradiol enhances the effect of Cyproterone by reducing the amount of androgens in the blood circulation. Thus, it was concluded that the tablets are meant for treatment of androgen diseases in women and not used as contraceptives;
- This conclusion of the SCN is not acceptable by them specifically in view of the scientific literature submitted by them along with the said letter of April 20, 2023 wherein it was specifically mentioned as under:
"This FDC does have contraceptive properties. CPA+EE FDC is as effective in preventing pregnancy as combined oral contraceptive pills and is widely used as such in other European countries. It is to be taken regularly in order to achieve the therapeutic efficacy and the required

contraceptive Protection. Since previously used contraception used by the woman, if any, should be discontinued which is also specified in the product literature guidance. The dose regimen of Frewil is similar to the usual regimen of most of the combined oral contraceptives. Thus, the same administration rules must be considered."

- it is amply clear from the above mentioned literature Frewil can be used as contraceptive and hence, the claim of the Department that the subject medicine is only meant for the treatment of androgen dependent diseases in Women is not appropriate;
- the Department has not given cognizance to any of the abovementioned information and concluded that the subject goods are not oral contraceptives and issued the subject SCN;
- they have also made submissions while making the payment of the disputed amount of duty under protest, wherein we have mentioned the following:

"...as per the approval status as designated by the DCC, I in the product approval list only as a principle indication for the patient in India Cyproterone acetate & Ethinylestradiol Tablets 2mg/ 0.035mg is used for indication_ "Androgen dependent disease such as acne, alopecia & mild of hirsutism" but it can be recommended as an Oral Contraceptive by the physician/medical doctors as the product is clinically proven for another treatment as an Oral Contraceptive. It is however a fact as evidence there are many finished product manufacturers / importers in India who are commercializing this fixed dose combination product under approved indication but also claiming therapeutic use of captioned drug product in "contraceptive Protection". Few examples of such manufacturers are Bayer Zydus Pharma PM Ltd. Diane 35 tablets : Cyproterone Acetate I.P. and Ethinylestradiol I.P. Tablets 2mg/ 0.035mg; DKT India Ltd. [Cypokare 2mg/0.035mg Tablets]; Taj Generics [Cyproterone Acetate 2mg and Ethinyl Estradiol 0.035mg Tablets USP TajPharma]; Macleods Pharmaceuticals Pvt Ltd [Elesaa Tablets _ Cyproterone (2mg) + Ethinyl Estradiol (0.035mg)]; Rainbow Human Care Pvt Ltd, Solun H.P. I Ethitake-35- Cyproterone Acetate 2mg + Ethinyl Estradiol 0.035mg Tablets]; CIPLA [Ginette 35 TAB- Cyproterone Acetate 2mg + Ethinyl Estradiol 0.035mg Tablets] . PILs' Literatures for the products commercialized in India are enclosed as Annexure I for your immediate reference (Enclosed as Annexure B) and consideration for use of this drug product as an Oral Contraceptive. However, we would once again like to brief Your goodself that we do supply/export this drug product in many overseas countries and every country has considered this drug product for both indications- - Treatment of moderate to severe acne related to androgen-sensitivity (with or without seborrhoea) and/or hirsutism in women of reproductive age and also as hormonal contraceptive, it must not be used in combination with other hormonal contraceptive-

- they have already presented Clinical supporting documents in their earlier submitted Scientific justification for drug regime/ Indication. It is already captured in many worldwide literatures as this combination product has dual indication and therapeutic use. There are many other overseas countries which consider this drug product for treatment of symptoms of polycystic ovary syndrome (PCOS) such as excessive hair growth (hirsutism), acne, irregular periods **and also has contraceptive properties;**
- This product is well prescribed worldwide to patients for both indications. Many physicians in India also prescribe this medicine as Oral Contraceptive for women;

- they are submitting literatures from other overseas countries and also the summarized comparison of overseas brands PILs with indications, dosage and usage as Annexure 2. (enclosed Annexure-B);
- in view of the submissions made above, they are of the view that the classification adopted by them is correct and therefore, there cannot be any change in the classification of the goods adopted by them and consequentially no duty liability on the clearance of the products to the DTA arises in the subject case;
- in view of the submissions made above, since the classification of goods adopted by them is as per the Customs Tariff, then is no violation of any principles done by them and hence, the goods cannot be confiscated and in the absence of any violations done by them that result in imposition of any confiscation of goods, the question of imposition of redemption fine would not arise;
- at the outset it is submitted that the imposition of penalty is not sustainable as the demand itself is not maintainable in light of submissions made above. It is well settled that penalty is not leviable when demand itself is not maintainable. Hence, there is no question of imposition of penalty in the present case;
- penalty under Section 112(a) is imposed when the person in relation to any goods does any act or omits to do any act or omission so as to render the goods imported liable to confiscation. Therefore, it can be stated that penalty under Section 112 of the Customs Act is linked to confiscation under Section 111 of the Customs Act i.e. where the goods are liable to confiscation under Section 111, only then penalty can be imposed under Section 112 *ibid*. As has been appropriately demonstrated in the submissions, there arises no case for confiscation of the goods under sections 111(m) of the Customs Act. Hence there is also no cue for invoking Section 112 to impose penalty on the Appellant;
- On perusal of the Section 114A of the Customs Act 1962, it is clear that penalty under this Section is only imposable where the person has done any of the acts with mens rea. In the present case, they were under the bona fide belief that the classification adopted by them for the products was correct. It is submitted that in terms of various decisions of the Supreme Court and various other High Courts and Tribunals, penalty cannot be imposed on the assessee in absence of mens rea on part of the assessee. They have relied upon judgment of the Hon'ble Supreme Court in the case of Hindustan Steel Ltd. 1978 (2) E.L. Z 1159 (SC) has held that no penalty should be imposed for technical or venial breach of legal provisions or where the breach flows from the bona-fide belief that the offender is not liable to act in the manner prescribed by the statute. Also relied upon judgment in the case of Kismat Cleaning Agency Vs. Commissioner of Customs (ACC and import), 2016 (344) ELT 413 (Tri-Mumbai).
- in view of the foregoing submissions, it is respectfully prayed that the proceedings initiate in the above show cause notice may kindly be dropped

15.2 M/s. PSI India Private Limited vide letter dated 17.11.2023 inter-alia submitted that:

- it is alleged by the department authorities that the literature of the said product (as available online) suggests that "Cyproterone" and "Ethinylestradiol" tablets (2 mg/0.035 mg) Frewil is used for the treatment of androgen dependent disease in women, such as acne, alopecia and mild forms of hirsutism. It is further alleged under the show cause notice that basis the online literature, the disputed products treat PCIS symptoms (i.e. Polycystic Ovary Syndrome) such as acne, excessive hair growth (hirsutism) and irregular periods. On the said analogy, the show cause notice has arrived at the preliminary conclusion that "Cyproterone" and "Ethinylestradiol" tablets (2 mg/0.035 mg) Frewil is primarily used for treatment of

'Androgen dependent diseases in women such as acne, alopecia and mild forms of hirsutism and should have been classified under CTH 30049099 and applicable duty @ 24.32% (BCD – 10% plus IGST – 12%) should have been payable thereon. In view thereof, the incorrect classification adopted on the part of MLL SEZ has resulted in non-levy of duty of Rs. 12,17,625/-;

- it is further alleged that the Noticee, while clearing the subject goods from SEZ into DTA had entered into conspiracy in collusion with MLL SEZ in the said acts of mis-declaration of correct classification of the subject goods and suppression of facts on the part of MLL SEZ as discussed in the show cause notice. Thus, the show cause notice has raised the allegation that since the Noticee purchased the subject goods, acquired possession and/ or dealt with the subject goods which they knew or had reasons to believe were liable to confiscation under section 111 (m) of the Customs Act, 1962 and thereby rendered themselves liable to penalty under section 112(b) of the Customs Act. Accordingly, the Noticee has been called upon to clarify why penalty should not be imposed upon them under section 112(b) of the Customs Act;
- At the outset, the Noticee denies the allegation contained under the show cause notice as incorrect and unsustainable on the following grounds which are without prejudice to one another;
- The Noticee has executed "Partnership Agreement" on non-exclusive basis, inter alia, with respect to distribution of disputed product in the territory of Uttar Pradesh and Rajasthan. The said "Partnership Agreement" is nothing but a distribution agreement and hence, does not involve any joint operations between the parties. As such, the allegation towards conspiracy in collusion with MLL SEZ is denied and disputed;
- At the outset, it is the submission of the Noticee that it has executed "Partnership Agreement" with MLL SEZ (hereinafter "Agreement") dated 24.12.2020, on non-exclusive basis, inter-alia, with respect to importation, stocking, promotion, marketing, sale and distribution of disputed product in the territory of Uttar Pradesh and Rajasthan. That it is further submitted that although the Agreement has been termed as "Partnership Agreement", the same is, in essence, an agreement with respect to distribution of "Products" in the territories of Uttar Pradesh and Rajasthan. Since the parties to the Agreement i.e. the Noticee and MLL SEZ are operating on principal-to principal basis, the said agreement as such, is not liable to be view as constituting partnership amongst them. The relevant clause from the Agreement evidencing the relationship between the parties is reproduced hereunder;
- since there is no partnership between the parties to the Agreement and the fact that the said parties are operating on principal-to principal basis, it is incorrectly alleged under the show cause notice that the Noticee has entered into conspiracy in collusion with MLL SEZ in the said act of mis-declaration of correct classification of the subject goods. In the facts of the present case, the allegation with respect to conspiracy on the part of the Noticee is based on assumption and presumption as the show cause notice has failed to cite even a single instance or positive act that would evidence the act of conspiracy on the part of the Noticee with MLL SEZ, with respect to mis-declaration of correct classification of the subject goods, with the intent to evade payment of tax. Thus, the aforesaid allegation in the show cause notice is vague and therefore, cannot be sustained;
- since the disputed "product" in question confirmed to the requirement of being used as a contraceptive medicine, the Noticee placed requisite orders with MLL SEZ, as a bonafide purchaser. It is further pertinent to mention that as a bonafide commercial transaction, the Noticee only negotiated the per unit price of the

product along with the quantity to be purchased/ lifted and other applicable terms and conditions with respect to;

- it is the submission of the Noticee that as per general practice of commercial negotiation prevalent across the industry, what is generally negotiated is the price of the product, quantity, place of delivery, mode of delivery, and time of delivery. Therefore, commercially speaking, one does not generally inquire about the HSN code or CTH under which the product would be determined. Also, once the price and quantity are negotiated, the buyer is obligated to pay the price of the goods along with tax applicable thereon, depending upon the terms of purchase. Therefore, the agreement with respect to HSN code or CTH is of no consequence when the goods purchased by a buyer are meant for further sale. Accordingly, the Noticee had no say/ involvement in the classification being adopted by MLL SEZ (i.e., seller), so as to allege conspiracy on the part of the Noticee;
- No conspiracy/ collusion on the part of Noticee with the intent to evade payment of tax as Noticee was entitled to pass on tax component, if any, upon the retailer/ stockist. Thus, the situation is revenue neutral, hence, allegation of conspiracy is legally incorrect and unsustainable;
- Reliance in support of the above is placed on the judgment in the case of Hindustan Lever Ltd. vs. Collector of Customs, Bombay 1996 (83) E.L.T. 520 (Tribunal), wherein the Hon'ble tribunal set aside the order with respect to confiscation of goods as well as imposition of penalty under section 112 of the Customs Act.;
- The allegation against the Noticee with respect to conspiracy is totally vague. No positive evidence with respect to alleged abatement or collusion or any active involvement on the part of the Noticee has been brought forward under the show cause notice. Thus, the allegations levelled against the Noticee are liable to be dropped;
- reliance on the judgment of Supreme Court in the case of Shri Ram vs. State of Uttar Pradesh AIR 1975 SC 175, wherein it is clearly held by the Hon'ble court that in order to constitute abetment, the abettor must be shown to have intentionally aided to commission of the crime. in the present case, there is no iota of evidence brought out for invoking provisions of Section 112(b) of the Customs Act. Thus, the allegations levelled against the Noticee are incorrect and the proposal to impose penalty under section 112(b) of the Customs Act is liable to be dropped;
- relies on the judgment of the Hon'ble Supreme Court judgement in the case of G.T.C. Industries Ltd. vs. Collector 1997 (94) E.L.T. 9 (S.C.), wherein the Court held that each show cause notice must be limited to the case that is made out therein;
- Reliance placed on Customs, Mumbai vs. M. Vasi - 2003 (155) E.L.T. (312);
- Section 111(m) of the Customs Act is not attracted, since the Noticee has acted bonafidely. Abetment of doing or omission to do an act renders goods liable for confiscation on the part of the Noticee - if the show cause notice does not allege any abetment of offence imposition of penalty on the ground of abetment is invalid - Sections 111(m) read with 112(b) of the Customs Act;
- the show cause notice has also failed to cite the relevant sub- clause of section 112(b) of the Customs Act under which the penalty is proposed. Since different quantum of penalties are provided under the various sub-clauses of section 112(b) for various types of offences, the uncertainty of proposal towards quantum of penalty is vague. Thus, for this reason also the show cause notice against the Noticee is vague and suffers from infirmity and hence, cannot be sustained;
- Reliance is placed on the judgment in the case of Dass Photo Electronics Vs. Collector of Customs, New Delhi 1987 (30) E.L.T. 988 (Tribunal). Reliance is also

place on the judgment in the case of Commissioner of Customs, Kandla Vs. Essar Oil Ltd. 2004 (172) E.L.T. 433 (SC);

- no statement of the Directors of Noticee company were ever recorded during the investigation process, so as to allege conspiracy on the part of the Noticee. In absence of any positive act being brought forward by the department authorities in the show cause notice, such allegations cannot be sustained and consequently, no penalty can be imposed under section 112(b) of the Customs Act upon the Noticee basis such assumption;
- The disputed issue, at best, involves a classification dispute and does not involve any degree of conspiracy on the part of the Noticee, so as to attract penalty;
- In view of the foregoing submissions, it is prayed that the allegations raised in the show cause notice with respect to exercise of conspiracy on the part of the Noticee in collusion with MLL SEZ, in the act of alleged misdeclaration of classification of goods is factually incorrect and hence, is liable to be dropped forthwith in favour of the Noticee.

PERSONAL HEARING:

16. Personal Hearing was fixed on 14.05.2024 which was adjourned to 07.06.2024. The Personal Hearing in this case has been held on 07.06.2024 wherein Shri Ravikumar Yanamandra, Head of Indirect Tax and Customs, India for noticee – M/s. Mylan Laboratories Limited appeared for PH and reiterated the submission as detailed in written submission dated 17.11.2023. He also submitted that their product 'Frewil' is also used as contraceptive pill therefore classification under 3006 60 10 is correct. Shri Vishal Kumar, Advocate for noticee – M/s. PSI India Private Limited appeared for PH and reiterated the submission as detailed in written submission dated 17.11.2023. He also submitted that they purchased the product 'Frewil' as contraceptive pill, which is anyways NIL rated, hence, they are not in connivance with M/s.Mylan Laboratory regarding any Classification of the product to evade duty. They have furnished following documents:

- Six Case laws reported as- 2009(248)ELT 228(Tri.-Del); 2007(219)ELT 256(Tri.-Bang); 1999(111)ELT 143(Tri.); 1996(83)ELT 520(Tribunal); 1978(2)ELT (J159) (SC); 2007(208)ELT 299(Tri.-Kolkata);
- Audit report for the period of 2021-22 and 2022-23;
- Memorandum of Association of PSI India Pvt. Ltd. and
- SC judgment in the case of Bihar State Electricity Board Vs M/s.Green Rubber Industries & Ors.

DISCUSSIONS AND FINDINGS:

17. I have carefully gone through the Show Cause Notice dated 07.08.2023, written submissions made by the Noticees, submission as well as the arguments and discussions made by the noticee during the course of personal hearing. I find that in the present case, mainly the issue before me is

(A)

- (i) Whether the goods i.e. "Cyproterone and Ethinylestradiol Tablets (2 mg / 0.035 mg) (Frewil)', cleared in DTA by M/s.Mylan Laboratories Limited (SEZ Unit) be held appropriately classifiable under Customs Tariff Head 30049099 of the first Schedule to the Customs Tariff Act, 1975;
- (ii) Whether the goods i.e. "Cyproterone and Ethinylestradiol Tablets (2 mg / 0.035 mg) (Frewil)' cleared in DTA to M/s. PSI India Private Limited, totally valued at Rs.50,06,680/-(Rupees Fifty Lakh Six Thousand Six Hundred Eighty Only) as detailed in Annexure-A to the SCN be confiscated under Section

111(m) of the Customs Act, 1962. However, as the said goods are not available for confiscation, why redemption fine in lieu of confiscation should not be imposed under Section 125 of the Customs Act, 1962;

- (iii) Whether the differential Customs duty amounting to **Rs.12,17,625/- (Rupees Twelve Lakh Seventeen Thousand Six Hundred Twenty Five only)**, as detailed in **Annexure-A** to SCN, evaded by M/s.Mylan Laboratories Limited (SEZ Unit) on the said goods, be demanded and recovered from them under Section 28(4) of the Customs Act, 1962 read with Section 30 of the Special Economic Zones Act, 2005, by invoking extended period of limitation;
- (iv) Whether interest be recovered from them on the said differential Customs duty as mentioned at (iii) above, under Section 28AA of the Customs Act, 1962;
- (v) Whether penalty be imposed on them under Sections 114A and / or 112 (a) of the Customs Act, 1962.

(B) Whether penalty be imposed on M/s. PSI India Private Limited under Section 112(b) of the Customs Act, 1962.

(C) Appropriation of duty and interest already paid by the noticee under protest.

18. I find that M/s. Mylan Laboratories Limited (MLL-SEZ), Zydus-Pharmaceutical SEZ, Sanand, Ahmedabad, is engaged in the manufacturing of Contraceptive Pills, falling under Chapter 30 of the First Schedule to the Customs Tariff Act, 1975, as per LOA No. KASEZ/P&C/6/44/07-08/4232 dated 19.07.2007, as amended from time to time. They had manufacture "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" tablets and cleared in Domestic Tariff Area (DTA) sales to M/s. PSI India Private Limited (PIPL-DTA), Lucknow by way of filing of Bills of Entry for Home Consumption on behalf the DTA buyer in terms of proviso to Sub- Rule 1 of Rule 48 of the Special Economic Zones Rules, 2006 and Rule 47(1) of the SEZ Rules, 2006, classifying under Tariff Item 3006 60 10 and at NIL rate of duty.

19. I find that the Literature of the said product furnished by the noticee during the courser of Customs Receipt Audit (CRA) and available online suggested that "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" is used for the treatment of 'Androgen-dependent diseases in women, such as Acne, Alopecia and mild forms of Hirsutism'. Further, it is stated in FAQ available on "<https://www.lmg.com/drugs/frewil-2mg-0.035mg-tablet-323190?wpsrc=Google+Organic+Search>" that "Frewil 2mg / 0.035 mg Tablet" is a combination of two hormonal medicines: Cyproterone and Ethinylestradiol. It treats PCOS symptoms (Polycystic Ovary Syndrome) such as Acne, excessive hair growth (Hirsutism) and irregular periods. Cyproterone works by blocking the overproduction of androgens (male hormones) in the ovaries, thereby reducing unwanted hair growth and acne. Ethinylestradiol enhances the effect of Cyproterone by reducing the amount of androgens in the blood circulation."

20. I find that the M/s. MLL-SEZ, has submitted "literature based scientific justification / dosage regimen recommendation" for the fixed dose combination drug dosage regimen Cyproterone and Ethinylestradiol Tablets – 2 mg. / 0.035 mg (Brand Name – Frewil), which indicates that both the active drugs which are considered for fixed dosage formulation are classified as hormones and as per the fixed dosage product information study, Frewil 2 mg /0.035 mg Tablet is a combination of two hormonal active drug medicines used to treat symptoms of polycystic ovary syndrome (PCOS) such as excessive hair growth (hirsutism), acne, and irregular periods which also has contraceptive properties.

21. I find that in their written submission and during Personal Hearing they had inter-alia contested that the Frewil 2mg/0.035mg Tablet is a combination of two hormonal active drug medicines used to treat symptoms of polycystic ovary syndrome (PCOS) such as excessive hair growth (hirsutism), acne, and irregular periods which also has contraceptive properties. Though, Frewil is not primarily registered in India as a contraceptive, it is to be taken regularly in order to achieve the therapeutic efficacy and required contraceptive protection. Frewil can be used as contraceptive. It is clearly emerged from their submission that the Frewil is not primarily registered in India as a contraceptive and the is registered for the treatment of "androgen dependent diseases in women such as Acne, Alopecia and mild of hirsution".

22. I find that the interpretation of the Tariff schedule is strictly governed by six "Interpretative Rules" incorporated in First Schedule itself and As per Rule 1 of the General Rules for the Interpretation *'the titles of Sections, Chapters and sub-chapters are provided for ease of reference only; for legal purposes, classification shall be determined according to the terms of the headings and any relative Section or Chapter Notes and, provided such headings or Notes do not otherwise require, according to the following provisions.'*

23. The classification of an item is generally decided in view of how it is described in commercial parlance. Goods should be classified according to their popular meaning or as they are understood in their commercial sense. *It is a settled position in law that while interpreting the entry for the purpose of taxation recourse should not be made to scientific meaning of the terms or expressions used but to their popular meaning, that is to say, the meaning attached to them, by those dealing in them. It is known as Common Parlance Test. Various judicial authorities including the Hon'ble Apex Court time & again in various cases has uniformly held that any product which is made available for purchase to the general public, must be classified in such a manner that is commonly understood and perceived since it takes precedence over the scientific and technical terminology used to describe the goods. It has been held that for classification of goods under statutes for taxation of commercial supplies thereof, the primary test is their identity in the market, or in other words, in common parlance.*

24. It is undisputed that the product "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" is not primarily registered in India as a contraceptive. The said product in dosage form is also not registered in India as contraceptive by Drug Controller General of India (DCGI). The content and/or dosage of product is not indicated to be used as "Contraceptive". It is primarily used for treatment of 'Androgen dependent diseases in women, such as acne, alopecia and mild forms of hirsutism'. The plea taken by the notice for their contentions is that the product also has contraceptive properties. From the above, I find that it is clearly established that:

- (i) the identity of the product "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" in market is not as contraceptive;
- (ii) they have not patented the product as contraceptive;
- (iii) the product doe not have popular meaning to be sold as contraceptive as the meaning attached with usage of a product and the product is primerily not used as contraceptive;
- (iv) the product for use as contraceptive can be a subsidiary curative value.

25. I find that for the purpose of classification of a product, it is settled position of law that primary usage of that product should be seen. The Hon'ble Supreme Court in the case of Alpine Industries Vs. CCE, reported at 2003(152)ELT 16 (SC) held that 'Lip save' (a

cream used to protect lips in high altitude areas by military personnel) will be classified as 'skin care cream' as per commercial parlance, and not as medicament, even if it has subsidiary curative value.

26. The Hon'ble Supreme Court in the case of Atul Glass Industries Ltd. *Versus* Collector of Central Excise, reported at 1986 (25) E.L.T. 473 (S.C.) held that:

".....It is a matter of common experience that the identity of an article is associated with its primary function. It is only logical that it should be so. When a consumer buys an article, he buys it because it performs a specific function for him. There is a mental association in the mind of the consumer between the article and the need it supplies in his life. It is the functional character of the article which identifies it in his mind....."

The above findings of the Hon'ble apex court has been followed in series of cases and same view has been taken in the cases including in the case of CCE Vs. Fusebase Eltoto Ltd., reported at 1994 (67) ELT 30 (SC); in the case of Real Optical Co. Vs. Appellate CC, reported at 2001 (129) ELT 7(SC).

27. The Hon'ble Supreme Court in the case of Commissioner of Central Excise *Versus* Wockhardt Life Sciences Ltd., reported at 2012 (277) E.L.T. 299 (S.C.), has *inter alia*, laid down the principles for the classification of goods observing that:

"30. There is no fixed test for classification of a taxable commodity. This is probably the reason why the 'common parlance test' or the commercial usage test' are the most common [see *A. Nagaraju Bors. v. State of A.P.*, 1994 Supp (3) SCC 122 = 1994 (72) E.L.T. 801 (S.C.)]. Whether a particular article will fall within a particular Tariff heading or not has to be decided on the bases of the tangible material or evidence to determine how such an article is understood in 'common parlance' or in 'commercial world' or in 'trade circle' or in its popular sense meaning. It is they who are concerned with it and it is the sense in which they understand it that constitutes the definitive index of the legislative intension, when the statute was enacted [see *D.C.M. v. State of Rajasthan*, 1980 (4) SCC 71 = 1980 (6) E.L.T. 383 (S.C.)]. One of the essential factors for determining whether a product falls Chapter 30 or not is whether the product is understood as a pharmaceutical product in common parlance [see *C.C.E. v. Shree Baidyanath Ayurved*, 2009 (12) SCC 413 = 2009 (237) E.L.T. 225 (S.C.)]; *Commissioner of Central Excise, Delhi v. Ishaan Research Lab (P) Ltd.* - 2008 (13) SCC 349 = 2008 (230) E.L.T. 7 (S.C.)]. Further, the quantity of medicament used in a particular product will also not be a relevant factor for, normally, the extent of use of medicinal ingredients is very low because a larger use may be harmful for the human body. [*Puma Ayurvedic Herbal (P) Ltd. v. C.C.E., Nagpur* - 2006 (3) SCC 266 = 2006 (196) E.L.T. 3 (S.C.)]; *State of Goa v. Colfoax Laboratories* - 2004 (9) SCC 83 = 2003 (158) E.L.T. 18 (S.C.)]; *B.P.L. Pharmaceuticals v. C.C.E.* - 1995 Supp (3) SCC 1 = 1995 (77) E.L.T. 485 (S.C.)].

31. However, there cannot be a static parameter for the correct classification of a commodity. This Court in the case of *Indian Aluminium Cables Ltd. v. Union of India*, 1985 (3) SCC 284 = 1985 (21) E.L.T. 3 (S.C.), has culled out this principle in the following words :

"13. To sum up the true position, the process of manufacture of a product and the end use to which it is put, cannot necessarily be determinative of the classification of that product under a fiscal schedule like the Central Excise Tariff. What is more important is whether the broad description of the article fits in with the expression used in the Tariff...."

32. Moreover, the functional utility and predominant or primary usage of the commodity which is being classified must be taken into account, apart from the

understanding in common parlance [see *O.K. Play (India) Ltd. v. C.C.E.*, - 2005 (2) SCC 460 = 2005 (180) E.L.T. 300 (S.C.); *Alpine Industries v. C.C.E.*, New Delhi - 1995 Supp. (3) SCC 1; *Sujanil Chemo Industries v. C.C.E. & Customs* - 2005 (4) SCC 189 = 2005 (181) E.L.T. 206 (S.C.); *ICPA Health Products (P) Ltd. v. C.C.E.* - 2004 (4) SCC 481 = 2004 (167) E.L.T. 20 (S.C.); *Puma Ayurvedic Herbal (supra)*; *Ishaan Research Lab (P) Ltd. (supra)*; *C.C.E. v. Uni Products India Ltd.*, 2009 (9) SCC 295 = 2009 (241) E.L.T. 491 (S.C.)].

33. A commodity cannot be classified in a residuary entry, in the presence of a specific entry, even if such specific entry requires the product to be understood in the technical sense [see *Akbar Badrudin v. Collector of Customs*, 1990 (2) SCC 203 = 1990 (47) E.L.T. 161 (S.C.); *Commissioner of Customs v. G.C. Jain*, 2011 (12) SCC 713 = 2011 (269) E.L.T. 307 (S.C.)]. A residuary entry can be taken refuge of only in the absence of a specific entry; that is to say, the latter will always prevail over the former [see *C.C.E. v. Jayant Oil Mills*, 1989 (3) SCC 343 = 1989 (40) E.L.T. 287 (S.C.); *H.P.L. Chemicals v. C.C.E.*, 2006 (5) SCC 208 = 2006 (197) E.L.T. 324 (S.C.); *Western India Plywoods v. Collector of Customs*, 2005 (12) SCC 731 = 2005 (188) E.L.T. 365 (S.C.); *C.C.E. v. Carrier Aircon*, 2006 (5) SCC 596 = 2006 (199) E.L.T. 577 (S.C.)]. In *C.C.E. v. Carrier Aircon*, 2006 (5) SCC 596 = 2006 (199) E.L.T. 577 (S.C.), this Court held :

"14....There are a number of factors which have to be taken into consideration for determining the classification of a product. For the purposes of classification, the relevant factors inter alia are statutory fiscal entry, the basis character, function and use of the goods. When a commodity fall within a tariff entry by virtue of the purpose for which it is put to (sic. produced), the end use to which the product is put to, cannot determine the classification of that product."

34. In our view, as we have already stated, the combined factor that requires to be taken note of for the purpose of the classification of the goods are the composition, the product literature, the label, the character of the product and the user to which the product is put. However, the miniscule quantity of the prophylactic ingredient is not a relevant factor....."

28. In view of the findings enumerated in the foregoing para in the judicial pronouncements, I find that the product "Cyproterone and Ehinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" cannot be classified as contraceptive as the product is not used as contraceptive predominantly.

29. I find that "Cyproterone and Ehinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" is classified under Chapter 30 of the CTH system, which is for pharmaceutical products. I find that the heading and sub-heading of classification whereunder the product is classified and cleared by M/s. MLL-SEZ as under:

3006	Pharmaceutical goods specified in Note 4 to this Chapter
3006 60	- Chemical contraceptive preparations based on hormones, on other products of heading 2937 or on spermicides :
3006 60 10	--- Based on hormones

30. From the above description of sub-heading it is apparent that the product meant as contraceptive and known as contraceptive is liable for classification under the heading 3006, which is not in the present case in as much as the product under dispute i.e. "Cyproterone and Ehinylestradiol Tablets (2 mg/0.035 mg) (Frewil)", is neither primarily used as contraceptive nor it is being prescribed as Contraceptive pill. The product

"Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" is indicated for use in Androgen dependent disease in women such as acne, alopecia & mild of hirsution. Thus, the said product is medicament consisting of mixed products for therapeutic or prophylactic use. Further, the said product is put up in measured doses or in forms or packings for retail sale.

31. I find from the other heading and sub-heading of classification that the most appropriate heading for classification of this product is as under:

3004	<i>Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale</i>
3004 90	- Other
3004 90 99	--- Other

32. It is evident from the submission of M/s. MLL-SEZ that the said product in dosage form is also not registered in India as contraceptive by Drug Controller General of India (DCGI). Though their submission indicates the dual use of the dosage form / combination of the said goods, the same is registered for the treatment of "androgen dependent diseases in women such as Acne, Alopecia and mild of hirsution" but not as contraceptive. Thus, it is clear from above facts that "Cyproterone and Ethinylestradiol Tablet (2 mg/0.035 mg) (Frewil)" is primarily used for treatment of 'Androgen-dependent diseases in women, such as acne, alopecia and mild forms of hirsutism' and while clearing the same into DTA by M/s MLL-SEZ it was not correctly classified resulted in non-payment of appropriate Customs duty leviable on the product. It should have been classified under CTH 30049099 and applicable duty @ 24.32% (BCD-10% and IGST-12%) should have been paid on it. Therefore, incorrect classification of goods has resulted in non-levy of duty of Rs.12,17,625/-

33. I find that Section 17 of the Customs Act, 1962 provides for self-assessment of duty on import and export goods by the importer or exporter himself by filing a bill of entry or shipping bill as the case may be, in the electronic form, as per Section 46 or 50 respectively. Thus, under self-assessment, it is the importer or exporter who will ensure that he declares the correct classification, applicable rate of duty, value, and benefit or exemption notification claimed, if any, in respect of the imported / exported goods while presenting Bill of Entry or Shipping Bill. In the present case, it is evident that the factual facts about the product were only known to M/s. MLL-SEZ and M/s. PIPL-DTA and aforesaid facts came to light only subsequent to the in-depth investigation during the course of Audit by the CRA - Audit Party. Therefore, M/s MLL-SEZ has deliberately contravened the above said provisions with an intention to evade payment of Customs Duty leviable and payable on the DTA Sale from SEZ to DTA of "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" as specified in the first schedule under Section 2 of Customs Tariff Act, 1975. M/s MLL-SEZ had contravened the provisions of Section 46(4A) of the Customs Act, 1962 in as much as M/s. MLL-SEZ, while filing DTA Sale - Bill of Entry had to ensure the accuracy and completeness of the information given therein for assessment of Customs duty, whereas in the instant case, M/s. MLL-SEZ had failed to fulfil this legal obligation in respect of DTA Sale of "Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil)" for its correct and accurate classification.

34. From the above discussion and evidences, it emerged that M/s. MLL-SEZ, while clearing the subject goods into DTA, had entered into a conspiracy to evade payment of Customs duty by intentionally wrongly classifying the goods with an intent to evade payment of Customs duties on the DTA clearance of subject goods from their SEZ unit. In fact, these DTA Sale - Bills of entry were filed by M/s. MLL-SEZ on behalf of M/s. PIPL-DTA in terms of proviso to Rule 48(1) of the SEZ Rules, 2006, therefore, it was expected from M/s. MLL-SEZ to classify the product under proper HSN Code. Hence, it appears that M/s. MLL-SEZ knowingly and deliberately indulged in misclassification of the said goods and thereby contravened the provisions of Rule 47(4) of the SEZ Rules, 2006 read with Section 46(4) of the Customs Act, 1962 in as much as they had filed DTA sale Bills of Entry with incorrect information in regard to classification of the said goods cleared by them by wrongly classifying the said goods in duty free Tariff Item (HSN code), sold by them to M/s. PIPL-DTA. These were cleared on the strength of invoices submitted along with the respective DTA Sale Bills of Entry, which did not reflect the actual HSN code of the goods on which duty of Customs was payable. The usage of the said product as well as the fact that the said product is not registered with the Drug Controller General of India (DCGI) to be used as contraceptives was never informed by M/s. MLL-SEZ. The complete details of the product for its proper classification were thus suppressed from the Department with an intent to evade payment of duty. M/s. MLL-SEZ has wilfully suppressed the actual HSN code. M/s. MLL-SEZ has engaged in mis-declaration & suppression of facts with an intent to evade payment of Customs duties on the clearance of subject goods into DTA from their SEZ unit. M/s. MLL-SEZ has not correctly classified the product under actual HSN code of the subject goods as required in terms of Rule 1 of the General Rules for Interpretation read with section 46(4) the Customs Act, 1962. Thus, the provisions of extended period for demand of duty as contained in Section 28 (4) of the Customs Act, 1962 applicable in the instant case.

35. Further, it appears that M/s. MLL-SEZ was well aware of the duty structure under CTH 30049099 and CTH 30066010. However, they wrongly claimed classification under CTH 30066010 with a *mala-fide* intention of evading Customs duty. M/s. MLL-SEZ, with the intent to evade payment of Customs Duty had consciously and intentionally mis-declared the goods under CTH 30066010 in the DTA Sale Bills of Entry by suppressing the fact that, 'Cyproterone and Ethinylestradiol Tablets (2 mg / 0.035 mg) (Frewil)' is neither used primarily as contraceptive nor registered in India as contraceptive, but it is a mixed product for therapeutic use in measured dose for treating the symptoms / diseases of androgen sensitivity. The above wilful suppression and wilful mis-statement was done by them with the intention to evade payment of Customs Duty leviable and payable on DTA sale of "Cyproterone and Ethinylestradiol Tablets (2 mg/ 0.035 mg) (Frewil)" as specified in the first Schedule under Section 2 of the Customs Tariff Act, 1975. Hence, it appears that the importer had knowingly involved themselves in the suppression of the material facts and also indulged in mis-statement of facts.

36. In view of the above, the differential amount of Customs duty of **Rs.12,17,625/-**, as worked out in Annexure-A of this Show Cause Notice is required to be recovered from M/s. MLL-SEZ under the provisions of Section 28(4) of the Customs Act, 1962 read with Section 30 of the SEZ Act, 2005, along with applicable interest in terms of Section 28AA of Customs Act, 1962.

37. The said act of mis-declaration and suppression of facts on the part of M/s. MLL-SEZ, as discussed in the foregoing paras constitute an offence of the nature described in Section 111(m) of the Customs Act, 1962 and thereby render the said goods *viz.* "Cyproterone and Ethinylestradiol Tablets (2 mg / 0.035 mg) (Frewil)" cleared in DTA to

M/s. PIPL-DTA, valued at Rs. 50,06,680/-, liable for confiscation under Section 111(m) of the Customs Act, 1962. However, as the said goods are not available for confiscation, hence the fine in lieu of confiscation is liable to be imposed.

38. M/s. MLL-SEZ had made DTA clearance of 'Cyproterone and Ethinylestradiol Tablets (2 mg / 0.035 mg) (Frewil)' valued at **Rs.50,06,680/-**, by deliberately suppressing the material fact and by way of wilful mis-statement in contravention of the provisions of Section 46 (4) of the Customs Act, 1962, by classifying the same under CTH 30066010. In terms of Section 46(4) of the Customs Act, 1962, the importer was required to make a declaration as to truth of the contents of the DTA sale-Bills of Entry submitted for assessment of Customs duty, which in the instant case, M/s MLL-SEZ had failed to fulfil in respect of DTA clearance of 'Cyproterone and Ethinylestradiol Tablets (2 mg/0.035 mg) (Frewil) cleared through PHARMEZ (INZIP6). For these contraventions and violations, the goods fall under the ambit of 'smuggled goods' within the meaning of Section 2(39) of the Customs Act, 1962, and are liable for confiscation under the provisions of Section 111(m) of the Customs Act, 1962.

39. As the impugned goods are found liable to confiscation under Section 111 (m) of the Customs Act, 1962, I find it necessary to consider as to whether redemption fine under Section 125(1) of Customs Act, 1962 can be imposed in lieu of confiscation in respect of the imported goods, which are not physically available for confiscation. Section 125 (1) of the Customs Act, 1962 reads as under:-

"125 Option to pay fine in lieu of confiscation –

(1) Whenever confiscation of any goods is authorised by this Act, the officer adjudging it may, in the case of any goods, the importation or exportation whereof is prohibited under this Act or under any other law for the being in force, and shall, in the case of any other goods, give to the owner of the goods [or, where such owner is not known, the person from whose possession or custody such goods have been seized.] an option to pay in lieu of confiscation such fine as the said officer thinks fit..."

40. I find that even in the case where goods are not physically available for confiscation, redemption fine is imposable in light of the judgment in the case of **M/s. Visteon Automotive Systems India Ltd. reported at 2018 (009) GSTL 0142 (Mad)** wherein the Hon'ble High Court of Madras has observed interalia in Para 23 as under:

.....
.....

" 23. The penalty directed against the importer under Section 112 and the fine payable under Section 125 operate in two different fields. The fine under Section 125 is in lieu of confiscation of the goods. The payment of fine followed up by payment of duty and other charges leviable, as per sub-section (2) of Section 125, fetches relief for the goods from getting confiscated. By subjecting the goods to payment of duty and other charges, the improper and irregular importation is sought to be regularised, whereas, by subjecting the goods to payment of fine under sub-section (1) of Section 125, the goods are saved from getting confiscated. Hence, the availability of the goods is not necessary for imposing the redemption fine. The opening words of Section 125, "Whenever confiscation of any goods is authorised by this Act", brings out the point clearly. The power to impose redemption fine springs from the authorisation of confiscation of goods provided for under Section 111 of the Act. When once power of authorisation for confiscation of goods gets traced to the said Section 111 of the Act, we are of the opinion that the physical availability of goods is not so much relevant. The redemption fine is in fact to avoid such consequences flowing from Section 111 only. Hence, the

payment of redemption fine saves the goods from getting confiscated. Hence, their physical availability does not have any significance for imposition of redemption fine under Section 125 of the Act. We accordingly answer question No. (iii)."

41. Hon'ble High Court of Gujarat by relying on this judgment, in the case of **Synergy Fertichem Ltd. Vs. Union of India**, reported in 2020 (33) G.S.T.L. 513 (Guj.), has held interalia as under:-

"

174. In the aforesaid context, we may refer to and rely upon a decision of the Madras High Court in the case of *M/s. Visteon Automotive Systems v. The Customs, Excise & Service Tax Appellate Tribunal*, C.M.A. No. 2857 of 2011, decided on 11th August, 2017 [2018 (9) G.S.T.L. 142 (Mad.)], wherein the following has been observed in Para-23;

"23. The penalty directed against the importer under Section 112 and the fine payable under Section 125 operate in two different fields. The fine under Section 125 is in lieu of confiscation of the goods. The payment of fine followed up by payment of duty and other charges leviable, as per sub-section (2) of Section 125, fetches relief for the goods from getting confiscated. By subjecting the goods to payment of duty and other charges, the improper and irregular importation is sought to be regularised, whereas, by subjecting the goods to payment of fine under sub-section (1) of Section 125, the goods are saved from getting confiscated. Hence, the availability of the goods is not necessary for imposing the redemption fine. The opening words of Section 125, "Whenever confiscation of any goods is authorised by this Act...", brings out the point clearly. The power to impose redemption fine springs from the authorisation of confiscation of goods provided for under Section 111 of the Act. When once power of authorisation for confiscation of goods gets traced to the said Section 111 of the Act, we are of the opinion that the physical availability of goods is not so much relevant. The redemption fine is in fact to avoid such consequences flowing from Section 111 only. Hence, the payment of redemption fine saves the goods from getting confiscated. Hence, their physical availability does not have any significance for imposition of redemption fine under Section 125 of the Act. We accordingly answer question No. (iii)."

175. We would like to follow the dictum as laid down by the Madras High Court in Para-23, referred to above."

42. The aforesaid acts of non-payment of duty of **Rs.12,17,625/-** on the part of M/s. MLL-SEZ by suppression of facts and wilful mis-statement appears to have rendered them liable for penalty under Section 114A of the Customs Act, 1962, inasmuch as the duty amounting to **Rs.12,17,625/-** was not levied by reason of wilful mis-statement and suppression of facts with a *mala fide* intention of evasion of Customs duty.

42.1 I find that after raising the objection by audit, the noticee has accepted the mistake and already paid the duty amount equal to duty payable on the goods clearly by way of misclassification alongwith interest amount calculated by them. Therefore, they are liable to pay penalty as per the provisions of the Customs Act, 1962.

42.2 I find that ingredients of Section 114A of the Customs Act, 1962 is very well covered in the present case. The show cause notice gives sufficient materials and the evidences on the basis of which the noticee is liable for penal action under Section 114A of the Customs Act, 1962. I find that as per Section 114A, imposition of penalty is mandatory

once the elements for invocation of extended period is established. Hon'ble Supreme Court in the case of *Grasim Industries Ltd. V. Collector of Customs, Bombay* [(2002) 4 SCC 297=2002 (141) E.L.T.593 (S.C.)] has followed the same principle and observed:

"Where the words are clear and there is no obscurity, and there is no ambiguity and the intention of the legislature is clearly conveyed, there is no scope for Court to take upon itself the task of amending or altering the statutory provisions." (para 10).

Therefore, the noticee is liable for penalty under Section 114A of the Customs Act, 1962.

43. I find that fifth proviso to Section 114A stipulates that "where any penalty has been levied under this section, no penalty shall be levied under Section 112 or Section 114." Hence, I refrain from imposing penalty on the importer under Section 112 (a) and 112 (b) of the Customs Act, 1962.

44. I find that the noticee M/s. MLL-SEZ, has paid "Under Protest" customs duties of Rs.12,17,628/- alongwith interest of Rs.5,45,485/- on 24.07.2023 under Challan No.SEZ/ZIPL/094/22-23 dated 24.07.2023. The Specified Officer, Pharmaez SEZ, Ahmedabad vide e-mail dated 26.06.2024 has confirmed the payment. I find that after raising the objection by audit, the noticee has accepted the mistake and paid the duty amount alongwith interest and thus, there was no good reason for the noticee to deposit the duty under protest. In view of the same the amount of duty and interest paid by the noticee under the above Challan is required to be appropriated against the duty demand proposed under the SCN under adjudication.

45. I have gone through the proposal of penalty under Section 112(b) of the Customs Act, 1962 upon M/s.PSI India Private Limited, DTA buyer of the noticee M/s.Mylan Laborat, wherein it is alleged that M/s.PSI India Private Limited had entered into conspiracy in collusion with M/s.Mylan Laboratory in the said act of mis-declaration of correct classification of the subject goods.

45.1 From the submissions made before me by the noticee M/s.PSI India Private Limited, I *inter-alia* find that M/s. MLL-SEZ and M/s. PIPL-DTA has executed "Partnership Agreement" with respect to importation, stocking, promotion, marketing, sale and distribution of disputed product in the territory of Uttar Pradesh and Rajasthan and though the agreement has been termed as "Partnership Agreement" but the agreement was with respect to distribution of "Products"; In the negotiation with the supplier they had negotiated the price of the product, quantity, place of delivery, mode of delivery, and time of delivery and did not inquire about the HSN; They were entitled to pass on tax component, if any, upon the retailer/ stockist. Thus, the situation is revenue neutral. The noticee has also contested that no positive evidence with respect to alleged abatement or collusion or any active involvement on the part of the Noticee has been brought forward under the show cause notice.

45.2 I find that Section 112(b) of the Customs Act, 1962 provides that:

"(b) who acquires possession of or is in any way concerned in carrying, removing, depositing, harbouring, keeping, concealing, selling or purchasing, or in any other manner dealing with any goods which he knows or has reason to believe are liable to confiscation under section 111, shall be liable, -
(ii) in the case of dutiable goods, other than prohibited goods, subject to the provisions of section 114A, to a penalty not exceeding ten per cent. of the duty sought to be evaded or five thousand rupees, whichever is higher:"

45.3 From contents of the section 112(b) it can be seen that penalties can be imposed only if any individual was in knowledge or concern with the act of omission. Further, for imposition of penalty under Section 112(b) of the Customs Act, 1962, in the case like the case in hand for adjudication, the knowledge of offence on part of the person has to be established with documentary evidences. The present case being of classification in nature, I find merits in submissions of the noticee in as much as no corroboration is emerged from the Notice, which establishes direct involvement or knowledge of the noticee M/s.PSI India Private Limited in support of the alleged conspiracy and collusion for imposition of penalty under Section 112(b) of the Customs Act, 1962. My above views are supported with the findings of the Hon'ble double bench of the CESTAT, Ahmedabad in the case of Vipul Joshi Vs. C.C.-Ahmedabad, reported as 2022(10)LCX0103, wherein the Hon'ble Tribunal held that:

"6.17 We also find that the appellant cannot come within the ambit of Section 112(b) because appellants had never acquired possession or in any way concerned of the activities mentioned in the Section or any measure dealing with any goods which the appellants knew or had reason to believe are liable to confiscation. In the absence of the department having not proved the knowledge of the appellant in the activities relating to the smuggled gold, there were no grounds for imposition of penalty on him. It is now well established that mensrea is an important ingredient for imposing a penalty on the persons enumerated in Section 112(b) of the Customs Act. The evidence brought out by the department nowhere suggests that the appellants were aware that the goods in question were smuggled into the India. The penalty imposed on Appellant, therefore, cannot be sustained."

45.4 In view of the above, I drop the proceeding initiated in the SCN under adjudication against M/s.PSI India Private Limited.

46. Further M/s.Mylan Laboratories Limited have relied upon judgments in support of their contention. I find that the ratio of the relied upon case laws are not squarely applicable in the facts and circumstances of the present case. I have gone through the facts of the case laws relied upon by the importer and compared the same with the factual details of the present case in hand. I find that there is quite difference in the facts and circumstances of their own case. Hence, the noticees cannot get benefit therefrom. I would like to rely on the judgment of the Hon'ble Supreme Court of India in the case of **Escorts Ltd. Versus Commissioner of Central Excise, Delhi-II**, reported at 2004 (173) E.L.T. 113 (S.C.), wherein the Hon'ble apex court observed that:

"10. Circumstantial flexibility, one additional or different fact may make a world of difference between conclusions in two cases. Disposal of cases by blindly placing reliance on a decision is not proper."

Further reliance is placed on the judgment of the Hon'ble Apex court in case of '**Collector of Central excise, Calcutta Vs Alnoori Tobacco Products**' (2004(170)ELT 135 SC), where it was observed by the Hon'ble Apex Court-

*"11. Courts should not place reliance on decisions without discussing as to how the factual situation fits in with the fact situation of the decision on which reliance is placed. Observations of Courts are neither to be read as Euclid's theorems nor as provisions of the statute and that too taken out of their context. These observations must be read in the context in which they appear to have been stated. **Judgments of Courts are not to be construed as statutes. To interpret words, phrases and provisions of a statute, it may become necessary for judges to embark into lengthy discussions but the discussion is meant to explain and not to define. Judges interpret statutes, they do not interpret judgments. They interpret words of statutes; their words are not to be interpreted as statutes.**"*


47. In view of my findings in the paras *supra*, I pass the following order:

::ORDER::

- a) I reject the declared classification of the goods i.e. "Cyproterone and Ethinylestradiol Tablets (2 mg / 0.035 mg) (Frewil)" under Customs Tariff Head 30066010 and hold classification of the said product under Customs Tariff Head 30049099 of the first Schedule to the Customs Tariff Act, 1975;
- b) I hold the subject goods having assessable value of **Rs.50,06,680/- (Rupees Fifty Lakh Six Thousand Six Hundred & Eighty Only)** as detailed in **Annexure-A to the SCN**, cleared by M/s.Mylan Laboratories Limited by mis-classifying the subject goods, liable for confiscation under Section 111(m) of the Customs Act, 1962. However, I give them the option to redeem the goods on payment of Fine of **Rs.5,00,000/- (Rupees Five Lakhs only)** under Section 125 of the Customs Act, 1962;
- c) I confirm the demand of Duty of Customs amounting to **Rs.12,17,625/- (Rupees Twelve Lakh Seventeen Thousand Six Hundred & Twenty Five only)**, as detailed in **Annexure-A to SCN**, and order recovery of the same from M/s.Mylan Laboratories Limited in terms of the provisions of Section 28(4) of the Customs Act, 1962 and an amount of Rs.12,17,625/- already paid under protest by them as Customs duty under Challan No.SEZ/ZIPL/094/22-23 dated 24.07.2023, is appropriated towards the duty demanded and confirmed at (a) above;
- d) I order that interest at appropriate rate under Section 28AA of the Customs Act, 1962 on the duty confirmed under (c) above, be charged and recovered from them and an amount of Rs.5,45,485/- already paid under protest by them as interest under Challan No.SEZ/ZIPL/094/22-23 dated 24.07.2023, is appropriated towards the interest payable on the duty demanded and confirmed at (c) above;
- e) I impose a penalty of **Rs.12,17,625/- (Rupees Twelve Lakh Seventeen Thousand Six Hundred & Twenty Five only)** on M/s.Mylan Laboratories Limited **plus** penalty equal to the applicable interest under Section 28AA of the Customs Act, 1962 payable on the Duty demanded and confirmed at (a) above under Section 114A of the Customs Act, 1962. However, in view of the first and second proviso to Section 114A of the Customs Act, 1962, if the amount of Customs Duty confirmed and interest payable thereon is paid within a period of thirty days from the date of the communication of this Order, the penalty shall be twenty-five percent of the duty, subject to the condition that the amount of such reduced penalty is also paid within the said period of thirty days;
- f) I refrain from imposing penalty on M/s.Mylan Laboratories Limited under Section 112 (a) of the Customs Act, 1962 for the reasons discussed in para 43 *supra*;
- g) I drop the proceeding initiated in the SCN under adjudication against M/s.PSI India Private Limited for the reasons discussed herein above under para 45.

48. This order is issued without prejudice to any other action that may be taken under the provisions of the Customs Act, 1962 and Rules/Regulations framed thereunder or any other law for the time being in force in the Republic of India.

49. The Show Cause Notice No. GEN/ADJ/ADC/1563/2023-TECH dated 07.08.2023 is disposed off in above terms.


(Vishal Malani)
Additional Commissioner
Customs, Ahmedabad

BY SPEED POST/e-mail/By Hand

F. No. GEN/ADJ/ADC/1563/2023-TECH

Date: 01.07.2024

DIN: 20240771MN0000615726

To:

1. M/s.Mylan Laboratories Limited.
Pharma SEZ, Plot No.20 and 21,
Matoda Village, Matoda, Sanand,
Ahmedabad, Gujarat, India-382213.
2. M/s. PSI India Private Limited,
E-119, Transport nagar,
Kanpur road, Lucknow,
Uttarpradesh, India-2260123.

Copy to:

1. The Principal Commissioner of Customs, Customs Commissionerate, Ahmedabad (RRA Section) for information please.
2. The Specified Officer, Office of the Development Commissioner, -Pharma SEZ, Plot No.20 and 21, Matoda Village, Matoda, Sanand, Ahmedabad, Gujarat, 382213
3. The Deputy/Assistant Commissioner, (TRC), Customs Commissionerate, Ahmedabad
4. The Superintendent (Systems), Customs Commissionerate, Ahmedabad, for uploading on the website of the Commissionerate/Zone
5. Guard file.