CUSTOMS, EXCISE & SERVICE TAX APPELLATE TRIBUNAL, MUMBAI
REGIONAL BENCH

Excise Appeal No. 86775 of 2016

(Arising out of Order-in-Appeal No. CD/288/M-III/2016 dated 25.04.2016 passed by the Commissioner of Central Excise (Appeals), Mumbai)

M/s. Advy Chemical Pvt. Ltd. **Appellant**
Plot No. A-334/336/338, Road No.26,
Wagle Industrial Estate, Thane 400 604.

Vs.

Commissioner of Central Excise, Mumbai-III **Respondent**
3rd & 4th Floor, Vardaan Centre,
MIDC, Wagle Industrial Estate,
Thane (W), Mumbai 400 604.

WITH

Excise Appeal No. 87411 of 2018

(Arising out of Order-in-Appeal No. PVNS/271/APPEALS THANE/TH/17-18/2344 dated 06.03.2018 passed by the Commissioner of GST & Central Excise (Appeals), Thane)

M/s. Advy Chemical Pvt. Ltd. **Appellant**
Plot No. A-334/336/338, Road No.26,
Wagle Industrial Estate, Thane 400 604.

Vs.

Commissioner of CGST, Thane **Respondent**
3rd & 5th Floor, ACCFL House, Road No.22,
Wagle Ind. Estate, Thane 400 604.

Appearance:

Shri Vishal Agarwal with Shri Abhishek Kapadia, Advocates, for the Appellant
Shri Deepak Bhilegaonkar, Additional Authorised Representative for the Respondent

CORAM:

HON'BLE MR. SANJIV SRIVASTAVA, MEMBER (TECHNICAL)
HON'BLE DR. SUVENDU KUMAR PATI, MEMBER (JUDICIAL)

Date of Hearing: 10.11.2022
Date of Decision: 10.11.2022

FINAL ORDER NO. A/86285-86286/2022

PER: SANJIV SRIVASTAVA

These appeals are directed against Order-in-Appeal No. CD/288/M-III/2016 dated 25.04.2016 of the Commissioner of Central Excise (Appeals), Mumbai and Order-in-Appeal No.

PVNS/271/APPEALS THANE/TH/17-18/2344 dated 06.03.2018 of the Commissioner of GST & Central Excise (Appeals), Thane. By the impugned orders, Commissioner (Appeals) has allowed the appeals filed by the Revenue setting aside Order-in-Original No. 21 to 23/MSA/2015-16/1175 dated 23.06.2015 of the Joint Commissioner, Central Excise, Mumbai-III and Order-in-Original No. 35/MRL/2016-17 dated 23.02.2017 of the Additional Commissioner, Central Excise, Mumbai-III holding as follows:-

Order-in-Original No. 21 to 23/MSA/2015-16/1175 dated 23.06.2015

"ORDER

6. Accordingly I pass the following order:-

I hereby drop proceedings of the three notices mentioned at para 2 of the this order and drop the total duty demand of Rs.65,27,176/- (Rs. Sixty Five Lakh Twenty Seven Thousand One Hundred Seventy Six only)."

Order-in-Original No. 35/MRL/2016-17 dated 23.02.2017

"ORDER:

(i) I order that the product viz 'Diagnostic kits for detection of Dengue, Malaria, Troponin I. Typhi should be classified under CETSH No.3822 0090. of CETA. 1985 attracting appropriate Central Excise Duty.

(ii) I hereby confirm the demand of Rs 76,02,125/-(Rupees Seventy Six Lakhs Two Thousand One Hundred Twenty Five Only)., initiated vide SCN No. F.No. V.Adi Show Cause Notice)15-38/Commr/W-1/2015-16/ dated 5th April 2016 and also order the recovery of the said amount from M/s. Advy Chemical Pvt. Ltd, Thane under provisions of Section 11A(1) of the Central Excise Act 1944.

(iii) I order the noticee M/s. Advy Chemical Pvt. Ltd. Thane, to pay Interest under Section 11AA of the Central Excise Act, 1944, on the amount determined under (i) above.

(iii) I impose penalty of Rs 7,00,000/- (Rupees Seven Lakhs Only) upon M/s. Advy Chemical Pvt. Ltd, Thane, under the provisions of Rule 25 of Central Excise Rules 2002.

The amount should be paid forth with."

2.1 Appellant is engaged in manufacture of excisable goods viz. Diagnostic kits for detection of Dengue, Malaria, Troponin I, Typhi, falling under Chapter 38220090 and Human/Animal Blood products viz. Anti CRP Serum, Anti IgG Serum, Anti IgM Serum of Goat Blood, Normal Goat Plasma, etc. falling under Chapter Sub Heading 30029020 and 30021091 of the first Schedule to Central Excise Tariff Act.

2.2 Four show cause notices as detailed in table below are issued to the appellant:-

S. No	SCN No & date	Duty demanded (Rs)	Period involved
1	V.Adj(SCN)15-60/ADC/W-I/M-III/2013-14 dated 06.08.2014	41,33,586	July.-13 to Mar.-14
2	V/Adj/W-ISCN/Advy/15-37/13-14/4038 dated 13.02.2014	4,01,088	Jan.-13 to Mar.-14
3	V.Adj(SCN)15-(SCN)15-41/ADC/W-I/M-III/2014-15 dated 15.04.2015	19,92,502	April, 14 to Feb.-15
4	V.Adj/SCN/15-38/Commr/W-I/2015-16 dated 05.04.2016	76,02,125	Apr.-15 to Jan.-16

2.3 In the ER-1 filed by the appellant they had shown the description of the goods as malaria/dengue/troponin I/Typhi kits falling under CET SH No.30029020 with nil rate of duty and nil assessable value for the clearance of said goods.

2.4 The show cause notice states that the classification of the goods was modified by the appellant from CET SH No. 38220090 to CET SH No. 30029020 without any appropriate reasons. The change in the classification made by the appellant is not acceptable as they themselves classified these products under

CT SH No. 38220090 and availed SSI exemption Notification No. 08/2003-CE dated 01.03.2003. These products are more appropriately classifiable under CET SH No. 38220090. These products are used for detection of malaria infection in human blood. Further nowhere on the primary packing of the product or on the outer cover/box or leaflet literature of the product that these goods are made out of blood to support the classification claimed by the appellant. The correct classification of these goods was under Chapter Heading 38.22 and is also supported by the HSN Explanatory Notes.

2.5 Accordingly the first show cause notice was issued to the appellant asking them to show cause as to why:-

"(i) Classify the product viz 'Diagnostic kits for detection of Dengue, Malaria, Troponin I, Typhi under CETSH No.3822 0090, attracting appropriate Central Excise Duty and to consider ER-1 returns accordingly;

(ii) demand and recover Central Excise duty amounting to Rs.41,33,586/- (Rs.40,13,190/- BED + Rs.80,264/-Ed. Cess + Rs. 40,132/- S & H. Ed.Cess (Rupees Forty One Lakh Thirty Three Thousand Five Hundred and Eighty Six Only) under Sec.11A(1) of the Central Excise Act, 1944;

(ill) order and recovery of Interest at appropriate rate under Sec.11 AA of the Central Excise Act, 1944 and;

(iv) impose Penalty under Rule 25 of Central Excise Rules, 2002."

Subsequently the other show cause notices were issued.

2.6 The Joint Commissioner adjudicated the three show cause notices, dropping the demand. Aggrieved Revenue filed appeal before the Commissioner (Appeals) which was allowed by the Commissioner (Appeals). Subsequently one show cause notice was adjudicated by the Additional Commissioner after taking note of the Commissioner (Appeals) order setting aside Joint Commissioner's order confirming the demand made in the three show cause notices, confirmed the demand made. Appellant filed appeal before Commissioner (Appeals) which was dismissed by the Commissioner (Appeals). More or less the similar reasoning has been given by the Commissioner (Appeals) in the earlier order. Hence these appeals.

3.1 We have heard Shri Vishal Agarwal with Shri Abhishek Kapadia, Advocates, for the appellant and Shri Deepak Bhilegaonkar, Additional Commissioner, Authorised Representative for the Revenue.

3.2 Arguing for the appellant, learned counsel submits that:-

- The essential character of RDT kit is the cassette and more specifically the monoclonal antibodies obtained from mouse ascites or animal blood fractions contained therein. The essential components of the kit do not come from the component like buffer solution but from the test strip coated with monoclonal goat anti-mouse antibodies and animal blood antibodies sprayed conjugates contained in the plastic cassette. The essential component of the RDT is the animal blood fraction without which the diagnostic test would not be possible. The human blood sample interacts with the animal antibody conjugate and strips which enables detection of the life-threatening disease.
- Reliance is placed on the decision in the case of Reckon Diagnostics [2012 (275) ELT 242 (Tri.-Ahmd.)].
- HSN Explanatory Notes clearly provide that diagnostic kits which contain animal blood fractions would be classified under Heading 30.02 only.
- They also relied on the decision of Hon'ble Supreme Court in the case of Span Diagnostics Ltd. [2007 (211) ELT 521 (SC)] and of Tribunal in the case of Mitra & Co. Ltd. [2013 (288) ELT 229 (Tri.-Del)].
- The impugned orders are beyond the scope of the show cause notices and hence bad in law as has been held in the case of Toyo Engineering India Ltd. [2006 (201) ELT 513 (SC)] and Ballarpur Industries Ltd. [2007 (215) ELT 489 (SC)].

3.3 Learned AR submits that the order of Commissioner (Appeals) is based on the terms of the chapter heading. He further submits that with effect from 01.02.2022 the Customs Tariff has been specifically amended to classify the test kit for malaria etc. under Chapter 38.

4.1 We have considered the impugned orders along with the submissions made in appeal and during the course of arguments.

4.2 Since the issue is common in both these appeals, we are referring to appeal No. E/86775/2016.

4.3 After reproducing the tariff entries in his order, adjudicating authority has observed as follows:-

"5.4 From the above it is seen that the heading 3002 covers "Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products". Sub Heading no. 30029020 covers "Animal blood prepared for therapeutic, prophylactic or diagnostic uses".

5.5 Heading 3822 covers "Diagnostic or laboratory reagents on a backing,

3822 0011:----Pregnancy confirmation reagents

3822 0012: Reagents for diagnosing AIDS

3822 0019: ----Other

3822 0090: ---Other

Thus it is seen that the Sub Heading No. 38220090 covers diagnostic or laboratory agents, other than "Pregnancy confirmation reagents" and "Reagents for diagnosing AIDS".

5.6 Thus I find that the diagnostic or laboratory reagents are covered under sub heading 3002 as well as sub heading 3822. It can be seen from the description of heading of 3822 that the heading specifically excludes diagnostic or laboratory reagents falling under Sub heading 3002. Further, the Sub Heading no.30029020 covers "Animal blood prepared for therapeutic, prophylactic or diagnostic uses". Thus from the combined reading of the above, I find that the diagnostic kits covered under heading 3822 are those kits which are not made out of blood.

5.7 The notices In para 1, states that the assessee is engaged in manufacture of "Animal Blood products". Thus I find that the goods viz. "Diagnostic kits for detection of Dengue, Malaria, Troponin I, Typhi" are not classifiable under heading 3822. As the assessee's product is made out of blood, the Sub Heading no. 30029020 is appropriate sub-heading.

5.7.1 The certificate submitted by the assessee issued by their technical head shows that their product viz. "EzDx Malaria Pv/Pt is prepared out of blood. Further, in the list of products attached to the FDA license show the said product and is the only product manufactured by them."

4.4 Thereafter, relying on various decisions the adjudicating authority has observed as follows:-

"5.11 I therefore hold that the product of the assessee viz. "Diagnostic kits for detection of Dengue, Malaria, Troponin I, Typhi" is classifiable under 30029020 and attracts tariff NIL rate of duty.

5.12 I also find that the notice is founded on the premise that the assessee themselves had classified the said product under 38220090 and mentioned the same in their returns, till the month of June, 2013. However, I find that just as department can recover the duty in accordance with and subject to provisions of Section 11A of CEA, 1944 for a period of one year or five years from the date of demand notice on any ground including classification of the product, the assessee also have right to rectify any mistake subject to section 118 ibid. for past period and for current period with due Intimation to the department. Thus mere wrong only after the filing of returns by the assessee with changed classification, the department issued the Impugned demand notices. Hence I do not agree with the ground put forth in the notices for non accepting the changed classification. In this regard I find the decisions cited by the assessee as applicable to their case.

5.13 I thus find that the product "Diagnostic kits for detection of Dengue, Malaria, Troponin 1, Typhi is classifiable under Sub Heading no. 30029020 attracting NIL rate of duty as per Tariff rate. As the duty chargeable on the goods of the assessee is at NTL rate, there is no duty liability on the assessee.

5.14 I thus find that the notices are not tenable and are required to be dropped."

4.5 Commissioner (Appeals) has set aside the order of the adjudicating authority after observing as follows:-

"6.1. By virtue of Central Excise Tariff (Amendment) Act, 2004, the Central Excise Tariff Act, 1985 has been amended with effective from 28.02.2005 by introducing the 8 digit classification code and the CBEC Board vide Circular No. 808/05/2005-CX dated 25.02.2005 has issued clarifications in this regard. The "-", in the article or group of articles has their defined meaning as given in the general given explanatory notes of the general rules for the interpretation of the First Schedule Accordingly, the Chapter Heading 3002 and its subheading reads as under:

Heading No.	*Sub-heading No.*	*Description of goods*	*Rate of duty*
(1)	*(2)*	*(3)*	*(4)*
30.02	*3002.00*	*Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes; Vaccines, Toxins, Cultures of micro-organisms (excluding yeasts) and similar products*	*Nil*
	300290	*--- Other*	
	30029010	*---Human blood*	*Nil*
	30029020	*---Animal blood prepared for therapeutic, prophylactic or diagnostic uses*	*Nil*
	30029030	*---Cultures of micro-organisms (excluding yeasts)*	*Nil*
	30029040	*---Toxins*	*Nil*
	30029090	*---Other*	*Nil*

6.2. As per the above description, it is clear that the blood fractions would come under chapter 3002 and the animal blood prepared for therapeutic, prophylactic or diagnostic uses would come under 30029020 and the appellant had classified the impugned goods Le Diagnostic kits for detection of Dengue, Malaria, Troponin I. Typhi under Chapter 30029020.

7. After amendment in the Central Excise Tariff Act, 1985, with effective 28.02.2005, the Chapter Heading 3822 and its subheading reads as under:

Heading No.	Sub-heading No.	Description of goods	Rate of duty
(1)	(2)	(3)	(4)
38	3822	Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading 3002 or 3006; certified materials	
	3822 00	-Diagnostic or laboratory reagents on a backing, other than those of heading 3002 or 3006; certified reference materials : ---For Medical diagnosis :	
	3822 00 11	----Pregnancy confirmation reagents	12%
	3822 00 12		12%
	3822 00 19	----Reagents for diagnosing AIDS	12%
	3822 00 90	----Other	12%
		----Other	

8. As per the above description, from the plain reading, it is clear that for medical diagnosis, the diagnostic or laboratory reagents on a backing, other than those of heading 3002 or 3006 and certified reference materials gets their proper classification under Chapter Head 3822

9. Before the amendment the classification of testing kit for medical diagnosis was not clear and after the amendment it was specifically included in the chapter subhead 3822. It is not in doubt that the 'Diagnostic kits for detection of Dengu, Malaria, Troponin I, Typhi' is being used for medical diagnosis. The similar testing kits like Pregnancy confirmation regents and Reagents for diagnosing AIDS get their proper classification under chapter subhead 3822 00 11 and under 3822 00 12. In the instant case it is the beyond doubt that the impugned goods i.e. 'Diagnostic kits for detection of Dengue, Malaria, Troponin 1,

Typhi' manufactured as provided in the certified reference materials. It is also the admitted fact that this kit is prepared from fractionation of mouse white blood cell secretion. But the Diagnostic kits for detection of Dengue. Malaria, Troponin 1, Typhi' is not containing only the blood fractions, admittedly it contains complete kits for diagnosis and with the help of the certain components, the complete diagnostic and laboratory reagents as mentioned in the HSN of Chapter 3822 comes into existence. The classification cannot be made only on the basis of the strips. The respondent cannot choose the classification which is beneficial to them. Without the certain nomenclature and universally certified reference materials, such testing kits cannot be manufactured and accepted in laboratories. The case laws cited by the respondent are of no avail as they are of prior to the amendment in the Tariff and when the goods of medical diagnosis were not properly classified with their specific classification. When the reagents for medical diagnosis has been specifically classified in the Chapter subhead 3822, the correct classification of the impugned goods Diagnostic kits for detection of Dengue, Malaria."

4.6 It is not in dispute that the said diagnostic kits are based on animal blood fractions. During the course of hearing, a technical expert was also present to explain the functioning of the kit. While referring to HSN Explanatory Notes for Heading 3002, we had sought an explanation from the counsel on the basis of the submission made through the technical expert. Following submissions have been made:

"(E) Diagnostic kits

Diagnostic kits are classified here when the essential character of the kit is given by any of the products of this heading. Common reactions occurring in the use of such kits include agglutination, precipitation, neutralization, binding of complement, haemagglutination, enzyme-linked immunosorbent assay (ELISA), etc. Malaria diagnostic kits based on monoclonal antibodies to pLDH (plasmodium lactate dehydrogenase) are for instance classified here. The essential character is given by that single component which governs to the greatest extent the specificity of the test procedure."

4.7 Commissioner (Appeals) has in his order reproduced the relevant competing heading. Heading No. 3822 as it existed at the relevant time clearly seeks to include those products which are classifiable under 3002 or 3006. To explain the changes made in the tariff from 2012 to 2022, reference was made to the changes made in the HSN during this period. Heading 3002 as it existed in 2012 was amended in 2017 and in 2022. Heading 3822 was also amended in 2022 which formed the basis for the amendments made in the Customs Tariff which was relied upon by the learned AR. All the above changes are reproduced below:-

Entries in HSN as they existed in 2012

30.02		Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products.
3002.10	-	Antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes
3002.20	-	Vaccines for human medicine
3002.30	-	Vaccines for veterinary medicine
3002.90	-	Other

Entries in HSN after amendment made in 2017

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

	-	Antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes :
3002.11	--	Malaria diagnostic test kits
3002.12	--	Antisera and other blood fractions
3002.13	--	Immunological products, unmixed, not put up in measured doses or in forms or packings for retail sale
3002.14	--	Immunological products, mixed, not put up in measured doses or in forms or packings for retail sale
3002.15	--	Immunological products, put up in measured doses or in forms or packings for retail sale
3002.19	--	Other
3002.20	-	Vaccines for human medicine
3002.30	-	Vaccines for veterinary medicine
3002.90	-	Other

Amendment made in HSN in 2022

1. This Chapter does not cover :
(a) …….
(b) …….
(c) …….
(d) …….
(e) ……..
(f) ……..
(g) ……..
(h) ……

(ij) Diagnostic reagents of heading 38.22.

30.02		Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines,

		toxins, cultures of micro-organisms (excluding yeasts) and similar products; cell cultures, whether or not modified.
	-	Antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes :
3002.12	--	Antisera and other blood fractions
3002.13	--	Immunological products, unmixed, not put up in measured doses or in forms or packings for retail sale
3002.14	--	Immunological products, mixed, not put up in measured doses or in forms or packings for retail sale
3002.15	--	Immunological products, put up in measured doses or in forms or packings for retail sale
	-	Vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products :
3002.41	--	Vaccines for human medicine
3002.42	--	Vaccines for veterinary medicine
3002.49	--	Other -Cell cultures, whether or not modified :
3002.51	--	Cell therapy products
3002.59	--	Other
3002.90	-	Other

38.22		Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 30.06; certified reference materials.

	-	Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits :
3822.11	--	For malaria
3822.12	--	For Zika and other diseases transmitted by mosquitoes of the genus Aedes
3822.13	--	For blood-grouping
3822.19	--	Other
3822.90	-	Other

4.8 Explaining the impact of amendments made in 2022, HSN Committee has issued following guidance table:

2022 Version	2017 Version	Remarks
3822.11	3002.11 ex3002.13 ex3002.14 ex3002.15	Creation of new exclusion Note 1 (ij) to Chapter 30 and new subheadings 3822.11, 3822.12 and 3822.19 entail the transfer of diagnostic reagents and kits (including malaria diagnostic kits) from subheadings 3002.11, 3002.13, 3002.14 and 3002.15 to new subheadings 3822.11, 3822.12 and 3822.19. At the same time, deletion and substitution of Note 4 (e) to Chapter 30 and creation of new subheading 3822.13 entail the transfer of blood grouping reagents from subheading 3006.20 to new subheading 3822.13.
3822.12	ex3002.13 ex3002.14 ex3002.15 ex3822.00	
3822.13	3006.20	
3822.19	ex3002.13 ex3002.14 ex3002.15 ex3822.00	
3822.90	ex3822.00	

3002.11	ex3822.11
3002.13	3002.13 ex3822.11 ex3822.12 ex3822.19

3002.14 3002.15 3002.20 3002.30 3002.90	3002.14 ex3822.11 ex3822.12 ex3822.19 3002.15 ex3822.11 ex3822.12 ex3822.19 3002.41 3002.42 3002.49 3002.51 3002.59 3002.90
3002.19	This subheading was considered by the HS Committee to be empty and it was therefore deleted

4.9 The above table issued by HSN Committee clearly shows that for period prior to amendments made in 2022 as per HSN also the impugned goods were classifiable under Chapter 30.

4.10 For the period for which we are concerned as per the above, we do not have any hesitation in holding that these goods were more appropriately classified under Heading No.3002 as has been held by the Joint Commissioner in his order referred to in para 4.2 above. By the amendment made in 2017 Heading 3002.10 (-) was expanded to include Malaria diagnostic test kits under Heading 30211. The single dash continued as it was for Heading 3002.10 prior to this amendment. Making it clear that as per HSN, these goods were more appropriately classified under Chapter 30. In the order the main basis for holding otherwise is that certain other goods are present in the kit which gives the essential character. Commissioner (Appeals) has concluded that these kits are prepared from fractionation of mouse white blood cell secretion. That being so, the essential character of the kit is to be determined from the function intended to be performed. The function to be performed is that of detection of the disease like dengue, malaria, troponin I, typhi and it is why suitable reaction with these infections done. Accordingly we do not find any merits in this order of the Commissioner (Appeals).

4.11 Further the Commissioner (Appeals) has referred to the amendment made while introducing 8-digits tariff in the year 2015. Commissioner (Appeals) has observed that prior to the said amendment the things were not clear and thereafter Heading 3822 provided specifically for classification under Heading 3822. We do not find any merits in the said submission as nothing was changed in respect of these two headings as at the 6-digits level. The heading continued to be the same. There was no amendment made in the HSN also as we have referred above.

5.1 Since we hold that these goods are more appropriately classifiable under Chapter 30, the impugned orders do not have any merits.

5.2 Appeals are allowed.

(Order pronounced in the open court)

(Sanjiv Srivastava)
Member (Technical)

(Dr. Suvendu Kumar Pati)
Member (Judicial)

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