SUPREME COURT OF INDIA

Span Diagnostics Ltd

Vs.

Commissioner of Central Excise, Surat

C.A.No.5322 of 2002

(S.H. Kapadia and B. Sudershan Reddy JJ.)

30.04.2007

JUDGMENT

KAPADIA, J.

From the impugned judgment dated 1.1.2002 delivered by the Customs, Excise and Gold (Control) Appellate Tribunal ('CEGAT', for short), New Delhi, vide Appeal No.E/1644 and 1645 of 2000-C, C.A. No.5322 of 2002 and C.A. No.1953-54 of 2003 have been filed by the assessees and by the Department respectively. For the sake of convenience and clarity we proceed to decide each of the following civil appeals serially.

C.A.No.5322/2002filed by M/s. J. Mitra & Co.Ltd. (Assessee) In this civil appeal we are concerned with the classification of biotech products.

The said assessee was engaged in the manufacture of blood-grouping reagents and diagnostic and laboratory reagents. It had obtained registration on 10.9.99 for the manufacture and clearances of the following products:

(1) Anti-A Mono Clonal (2) Anti-B Mono Clonal (3) Anti-Decoders Mono Clonal (4) Anti-Decoders Mono Clonal (5) Anti-Decoders 1gM Mono Clonal (6) Anti-Decoders 1gG Mono Clonal The above six items are called Monoclonal Antibodies (for short, 'MABs'). They were classified by the assessee under Chapter Sub-heading 3002.00 (Chapter Heading 30.02) of Central Excise Tariff Act (for short, 'CETA') whereas the Department classified the MABs under CSH 3005.90 (Chapter Heading 30.05) of CETA.

The assessee classified MABs as "cultures of micro- organisms" whereas the Department classified the said MABs as "pharmaceutical products, not elsewhere specified or included".

The CEGAT (Tribunal), vide the impugned judgment, upheld the classification of MABs under CSH 3005.90 of CETA as claimed by the Department, hence this civil appeal is filed by the assessee.

For the sake of convenience, we quote hereinbelow Chapter Note 3 in Chapter 30 of the CETA concerning pharmaceutical products which reads as under:

"CHAPTER 30 PHARMACEUTICAL PRODUCTS Notes :

1. and 2. xxx xxx xxx

3. Heading No.30.05 applies only to the following, which are to be classified in that heading and in no other heading of this Schedule:- (a) to (d) xxx xxx xxx (e) Blood grouping reagents;

(f) to (h) xxx xxx xxx"

We quote hereinbelow Chapter Heading 30.02 and CSH 3002.00 of CETA which read as under:

"CHAPTER 30 PHARMACEUTICAL PRODUCTS Notes : 1. to 5. xxx xxx xxx Heading No.

Sub-heading No.

Description of goods Rate of duty (1) (2) (3) (4) 30.02 3002.00 Antisera and other blood fractions; Vaccines, Toxins, Cultures of micro-organisms (including ferments but excluding yeasts) and similar products Nil We quote hereinbelow Chapter Heading 30.05 in entirety of CETA which reads as under:

"CHAPTER 30 PHARMACEUTICAL PRODUCTS Notes : 1. to 5. xxx xxx xxx Heading No.

Sub-heading No.

Description of goods Rate of duty (1) (2) (3) (4) 30.05 Pharmaceutical goods, not elsewhere specified 3005.10 Chemical contraceptives Nil 3005.20 Dental cements and other dental fillings 15% 3005.90 Others 15% We also quote hereinbelow relevant extracts of Chapter Note No.2 in Chapter 30 of HSN (Second Edition) which read as follows:

"CHAPTER 30 PHARMACEUTICAL PRODUCTS Chapter Notes.

1. xxx xxx xxx

2. For the purposes of heading No.30.02, the expression "modified immunological products" applies only to monoclonal antibodies (MABs), antibody fragments, antibody conjugates and antibody fragment conjugates."

We also quote hereinbelow Chapter Heading 30.02 in entirety from the said HSN which reads as under:

"30.02 HUMAN BLOOD; ANIMAL BLOOD

PREPARED FOR THERAPEUTIC, PROPHYLACTIC

OR DIAGNOSTIC USES; ANTISERA AND OTHER BLOOD FRCTIONS AND MODIFIED IMUNOLOGICAL PRODUCTS, WHETHER OR NOT OBTAINED BY MEANS OF BIOTECHNOLOGICAL PROCESSES;

VACCINES, TOXINS, CULTURES OF MICRO- ORGANISMS (EXCLUDING YEASTS) AND SIMILAR PRODUCTS.

3002.10 Antisera and other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes 3002.20 Vaccines for human medicine 3002.30

Vaccines for veterinary medicine 3002.90 Other This heading covers:

(A) Human blood (e.g., human blood in sealed ampoules).

(B) Animal blood prepared for therapeutic, prophylactic or diagnostic uses Animal blood not prepared for such uses falls in heading 05.11.

(C) Antisera and other blood fractions and modified immunological products.

These products include:

(1) Antisera and other blood fractions.

Sera are the fluid fractions separated from blood after clotting.

The heading covers, inter alia, the following products derived from blood:

"normal" sera, human normal immunoglobulin, plasma, fibrinogen, fibrin, blood globulins, serum globulins and haemoglobin. The heading also includes blood albumin (e.g., human albumin obtained by fractionating the plasma of whole human blood), prepared for therapeutic or prophylactic uses.

Antisera are obtained from the blood of humans or of animals which are immune or have been immunized against diseases or ailments, whether these are caused by pathogenic bacteria and viruses, toxins or allergic phenomena, etc. Antisera are used against diphtheria, dysentery, gangrene, meningitis, pneumonia, tetanus, staphylococcal or streptococcal infections, snake bite, vegetable poisoning, allergic diseases, etc. Antisera are also used for diagnostic purposes, including in vitro tests. Specific immunoglobulins are purified preparations of antisera.

The heading does not cover blood albumin not prepared for therapeutic or prophylactic uses (heading 35.02) or globulins (other than blood globulins and serum globulins) (heading 35.04).

The heading also excludes medicaments which are not separated from the blood but which in some countries are described as "sera" or "artificial sera";

they include isotonic solutions based on sodium chloride or other chemicals and suspensions of pollen which are used against allergic diseases.

(2) Modified immunological products, whether or not obtained by means of biotechnological processes.

Products whose antigen-antibody reaction corresponds to natural antisera and which are used for diagnostic or therapeutic purposes and for immunological tests are to be regarded as falling within this product group. They can be defined as follows:

(a) Monoclonal antibodies (MABs) specific immunoglobulins from selected and cloned hybridoma cells cultured in a culture medium or ascites.

(b) Antibody fragments parts of an antibody protein obtained by means of specific enzymatic splitting.

(c) Antibody and antibody fragment conjugates - enzymes (e.g., alkaline phosphatase, peroxidase or betagalactosidase) or dyes (fluorescin) covalently bound to the protein structure are used for straightforward detection reactions.

(D) Vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products.

These products include:

(1) Vaccines preparations of microbial origin containing either viruses or bacteria suspended in saline solutions, oil (lipovaccines) or other media. These preparations have usually been treated to reduce their toxicity without destroying their immunising properties.

The heading also covers mixtures (such as Diphtheria, Tetanus and Pertussis (DPT) vaccine) consisting of vaccines and toxoids.

(2) Toxins (poisons secreted by bacteria), toxoids, crypto-toxins and anti-toxins, of microbial origin.

(3) Cultures of micro-organisms (excluding yeasts). These include ferments such as lactic ferments used in the preparations of milk derivatives (kephir, yogurt, lactic acid) and acetic ferments for making vinegar; moulds for the manufacture of penicillin and other antibiotics; and cultures of micro-organisms for technical purposes (e.g., for aiding plant growth).

Milk or whey containing small quantities of lactic ferments is classifiable in Chapter 4.

(4) Virus, human, animal and vegetable and anti-virus.

(5) Bacteriophage.

The heading also includes diagnostic reagents of microbial origin, other than those provided for in Note 4 (d) to this Chapter see heading 30.06. It does not cover enzymes (rennet, amylase, etc.) even if of microbial origin (streptokinase, streptodornase, etc.) (heading 35.07) nor dead single-cell micro-organisms (other than vaccines) (heading 21.02).

The products of this heading remain classified here whether or not in measured doses or put up for retail sale and whether in bulk or in small packings."

We also quote hereinbelow Chapter Heading 30.06 of HSN which is equal to Chapter Heading 30.05 in CETA and which reads as under:

"30.06 PHARMACEUTICAL GOODS SPECIFIED IN NOTE 4 TO THIS CHAPTER.

3006.10 Sterile surgical catgut, similar sterile suture materials and sterile tissue adhesives for surgical wound closure;

sterile laminaria and sterile laminaria tents; sterile absorbable surgical or dental haemostatics 3006.20 Blood-grouping reagents 3006.30 Opacifying preparations for X-ray examinations;

diagnostic reagents designed to be administered to the patient 3006.40 Dental cements and other dental fillings; bone reconstruction cements 3006.50 First-aid boxes and kits 3006.60 Chemical contraceptive preparations based on hormones or spermicides This heading covers only the

following goods:

(1) Sterile surgical catgut, similar sterile suture materials and sterile tissue adhesives for surgical wound closure.

This item covers all kinds of ligatures for surgical sutures, provided they are sterile. These ligatures are usually put up in antiseptic solutions or in sealed sterile containers.

The materials used for such ligatures include:

(a) catgut (processed collagen from the intestines of cattle, sheep or other animals);

(b) natural fibres (cotton, silk, linen);

(c) synthetic polymer fibres, such as polyamides (nylons), polyesters;

(d) metals (stainless steel, tantalum, silver, bronze).

The item also covers tissue adhesives such as those consisting of butyl cyanoacrylate and a dye; after application, the monomer polymerises and the product is therefore used in place of conventional suture materials for closing internal for closing internal or external wounds of the human body.

The heading excludes non-sterile suture materials. These are classified according to their nature e.g. catgut (heading 42.06), silkworm put, textile yarns, etc. (Section XI), metal were (Chapter 71or Section XV).

(2) Sterile laminaria and sterile laminaria tents.

This item is restricted to sterile laminaria and sterile laminaria tents (small lengths of algae, sometimes brown and with a rough grooved surface). They swell considerably on contact with moist substances and become smooth and flexible.

They are therefore used in surgery as a means of dilation.

Non-sterile products are excluded (heading 12.12) (3) Sterile absorbable surgical or dental haemostatics.

This item covers sterile products used in surgery or dentistry to stop bleeding and having the property of being absorbed by the body fluids. It includes oxidized cellulose, generally in the form of gauze of fibres ("wool"), in pads, pledgets or strip, gelatin sponge or foam; calcium alginate gauze, "wool" or "film".

(4) Blood-grouping reagents.

The reagents under this heading must be suitable for direct use in blood-grouping.

They are either sera of human or animal origin, or vegetable extracts of seeds or other parts of plants (phytagglutinins).

These reagents are used in the determination of blood-groups by reference to the characteristics of

the blood corpuscles or of the blood serum.

In addition to the active principle(s), they may contain substances to strengthen their activity or stabilize them (antiseptics, antibiotics, etc.).

A. The following are to be regarded as reagents for determining blood-group by reference to the characteristics of blood corpuscles:

(i) Preparations for determining the A, B, O and AB groups. A1 and A2 sub- groups and Factor H.

(ii) Preparations for determining the M, N, S and P groups and other groups such as Lu, K and Le.

(iii) Preparations for determining the Rh groups and C, F, V, etc. sub-groups.

(iv) Preparations for determining the blood-groups of animals.

B. The preparations to be regarded as reagents for determining the characteristics of sera are those used to determine:

(i) characteristics of Gm, Km, etc., systems;

(ii) serum groups Gc, Ag, etc.

C. Anti-human globulin serum (Coombs serum), which is essential in certain blood-grouping techniques, is also to be regarded as a reagent of this heading."

D. xxx xxx xxx 5. to 8. xxx xxx xxx"

According to the assessee, MAB is produced by hybridoma technology in which hybrids (fused cells) are allowed to grow by multiplication in culture medium and in that process they secrete the antibodies. According to the assessee, these hybrids (fused cells) are micro- organisms and as they grow in culture medium, therefore, they are classifiable under CSH 3002.00 as "cultures of micro-organisms". In this connection, reliance is place on "Compendium of Transfusion of Medicine" by Dr. R. N. Makroo. In his book Dr. R.N.

Makroo has stated that with advancement in biotechnology, hybridoma technology has made available a new source of reagents; that before the introduction of hybridoma technology, the A.B.O grouping reagents were derived from human donors with or without immunization. According to Dr. Makroo, the main reagent used in blood-bank laboratory is antisera (which is an antibody). Essentially MAB, according to Dr.

Makroo, is obtained from cell culture. It helps in blood- grouping. The development of MAB obtained from cell culture secreting antibodies called hybridoma, has made available a new source of blood-grouping reagents.

According to the assessee, Chapter Heading 30.05 of CETA is the same as Chapter Heading 30.06 of HSN.

Under Chapter Heading 30.06, there is an Explanatory Note in HSN which states that "blood-grouping reagents"

(which term also finds place in Chapter Note '3' to Chapter 30 of CETA) are either the sera of human or animal origin, or vegetable extracts of seeds or other parts of plants and, therefore, such reagents fall under Chapter Heading 30.05 of CETA. However, according to the assessee, MAB is not the sera of human or animal origin or vegetable extracts or plant extracts and, therefore, it cannot fall under Chapter Heading 30.05 of CETA and consequently it has to fall under Chapter Heading 30.02 of CETA. According to the assessee, only polyclonal antibodies are covered under Chapter Heading 30.05 whereas MABs are covered under Chapter Heading 30.02 as "culture of micro-organism".

According to the Department, on the other hand, MAB is a "blood-grouping reagent" which is used in hospitals for blood-grouping. These reagents, according to the Department, are used in the determination of blood-groups by reference to the characteristics of blood corpuscles of blood-serum and, therefore, the said MAB falls under Chapter Heading 30.05. According to the Department, the said MAB has no therapeutic or prophylactic value; that they are merely blood-grouping reagents and, therefore, they fall in Chapter Note '3' which states that all "blood-grouping reagents" fall under Chapter Heading 30.05. On behalf of the Department, it is further argued that on account of Note 3(e) to Chapter 30 of CETA, MAB can only be classified under Chapter Heading 30.05 of CETA. According to the Department, even in common parlance MAB is known as "blood- grouping reagent" and, therefore, it falls under Chapter Heading 30.05 of CETA. On behalf of the Department, it is argued that in the present case we should not go by HSN. According to the Department, HSN deals with human blood, animal blood prepared for diagnostic uses;

antisera and other blood fractions and Modified Immunological Products (for short, 'MIP'), whether or not obtained by means of biotechnological process; vaccine, toxin, cultures of micro-organisms and similar products whereas Chapter Heading 30.02 of CETA does not deal with items like human blood and MIP which items are dealt with by HSN and, therefore, according to the Department, in the present case, one should not rely upon the Explanatory Note to HSN.

We find merit in the arguments advanced on behalf of the assessee. There is no dispute that MAB is a blood- grouping reagent. The question is : whether merely because MAB is a blood-grouping reagent, should it be classified under Chapter Heading 30.05 on account of Note No.3(e) to Chapter 30 of CETA, even though MAB is a "culture of micro-organism" falling under CSH 3002.00 (Chapter Heading 30.02). It is well-settled that the width of the Heading under CETA cannot be expanded by reading Note 3(e) to Chapter 30. In our view, MAB is a "culture of micro-organism". It falls specifically under Chapter Heading 30.02 of CETA. MAB is not a sera of human or animal origin, it is not a vegetable extract, it is not a plant extract and on the other hand it is obtained by hybridoma technology (cellular fusion). Therefore, it cannot fall under Chapter Heading 30.05 of CETA.

Moreover, Chapter Heading 30.05 is residuary. The width of Chapter Heading 30.05 is restricted to products which are mentioned in Note 3(e) to Chapter 30. In other words, not all those pharma products which could not be classified elsewhere in the tariff would fall under Chapter Heading 30.05, but only those which are specified in Note No.3 would fall under Chapter Heading 30.05. In the present case, MAB specifically falls in Chapter Heading 30.02 as culture of micro-organism. If an item like MAB is specifically falling in Chapter Heading 30.02, it cannot be classified under Chapter Heading 30.05 merely on account of Chapter Note '3'. In the present case, the Department seeks to expand the scope of Chapter Heading 30.05, which is residuary, by relying upon Note '3' even when MAB falls under Chapter Heading 30.02 as "culture of micro-organism". In the present case MAB is not polyclonal, it is monoclonal and, therefore, it is known as MAB. In the case of

Inter Care Ltd. v.

Collector of Customs, New Delhi 1997 (89) ELT 545 (Tribunal) it has been held that polyclonal product would fall under Chapter Heading 30.05. However, in the present case, MAB is not polyclonal, it is monoclonal and it is obtained by culture of micro-organism and, therefore, it would fall under Chapter Heading 30.02 (CSH 3002.00). Our view is also supported by the Explanatory Note in HSN to Chapter Heading 30.02 which refers to MIP. The said Note conclusively proves that MAB is a "culture of micro-organism" and, therefore, it would fall under Chapter Heading 30.02. Lastly, even the HSN Explanatory Note to Chapter Heading 30.06 corresponding to Chapter Heading 30.05 of CETA, shows that MAB is excluded from Chapter Heading 30.05. That Heading states that blood-grouping reagents, suitable in blood-grouping, are sera either of human or animal origin or vegetables' extracts or plants' extracts. In other words, MAB which is not the sera of either human or animal origin or vegetable or plant extracts, cannot fall under Chapter Heading 30.05, particularly, when MAB is a culture of micro-organism. There is one more aspect which needs to be highlighted. In the HSN, we have Chapter Heading 30.02 which refers to human blood;

animal blood; "antisera and other blood fractions and MIP"; therefore, human blood is one item, animal blood is another item whereas "antisera, blood fraction and MIP"

is the third item. Therefore, the third item forms one separate class. In that class we have MIP which includes MAB. Therefore, if one reads the third item as a separate class as "antisera and blood fractions" then abridgement of HSN entries by CETA cannot rule out MIP which includes MAB. Therefore, when HSN treats antisera, blood fractions and MIP including MAB as one class then there is no contradiction between Chapter Heading 30.02 of CETA and Chapter Heading 30.02 of HSN. Therefore, taking any view of the matter, HSN cannot be ruled out.

For the above reasons, we find merit in the civil appeal filed by the assessee (Civil Appeal No.5322 of 2002) and, accordingly, we classify the above six items under Chapter Heading 30.02 of CETA.

Accordingly, the said civil appeal is answered in favour of the assessee and against the Department.

C.A.Nos.1953-1954/2003filed by the Department The short question which needs to be decided in these civil appeals is : Whether Beta Visipreg, Visipreg Strip, Pregnancy Test Card fall as "antisera" under Chapter Heading 30.02 of CETA (according to the assessee) or whether it falls under Chapter Heading 38.22 of CETA as "diagnostic or laboratory reagent" (as contended by the Department).

The above three products were cleared by the assessee as Pregnancy Test Kits (PTK). According to the assessee the above three products are for the detection of hCG hormones in urine, as a test for pregnancy. The three products are meant for in-vitro diagnostic use only.

According to the assessee, Chapter Heading 30.02 covers antisera of all forms.

On the other hand, it was argued on behalf of the Department that although PTK was an antisera, the above three products were classifiable as diagnostic or laboratory reagents under Chapter Heading 38.22 as they were used exclusively in laboratory for diagnostic purposes. According to the Adjudicating Authority, Chapter Heading 30.02 applied only to crude antisera and since the above three products were refined antisera, they did not fall under Chapter Heading 30.02.

At the outset, we quote hereinbelow Chapter Heading 38.22 (CSH 3822.00) which reads as under:

"CHAPTER 38 MISCELLANEOUS CHEMICAL PRODUCTS Notes:

1. to 3. xxx xxx xxx Heading No.

Sub-heading No.

Description of goods Rate of duty (1) (2) (3) (4) 38.22 3822.00 Composite diagnostic or laboratory reagents, other than those of Chapter 30 20% As stated above, Chapter Heading 30.02 refers to antisera and other blood fractions. According to the Explanatory Note in HSN (Seventh Edition), antisera is obtained from the blood of humans or animals which are immune against diseases. Antisera is used for diagnostic purposes, including in-vitro tests. There is nothing like crude antisera and refined antisera. In the present case, even according to the Department, PTK is an antisera, however, according to the Department, PTK is a refined antisera. As stated, antisera falls under Chapter Heading 30.02. In the circumstances, "antisera" is covered by Chapter Heading 30.02 and since it is covered by that Heading, Chapter Heading 38.22 will not apply. If one reads Chapter Heading 38.22, it becomes clear that there could be diagnostic or laboratory reagents which could fall under Chapter Heading 30.02 and also under Chapter Heading 38.22. However, if a diagnostic or laboratory reagent like antisera falls under Chapter Heading 30.02 then it stands excluded from Chapter Heading 38.22.

Before concluding we may record the statement made on behalf of M/s. J. Mitra & Co. Ltd. that they have closed down their business in producing the following two items, namely, Syphilis RPR (VDRL) and Salmonella Antigens. Hence, they do not seek to press the classification issue concerning the said two items.

Hence we answer C.A. No.1953-54 of 2003, filed by the Department, in favour of the assessee and against the Department.

For the above reasons, the assessee succeeds on Item Nos. 1 to 9, mentioned at page No.5 of the paper book in C.A.Nos.1953-54/2003 and, therefore, the Department was not entitled to invoke the extended period of limitation under Section 11A of the Central Excise Act, 1944.

C.A.Nos.1076-1080/2002 filed by M/s. Span Diagnostics Ltd. (assessee) These civil appeals are filed by M/s. Span Diagnostics Ltd. (assessee) under Section 35(L) of the Central Excise Act, 1944, against the decision of the CEGAT (for short, 'Tribunal') dated 4.12.2001.

In these civil appeals we are concerned with Item Nos.21 to 32, referred to in Annexure A to the paper book (at pages 27-28), Item Nos.35, 36 and 37 in Annexure A to the paper book (at pages 27-28) and Item Nos.1 to 15 in Annexure B to the paper book (at page 29).

At the outset we quote hereinbelow Item Nos.21 to 32 of Annexure A which read as under:

"ANNEXTURE- 'A' Name of the products which will fall under chapter sub-heading 3005.90 ---------- Sr. Code No. Item Pkg.

No.

---

21. 11127A Anti-A (Monoclonal) 5 ML

22. 11127B Anti-A (Monoclonal) 10 ML

23. 11127C Anti-A (Monoclonal) 3x5 ML

24. 11128A Anti-B (Monoclonal) 5 ML

25. 11128B Anti-B (Monoclonal) 10 ML

26. 11128C Anti-D (Monoclonal lgG+lgM) 3x5 ML

27. 11129A Anti-D (Monoclonal IgM) 5 ML

28. 11129B Anti-D (Monoclonal IgM) 10 ML

29. 11129C Anti-D (Monoclonal IgM) 3x5 ML

30. 11130A Anti-D (Monoclonal IgG + IgM) 5 ML

31. 11130C Anti-D (Monoclonal IgG + IgM) 3x5 ML

32. 11131A Anti-A, B & D (Mono. IgM) 3x5 ML ---------- ---------- It is not in dispute that above Item Nos.21 to 32 are identical to Item Nos.1 to 6 in C.A. No.5322 of 2002 - filed by M/s. J. Mitra and Co. (assessee).

In the circumstances, we hold for the above reasons that Item Nos.21 to 32 would fall under Chapter Heading 30.02 of CETA. Accordingly, the assessee succeeds in this regard.

As regards Item Nos.35, 36 and 37 of Annexure A is concerned, we quote hereinbelow the exact description of the said three items which read as under:

"ANNEXTURE- 'A' Name of the products which will fall under chapter sub-heading 3005.90 ---------- Sr. Code No. Item Pkg.

No.

---

35. 18411 P.P.D. STU/0.1 ML 5 ML

36. 18411A P.P.D. 10TU/0.1 ML 5 ML 37. 18412A Tuberculin P.P.D.

Lyophilized 10TU/0.1 ML 500 TU ---------- ---------- On this point we may state that the Adjudicating Authority had referred the matter for opinion to Dy. Chief Chemist who opined that the three items were "cultures of micro-organisms" and, therefore, they came under Chapter Heading 30.02 and not under Chapter Heading 30.05. Apart from the question as to whether the Dy.

Chief Chemist was or was not entitled to classify, the fact remains that the question as to whether the above produces are "diagnostic reagents" was not referred.

In this case we are concerned with classification of diagnostic reagent for vivo detection of T.B.

mycobacteria.

According to the Adjudicating Authority, these reagents are of mycobacterium origin but they are injected intradermally into the patient and, therefore, they are classifiable under Chapter Heading 30.05 (CSH 3005.90).

According to the Department, the above three items are put up by the assessee for sale in measured doses and, therefore, they were classifiable under Chapter Heading 30.05. In this connection, reliance is placed on Chapter Note 3(d) to Chapter 30 which reads as under:

"CHAPTER 30 PHARMACEUTICAL PRODUCTS Notes:

1. to 2. xxx xxx xxx

3. Heading No.30.05 applies only to the following, which are to be classified in that heading and in no other heading of this Schedule: - (a) to (c) xxx xxx xxx (e) Opacifying preparations for X-ray examinations and diagnostic reagents designed to be administered to the patient, being unmixed products put up in measured doses or products consisting of two or more ingredients which have been mixed together for such uses;

(f) to (h) xxx xxx xxx "

(emphasis supplied) On reading Chapter Note 3(d) it is clear that preparations for X-ray examinations and diagnostic reagents designed to be administered to the patient, put up in measured doses would fall under Chapter Heading 30.05. However, in this case there is no finding given by any of the Authorities below as to whether Item Nos.35, 36 and 37, quoted above, are diagnostic reagents. This question has got to be decided as the assessee contends that the above three products are not diagnostic reagents, they are "diagnostic aid". In this connection, reliance is placed on Pharmacopoeia of India (Third Edition) by Ministry of Health and Family Welfare (GOI) and also on The National Medical Series for Independent Study (Microbiology - 2nd Edition) by Dr.

David T. Kingsbury and Gerald E. Wagner.

Since this question has not been answered we remit the matter to the Adjudicating Authority to decide whether Item Nos.35, 36 and 37, quoted hereinabove, are diagnostic reagents or whether they are in aid of diagnosis.

Now, coming to Item Nos.1 to 15 of Annexure B, we quote hereinbelow the said items which read as under:

"ANNEXTURE - 'B' Name of the products which will fall under chapter sub-heading 3822 ---------- ---------- Sr. Code No. Item Pkg.

No.

---

1. 17401A Anti Sheep Hemolysin 5 ML

2. 19404 Chem. Control (Assayed) 5x3 ML

3. 19404A Chem. Control (Unassayed) 5x3 ML

4. 17405 Fraund's Adjuvant (Com) 10 ML

5. 17406 Guinea pig (Complement) 5x1 ML

6. 19408 Kahn VDRL + Va control 5 ML

7. 19409 Kahn VDRL - Va control 5 ML

8. 19444 Chem. Control Assayed Normal 5x3 ML

9. 19444A Chem. Control Assayed Abnormal 5x3 ML

10. 25907 R.A. Test (Latax Test) 10 T

11. 25907A R.A. Test (Latax Test) 20 T

12. 25934 C.R.P. (Latax Test) 20 T

13. 25947 ASO (Latax Test) 20 T

14. 25946B Austragen (Latax Test) 25 T

15. 25946C Austragen (Latax Test) 50 T ---------- According to the assessee, the above 15 items fall under Chapter Heading 30.02 as they are "blood fractions". This is not disputed by the Department.

However, according to the Department, since Item Nos.1 to 15 are manufactured by coating latex particles with protein, they fall under Chapter Heading 38.22 of CETA.

However, according to the Tribunal, the said items fall under Chapter Heading 30.05 of CETA. At this stage we may note that according to the Department, the said 15 items came under Chapter Heading 38.22 whereas, according to the assessee, they came under Chapter Heading 30.02. The only question before the Tribunal was whether it came under Chapter Heading 38.22 or whether it came under Chapter Heading 30.02. In M/s.

Mitra's case (which we have decided hereinabove vide C.A.No.5322 of 2002), we have taken the view that "blood fractions" fall under Chapter Heading 30.02. Chapter Heading 30.02 refers to "blood fractions". Merely because the medium used is latex (rubber) or paper, will not bring the items under Chapter Heading 38.22. Once an item is a "Blood Fraction" it falls under Chapter Heading 30.02. The medium is irrelevant. The medium could be paper or rubber. The configuration of the product and the function are important. In our opinion, Item Nos.1 to 15 are "Blood Fractions". They are "Blood Fractions" even according to the Department.

In the circumstances, we classify Item Nos.1 to 15 of Annexure B to the paper book under Chapter Heading 30.02 (CSH 3002.00).

Accordingly, except for Item Nos.35, 36 and 37 of Annexure A, the assessee M/s. Span Diagnostics Ltd.

succeeds in C.A. Nos.1076-1080 of 2002. However, with regard to Item Nos.35, 36 and 37 of Annexure A, the matter shall stand remitted to the Adjudicating Authority for fresh decision in accordance with law. Consequently the question of limitation will remain open only with regard to Item Nos.35, 36 and 37 of Annexure A in C.A.

Nos.1076-1080 of 2002.

Accordingly, the above C.A. No.5322 of 2002, C.A.

Nos.1953-54 of 2003 and C.A. Nos.1076-1080 of 2002 stand disposed of with no order as to costs.