

B.P.L. PHARMACEUTICALS LTD. A
v.
COLLECTOR OF CENTRAL EXCISE, VADODARA

MAY 4, 1995

[P.B. SAWANT AND K. VENKATASWAMI, JJ.] B

Central Excise Tariff Act, 1985—Tariff Schedule—Sub-headings Nos. 3305.90 and 3003.19—Classification of Selenium Sulfide Lotion U.S.P.—Whether medicine or cosmetic product—Selenium Sulfide the only active ingredient used but constituting only 2.5% of the entire solution—Used for treatment of skin disease ‘seborrhoeic dermatitis’ commonly known as dandruff—Label and literature showed it was for medicinal use—Classified as medicine under the Central Excise Tariff Act, 1944—Held, it is classifiable as medicine. C

The appellant was manufacturer of ‘Selenium Sulfide Lotion U.S.P.’ which contain 2.5% of Selenium Sulfide which was the only active ingredient. 97.5% of the lotion consisted of water, surfactant and inter stabilizer. The product was used for treatment of skin disorder ‘seborrhoeic dermatitis’ more commonly known as ‘dandruff’ and ‘tinea versicolor’. The Food and Drug Administration had certified the product as drug within the meaning of Section 3(b) of the Drugs and Cosmetics Act. The label of the product described it as a poison and a drug. It further advised use of the product as per the direction of physician. The literature relating to the product was addressed to physicians describing the product and the result of various studies relating to the product. The product was D
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The product was classified as a medicine under the Central Excise and Salt Act, 1944 and the said classification was upheld by the Central Board of Excise and Customs. However, after coming into force of the Central Excise Tariff Act, 1985, the product was classified as a "preparation for use on the skin" under sub-heading No. 3305.90 by the order of the Assistant Collector on the ground that Selenium Sulfide had only subsidiary curative and prophylactic value in the solution and therefore Chapter Notes No. 2 of Chapter 33 of the Central Excise Tariff Act, 1985 was attracted and the product was cosmetic and not a medicine. On

A appeal, the Collector of Central Excise (Appeals) set aside the order of the Assistant Collector and held that the product was classifiable under sub-heading No. 3003.19 as a medicament. The respondent preferred an appeal to the CEGAT against the order of the Collector.

B In separate proceedings relating to the confiscation of the product as they were allegedly not accounted for in the statutory RG-1 Register, the Additional Collector, Central Excise held that the product was a cosmetic and fell under sub-heading No. 3305.90 of the Central Excise Tariff Act 1985. The Additional Collector held that Selenium Sulfide was only a minor constituent of the solution and the product was commonly
C known, bought and sold as 'selsun shampoo'. Being aggrieved, the appellant preferred appeal to the CEGAT.

The CEGAT by a common order in appeals of both the appellant as well as the respondent held that the product would fall under sub-heading No. 3305.90 of Chapter 33. The CEGAT, apart from concurring with the
D reasons given by the Assistant Collector and the Additional Collector, also held that classification of the product as a drug under the Central Excise and Salt Act, 1944 was not conclusive as under the old Act of 1944 the tariff heading corresponding to the sub-heading No. 3305 covered "preparation for the care of the hair" whereas under the new Act of 1985 sub- heading
E No. 3305 covered "preparation for use on the hair".

Hence the present appeals.

Allowing the appeals, this court

F HELD : 1. Having regard to the preparation, label, literature, character, common and commercial parlance, understanding and the earlier discussions of the Central Board of Excise and Customs, the product would fall under sub-heading 3003.19. [1260-E]

G 2. The product in question is not intended for cleansing, beautifying, promoting attractiveness or altering appearance. The product in question is intended as a medicine for curing the disease 'Tinea Versicolor' and as such applied to the skin whenever necessary apart from curing dandruff by applying on the scale. It is admitted fact that even bald persons suffer dandruff and that being the position the view taken by the CEGAT that
H the product will fall under the heading preparation for use on the hair is

not sustainable. [1258-F]

3.1. In order to attract note 2 to chapter 33 of the Central Excise Tariff Act, 1985, the product must first be a cosmetic, the product should be suitable for use as goods under heading 33.03 to 33.08 and they must be put in packing as labels, literature and other indications showing that they are for use as cosmetic or toilet preparations. Contrary to the above in the present case none of the requirements are fulfilled. [1256-F]

3.2. In the present case the labels of the product give the warning, precaution and directions for use making it different from that of ordinary shampoo which will not contain such warning or precaution for use.

[1258-H, 1259-A]

4.1. The reasons given by the Authorities that the product contains 2.5% w/v of Selenium Sulfide which has only a subsidiary curative or prophylactic value is without substance. The position is that therapeutic quantity permitted as per technical references including U.S. Pharmacopoeia is 2.5%. Anything used in excess is likely to harm or result in adverse effect. The important factor is that Selenium Sulfide is the main ingredient and is the only active ingredient. [1256-F, G]

4.2. Addition of insignificant quantity of perfume to suppress the smell will not take away the character of the products as drug or medicine.

[1260-C]

5.1. Notwithstanding the fact that the appellants had described the product as Selsun Shampoo, the Central Board of Excise and Customs had classified the same as patented proprietary medicine. The respondents have accepted the same. Therefore, there is no force in the submission that the product must be equated with shampoo. [1256-B, C]

5.2. That the product is understood in the common and commercial parlance as a patent and proprietary medicine was also, found by the Central Board of Excise and Customs as early as in 1981 and accepted by the Excise Authorities. There is no good reason to change the classification merely on the ground of coming into force of the Central Excise Tariff Act, 1985 without showing more that the product has changed its character.

[1259-H, 1260-A, 1259-F]

Indian Metals and Ferro Alloys Ltd. v. Collector of Central Excise, (1991) 51 ELT 165 SC, relied on.

A CIVIL APPELLATE JURISDICTION : Civil Appeal Nos. 2516-2517 of 1994.

From the Judgment and Order dated 29.10.93 of the Central Excise and Salt Act, 1944 of the Customs Excise and Gold (Control) Appellate Tribunal, New Delhi in O.Nos. 336 & 337 of 1993 in A.No. E/610/88-6 & B E/1935/89-C.

Ravinder Narain, S. Shroff, Ms. Amrita Mitra, Nitinbhai, Ranjan Narain and Sonu Bhatnagar for the Appellant.

C M. Gaurishankar Murthy, S.D. Sharma and V.K. Verma for the Respondent.

The Judgment of the Court was delivered by

D K. VENKATASWAMI, J. These two appeals preferred under Section 35L of the Central Excise and Salt Act, 1944 are directed against the orders of the Customs, Excise and Gold (Control) Appellate Tribunal (hereinafter referred to as the 'CEGAT' for short) in order nos. 336 and 337/93C dated 29.10.93. By the orders impugned, the CEGAT has upheld the classification of the product manufactured by the appellants on behalf of their Principals, Abbott Laboratories (India) Limited, Bombay and marketed E under the brand name 'Selsun' (hereinafter called as the 'Product') as a cosmetic under sub-heading 3305.90.

Brief facts are the following :

F The appellants have a factory at 39 G.I.D.C., Vapi, Bhusar and are engaged in the manufacture of 'Selenium Sulfide Lotion U.S.P.' containing 2.5% Selenium Sulfide w/v. The said product was manufactured by the appellants under a loan licence from the Abbott Laboratories in accordance with Abbott's specifications, raw materials and packing materials and quality control. The said product was sold under the Abbott Laboratory's brand name 'Selsun'. It is claimed that 'Selenium Sulfide' is the only active G ingredient and it is used in the required therapeutic quantity, i.e. 2.5% w/v and the other ingredients merely serve the purpose of a bare medium. It is not seriously disputed that the product namely, 'Selsun' is prescribed by physicians for the treatment of skin diseases known as 'Seborrhoeic Dermatitis' commonly known as 'dandruff' and 'Tinea Versicolour' which H is caused by an organism known as 'Pytyriasis versicolour'. This product

has been described and held out to be a drug or a medicinal product and is not held out to be a cosmetic or toilet preparation. In support of this claim, the appellants have produced the label and the literature connected with this product. Details in the label and also the literature will be referred to at the appropriate place. It is also claimed that this product is considered to be an ethical product in medical literature and the same should be used under medical advise.

It is also claimed that the product is manufactured under a Drug licence dated 20th September 1981 issued by the Food and Drug Administration. The said Administration has given a certificate certifying that 'Selsun' is a drug within the meaning of Section 3(b) of the Drugs and Cosmetics Act. It is the case of the appellants that Selsun is not available in the Departmental Stores, but only with Chemists who have a licence under the Drug and Cosmetics Act to sell the same. Abbott Laboratories send their literature only to physicians for their recommendations to their patients. To support the stand taken by the appellants that the product is a drug/medicine they have filed affidavits of chemists stating that the product is a patent and proprietary product and that the chemists require a valid drug licence to buy, stock and sell the same. Normally it is sold to the customers who come with a prescription for Selsun from a Registered Medical Practitioner. In addition to that, the appellants have also filed letters from Doctors and users of the Product specifically stating that Selsun is a useful product in the treatment of the diseases already mentioned above.

It is an admitted fact that this product prior to 28.2.1986 (i.e. before the coming into force of the Central Excise Tariff Act, 1985) was classified as a drug under item 14E of the First Schedule to the Central Excise and Salt Act, 1944. As a matter of fact an issue was once raised whether the product in question and fall under the head of 'medicine' or 'cosmetic' and the Central Board of Excise and Customs by its detailed and exhaustive order dated 17.1.1981 held that the product was a drug or a medicine and the reasons for coming to that conclusion as given by the Board will be referred to later on while discussing the issue.

After the coming into force of the Central Excise Tariff Act, 1985, the appellants filed a classification list dated 10.3.1986 before the Assistant Collector, Central Excise, Bulsar classifying the product falling under

- A sub-heading 3003.19. The Assistant Collector provisionally accepted the same subject to the result of chemical test for which the product was sent. After receiving the report and after hearing the appellants the Assistant Collector by order dated 30.12.1987 held that the product in question will fall under sub-heading 3305.90 and not under 3003.19 as claimed by the appellants. The reasons for coming to that conclusion by the Assistant Collector were the following:

- C "As per the arguments putforth by the party at the time of personal hearing I also referred the technical/chemical literature of the product and as per the information on the container of the product the selenium sulfide USP is 2.5% which is very small proportion looking to the following other ingredients:

D	Surfactant	17.0%
	Inter stabilizer	5.2%
	and water	75.3%

- E and thus as a whole selenium sulfide has got very subsidiary curative or prophylactic value as to other ingredients have in proportion of 97.5% will have the substantial effect. It is also further revealed from the Cosmetics-Science and Technology edited by Edward Sangairal at page 647. The most recently developed preparation of this type is the detergent suspension 'Selsun' which is used in conjunction with the hair cleaning process to counteract seborrhoeic scalp condition. The suspension itself is an effective germistatic agent but the prime reason for its success may be that each use of selsun demands a 5 to 10 minutes cleaning massage. Such a scalp cleaning routine is a very effective 'antidandruff' or antibacterial treatment. The preparation of selsun suspension is shown in formula:

G	Selenium disulphide	2.5%
	Surfactant	17.0%
	Inter stabilizer	5.2%
H	Water	75.3%

and also Selenium sulfide lotion also figures in U.S.P XX page-721 wherein, it is shown to contain a suitable buffer, detergent and dispersing agent. It is further stated on page 5 of the Cosmetic-Science and Technology and 'Undoubtedly, many products conform to the definitions of both drugs and cosmetics under the Act, such as complex remedies, acna remedies, hormone preparations, antiperspirants and many other preparations which can logically be called both drugs and cosmetics.

Now as per Chapter notes No. 2 of Chapter 33 of Central Excise Tariff Act, 1985 heading No. 3303 to 33.08 *inter alia* apply and include products. Whether or not they contain subsidiary pharmaceutical or antiseptic constituents or are held out as having subsidiary curative Prophylactic value, thus as discussed in the foregoing paras. The product under questions having subsidiary curative and prophylactic value is classifiable under sub-heading No. 3305.90.

Further, considering the question why 'Selsun suspension' is not classifiable as medicament under Chapter 30, it will be interesting to refer to Note No. 1(d) of Chapter 30 of Central Excise Tariff Act, 1985 which *inter alia* provides that Chapter 30 does not cover of preparation of Chapter 33 even if they have therapeutic or prophylactic properties.

Further more rule 3(b) of interpretation of Schedule of Central Excise Tariff Act, 1985 states that when goods are not classifiable by reference to 3(a) or 3(b) they shall be classified under the sub-heading which occurs last in numerical order among those which equally merit consideration."

The officers of the Department during a check of the premises of the appellants on or about 7.11.1986 found that a quantity of 17950 bottles of 60 ml. each were offending goods liable to confiscation under the Central Excise law as the goods were found to have been not accounted for in the statutory RG-1 Register though in fully manufactured and marketable condition. A show cause notice was issued on that ground. The matter was heard by the Additional Collector, Central Excise before whom the appellants contended that the goods subjected for confiscation were not fully prepared ones and therefore there was no violation of any of the provisions

A of the Central Excise Law and the goods in question were classifiable under Chapter 30 as a drug/medicine and they will not fall under Chapter 33 as claimed by the Department.

B The Additional Collector by order dated 21.12.1987 held that the product will fall under Chapter 33 and the goods were found in a fully prepared manner and, therefore, the confiscation was proper and a fine of Rs. 35,000 was imposed in lieu of confiscation. A penalty of Rs. 25,000 was also imposed on the appellant. The Additional Collector, Central Excise gave the following reasons in support of his conclusion that the product would fall under sub-heading 3305.90:-

- C (a) That the other manufacturers of similar type of product (i.e. Selsun suspension of M/s. B.P.L. Pharmaceuticals Pvt. Ltd., Vapi) are in possession of licence for 'cosmetics' and evidently mentioned on the respective bottles.
- D (b) That the medicinal properties (i.e. Selenium Sulfide) meant for preventing "Dandruff" comes form 2.5% of Selenium Sulfide which is at a minor constituents as against the total composition of the product and the remaining percentage are of farming agent, flavouring agent, thickening agent and buffer etc."
- E (c) That the "Selsun Suspension" is an "Anti-Dandruff" and is properly formulated "Shampoo";
- F (d) That the usage of the said "Selsun Suspension" is equivalent to other shampoos available in the market;
- F (e) That in common parlance the said Selsun Suspension is commonly known, bought and sold as "Selsun Shampoo" and not as "Selsun Suspension" or "Lotion";
- G (f) That if the said product is P. & P. Medicines then naturally the said product could have been sold by owner of the medical shop on presentation of valid Doctor's prescription;
- H (g) That with intention to evade Central Excise duty, the said M/s. Abbott Laboratories (India) Ltd., Bombay have delivered/removed the words "Dandruff Treatment Shampoo"

in the old bottles as mentioned in new bottles "Selenium Sulfide Lotion U.S.P. Selsun the medical treatment for Dandruff". A

- (h) That the goods in question were filled in the respective bottles of 60 ml. on 31.10.86 at 14.00 hrs. hence the goods have been completely manufactured in all respect and as per the contents of the panchnama which has been agreed by the Director, Shri J.T. Shah, in his statement dated 27.11.1986. As such the seizure effected is correct and the plea that the goods placed under seizure remains to be rubber stamped with date of manufacturing, both number and date of expiry is not acceptable." B C

Aggrieved by the orders of the Assistant Collector and the Additional Collector of Central Excise, the appellants preferred Appeals to the Collector of Central Excise (Appeal) and CEGAT respectively. D

The First Appellate Authority by order dated 20.2.1989 found that the product in question will fall under Chapter 30 and not under Chapter 33 as held by the Assistant Collector, Central Excise. He gave the following reasons: E

"The Assistant Collector arrived at his conclusion that Selsun has subsidiary value on the proportion of the ingredients of Selsun- which are as under:-

Selenium disulphide	2.5%	F
Surfactant	17.0%	
Inter stabilizer	2.5%	
Water	75.3%	G

He further observed that the other ingredients will have the substantial aspect. On the contrary it is seen that the selenium sulphide is the only active ingredient in the preparation and that the other ingredients merely serve the purpose of base, medium and the dispersing agent. H

A As per Chapter Note 2 to Chapter 33 those items or products which contain only subsidiary pharmaceutical or antiseptic constituents or have only subsidiary curative or prophylactic value will only be covered under Chapter 33. In the instant case the appellant adduced evidence contained in the standard technical works on the subject, the opinion of the technical experts and the fact that the product is known among the people who deal in it, to show that selsun is essentially a medicine only and, therefore, it cannot be classified in Chapter 33 as a cosmetic. It is rightly classifiable as medicine falling under Chapter heading 3003.19."

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C Aggrieved by the above said order of the first Appellate Authority, the respondent preferred an appeal to the CEGAT. The appellants also filed Appeal to the CEGAT as noticed earlier against the order of the Additional Collector dated 21.12.1987. The Tribunal by a common order, while holding that the confiscation was not legal reversed the conclusion of the Collector (Appeals) Central Excise who held that the product in question will fall under Chapter 30 and not under Chapter 33. In other words, the Tribunal concurred with the reasonings given by the Assistant Collector as well as the Additional Collector for classifying the product in question under sub-heading 3305.90. The CEGAT apart from accepting the reasons given by the Assistant Collector and the Additional Collector

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E in their separate orders for holding that the product in question will fall under sub-heading 3305.90 also held that the classification of the subject goods as a medicine under the old tariff will not be conclusive of classification of the said goods under the new tariff (3305.90) since the earlier tariff heading covered, *inter alia*, "preparation for the care of the hair including champoos whether or not containing soap or organic surface active agents" and the corresponding heading of the new tariff reads "preparation for use on the hair" including champoos whether or not containing surface active agent. Further the new tariff incorporates the rules of interpretation which were not there under the old tariff." Aggrieved by that the present

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G appeals are filed by the appellants.

H The respondent has not filed any appeal against that portion of the order of CEGAT holding the confiscation as bad. Therefore, the only issue which is common in both these appeals is whether the product 'Selenium Sulfide Lotion U.S.P.' - "Selsun" is classifiable as 'medicine' under sub-heading 3003.19 as contended by the appellant or is classifiable as

'cosmetic' under sub-heading 3305.90 as claimed by the respondent. A

Mr. Ashok Desai, learned Senior counsel appearing for the appellants took us through the orders of the authorities below including the Tribunal and also the earlier order of the Central Board of Excise and Customs dated 17.1.1981. According to the learned counsel the Tribunal has misdirected itself in construing the scope of Chapters 30 and 33 in general and in particular in understanding the Chapter notes and also the interpretation clause. The learned counsel reiterated as his submission the reasoning given by the Central Board of Excise and Customs in its order dated 17.1.1981. He also invited our attention to the numerous affidavits and letters filed by the Chemists, Doctors and the Customers. He contended that except advancing arguments that those affidavits and letters should not be relied upon as they are stereotyped no other concrete material was placed before the Court by the respondent to discredit them. According to the learned counsel in the common as well as commercial parlance the product will not be considered as a shampoo to be brought under Chapter 33. The learned counsel also cited decisions in support of his arguments which will be referred to at the appropriate place. B
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Learned counsel appearing for the Department contending contra submitted that the Tribunal was right in understanding the scope of the Chapters as well as the Chapter notes and the interpretation clause. Merely because under the earlier tariff item, the product was classified as a drug, the same cannot be pressed into service notwithstanding the new classification brought in by the Central Excise Tariff Act, 1985. He also criticised the stereo-typed affidavits and letters filed by the appellants to support the claim that Selsun is a medicine characterising them as 'manufactured evidence'. According to the learned counsel the product in question having only a subsidiary value of therapeutic or prophylactic use, it will fall under Chapter 33 having regard to Chapter notes as pointed out by the Tribunal. According to the learned counsel the commercial parlance cannot be a sure guide for classifying the product under one Chapter or the other and, therefore, the reliance placed on 'commercial parlance theory' cannot be accepted. Learned counsel also cited some decisions in support of his contention which will be referred to at the relevant place. E
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Before considering the rival contentions elaborately, it is necessary and useful to set to relevant portions in the tariff items, Chapter notes and H

A the Rules for the interpretation of the Schedule. Relevant portions in Chapter 30 are set out below :-

"Pharmaceutical products

Notes:

- B 1. This Chapter does not cover :
- (a)
- (b)
- C (c) Aqueous distillates or aqueous solutions of essential oils, suitable for medicinal uses (Chapter 33),
- (d) Preparations of Chapter 33 even if they have therapeutic or prophylactic properties;
- D 2. For the purposes of heading No. 30.03,
- (i)
- (ii) 'Patent or proprietary medicament' means any drug or medicinal preparation, in whatever form, for use in the internal or external treatment of, or for the prevention of ailments in human beings or animals, which bears either on itself or on its containers or both, a name which is not specified in a monograph, in a Pharmacopoeia, Formulary or other publications, namely:-
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- F (a) The Indian Pharmacopoeia;
- (b) The International Pharmacopoeia;
- (c) The National Formulary of India;
- G (d) The British Pharmacopoeia;
- (e) The British Pharmaceutical Codex;
- (f) The British Veterinary Codex;
- H (g) The United States Pharmacopoeia;

(h) The National Formulary of the U.S.A A

(i) The Dental Formulary of the U.S.A.; and

(j) The State Pharmacopoeia of the U.S.S.R.

or which is a brand name, that is, a name or a registered trade mark under the Trade and Merchandise Marks Act, 1958 (43 of 1958), or any other mark such as a symbol, monogram, label, signature or invented words or any writing which is used in relation to that medicine for the purpose of indicating or so as to indicate a connection in the course of trade between the medicine and some person, having the right either as proprietor or otherwise to use the name or mark with or without any indication of the identity of that person." B
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Heading No. 30.03 Medicaments (including veterinary medicaments) D

Patent or proprietary medicaments, other than those medicaments which are exclusively Ayurvedic, Unani, Siddha, Homeopathic or Bio-chemic; E

Sub-Heading No.
3003.19 - Other

Relevant portions in *Chapter 33* are set out below: F

"ESSENTIAL OILS AND RESINOIDS : PERFUMERY,
COSMETIC OR TOILET PREPARATIONS

NOTES :

1. This Chapter does not cover: G

(a) Soap or other products of heading No. 34.01;

(b) Gum, wood or sulphate turpentine or other products of Chapter 38; or H

- A (c) Perfumery, cosmetics and toilet preparations containing alcohol or opium, Indian hemp or other narcotics and for this purpose these expressions have the meanings respectively assigned to them in Section 2 of the Medicinal and Toilet Preparations (Excise Duties) Act, 1955 (16 of 1955).
- B 2. Heading Nos. 33.03 to 33.08 apply, *inter alia*, to products, whether or not mixed (other than aqueous distillates and aqueous solutions of essential oils), suitable for use as goods of these headings and put up in packings with labels, literature or other indications that are for use as cosmetics or toilet preparations or put up in a form clearly specialised to such use and includes products whether or not they contain subsidiary pharmaceutical or antiseptic constituents, or are held out as having subsidiary curative or prophylactic value."
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Heading No.

- E 33.05 Preparations for use on the hair, including brilliantines, perfumed hair oils, hair lotions, pomades and creams, hair dyes (in whatever form), shampoos, whether or not containing soap or organic surface-active agents.

Sub-heading No.

F 3305.90 - Other

Heading No.

- G 33.06 3306.00 Preparations for oral or dental hygiene, including dentifrices (for example, toothpaste and tooth powder) and denture fixative pastes and powders.
- H 33.08 Prepared room deodorisers, whether or not perfumed or having disinfectant properties, including oderiderous preparations used during religious rites."

Relevant rules for the interpretation of the schedule are set out below:- A

"3. When by application of sub-rule (b) of rule 2 or for any other reason, goods are, *prima facie*, classifiable under two or more headings, classification shall be effected as follows:-

(a)

(b)

(c) When goods cannot be classified by reference to (a) or (b), they shall be classified under the heading which occurs last in the numerical order among those which equally merit consideration." B C

It is also necessary to set out the corresponding previous tariff items as they stood prior to 1.3.1986, namely, 14E and 14F relating to patent or proprietary medicines and toilet preparations respectively. They read as follows:- D

"Tariff Item 14E - Patent or Proprietary Medicines:

14E. Patent or proprietary medicines not containing alcohol, opium, Indian hemp or other narcotic drugs or other narcotics other than those medicines which are exclusively Ayurvedic, Unani, Siddha or Homeopathic. E

Explanation I. Patent or Proprietary Medicines means any drug or medicinal preparation, in whatever form, for use in the internal or external treatment of or for the prevention of ailment 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 notified in this behalf by the Central Government in the Official Gazette, or which is a brand name, that is, a name or a registered trade mark under the Trade and Merchandise Marks Act, 1958 (43 of 1958), or any other mark such as symbol, monogram, label, signature or invented words of any writing which is used in relating to that medicine for the purpose of indicating or so as to indicate a connection in the course of trade between the medicine and some person, having the F G H

A right either a proprietor or otherwise to use the name or mark with or without any indication of the identity of that person.

Explanation II - 'Alcohol', 'opium', 'Indian hemp', 'Narcotic Drugs' and 'Narcotics' have the meanings respectively assigned to them in Section 2 of the Medicinal and Toilet Preparations (Excise Duties) Act 1955.

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Item No. 14E - Cosmetics and Toilet Preparations :

14F. Cosmetics and toilet preparations not containing alcohol or opium, Indian hemp or other narcotic drugs or narcotics, namely:-

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(i) Preparations for the care of the skin, beauty or make-up preparations and manicure or pedicure preparations, such as, beauty creams; vanishing creams, cold creams, make-up creams, cleansing creams, skin foods and skin tonics, face powders and grease paints lipsticks, eye-shadow and eye-brow pencils, nail polishes and varnishes, cuticle removers and other preparations for use in manicure or chiropody, sub-burn preventive preparations and sub-tan preparations, barrier creams to give protection against skin irritants, personal (body) deodorants, depilatories.

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(ii) Preparations for the care of the hair, such as; brilliantines, perfumes hair oils, hair lotions, pomades and creams, hair dyes, shampoos whether or not containing soap or organic surface active agents.

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(iii) Shaving creams, whether or not containing soap or organic surface active agents.

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Explanation I - "Alcohol", "opium", "Indian hemp", "Narcotic Drug" and "Narcotics" have the meanings respectively assigned to them in Sections 2 of the Medicinal and Toilet Preparation (Excise Duties) Act, 1955.

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Explanation II - This item includes cosmetics and toilet preparations whether or not they contain subsidiary pharmaceutical or antiseptic constituents, or are held out as having subsidiary curative or prophylactic value.

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Explanation III. - This item includes unmixed products only when they are in packing of a kind sold to the consumer and put up with labels, literature or other indications that they are for use as cosmetics or toilet preparations or put up in a form clearly specialised to such use." A

It will be useful to set out the reasons which weighed with the Central Board of Excise and Customs to hold that the product in question is a drug or medicine, of course under the old tariff entry namely, 14E. Those reasons given by the Board are the following :- B

"(a) It was used for the treatment of a disease known as Seborrhoeic Dermatitis, commonly known as Dandruff. C

(b) It was manufactured under a Drug licence.

(c) The Food and Drugs Administration had certified it as a drug.

(d) That the Drug Controller had categorically opined that Selenium Sulphide present in Selsun was in a therapeutic concentration. D

(e) The brand name "Selsun" was derived from the name of the drug Selenium Sulfide. E

(f) It was included as a drug in the National Formulary, U.S. Pharmacopia and the Merck Index.

(g) It fulfilled the requirements of a drug as understood in common parlance. F

(h) Selenium Sulfide was sold only on medical prescription and used as a medicine;

(i) Selsun was not a medicated shampoo, which was recommended as conditioners with subsidiary medicinal effect. Selsun was on the contrary being recommended by physicians; G

(j) Various standard books and treatises such as (i) The Pharmacological Basis of Therapeutics by Goodman and Gilman (ii) Harry's Cosmeticology referred to Selsun as a drug. H

- A (k) It was being marketed as a Patent or Proprietary medicine through Registered Pharmacists who hold valid drug licence, and not by any dealer like other shampoos;
- (l) Abbott's literature referred to it as a drug and such literature was addressed to physicians, also the label on the container mentioned that the product was to be used as directed by physicians.
- B (m) Affidavits of leading doctors established that Selsun was being manufactured for use as a drug.
- (n) The Sales Tax authorities taxed Selsun as a drug.
- C (o) Selsun was repeatedly held by the Excise authorities as a drug.
- (p) Johnson's Prickly Heat Powder and Nycil have been recognised as drug and Selsun stood on a stronger ground;
- D (q) That the Excise Department had made inquiries from the trade and found that other shampoos like Clinic, Tata, Halo Etc. were much cheaper and that their advertisement campaigns were "to leave the hair silky, soft and healthy" whereas Selsun was not so advertised. On the contrary there are precautions in use mentioned."
- E
- Similarly it is very relevant to bear in mind the label, literature and medicinal properties concerning the product in question. The labels specifically mention as follows:
- F (i) That it is a poison;
- (ii) Gives a cautionary note that the product should be used for external use only and should be kept out of the eyes and away from children and also that it should not be used immediately after bleaching, tinting or permanent waving of the hair or on inflamed scalp;
- G (iii) That it should be used twice weekly initially and then as often as necessary or as directed by the physician.
- H (iv) That it is a medical treatment for dandruff.

(v) That it contains selenium sulphide SSP 2.5% w/v. A

(vi) That the hair should be washed first and then the Selsun should be massaged into the scalp and left for 2 or 3 minutes and thereafter rinsed thoroughly.

Regarding the literature which is given by appellants in the Paper Book, the same can be briefly set out as follows :- B

(1) That the literature is for use only by Registered Medical Practitioners or a Hospital or a Laboratory.

(2) The literature indicates that Selsun effectively controls Dandruff and clears scalp and Seborrhea and thereby controls Acne, stitis external and Bleph-aritis. C

(3) The literature shows that Selsun is an effective and safe treatment for the disease Tinea Versicolor and Pityriasis Versicolor which are an infection of the skin and appears frequently on the trunk, neck, face and proximal portions of the arms and legs. D

(4) The literature also informs physicians of the results of various studies relating to the effectiveness of Selsun for curing the above diseases. E

(5) The literature states that if neglected, Dandruff can lead to itching, scaling, falling of hair, acne and blepharitis.

(6) Physicians are also informed regarding the directions of use and it is suggested that the scalp should be rinsed for 3 to 4 changes of water and after 'treatment' the hands should be washed thoroughly, specially under the finger nails'. F

So far as medicinal properties of the product are concerned it can be gathered from the technical and/or pharmaceutical references that Selenium Sulfide has anti fungal and anti-seborrhoeic properties and is used in a detergent medium for the treatment of Dandruff on the scalp which is milder form of Seborrhoeic dermatitis and Tinea Versicolor. 2.5% of this compound is the Therapeutic quantity. G

At the risk of repetition, it must be pointed out that on the side of H

A the respondents, no other material is produced to discredit the affidavits and letters filed by the appellant before the CEGAT. As a matter of fact, it is seen from the order of the Central Board of Excise that such affidavits and letters were also produced in the year 1981 and they were taken note of by the Central Board of Excise. Nonetheless, the learned counsel appearing for the respondent, as pointed out earlier, criticised the affidavits as 'manufactured evidence'. We could like to comment on this that it is not fair to call the affidavits and other letters as 'manufactured evidence' as they were not produced before the Court for the first time. They were produced long ago before the Central Board of Excise and instead of taking steps to produce materials to dislodge that evidence, it is not open to the learned counsel for the respondent to merely state from the Bar that the affidavits and letters are manufactured evidence.

We have given above in detail the facts and circumstances leading to the filing of this appeal. Let us now take up the issue placed for the decision of this Court.

D In the earlier paragraphs we have seen that the product in question viz. 'Selsun' has been, for a long time, classified by the Excise Authorities as a patent and proprietary medicine accepting the decision of the Central Board of Excise and Customs rendered on 17.1.1981. The principal reason for changing this classification, as appears from the orders of the Authorities below, is the coming into force of the new Central Excise Tariff Act 1985 read with schedule thereunder and also the rules for interpretation of that schedule. Therefore, we will have to see whether there is justification for such a change of classification?

F The learned counsel for the respondent while supporting and justifying the impugned order submitted that the learned counsel for the appellants is not right in placing reliance on the previous classification of the product under the old tariff; nor right in relying on medicinal properties as set forth in the literature relating to the product and other technical or pharmacopoeal references not right in placing reliance on market understanding of the product and finally reliance place on the definition of 'drugs and cosmetics' in the Drug and Cosmetics Act is also not sustainable.

Elaborating the above submissions, the learned counsel for the respondents invited our attention to Chapter notes of Chapter 30 and Chapter 33 and also the Rules of interpretation. According to the learned

counsel a careful reading of Chapter notes of Chapter 30 would show that preparations of Chapter 33 even if they have therapeutic or prophylactic properties would not fall under Chapter 30. However, he fairly admitted that 'medicaments' are those that have therapeutic or prophylactic uses. Nevertheless those medicaments, if they are classifiable under Chapter 33 or Chapter 34 will not fall under Chapter 30, according to him, if they are more specifically preparations of Chapter 33 or Chapter 34. In other words, he wants to equate the product in question to 'shampoo' enumerated under heading 33.05. He also invited our attention to the fact that the appellants before the coming into force of the new Tariff Act described the product as shampoo and they have omitted the word 'shampoo' deliberately only to claim that the product would fall under Chapter 30.

We do not think that we can accept all the contentions of the learned counsel for the respondents except certain obvious admitted positions. The submission that the product in question must be equated to shampoo falling under Chapter 33 is not at all correct.

It is true that the learned counsel for the appellants have placed reliance on the definition of the words 'cosmetic and drug' as defined in the Drugs and Cosmetics Act, 1940. On a perusal of the definitions, we can broadly distinguish cosmetic and drug as follows :-

"A "cosmetic" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to the human body or any part thereof for *cleansing, beautifying, promoting attractiveness, or altering the appearance*, and includes any article intended for use as a component of cosmetic."

And "A "Drug" includes all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, *treatments, mitigation or prevention of any disease or disorder in human being or animals*, including preparations applied on human body for the purpose of repelling insects"

We cannot ignore the above broad classification while considering the character of the product in question. Certainly, the product in question is not intended for cleansing, beautifying, promoting attractiveness or

A altering appearance. On the other hand it is intended to cure certain diseases as mentioned supra.

B The fact that the appellants have previously described the product as 'Selsun Shampoo' will not conclude the controversy when the true nature of the product falls for determination. In fact, notwithstanding the fact that the appellants have described the product as Selsun Shampoo, the Central Board of Excise and Customs, as noticed earlier, has classified the same as patent and proprietary medicine. The respondents have accepted the same. Therefore, there is no force in the submission of the learned counsel for the respondents that the product must be equated with shampoo.

C The contention based on Chapter notes is also not correct. One of the reasons given by the Authorities below for holding that Selsun would fall under Chapter 33 was that having regard to the composition the product will come within the purview of note 2 to Chapter 33 of the schedule to Central Excise Tariff Act 1985 is without substance. According to the Authorities the product contains only subsidiary pharmaceutical value and, therefore, notwithstanding the product having a medicinal value will fall under Chapter 33. We have already set out note 2 to Chapter 33. In order to attract note 2 to Chapter 33 the product must first be a cosmetic, that the product should be suitable for use as goods of heading 33.03 to 33.08 and they must be put in packing as labels, literature and other indications showing that they are for use as cosmetic or toilet preparation. Contrary to the above in the present case none of the requirements are fulfilled. Therefore, note 2 to Chapter 33 is not attracted. Again it is without substance the reason given by the Authorities that the product contains 2.5% w/v of Selenium Sulfide which is only a subsidiary curative or prophylactic value. The position is that therapeutic quantity permitted as per technical references including U.S. Pharmacopoeia is 2.5%. Anything in excess is likely to harm or result in adverse effect. Once the therapeutic quantity of the ingredient used, is accepted, thereafter it is not possible to hold that the constituent is subsidiary. The important factor is that this constituent (Selenium Sulfide) is the main ingredient and is the only active ingredient.

H As rightly contended by the learned senior counsel for the appellants that merely because there is some difference in the tariff entries, the product will not change its character. Something more is required for

changing the classification especially when the product remains the same. We have noticed that the Excise Authorities have accepted the decision of the Central Board of Excise and Customs treating the product in question as patent and proprietary medicine by not challenging the same or by allowing the same to become final. We have also seen that the Central Board of Excise and Customs has given numerous points in support of its conclusions for holding the product in question as patent and proprietary medicine. Principal among them at the risk of repetition can be recalled. They are as follows :

(a) It was used for the treatment of a disease known as Saborhoetic Dermatitis, commonly known as dandruff.

(b) It was manufactured under a Drug licence.

(c) The Food and Drugs Administration had certified it as a drug.

(d) That the Drug Controller had categorically opined that Selenium Sulphide present in Selsun was in a therapeutic concentration.

(f) It was included as a drug in the National formulary, U.S. Pharmacoeopia and the Merck Index.

(g) It fulfilled the requirements of a drug as understood in common parlance.

(h) Selenium Sulfide was sold only on medical prescription and used as a medicine;

(i) Selsun was not a medicated Shampoo, which was recommended as conditioners with subsidiary medicinal effect. Selsun was on the contrary being recommended by physicians;

(j) Various standard books and treaties such as (i) The pharmacological Basis of therapeutics by Goodman and Gilman (ii) Harry's Cosmetionlogy referred to Selsun as a drug.

(k) It was being marketed as a Patent or Proprietary medicine through Registered Pharmacists who hold valid drug licence, and not by any dealer, like other shampoos;

A (l) Abbott's literature referred to it as a drug and such literature was addressed to physicians, also the label on the container mentioned that the product was to be used as directed by physicians.

(m) Affidavits of leading doctors established that Selsun was being manufactured for use as a drug.

B (q) That the Excise Department had made inquiries from the trade and found that other shampoos like Clinic, Tata, Halo etc. were much cheaper and that their advertisement campaigns were "to leave the hair silky, soft and healthy" whereas Selsun was not so advertised. On the contrary there are precautions in use mentioned."

C The above conclusions of the Central Board of Excise and Customs were reached on the basis of materials produced before it. The same materials are also placed before us and we have gone through them. We find no good reason to differ from the above conclusions of the Central Board of Excise and Customs especially in the absence of any other materials produced by the respondents to persuade us to take a different view. Certain contrary finding of the Authorities below such as that 'Selsun' is only a medicated shampoo without any acceptable supporting material cannot be sustained.

E Another reason given by the CEGAT is that heading 33.05 uses the word "Preparation for use on the hair" and therefore the product in question can be brought under the said heading. The Tribunal forgets that the product in question is intended as a medicine for curing the disease 'Tinea Versicolor' and as such applied to the skin wherever necessary apart from curing dandruff by applying on the scalp. It is also an admitted fact that even bald person suffer from dandruff and that being the position the view taken by CEGAT that the product will fall under the heading preparation for use on the hair is not sustainable. We have already noted the contents of labels and literature and a perusal of the same will show that the appellants have nowhere indicated that the product is to be used as a cosmetic or toilet preparation nor they have held out the product to be a cosmetic.

H The labels which give the warning, precaution and directions for use do make a difference from that of ordinary shampoo which will not contain

such warning or precautions for use. Further no individual would be prepared to say in a social gathering that he or she is using Selsun to get rid of dandruff or other similar diseases whereas nobody would hesitate to state in a similar gathering that he or she is using a particular brand of shampoo for beautifying his or her hair. Thus there are lot of favourable materials to treat the product in question as a medicine rather than cosmetic. In this connection the reliance placed by the learned counsel for the appellants on a decision of this Court reported in case *Indian Metals and Ferro Alloys Ltd. v. Collector of Central Excise*, (1991) 51 E.L.T. 165 SC can be usefully referred to. In that case this Court held :-

"It (the Tribunal) seems to say that, even if the goods manufactured by the appellant had been rightly classified under Item 26AA before 1.3.1975, the introduction of Item 68 makes a difference to the interpretation of Item 26AA. This is not correct. Item 68 was only intended as a residuary item. It covers goods not expressly mentioned in any of the earlier items. If as assumed by the Tribunal the pales manufactured were rightly classified under Item 26AA, the question of revising the classification cannot arise merely because Item - 68 is introduced to bring into the tax net items not covered by the various items set put in the schedule. It does not and cannot affect the interpretation of the items enumerated in the schedule. This logic of the Tribunal is, therefore, clearly wrong."

This judgment supports the case of the appellant when it is contended that there is no good reason to change the classification merely on the ground of coming into force of the new Central Excise Tariff Act 1985 without showing more that the product has changed its character.

The learned counsel also place reliance on a number of judgments to support his argument that in common and commercial parlance the product is known as medicine rather than cosmetic. As pointed out already and in support of that submission affidavits and letters from Chemists, Doctors and customers are filed to show that the product is sold under proscriptioin only in Chemists shops unlike shampoos sold in any shop including provision shops. This conclusion, namely, the product is understood in the common and commercial parlance as patent and proprietary medicine was also found by the Central Board of Excise and Customs as

A early as in 1981 and accepted by the Excise Authorities and in the absence of any new material on the side of the respondents there is no difficulty in accepting this contention without referring to decision cited by the counsel for the appellants.

B Yet another reason given by the CEGAT for not accepting the case of the appellants was that the product is sold with a pleasant odour and, therefore, it must be treated as a cosmetic. Selenium Sulphide as an unpleasant odour and to get rid of it insignificant amount of perfume is used and make it acceptable to the consumers. A medicine, for example, sugar - coated pill will nevertheless be medicine notwithstanding the sugar-coating. Likewise the addition of insignificant quantity of perfume to suppress the smell will not take away the character of the product as a drug or medicine. Again one other reason given by the Tribunal is regarding the packing. The Tribunal has held that the product is cosmetic because it is packed in an attractive plastic bottle. This by itself will not change the character, as cosmetic is put up for sale with some indication on the bottle or label that it is to be used as cosmetic or it is held out to be used as a cosmetic. As already noted the label here gives warnings. The fact that it is packed in a plastic bottle is wholly irrelevant criteria.

E On a perusal of the entire material we are satisfied that the product in question, having regard to the preparation lable, literature, character, common and commercial parlance understanding and the earlier decisions of the Central Board of Excise and Customs, would fall under sub-heading 3003.19 and there is no justifiable reason for changing the classification. As we have reached the above conclusion with reference to the materials placed before us on facts, we do not think it necessary to go into other decisions cited at the Bar. In the result the appeals are allowed holding that the product 'Selsun' will fall under tariff Item 3003.19. However, there will be no order as to costs.

B.K.M.

Appeals allowed.