



IN THE HIGH COURT OF KERALA AT ERNAKULAM

PRESENT

THE HONOURABLE MR. JUSTICE A.K.JAYASANKARAN NAMBIAR

&

THE HONOURABLE MR.JUSTICE MOHAMMED NIAS C.P.

TUESDAY, THE 11TH DAY OF JULY 2023 / 20TH ASHADHA, 1945

OT.APPEAL NO. 3 OF 2015

APPELLANT/S:

DR.REDDYS LABORATORIES LTD.
42/2159 E, 2ND FLOOR, CB TOWERS, K.K. PADMANABHAN ROAD,
KOCHI-18, REPRESENTED BY ITS AUTHORISED AGENT,MR.
RAMAKRISHNAN A, S/O. P. PRBHAKARAN NAIR, AMAR PLAZA,
NEAR VALLATHOL JN, THRIKKAKARA KOCHI-21

BY ADV SRI.P.R.VENKATESH

RESPONDENT/S:

- 1 THE COMMISSIONER OF COMMERCIAL TAXES
KARAMANA, THIRUVANANTHAPURAM 650 002
- 2 THE DEPUTY COMMISSIONER (INT.)
DEPARTMENT OF COMMERCIAL TAXES, EDAPPALLY, ERNAKULAM 24
- 3 THE INTELLIGENCE OFFICER (IB)
DEPARTMENT OF COMMERCIAL TAXES, EDAPPALLY, ERNAKULAM -
24.

THIS OTHER TAX APPEAL HAVING COME UP FOR ADMISSION ON 11.07.2023,
THE COURT ON THE SAME DAY DELIVERED THE FOLLOWING:



A.K.JAYASANKARAN NAMBIAR,
&
MOHAMMED NIAS C.P., JJ

.....

O.T. Appeal No.3 of 2015

.....

Dated this the 11th day of July, 2023

JUDGMENT

Mohammed Nias C.P., J.

This appeal is filed challenging the order passed by the authority for clarification under Section 94 of the Kerala Value Added Tax Act, 2003 (for short, 'KVAT Act') that dismissed the application preferred by the appellant seeking clarification on the rate of tax of the commodities Clohex, Clohex Plus and Senquel-AD Mouthwashes.

2. The appellant is engaged in manufacturing and trading pharmaceutical products, Clohex, Clohex Plus and Senquel-AD, which are being used as medicaments, with Mouthwash having prophylactic and therapeutic effects. The appellant contends that under the Central Excise Tariff Act, all the above products have been assigned HSN Code 3003.3900,



treating them as medicaments. The appellant was accordingly submitting returns under the KVAT Act, treating them as medicaments and paying tax at 4% and later 5%. Earlier, under the Kerala General Sales Tax Act also, they were treated as medicaments, and taxes were paid accordingly. The third respondent assessing authority issued Exts.P1 to P5 under Section 67(1) of the KVAT Act demanding penalty for the assessment years 2008-2009 to 2012-2013, alleging that these products would actually come under Serial No. 92(6) of SRO 82/2006 under 'Mouthwash' and they should be assigned HSN Code 3306.10.90, and the dealer had wrongly included them under the group 'medicaments.' In the said circumstances, the petitioner filed an application for clarification under Section 94 of the KVAT Act, which this Court directed the authority to consider.

3. The authority passed an order dated 9.01.2015 holding that two of the products, Clohex and Clohex Plus, are to be treated as medicaments and hence, would attract tax only at 5% as they are classifiable under HSN Code 3004.9099. However, in the case of one product, namely Senquel-AD, it was held that it cannot be classified as a medicament and, therefore, will attract tax at the rate of 14.5% by virtue of entry No.92(6) of SRO 82/2006. The instant appeal is against that part of the order of the clarificatory authority that did not classify Senquel-AD as a medicament.

4. We have heard Sri. P.R. Venkatesh, the learned counsel appearing for the appellant and Sri. Mohammed Rafiq, the learned Special Government



Pleader (Taxes).

5. Sri. Venkatesh argues that the authority erred in finding that the literature in the package described the product as a desensitising Mouthwash and that sensitivity cannot be treated as a specific disease condition and any person can use this product for desensitising as advertised on the label. The authority found that though the product is not used to treat any specific disease condition, it has some prophylactic or therapeutic use for general dental hygiene. It is the contention of the learned counsel that various literature relating to the medicinal effect of the composition of both Potassium Nitrate and Sodium Fluoride in equal proportion were submitted, and they were not properly considered. It is also the submission that Senquel-AD is also manufactured under a similar drug licence given to Clohex and Clohex Plus. According to the learned counsel, dental caries, in general parlance, known as tooth decay, is a medical condition caused by bacteria and damaging substances such as acid that come into contact with teeth, and it is the second stage after accumulation of plaque and tartar. This can degrade the enamel on the teeth leading to holes in the enamel, which are called dental caries or cavities. If tooth decay is not stopped at the dentin layer, the disease organisms can enter the pulp chamber, where they will multiply quickly, producing an acute inflammation and, if unchecked, spread through the blood vessels to other parts of the body. It is for preventing such conditions that Senquel-AD is being used; therefore, it cannot be understood to be just



for maintaining oral hygiene. The relevant passages from the literature like 'The New Complete Medical and Health Encyclopedia' were also produced. The authority also went wrong in not considering the relevant fact that the product would come within the definition of a drug contemplated under the Drugs and Cosmetics Act. Senquel-AD is also being used by those experiencing Dentinal Hypersensitivity, which is certainly a disorder affecting a normal dental condition to restore normalcy by desensitizing and removing the hypersensitivity state, the same is done with the help of medical treatment and since Senquel-AD does that, the same ought to be treated as a medicament. The learned counsel also argues, going by the judgments of the Honourable Supreme Court, in **B.P.L. Pharmaceuticals Ltd. v. Collector of Central Excise Vadodara [1995 (77) E.L.T. 485 (SC)]** and **Commissioner of Central Excise, Mumbai IV and another v. CIENS Laboratories, Mumbai and another [(2013) 14 SCC 133]** to argue that the conclusion arrived by the clarificatory authority is clearly wrong. The learned counsel also cited the decision in **ICPA Health Products (P) Ltd. v. Commissioner of Central Excise, Vadodara**, reported in **[(2004) 4 SCC 481]** and argues that if a product comprises of two or more constituents that have been mixed together for therapeutic or prophylactic uses, then it would be a medicament. According to the learned counsel, since the product in question has both therapeutic properties and prophylactic uses, they are to be treated as medicament falling under Chapter 30. He also argued that Clohex and Clohex Plus were considered by the clarificatory authority as medicaments, and the reason stated for not



giving the same treatment to Senquel-AD is clearly wrong. It is also his contention that if two interpretations are possible, one in favour of the assessee ought to have been preferred more so when there is a specific entry dealing with medicament, it could not have been treated as coming under any other entry.

6. On the other hand, Sri. Mohammed Rafiq argues that the very labelling suggested that Senquel-AD is nothing but a mouthwash, and the same is marketed as such. The learned Special Government Pleader argues that in view of the note to Chapter 30, which deals with pharmaceutical products, the preparations of headings 3303 to 3307, even if they have therapeutic or prophylactic properties, the same stands excluded from Chapter 30 and on that ground, the appellant is not entitled to succeed. It is also his argument that going by the case laws, especially the later decisions, the fact that a drug licence is obtained may not be a decisive factor as several tests are to be considered for classifying a product. Based on the decisions in **Reckitt Benckiser v. Commissioner of Commercial Taxes & others [(2015) 7 SCC 126]**, **Sreedhareeyam Ayurvedic Medicines (P) Ltd. v. State of Kerala [(2022) 19 KTR 561]** and **Himalaya Drug Company v. State of Kerala [2020 (3) KLT 799]**, it is his argument that since the KVAT is aligned with the Customs Tariff Act, 1975, which in turn is aligned with HSN, each product is required to be considered in the context of HSN code and the judgments based thereon. It is also his argument that for a product to be called a medicament, it



effectively has to be a disease-curing or disease-preventing item, and the same is not satisfied in the instant case. It is his further submission that, essentially this product is being marketed as a mouthwash which is a crucial factor. It is his further argument that Senquel-AD cannot be treated at par with Clohex and Clohex Plus and prayed for sustaining the clarificatory order.

7. At the outset, we note that Supreme Court in **Heinz India Limited v. The State of Kerala [JT 2023 (5) SC 155]**, after a survey of most of the authorities on the point, and in particular, the tests laid down in **Collector of Central Excise v. CIENS Laboratories [JT 2013 (11) SC 235]**, has summarised as follows:

- 1)When a product contains pharmaceutical ingredients with therapeutic/prophylactic or curative properties, the proportion of the ingredients is not decisive. The curative attributes of the ingredients render it a medicament and not a cosmetic. **(CIENS Laboratories)**
- 2)A product can be sold without a prescription from a medical practitioner. Yet it does not lead to the conclusion that the sale of over-the-counter products is cosmetics. Several products are sold over-the-counter and are yet, medicaments **(CIENS Laboratories)**
- 3)Before adjudicating whether a product is a medicament or not, courts have to consider what the people who use the product understand it to be. If a product's primary function is "care" and not "cure," it is not a medicament. Cosmetic products are used to enhance or



improve a person's appearance or beauty, whereas medicinal products are used to treat or cure some medical condition. A product that is used mainly in curing or treating ailments or diseases and contains curative ingredients, even in small quantities, is to be branded as a medicament (**CIENS Laboratories**)

4) Products cannot be classified as cosmetics solely on the basis of their outward packing. [**Meghdoot Gramodyog Sewa Sansthan, UP. v. Commissioner of Central Excise Lucknow [(2005) 4 SCC 15]**]

5) Mixing medical ingredients with other products or preservatives does not alter its character as a medicament [**Amrutanjan Ltd. v. Collector Central Excise [1996 (9) SCC 413]**]

6) That a licence under the Drugs Act is necessary is not a determinative or decisive factor always.

8. Likewise, in **Puma Ayurvedic Herbal Private Ltd. v. Collector of Central Excise [2006 (2) SCR 1120]**, the product considered, namely 'Nycil Powder' has all the qualities and ingredients of a medicine, and since the same is basically a talcum powder, which has preventive and curative power, the same was required to be brought under the special entry rather than general entry.

9. On a reading of the principles emerging from the above decisions, it can be seen that when a product contains pharmaceutical ingredients that have therapeutic or prophylactic or curative properties, the proportion of



such ingredients is not invariably decisive, and what is of importance is the curative attributes of such ingredients that render the product 'medicament' and not a cosmetic. Although a product is sold without a medical practitioner's prescription and is available over the counter, it does not lead to the conclusion that they are cosmetics. It is therefore necessary before adjudicating whether a product is a medicament or not, courts have to consider what the people who use the product understand it to be. If a product's primary function is "care" and not "cure," it is not a medicament, while medicinal products are used to treat or cure some medical conditions. A product used mainly in curing or treating ailments or diseases and containing curative ingredients, even in small quantities, is to be branded as a medicament. The dominant use to which the product is being used certainly has a bearing.

10. It is also to be seen that whenever a product has curative or prophylactic value as well, but the revenue still wants the said product to be brought under a different Chapter, the onus is on the revenue to show that it is not a medicament; the revenue will have to demonstrate that curative or prophylactic value is only subsidiary in nature or that the description covers the product under the Chapter wherein it is sought to be excluded. The product in the instant case normally should have come under Chapter 30 but for the specific exclusion under Note to Chapter 30. We also find that if a product is registered as a medicament by the Drugs Controller, that would be a strong factor to consider it as having curative or



prophylactic value as a medicament. Thus, we find that no single test can be employed to classify a product but a combination of different tests. Whether the product is one carrying predominantly pharmaceutical value has also to be considered, notwithstanding the Note to Chapter 30. In this context, the judgment of the Supreme Court in **Commissioner of Customs, Central Excise and Service Tax, Hyderabad v. Ashwani Homeo Pharmacy [JT 2023 (6) SC 324]** is of relevance. In the case on hand, the reason for holding against the appellant was that the appellant did not produce any material and that the product was not one treating a specific disease condition. We cannot accept the said finding, which did not consider the impact of either the literature produced by the appellant or the principles laid down in the above-mentioned judgments. The department also did not discharge its onus of proving that the product cannot be classified as a medicament, though it certainly has attributes of a medicament. We also find that the clarification order accepts the classification accorded to the other products Clohex and Clohex Plus by the assessee, as medicament based on the fact that they were manufactured under a drug licence. However, there is no reason discernible from the clarification order as to why Senquel-AD Mouthwash which is presented in a similar form cannot also be classified as a medicament more so when the Central Excise authorities had accepted the said classification during the relevant period.

Since the clarificatory authority did not consider these aspects, we



deem it appropriate to remit it to the same authority to consider all the above aspects in the first instance. Accordingly, we set aside the impugned order (Order No.C3/26631/13/CT) of the authority for clarification dated 09.01.2015 and remit it to the said authority for fresh consideration, in the light of the observations made by us and in accordance with law, with notice to the parties and within an outer time limit of three months from the date of receipt of a certified copy of this judgment. Until the authority takes a decision, as directed above, the interim order granted by this Court on 08.04.2016, staying all further proceedings pursuant to Annexures-A1 to A5, will continue to be in force.

The O.T. Appeal is allowed as above.

Sd/-

A.K.JAYASANKARAN NAMBIAR
JUDGE

Sd/-

MOHAMMED NIAS C.P.,
JUDGE

okb/

**APPENDIX OF OT.APPEAL 3/2015**

APPELLANT'S ANNEXURES

- ANNEXURE 1 TRUE COPY OF NOTICE DATED 27.6.2003 ISSUED BY THE 2ND RESPONDENT TO THE APPELLANT
- ANNEXURE 2 TRUE COPY OF APPLICATION FOR CLARIFICATION UNDER SECTION 94 OF THE KVAT DATED 4.9.2013
- ANNEXURE 3 TRUE COPY OF JUDGMENT DATED 18.10.2013 IN WPC NO. 23046/2013 OF THIS COURT
- ANNEXURE 4 TRUE COPY OF PENALTY ORDER DATED 18.11.2014 PASSED BY THE 2ND RESPONDENT
- ANNEXURE 5 TRUE COPY OF JUDGMENT DATED 9.2.2015 IN WPC NO. 3244/2014 OF THIS COURT
- ANNEXURE 6 TRUE COPY OF THE LITERATURE OF SENQUEL AD
- ANNEXURE 7 TRUE COPY OF RENEWAL OF DRUG LICENCE DATED 21.4.2012 ISSUED BY THE DRUGS CONTROLLER, STATE OF KARNATAKA
- ANNEXURE 8 TRUE COPY OF LITERATURE RELATING TO THE COMPOSITION OF THE SENQUEL AD ALONG WITH LITERATURE RELATING TO THE DISEASE DENTAL CARIES
- ANNEXURE 9 TRUE COPY OF RELEVANT PASSAGES FROM THE NEW COMPLETE MEDICAL & HEALTH ENCYCLOPEDIA 1997 EDITION
- ANNEXURE 10 TRUE COPY OF THE JUDGMENT REPORTED IN 1995 (77) ELT 485 (SC)
- ANNEXURE 11 TRUE COPY OF DECISION REPORTED IN 2013 (14) SCC 133
- ANNEXURE 12 TRUE COPY OF INVOICE OF SENQUEL AD