

COMMISSIONER OF CENTRAL EXCISE, HYDERABAD A

v.

M/S. SARVOTHAM CARE LIMITED

(Civil Appeal No.4480 OF 2005)

MAY 14, 2015 B

[A. K. SIKRI AND R. F. NARIMAN, JJ.]

Central Excise Tariff Act, 1985 – CHS 3003.10 and CHS 3305.99 – Ketoconazole Shampoo and Nizral Shampoo – Classification of, under CHS 3003.10 as ‘pharmaceuticals product’ or under CHS 3305.99 as ‘preparation for use on hair’ – Held: The essential properties of Ketoconazole Shampoo and Nizral Shampoo are medicinal in nature – Thus, the product is classifiable under CSH 3003.10 as pharmaceutical Product. C D

Disposing of the appeals, the Court

HELD: 1.1 The view taken by the tribunal that the product ‘Nizral Shampoo’ is classifiable under CSH 3003.10 as pharmaceuticals Product and not CSH 3305.99 as preparation for use on hair, is concurred with. [Para 13] [13-D] E

1.2 The product known as ‘Nizral Shampoo’ gives the nomenclature of the product as shampoo. To determine as to whether the product in question is primarily used as a shampoo or it is used as a medicament, it is necessary to keep in mind the essential characteristics of the product. On examination from the said perspective, it is concluded that the respondent is correct in submitting that the essential properties of the product are medicinal in nature. The manufacturer has given clear warning and precautions for the use of this F G H

A product. It is mentioned as to how the treatment should be given to a person suffering from various kinds of dandruffs. Even the adverse reactions of the treatment are mentioned by the manufacturers with specific advice that overdose of this shampoo is not expected. Thus, not only limited period use is stated, another important feature that appears in the literature supplied by the respondent is the information for the 'patient', describing the user of the product as a 'patient'. [Para 14, 15] [13-E-F, G; 14-A, G; 15-B-C, E-F; 16-C]

1.3 The use is suggested only on the advice of a Doctor and there is a suggestion that a Doctor should be consulted for any further information. The respondent has also provided the literature/material showing that dandruff is a disorder which affects the hairy scalp. It is generally triggered by a single celled organism which is a kind of fungus, with scientific name 'Pityrosporum Ovale'. For treatment of this disease, Nizral Shampoo 2% (i.e. shampoo containing 2% ('Ketoconazole') is shown as 'a new medicine' use whereof cures dandruff. It is suggested that it should be used once a week and on other days, normal shampoos may be used which clearly shows that 'Nizral Shampoo' is to be used like a medicine, unlike other normal Shampoos. Further, in order to show that the product was used only as a medicament for curing dandruff and not for using the same for the purpose of cleaning hair, the assessee filed affidavits of various Doctors. [Para 16,17] [16-F-H; 17-A-B]

1.4 The tribunal held that there is enormous evidence produced by the appellants with regard to the use of Ketoconazole Shampoo for treatment of several disorders and diseases mentioned in the pamphlet and the same is sold by a chemist under a prescription issued by a Registered medical Practitioner or a Hospital or a

Laboratory. Thus, the judgment of the tribunal does not A
call for any interference. As regards the other appeal, for
the reasons recorded in C.A. No. 4480 of 2005, the order
of the High Court as well as respondent No.2 demanding
differential duty is quashed. [Paras 19, 20, 22] [25-C-D,
E; 26-A-B] B

B.P.L. Pharmaceuticals Ltd. v. CCE, Vadodra
1995 (3) SCR 1235; 1995 Supp. (3) SCC 1 –
relied on.

Collector of Central Excise, Shillong v. Wood C
Crafts Products Ltd. 1995 (2) SCR 797; (1995) 3
SCC 454; *CCE, Hyderabad v. Bakelite Hylam*
1997 (91) ELT 13; *Amit Ayurvedic & Cosmetic*
Products v. Commissioner 2004 (168) ELT 354;
CCE Vapi v. Beta Cosmetics 2004 (173) ELT 255 D
– referred to.

Case Law Reference

1995 (2) SCR 797	Referred to.	Para 7	E
1997 (91) ELT 13	Referred to.	Para 8	
2004 (168) ELT 354	Referred to.	Para 9	
2004 (173) ELT 255	Referred to.	Para 9	
1995 (3) SCR 1235	Relied on.	Para 18	F

CIVIL APPELLATE JURISDICTION : Civil Appeal No.
4480 of 2005

From the Judgment and Order dated 18.01.2005 of the G
Customs, Excise & Service Tax Appellate Tribunal, South Zonal
Bench at Bangalore in Final Order No. 120 of 2005 in Appeal
No. 555 of 2002.

WITH

Civil Appeal No. 5752 of 2015 H

A A. K. Panda, S.K. Bagaria, Rajiv Nanda, T.M. Singh, B. Krishna Prasad, Alok Yadav, Anuj B., Udit Jain, Ajit, Harish Pandey, Ranjan Narain for the appearing parties.

The Judgment of the Court was delivered by

B **A. K. SIKRI, J.**

Civil Appeal No. 4480 of 2005

1. Respondent herein is the manufacture of 'Ketoconazole Shampoo' and 'Nizral Shampoo' which are sold in the bottles of 50 ml and 5 ml. Dispute is about the classification of the aforesaid product for the purposes of payment of central excise duty. The respondent had filed the declaration classifying the said product under CSH 3003.10 of the Central Excise Tariff Act, 1985 on the ground that it is basically a medicine. However, as per the appellant/Revenue, the appropriate classification of this product is under CSH 3305.99 as it perceives the product as 'preparation for use on on hair'.

E 2. Chapter 30 under which CSH 3003.10 falls deals with Pharmaceuticals products and the aforesaid entry thereof reads as under:

F "Patent or proprietary medicaments, other than those medicaments which are exclusively Ayurvedic, Unani, Siddha, Homoeopathic or Bio-chemic."

On the other hand, Chapter 33 deals with the products which fall under the nomenclature 'Essential Oils and Resinoids; Perfumery, Cosmetic or Toilet Preparation'.

G The entry CSH 3305.99 thereof is as under:

"Preparations for use on the hair

-Perfumed hair oils

-Other :

—Hair fixer

H —Other"

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M/S. SARVOTHAM CARE LTD. [A. K. SIKRI, J.]

3. It becomes clear from the reading of the aforesaid A
two entries that the respondent claims that the product in
question belongs to the specie of Pharmaceutical products
i.e. medicinal product and is covered by the expression
'patent or proprietary medicaments'. On the other hand, the
case of the Revenue is that it is simply a shampoo which is B
to be used for cleaning hair and is nothing but a 'toilet
preparation'. If the product is to be treated as Pharmaceutical
product covered by Entry 3003.10, excise duty prescribed
is 16%. The excise duty of goods covered by Entry 3305.99 C
is 24%.

4. The Revenue issued show cause notice demanding
differential duty amounting to Rs.8,12,194. After the reply
was given by the respondent along with the material placed
by it before the Adjudicating Authority, the Adjudicating D
Authority passed the Order-in-Original dated 18.11.1999
for the period December, 1998 to April, 1999 confirming
the differential duty of Rs.8,12,194 under Section 4A read
with Section 11A of the Central Excise Act, 1944. In appeal
preferred by the respondent, the aforesaid demand was E
upheld by the Commissioner (Appeals) vide order in
original dated 13.02.2002, resulting in the dismissal of the
appeal of the respondent. Next level appeal filed by the
respondent before the CESTAT, Bangalore, however, yielded
results favourable to the respondent, as this appeal is allowed F
by the Tribunal vide final Orders dated 18.01.2005 with
consequential reliefs, if any. It was held that there is enormous
evidence to show that the product in question was used for
treatment of several disorders/diseases and it has also
been sold by Chemists under the prescription issued by G
the Registered Medical Practitioners or the Hospitals.
Therefore, it is a medicinal product and not simply a shampoo
for use of hair. Naturally, the Revenue is not satisfied with
the aforesaid view of the Tribunal and, therefore, has preferred
the instant appeal in this Court. H

A 5. In his endeavour to demonstrate that the product 'Nizral
Shampoo' was simply a toilet preparation to be used on the
hair and could not be classified as a product belonging to
the family of Pharmaceutical products, Mr. Panda, learned
senior counsel appearing for the Revenue, drew our
B attention to the orders passed by the Commissioner
(Appeals) wherein findings in respect of this product are
arrived at after discussing the ingredients/properties of the
said product. On that basis, it was argued (as reasoned by
the Commissioner (Appeals) as well) that there was no
C dispute raised even by the assessee that the product 'Nizral'
was basically a shampoo preparation. Even if it was
coupled with therapeutic or prophylactic properties imparted
to it with the presence of an anti-fungal agent known as
D 'Ketoconazole', this would not change the basic character of
the product viz. shampoo, which is meant for the use of cleaning
hair. It was argued that such a classification was in conformity
with Chapter Note (6) to Chapter 33 which specified
'shampoos' whether or not containing soap or organic surface
E active agent. He further submitted that as per the packings,
labels, leaflet literature, it was apparent that the product in
question was held out commercially as having subsidiary
curative or prophylactic value with main purpose and the main
purpose of the produce was cleaning of scalp and hair.
F Therefore, Chapter Note (2) of Chapter 33 also got attracted
as per which how the product is explained and marketed by
the manufacturer itself becomes the determining factor. It
was also submitted that HSC of Chapter 33 also includes not
only shampoos containing soap and OSAC, but 'other
G shampoos' as well which would imply that those products
which are essentially shampoos would still be treated as
shampoos even if the subsidiary benefits of using such a
shampoo would be curative in nature. On that basis,
submission was that presence of 'Ketoconazole' which was
H hardly 2% W/V in the said shampoo making it anti-fungal

agent, would not change the pre-dominant character of the product as shampoo and turn it into a patent or proprietary medicament classifiable under Chapter sub-heading 3003.10. The learned senior counsel, in this behalf, drew our attention to the following justification given by the Commissioner (Appeal) in his order reflecting that mere 2% of presence of 'Ketoconazole' would not make any difference:

"It is rather unassailable that active ingredient 'Ketoconazole' is considered to prophylactic in nature for it to treat the cause of dandruff. Admitting that the active ingredient 'Ketoconazole' is for prophylactic for dandruff, it is clear that the product 'Nizral Shampoo' shall stand excluded from the purview of Chapter 30, in view of Chapter Note 1(d) to Chapter 30 which lays down that 'Preparation of Chapter 33 even if they have therapeutic or prophylactic properties' are not covered. On careful reading of the above Chapter Notes, which are statutory in nature and binding, a clear finding emerges that the impugned goods have a specific entry under Chapter 33 in terms of Chapter (6) to Chapter 33. The heading which provides the most specific description, shall be preferred to headings providing a more general description as per Rule 3(a) of Rules for the interpretations of the Schedule. Hence, by all the above statutory accounts the impugned goods would not permit classification under Chapter 30 of Central Excise Tariff Act, 1985 as medicament, but only as a 'preparation for use on hair'".

6. It was further argued by Mr. Panda that merely because the respondent was manufacturing this product on loan/licence basis from Johnson & Johnson Ltd., with the express permission/ licence of Drug Controller of India and Food & Drug Administration, would be of no avail to the respondent. Likewise, even if it was sold by the Chemist would be of no significance as the claim of the respondent that it

A could be sold only on specific prescription of the registered
medical practitioner was clearly wrong as the respondent
was widely publishing the product through advertisements
clearly conveying to the users that the same was available
with leading Chemists. Mr. Panda referred to those portions
B of the order of the Commissioner (Appeals) where the
aforesaid arguments of the respondent were discussed and
discarded. He pleaded that what was to be seen was the
pre- dominant use of the product in question; that is to say
whether the product 'Nizral Shampoo' was primarily used as
C a shampoo or as a medicinal product and argued that the
dominant purpose of the product was to use it as a shampoo
with ancillary/added advantage being prevention of scalp
related infection i.e. dandruff.

D 7. To buttress the aforesaid submissions, Mr. Panda took
the aid of certain judgments of this Court. First judgment on
which he relied is in the case of **Collector of Central Excise,
Shillong v. Wood Crafts Products Ltd.**¹, wherein this Court
emphasized that the criteria/classification laid down by
E Harmonised System Committee (HSC), established under
Article 6 of the International Convention on Harmonised
System, is to be acted upon while deciding the cases of
classification inasmuch as it was an expert body which was
assigned the main function of preparing explanatory notes,
F classification opinions or other advice as guides to the
interpretation of the Harmonised System and to secure
uniformity in the interpretation and application of the
Harmonised System. It was so held by this Court in the said
judgment in the following manner:

G "11. The Statement of Objects and Reasons of the
Central Excise Tariff Bill, 1985 which led to the
enactment of the Central Excise Tariff Act, 1985 is
indicative of the pattern of the structure of the Central
excise tariff enacted therein. It reads as under:

H ¹ (1995) 3 SCC 454

1. Central Excise duty is now levied at the rates specified in the First Schedule to the Central Excises and Salt Act, 1944. The Central Excises and Salt Act, 1944 originally provided for only 11 items. The number of items has since increased to 137. The levy, which was selective in nature, to start with, acquired a comprehensive coverage in 1975, when the residuary item 68 was introduced. Thus, barring a few items like opium, alcohol, etc., all other manufactured goods now come under the scope of this levy.

2. The Technical Study Group on Central Excise Tariff, which was set up by the Government in 1984 to conduct a comprehensive inquiry into the structure of the Central excise tariff has suggested the adoption of a detailed Central excise tariff based broadly on the system of classification derived from the International Convention on the Harmonised Commodity Description and Coding System (Harmonised system) with such contractions or modifications thereto as are necessary to fall within the scope of the levy of Central excise duty. The Group has also suggested that the new tariff should be provided for by a separate Act to be called the Central Excise Tariff Act.

3. The tariff suggested by the Study Group is based on an internationally accepted nomenclature, in the formulation of which all considerations, technical and legal, have been taken into account. It should, therefore, reduce disputes on account of tariff classification. Besides, since the tariff would be on the lines of the Harmonised System, it would bring about considerable alignment between the customs and Central excise tariffs and thus facilitate charging of additional customs duty on imports equivalent to excise duty. Accordingly,

A it is proposed to specify the Central excise tariff suggested by the Study Group by a separate tariff Act instead of the present system of the tariff being governed by the First Schedule to the Central Excises and Salt Act, 1944.

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4. The main features of the Bill are as follows:

(i) The tariff included in the Schedule to the Bill has been made more detailed and comprehensive, thus obviating the need for having a residuary tariff item. Goods of the same class have been grouped together to enable parity in treatment.

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xx xx xx

5. The Bill seeks to achieve the above objects. (emphasis supplied)

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12. It is significant, as expressly stated, in the Statement of Objects and Reasons, that the Central excise tariffs are based on the HSN and the internationally accepted nomenclature was taken into account to "reduce disputes on account of tariff classification". Accordingly, for resolving any dispute relating to tariff classification, a safe guide is the internationally accepted nomenclature emerging from the HSN. This being the expressly acknowledged basis of the structure of Central excise tariff in the Act and the tariff classification made therein, in case of any doubt the HSN is a safe guide for ascertaining the true meaning of any expression used in the Act. The ISI Glossary of Terms has a different purpose and, therefore, the specific purpose of tariff classification for which the internationally accepted nomenclature in HSN has been adopted, for enacting the Central Excise Tariff Act, 1985, must be preferred, in case of any difference between the meaning of the expression given in the HSN and the meaning of that term given in the Glossary of Terms of the ISI."

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8. He also pointed out that the aforesaid principle A
contained in Wood Crafts Products was reiterated in CCE,
Hyderabad v. Bakelite Hylam² as follows:

“17. Hence for the interpretation of the New Tariff B
harmonised system of nomenclature and its explanatory
notes are relevant. In the case of Collector of Central
Excise, Shillong v. Wood Crafts Products Ltd. 1995 (3) B
SCC 454, this Court, while considering the Central
Excise Tariff Act of 1985, has held that looking to the C
Statement of Objects and Reasons the Central Excise
Tariff under the 1985 Act is based on the Harmonised
System of Nomenclature (HSN) and the internationally
accepted nomenclature has been adopted to reduce
disputes on account of tariff classification. Accordingly, D
for resolving any dispute relating to tariff classification,
the internationally accepted nomenclature emerging from
the HSN is a safe guide, this being the expressly
acknowledged basis of the structure of the Central
Excise Tariff in the 1985 Act and the tariff classification E
made therein. In case of any doubt, the HSN is a safe
guide for ascertaining the true meaning of any expression
used in the Act.”

9. Mr. Panda also referred to certain decisions of the F
Tribunals wherein such shampoos with 2% anti-fungal agents
were still treated as shampoos and not a medicinal product.
Notably, among these decisions are (i) **Amit Ayurvedic &**
Cosmetic Products v. Commissioner³ and (ii) **CCE Vapi**
v. Beta Cosmetics⁴.

10. Mr. Bagaria, learned senior counsel, appearing G
for the respondent/assessee stoutly refuted the aforesaid

² 1997 (91) ELT 13

³ 2004 (168) ELT 354

⁴ 2004 (173) ELT 255

A arguments of the Revenue laying great emphasis on the plea that the product in question was basically a medicine which was pre-dominant use. In order to demonstrate that the product 'Nizral Shampoo' could only be used as medicine and not like any other general/ordinary shampoo, he pointed
B out the following features which stood established on record in the form of plethora of materials/evidence placed before the authorities below:

C (i) The medicinal properties of the product were adequately emphasized and the product was sold by the assessee on that basis in the market.

D (ii) There was a warning to the patients about the adverse reaction of the use of this shampoo, if used for a long period.

E (iii) The product was essentially described as 'medicine' only and not as a shampoo meant for cleaning the hair.

F (iv) The literature along with the product sold specifically stated the diseases which could be cured by the use of this shampoo.

G (v) Limited period use of the product was suggested, unlike a normal shampoo which could be used regularly for infinite period.

H 11. Mr. Bagaria argued that matter needed to be examined keeping in view the aforesaid essential attributes/ characteristics of the product and in this context, the fact that the product was held out by the respondent to the public at large as medicine; availability of the said product with the Chemists; sale of the product on the prescription of a Doctor; assume much relevancy in treating the product as medicament having therapeutic value and not as ordinary shampoo.

12. Mr. Bagaria also pointed out that presence of 2% A
'Ketoconazole' in the said shampoo could not be treated as
something insignificant. On the contrary, it was the maximum
percentage required to treat the dandruff inasmuch as
presence of more 'Ketoconazole' could be harmful. He further B
submitted that if it is less than that, then it may lose its
therapeutic value and for this reason, in those shampoos where
the assessee was earlier putting 1% to 1½% of
'Ketoconazole', the assessee was itself treating the said
product as shampoo only and not as Pharmaceutical C
product. He concluded his arguments by submitting that the
judgment of this Court in **B.P.L. Pharmaceuticals Ltd. v.
CCE, Vadodra**⁵ squarely covered the issue involved in this
case.

13. We have considered the submissions of counsel D
for the parties and find ourselves in agreement with the view
taken by the Tribunal holding that the product in question
'Nizral Shampoo' is classifiable under CSH 3003.10 and
not CSH 3305.99.

14. At the outset, we may mention that the product E
known as 'Nizral Shampoo' gives the nomenclature of the
product as shampoo. However, the respondent claim that it
is a patent or proprietary medicament as it's essential
characteristics is therapeutic in nature. It is the common case F
of the counsel for the parties the pre-dominant use of the
product in question is to be taken into consideration
while deciding the classification issue. Therefore, it is to be
determined as to whether the product in question is primarily
used as a shampoo or it is used as a medicament. To find G
answer to this question, it is necessary to keep in mind the
essential characteristics of the product. When the matter is
examined from the aforesaid perspective we come to the

⁵ 1995 Supp. (3) SCC 1

A conclusion that the respondent is correct in submitting that the essential properties of the product are medicinal in nature. It is clear from the following description:

“Pharmacodynamics

B Ketoconazole, a synthetic imidazole dioxolane derivative has a potent anti-fungal activity against dermatophytes, such as *Trichophyton* sp. *Epidermophyton* sp. *Microsporum* sp. and yeasts, such as *Candida* sp. And *Malassezia furfur* (*Pityrosporum ovale*).

C Ketoconazole shampoo rapidly relieves scaling and pruritus, which are usually associated with pityriasis versicolor seborrheic dermatitis and pityriasis capitis (dandruff).

D Pharmacokinetics

Percutaneous absorption of Ketoconazole shampoo is negligible since blood levels cannot be detected, even after chronic use. Systemic effects, therefore, are not expected.

E Indications

Treatment and prophylaxis of infections in which the yeast *Pityrosporum* is involved, such as Pityriasis versicolor (localized), seborrheic dermatitis and pityriasis capitis (dandruff).

F Contra-indications

Known hypersensitivity to Ketoconazole or the excipient.”

G The manufacturer has given clear warning and precautions for the use of this product which are follows:

“Warnings and Precautions

H To prevent a rebound effect after stopping a prolonged treatment with topical corticosteroid it is recommended

to continue applying the topical corticosteroid together with Nizral Shampoo 2% and to subsequently and gradually withdraw the steroid therapy over a period of 2-3 weeks. Seborrhoeic dermatitis and dandruff are often associated with increased hair shedding, and this has also been reported although rarely, with the use of Nizral Shampoo 2%.”

It is further mentioned as to how the treatment should be given to a person suffering from various kinds of dandruffs:

“Treatment:

- Pityriasis versicolor; once daily for maximum 5 days.
- Seborrhoeic dermatitis and pityriasis capitis; twice weekly for 2 to 4 weeks.

Prophylaxis:

- Pityriasis versicolor: once daily for a maximum 3 days during a single treatment course before the summer.
- Seborrhoeic dermatitis and pityriasis capitis: once every one or two weeks.”

Even the adverse reaction of the treatment are mentioned by the manufacturers with specific advice that overdoses of this shampoo is not expected, as is clear from the following:

“Adverse reactions

Topical treatment with Nizral Shampoo 2% is generally well tolerated. As with other Shampoos, a local burning sensation, itching, irritation and oily/dry hair may occur, but are rare, during the period of use of Nizral Shampoo 2%.

In rare instances, mainly in patients with chemically damaged hair or grey hair, a discolouration of the hair has been observed.

A Overdosage

Not expected as Nizral Shampoo 2% is intended for external use only. In the event of accident ingestion, only supportive measures should be carried out. In order to avoid aspiration, neither emesis nor gastric lavage should be performed.”

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C 15. Thus, not only limited period use is stated, another important feature that appears in the literature supplied by the respondent is the information for the ‘patient’, describing the user of the product as a ‘patient’. It is as under:

“Patient information
Ketoconazole Shampoo 2%
Nizral Shampoo 2%

D You have been advised by your doctor to use this shampoo to treat dandruff. This leaflet gives you some information that you should keep in mind while using Nizral Shampoo. It also gives some background information on dandruff, which is important for you to deal with it.
E Please read this leaflet carefully to get the best results from this treatment. Remember that it cannot answer all your questions, and that you should check with your doctor for any further information you may require.”

F 16. The use is suggested only on the advice of a Doctor and there is a suggestion that Doctor should be consulted for any further information. The respondent has also provided the literature/material showing that dandruff is a disorder which affects the hairy scalp. It is generally triggered by a single celled organism which is kind of fungus, with scientific name ‘Pityrosporum Ovale’. For treatment of this disease, Nizral Shampoo 2% (i.e. shampoo containing 2% ‘Ketoconazole’) is shown as ‘a new medicine’ use whereof cures clears a dandruff. It is suggested that it should be used
H once a week and on other days, normal shampoos may be

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used which clearly shows that 'Nizral Shampoo' is to be used like a medicine, unlike other normal Shampoos. A

17. We also find that in order to show that the product was used only as a medicament for curing dandruff and not for using the same for the purpose of cleaning hair, the assessee filed affidavits of various Doctors. B

18. Having regard to the aforesaid material on record, we find that the case is directly covered by the ratio of this Court's judgment in B.P.L. Pharmaceuticals Ltd. (supra). That was a case where the assessee was engaged in manufacture of Selenium Sulfide Lotion which contained 2.5% selenium sulfide W/V. The assessee was manufacturing this product under a loan licence from Abbott Laboratories in accordance with Abbott's specifications, raw materials, packing materials and quality control. It was sold under the private name 'Selsun'. The assessee in that case claimed that this product was used in the therapeutic quantity i.e. 2.5% W/V which was the only active ingredient and other ingredient merely served the purpose of a bare medium. It was also claimed that the product is manufactured under a drug licence issued by the Food and Drug Administration. The assessee, thus, wanted the product to be classified under heading 3003.19 as Pharmaceutical Product under Chapter 30. However, the Revenue took the plea that it would fall under sub-heading 3305.90 i.e. under Chapter 33. Thus, the respective contentions of the Department as well as the assessee were almost on the same lines as in the present case, namely, whether the said product was Pharmaceutical product or it was a cosmetic/toiletry preparation. The only difference was of sub-headings under those Chapters. This Court went into the essential characteristics of the product and found it that dominant use of the product was medicinal, as it was sold only on medical prescription as a medicine for C
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A treatment of disease known as Seborrhoeic Dermatitis, commonly known as Dandruff. It was manufactured under a Drug Licence; the Food and Drug Administration had certified it as a Drug; and the Drug Controller had categorically opined that Selenium Sulfide present in Selsun was in a therapeutic concentration etc. The relevant passages from the said judgment throwing light on these aspects are reproduced below:

C "19. 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 Versicolour 2.5% of this compound is the therapeutic quantity.

xx xx xx

E 24. 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 falling under Chapter 33 or Chapter 34. In other words, he wants to equate the product in question to 'shampoo' enumerated under Heading No. 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. A

25. 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. B C

26. 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: D

"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." E

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, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects." F G

27. 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 H

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

B 28. 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 [pic] 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.

D 29. 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 under Headings Nos. 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 of a subsidiary curative or prophylactic value. The position is that therapeutic quantity permitted as per technical references including US 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.

xx xx xx

33. 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 [pic]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 & Ferro Alloys Ltd. v. CCE 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 26-AA before 1-3-1975, the introduction of Item 68 makes a difference to the interpretation of Item 26-AA. 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 poles manufactured were rightly

A classified under Item 26-AA, 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 out in the Schedule. It does
not and cannot affect the interpretation of the items
B enumerated in the Schedule. This logic of the Tribunal
is, therefore, clearly wrong."

C 34. 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.

D 35. The learned counsel also placed 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
E to show that the product is sold under prescription only
in chemists' shops unlike shampoos sold in any
shop including provision shops. This conclusion, namely,
that the product is understood in the common and
commercial parlance as a patent and proprietary
F medicine was also found by the Central Board of Excise
and Customs as 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
G difficulty in accepting this contention without referring to
decision cited by the counsel for the appellants.

H 36. 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 Sulfide

has 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 a wholly irrelevant criteria.”

19. The aforesaid judgment not only provides a complete answer to the issue at hand, it also suitably answers the various arguments of the Revenue and the manner in which those arguments were rebutted by the Court in the said case. The Tribunal has summed up the entire legal proposition in para 5 of its judgment with which we entirely agree. This para reads as under:

“5. We have carefully considered the submissions made by the learned Counsel and the learned DR. We find from the extracted literature that the item comprises of 20 mg Ketoconazole in one ml and the pamphlet clearly indicates that it is for the use only of a Registered Medical Practitioner or a Hospital or a Laboratory. The pamphlet claims that the item is used for treatment and prophylaxis of infections in which the yeast pityrosporum is involved such as pityriasis versicolor (localized), seborrhoeic dermatitis and pityriasis

A capitis(dandruff). The procedure for treatment and the
adverse reactions on such treatment due to overdose is
also stated in the pamphlet. The Apex court, in the case
of Muller & Phipps (India) Ltd. v. CCE, 2004 (167) ELT
347 (SC) has clearly held that once the item has been
B manufactured under a Drug licence and the Department
has treated the item as a Drug, it would not cease to be
one notwithstanding the fact that new Tariff Act has come
into force. The Apex Court again held in the case of
CCE v. Pandit D.P. Sharma, 2003 (154) ELT 324 (SC)
C that once in the common parlance the item is treated as
a medicament and manufactured under drug licence
and the evidence is produced by the party with regard
to the item being a medicament, then it should be treated
D as such and should not treat 'Himtaj Oil' as 'perfumed
hair oil'. The Apex Court's ruling in the case of B.P.L.
Pharmaceuticals Ltd. v. CCE, 1995 (77) ELT 485 has
held that 'Selsun' and anti-dandruff preparation
E containing 2.5% selenium sulphide which is full
therapeutic limit permissible as per pharmacopoeia
and manufactured under Drug Licence and certified
by Food and Drugs Administration as a medicine,
and the same is put up as a medicine to be used under
F Doctor's advise in accompanying literature and sold
through chemist shops under doctor's prescription
should be considered as a medicament under Sub-
Heading 3003.19 of CE Act and not as a cosmetics. In
the present case also, same evidence is relied which
are identical to the facts of B.P.L. Pharmaceuticals Ltd.
G The item also acts as an anti-dandruff preparation with
2% Ketoconazole. The same is sold on doctor's
prescription and by the chemists and understood as a
medicine in common parlance as per he enormous
literature and affidavit produced. Therefore, there was
H no necessity for the Commissioner to have

distinguished this Apex Court judgment which applies A
on all fours to the facts of the present case. We also
find that the judgment of the Apex Court rendered in the
case of CCE v. Vicco Laboratories, 2005 (179) ELT 17
(SC) also applies to the facts of the case. In this case,
the Apex Court has clearly noted that the common B
parlance test should be applied for determining whether
a product is classifiable as a pharmaceutical product
under Chapter 30 of CET Act or as a cosmetics under
Chapter 33 ibid as laid down by the Supreme Court in
the case of Shree Baidyanath Ayurved Bhavan Ltd., 1996 C
(83) ELT 492 (SC). As there is enormous evidence
produced by the appellants with regard to the use of
Ketoconazole Shampoo for treatment of several
disorders and diseases mentioned in the pamphlet and D
the same is sold by a chemist under a prescription
issued by a Registered medical Practitioner or a Hospital
or a Laboratory, therefore, the appeal is required to
be allowed with consequential relief, if any.”

20. We, thus, are of the view that the judgment of the E
Tribunal does not call for any interference and the appeal is
dismissed with cost.

Civil Appeal No. 5752 of 2015
(arising out of SLP (C) No. 1531 of 2015) F

21. Leave granted.

22. This appeal is preferred by the assessee and the
issue arises is the same as discussed in Civil Appeal No. G
4480 of 2005. Here, respondent No.2 has passed an order
directing the appellant to pay differential duty, treating the
product as Shampoo and not Medicaments. Challenging
that order, appellant had filed the writ petition, which has been
dismissed by the High Court vide impugned judgment primarily H

- A on the ground the matter had left to the concerned authority to decide the classification on the basis of technical evaluation and it could not be decided by the High Court. For the reasons recorded in Civil Appeal No. 4480 of 2005, this appeal stands allowed hereby quashing the order of the
- B High Court as well as respondent No.2 dated 28.12.2001 demanding differential duty.

Nidhi Jain

Appeals disposed of.