Fdc Ltd and Another Vs. Commissioner of Central Excise and Another

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Court : Customs Excise and Service Tax Appellate Tribunal CESTAT Mumbai

Decided On : Jun-22-2010

Judge : The Honourable Mr. P.G. Chacko, Member (Judicial) &Amp;amp; the Honourable Mr. S.K. Gaule, Member (Technical)

Appeal No. : APPEALS NO: E/3208 of 2003 & E/1584 of 2004

Appellant : Fdc Ltd and Another

Respondent : Commissioner of Central Excise and Another

Advocate for Pet/Ap. : Shri S.S. Gupta, Consultant for the assessee-company Shri S.S. Katiyar, Authorised Representative (SDR) for the Revenue.

Judgement :

Per: P.G. Chacko:

The first appeal filed by the assessee involves a classification dispute for the period April 1997 to March 1998 while identical dispute is involved in the second appeal filed by the department for another period (April 1998 to February 1999). In both the appeals the dispute relates to classification of two products namely: "Vitcofol Syrup with Iron" and "Vitcofol Drops". For the period April 1997 to March 1998, the lower authorities classified both the items under Heading 29.36 (SH 2936.00) of the first schedule to the Central Excise Tariff Act and the assessee (appellant) wants both the items to be classified as medicaments under Heading 30.03 (SH 3003.10) of the said schedule. For the period April 1998 to February

1999, the lower appellate authority set aside the order-in-original and allowed the claim of the assessee for classification of both the items under SH 3003.10 and hence the Revenue's appeal.

2. It is not in dispute that "Vitcofol Syrup with Iron" and "Vitcofol Drops" have the following compositions:

Vitcofol Syrup with Iron

Vitcofol Drops

Each 5ml (approx. teaspoon full) contains:

Each ml (approx 30 drops) contains

Ferrous Fumarate I.P.

100 mg

Folic Acid I.P.

200 mcg

Folic Acid I.P.

0.5 mg

Cyanocobalamin I.P. Vitamin (B12)

5 mcg

Cyanocobalamin I.P. Vitamin (B12)

5 mcg

Nicotinamide I.P.

20 mg

Permitted colour :

Amaranth

Permitted colour :

Fast Red E

Flavoured vehicle

q.s.

Flavoured vehicle

q.s.

3. Heard both sides. Learned counsel submits that both the above items were manufactured under licence duly issued by the competent authority under the Drugs and Cosmetics Act, 1940 and the rules framed thereunder. In this connection, he refers to the description of the goods given in the lists appended to the licence. The compositions given in these lists are respectively the same as those given above. In addition to the composition given in each list we find a list, of excipients as follows:

Vitcofol Syrup

Excipients

Dealca V

Viscolizer

Polysorbate 80 I.P.

Surfactant

Glycerin I.P.

Vehicle

Sorbitol I.P.

Vehicle

Sodium Methylparaben I.P.

Preservative

Sodium Propylparaben I.P.

Preservative

Essence of Peach

Flavouring Agent

Essence of Strawberry

Flavouring Agent

Saccharin Sodium I.P.

Sweetening Agent

Anhydrous Citric Acid I.P.

Acidutant

Ammonium Molybdate U.S.P.

Stabilizer

Purified Water I.P. q.s.

Vehicle

Vitcofol Drops

Excipients

Sorbitol Solution I.P.

Vehicle and Sweetner

Sodium Hydroxide I.P.

Solubilizer

Sodium Methylparaben I.P.

Preservative

Sodium Propylparaben I.P.

Preservative

Disodium Edetate

Chelating Agent

Sodium Citrate I.P.

Buffer

Propylene Glycol I.P.

Vehicle

Glycerin I.P.

Vehicle

Cherry Sweet

Flavouring Agent

Anhydrous Citric Acid I.P.

Buffer

Ammonium Molybdate U.S.P.

Stabilizer

Butylated Hydroxy Anisole I.P.

Antioxidant

Purified Water I.P. q.s.

Vehicle

4. It is submitted by the learned consultant that each item of goods under classification is composed of a mixture of the active ingredients shown on its label admixed with the required excipients. It is submitted that the vitamins contained in each item of goods were present in such dosage as was required under the Drugs and Cosmetics Rules to have therapeutic value for the patient. In this connection, the learned consultant has referred to a literature on vitamins available on record ("PHARMACOLOGY AND PHARMACOTHERAPEUTICS" by R.S.Satoskar and S.D. Bhandarkar) and also to the "Standards for Patent or Proprietary Medicines" given in schedule V to the Drugs and Cosmetics Rules, 1945. It has been argued that, in terms of these standards prescribed under the Drugs and Cosmetics Act / Rules, the goods in question are liable to be classified as medicaments on account of the presence therein of active ingredients with therapeutic properties. The learned consultant has also shown us a list of dosages prescribed for the various vitamins, both for adults and children, under the Drugs and Cosmetics Rules. It is submitted that the dosages mentioned on the product labels tally with the dosages mentioned against the relevant vitamins under the said rules and, therefore, the admixtures of the vitamins can only be classified as Patent or Proprietary medicines under SH 3003.10. In respect of Vitcofol Syrup, the learned consultant has particularly referred to the prophylactic and therapeutic properties of ferrous fumarate, the main ingredient in the commodity. Indian Pharmacopoeia 1996 (excerpt available on record) gives an account of the chemical structure, dosage, description, etc. of ferrous fumarate. The consultant has referred to the dosage indicated in the pharmacopoeia and has contended that Vitcofol Syrup containing ferrous fumarate as the active ingredient can only be classified as a medicament under SH 3003.10. The consultant has relied on a few medical certificates (xerox

copies available on record) wherein the doctors, mostly oncologists, certified that Vitcofol Syrup / Drops were administered to patients.

5. The learned consultant has also relied on case law including Manish Pharmaceuticals Pvt. Ltd. vs. Commissioner 2006 (203) ELT 310 (Tri.-Mumbai) wherein certain tablets composed of Ascorbic Acid BP (Vitamin C) as the active ingredient and Ethyl Cellulose as excipient was classified as a medicament under SH 3003.10 and certain mixtures of vitamins were also so classified. It is submitted that the Tribunal's decision was upheld by the Supreme Court in Commissioner vs. Capsulation Services Ltd. 2007 (216) ELT 346 (SC). Consultant has also referred to a few other decisions of the Tribunal.

6. Learned SDR submits that mixtures of provitamins and vitamins are specifically covered under Heading 29.36 and same cannot be classified as medicaments inasmuch as such mixtures of provitamins and vitamins can only be classified under heading 29.36 of the tariff schedule read with HSN Explanatory Notes. It is pointed out that vitamins are described in HSN Notes as exogenous biocatalysts whose absence or deficiency in human body will give rise to metabolic disturbances known as "deficiency deceases." According to the learned SDR, both Vitcofol Syrup and Drops are only such biocatalysts which are used to make up vitamin deficiencies in the human body and cannot be classified as medicaments. It is submitted that the subject goods should be classified on the basis of its description on the product labels and not on the basis of anything contained in the drug licence held by the assessee. In any case, according to the SDR, the heading which provides the specific description for the goods should be chosen for classification of the subject goods. He has also reiterated the grounds of the Revenue's appeal.

7. We have given careful consideration to the submissions. It is not in dispute that the assessee was holding a drug licence for manufacture of both the items. The classification of the goods under the CETA schedule has, however, to be done in terms of the provisions of the relevant heading in the Tariff. SH 3003.10 is a heading for Patent or Proprietary medicaments, other than those medicaments which are exclusively Ayurvedic, Unani, Siddha, Homeopathic or Biochemic. The

term medicaments as defined under Note 2 to Chapter 30 means goods (other than foods or beverages such as dietetic, diabetic or fortified foods, tonic beverages) not falling within Heading 30.02 or 30.04 which are either:

(a) products comprising two or more constituents which have been mixed or compounded together for therapeutic of prophylactic uses; or

(b) unmixed products suitable for such uses put up in measured doses or in packings for retail sale or for use in hospitals.

8. The term 'Patent or Proprietary medicaments' also has been defined under the same Chapter Note and the same means "any drug or medicinal preparation, in whatever form, for use in internal or external treatment of, or for the prevention of ailments in human beings or animals, which bears either on itself or on its container or both, a name which is not specified in a monograph, in a pharmacopoeia, formulary or other publications, such as The Indian Pharmacopoeia, The British Pharmacopoeia, the US Pharmacopoeia, etc". To classify any goods under SH 3003.10, one has to employ the criteria laid down under the heading read with Chapter Note 2. In the case of Vitcofol Syrup, which contains ferrous fumarate as the main ingredient along with two vitamins in small quantities, we have found enough evidence of prophylactic or therapeutic property of the main ingredient depending on the dose. Indian Pharmacopoeia 1996 says that ferrous fumarate in a dose of 200mg daily has prophylactic property and in a dose of 400 to 600 mg daily has therapeutic property. According to the "Standards for Patent or Proprietary medicines" given under the Drugs and Cosmetics Rules, the content of active ingredients, other than vitamins, enzymes and antibiotics, in patent or proprietary medicines, shall be not less than 90% and not more than 110% of the labelled content. The labelled content of Ferrous Fumarate IP in 5 ml of Vitcofol Syrup is 100mg with the two vitamins present in traces (0.5mg and 5 mcg). It would thus appear that Vitcofol Syrup answers the description of goods given under SH 3003.10 of the Tariff Schedule. We classify the item accordingly.

9. The position is different with regard to Vitcofol Drops. The standards prescribed for patent or proprietary medicines under the Drugs and Cosmetics Rules are themselves seem to be working against the assessee's claim. According to these

standards, the content of active ingredients other than vitamins etc., in patent or proprietary medicines shall be not less than 90% and not more than 110% of the labelled content. This would indicate that the active ingredients of a patent or proprietary medicine cannot be vitamins. We have also had a closer look at the product label, which reads thus:

"may be administered directly on the tongue or mixed with milk formulae, fruit juices, sweetened water, cereals, soups, deserts or any other liquid or semi-liquid food".

Thus the very declaration on the product label given by the assessee is enough to rule out Vitcofol Drops as a medicament. Admittedly, it is a mixture of vitamins. The learned counsel has also submitted that it contains excipients also, for which, however, he has not claimed any prophylactic or therapeutic property. HSN Explanatory Notes under Heading 29.36 indicate that vitamins are only exogenous biocatalysts. These explanatory notes do not attribute any prophylactic or therapeutic property to any vitamin or any mixture of vitamins. The description of goods given under Heading 29.36 of the CETA schedule fits well for Vitcofol Drops manufactured by the assessee during the material period and we classify the product accordingly.

10. Learned consultant has referred to the Hon'ble Supreme Court's decision in the case of Capsulation Services Ltd. (supra). It was held in the said case that medicaments had been expressly excluded from the purview of tariff heading 29.36. It would mean that a mixture of vitamins with no prophylactic or therapeutic value must remain within the purview of heading 29.36. Learned consultant has also referred to the case of Manish Pharmaceuticals (supra) wherein certain mixtures of vitamins were held to be classifiable under SCH 3003.10. The Tribunal, in the said case, found that the products in question contained vitamins as well as other ingredients. The products were also found to have been marketed under brand names with dosages indicated. We have already noted, in the instant case, that the product label for Vitcofol Drops declared its intended use in admixture with milk formulae, fruit juices, soups, deserts or other liquid or semi-liquid food. P or P medicaments are not administered in this manner. The learned

consultant has also referred to the Tribunal's Larger Bench decision in Micropure Parenterals Pvt. Ltd. vs. Commissioner 2005 (190) ELT 23 (Tri.-Mumbai) wherein a fixed dose combination of vitamins B1, B2 and B12, both in injection form and tablet form, was classified under SH 3003.10 on account of its therapeutic/ prophylactic value which was evident from certain directions issued by the Drug Controller General. The factors considered by the Larger Bench are missing in the present case in respect of Vitcofol Drops. The case law cited by the learned consultant, however, is supportive of classification of Vitcofol Syrup under SH 3003.10.

11. In the result, the appeal filed by the assessee is partly allowed, Vitcofol Syrup having been classified under SH 3003.10 and the other product under SH 2936.00. Consequently, the appeal filed by the Revenue also will stand partly allowed, with Vitcofol Drops classified under SH 2936.00 and the classification of the other product retained under SH 3003.10.

12. The original authority will have to re-quantify the demand of duty in accordance with the classification decided by us. Considering the nature of the dispute in this case, we are of the view that it would be unreasonable to impose any penalty on the assessee. Therefore, the original authority shall not invoke any penal provision against the assessee.