

**Time Pharma Vs. Commissioner of Central Excise**

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**Court :** Customs Excise and Service Tax Appellate Tribunal CESTAT Mumbai

**Decided On :** Jan-21-1997

**Reported in :** (1998)(99)ELT643Tri(Mum.)bai

**Appellant :** Time Pharma

**Respondent :** Commissioner of Central Excise

**Advocate for Pet/Ap. :** Shri. A. Hidayatullah Id. Sr. Counsel

**Judgement :**

1. The Commissioner of Central Excise (Appeals), Mumbai, in the impugned order has disposed of two appeals relating to the classification of the product 'Moisturex' and the demand for duty based on that classification. The appellants filed classification lists from time to time classifying the product under Heading 30.03 Central Excise Tariff Act, 1985 (CETA) as medicament. But the jurisdictional Asstt.

Commissioner of Central Excise did not accept that it was so classifiable and passed an order holding that the product is classifiable as a cosmetic product being a preparation for the care of the skin under Heading 33.04. The Commissioner (Appeals) upheld the classification by the Assistant Commissioner and found that the ingredients in the product like urea have uses other than for medicinal purposes as per the condensed chemical Dictionary by Gestener G.Hawley; that even according to one of the documents submitted by the appellants "Uses of urea is cosmetology" use of urea in cosmetic preparation moisturising cream was indicated; that the primary function of the product was that

of cosmetic and that its ingredients have only subsidiary therapeutic or prophylactic value, and hence would still be classifiable as a cosmetic preparation as per Chapter Note 2 to Chapter 33 CETA. For the same reason, Commissioner (Appeals) also did not accept the affidavits produced by appellants from skin specialists, also observing that they were identically worded and stereotyped.

Commissioner (Appeals) also pointed out that the Deptt. Chemical Examiner had on a test of the sample of the product opined that similar preparations are known to find use for the care of skin, by their function in preventing drying and flaking of the skin. The Commissioner (Appeals) also observed that even assuming that the product will equally merit classification under Heading 30.03 CETA, Rule 3(c) of Rules for interpretation of the Tariff will come into play, which lays down that in such a case the goods have to be classified under the Heading in the Tariff which is numerically the last as such classification under Heading 33.04 would be attracted. Being aggrieved by this order of the Commissioner (Appeals) on classification, the appellants have preferred the present appeal.

2. Shri A. Hidayatullah Id. Sr. Counsel appearing for the appellants submitted that the main active ingredient in the product is urea 10% w/w which is added in therapeutic quantity recognised by Pharmacopoeia British and Indian Pharmacopoeia. Sr. Counsel referred besides the above, to various authoritative articles on dermatology including among others. Atlas of Clinical Dermatology by Anthony du Vivier, Martindale Extra Pharmacopoeia, an article entitled "The action of a Urealactic Acid ointment in Ichthyosis" by Cicely Blair, from the British Journal of Dermatology (1976). The Id. Sr. Counsel urged that the product was intended to cure a disorder of the skin known as Ichthyosis Vulgaris, whereby the skin becomes scaly in appearance, arising from the failure of skin to shed properly. It was submitted that it was for external use, mentioned an expiry date, set out indications for use and in other respects conformed to the requirements of Rule 94 and 96 of the Drugs & Cosmetics Rules, 1945. It was submitted that it would be evident from the articles and texts produced that Ichthyosis Vulgaris is a skin disease and that urea in therapeutic quantity as present in the appellant's product was used for treating that disease. Id. Sr. Counsel cited and relied upon Supreme

Court decision in the case of BPL Pharmaceuticals v. Collector of Central Excise - 1995 (77) E.L.T. 485 to say the ratio of that decision is applicable and when the active ingredient urea is in therapeutic quantity for the treatment of disease, then Note 2 of Chapter 33 CETA will not be attracted and it cannot be classified as a cosmetic preparation. Ld. Sr. Counsel also relied upon Tribunal decision in the case of Pasteur laboratories v.CCE -1987 (31) E.L.T. 192 in which Tribunal had referred to the product literature relating to the article in dispute which contained instructions as regards application of the product to "affected area".

In the product literature of Moisturex also there is such a decision, indicating its use as a medicament, not as a cosmetic product. The Calcutta High Court judgment in the case of G.D. Pharmaceuticals v. UOI [1992 (60) E.L.T. 205 (Cal.)] was cited to argue that the essential character of the product has to be looked into to classify it as a drug or as a cosmetic. .

3. Shri S.V. Singh Id. DR presented the department's case and submitted that the Supreme Court judgment in BPL case 9 supra is distinguishable from the present case. There the product was Selenium sulfide lotion VSP containing selenium sulfide as the one active ingredient, sold under brand name selsun. The label on the product indicated that it is medicament for treatment for dandruff, and also that it is to be applied as per doctor's direction. The Condensed Chemical Dictionary of G.G. Hawley refers to selenium sulfide as a medicine for such treatment. That was also a case where the product selsun was all along being classified as medicament by department which sought to change it to classify as product as cosmetic. Here the above aspects are absent, the product in question is only a moisturiser which gives cosmetic effect to skin the ingredients of which are used in cosmetic preparations as found by Commissioner (Appeals). The percentage of urea in the product is 10% but the literature produced by appellants shows that up to 40% of it is used in formulations. Therefore, that it is used in therapeutic quantity is questionable.

4. Even if it has prophylactic and therapeutic uses of a subsidiary value, it will still be classifiable as cosmetic preparation under Chapter 33 CETA in view of Chapter Note 2 thereof. As for the affidavits produced from dermatologists, the Id. DR

pointed out that these besides their stereotyped wording, they cannot be conclusive of the issue. Ld. DR in this context relied upon Supreme Court decision in the case of Baidyanath Ayurvedic Bhavan v. C.C.E. -1996 (83) E.L.T. 492 to say that this criterion is not the doctor's affidavit so much as how the consumer understands the product. In the product in question it is indicated that it is to be applied daily and there is no direction to take it as per doctor's prescription. The literature of this product is not available in the packing of the product and no dosage is indicated thereon. The fact that it is to be used daily is indicative of the fact that it is for cosmetic purposes. The product is described as Emollient and Humectant which means it is for a smooth skin and soothing it which again indicates to the consumer its use as a preparation for the care of the skin.

5. The submissions made by both the sides have been carefully considered. The dispute is whether the product "MOISTUREX" manufactured by the appellants is classifiable as a cosmetic under sub-heading 3304.00 of Central Excise Tariff Act, 1985 as per the department or as medicament under sub-heading 3003.10 which is the claim of these appellants.

6. Chapter 30 of CETA is for Pharmaceutical Products. Chapter Note I(d) says that the Chapter does not cover preparations of Chapter 33 even if they have therapeutic properties. Chapter Note 2(i) thereof defines 'medicament' as follows :-  
2(i) Medicaments means goods (other than foods or beverages such as dietetic, diabetic or fortified foods, tonic beverages) not falling within heading No. 30.02 or 30.04 which are either :- (a) products comprising two or more constituents which have been mixed or compounded together for therapeutic or prophylactic use; or (b) unmixed products suitable for such uses put up in measured doses or in packings for retail sale or for use in hospitals. 30.03 Medicaments (including veterinary medicaments) 3003.10 Patent or proprietary medicaments, other than those medicaments which are exclusively Ayurvedic, 7. Chapter Note 2(ii) to Chapter 30 says that 'Patent or proprietary medicaments' 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 container or both, a name which is not specified in a monograph, in a Pharmacopoeia, Formulary or other publications, namely :- 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...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.

8. Chapter 33, CETA covers inter alia cosmetic or toilet preparations.

Heading 33.04 is as follows :-33.04 3304.00 Beauty or make-up preparations and preparations for the care of the skin (other than medicaments), including sunscreen and suntan preparations; "Heading Nos. 33.03 to 33.07 apply, inter alia, to products, whether or not mixed...suitable for use as goods of these headings and put up in packings 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 and includes products whether or not they contain subsidiary pharmaceutical or antiseptic constituents, or are held out as having subsidiary curative or prophylactic value".

9. The main question to be answered in resolving the dispute is hence to distinguish between cosmetics and drugs or medicaments. The Supreme Court in the case of BPL Pharmaceuticals v. CCE (supra) has laid down the guidelines in this respect. The ratio thereof has relevance in the present case as that judgment has also considered the Chapters 30 and 33 of CETA on a similar issue whether the product in dispute is a medicament or cosmetic preparation."...we can broadly distinguish cosmetic and drug as follows", observed the Supreme Court. "A 'cosmetic'--means,any article intended to be rubbed, poured, sprinkled or sprayed on or introduced into, or otherwise applied to 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, treatment, mitigation or prevention of any disease or disorder in human beings or

animals, including preparations applied on human body for the purpose repelling insects." The Supreme Court observed that we cannot ignore the above broad classification while considering the character of the product in question.

10. The product in question here is called Moisturex and comprises the following constituents: "Indications: Ichthyosis Vulgaris, Fissure foot, Dry Scaly Skin conditions." 11. According to the Atlas of Clinical Dermatology by Anthony du Vivier, Physician in charge, the skin department, King's College Hospital, London, (one of the various authorities cited and relied upon by appellants) Ichthyosis Vulgaris is a common disorder that results in widespread scaling of the skin. The condition is thought to be a failure of the normal separation of the epidermal cells from each other as they reach the surface of the skin. Fissures occur on the foot due to excessive dryness of the surface of the foot. Dry skin conditions occur due to excessive loss of moisture from the skin like eczema.

12. It is further stated that the product literature is given for use by medical practitioners. This gives the pharmacology of the ingredients in the product; under the heading, "Indications & usage", it is stated that Moisturex cream is indicated in dryness of skin associated with winter, fissure feet, cracked nipples, in the treatment of pathological dry skin conditions like ichthyosis and it is also indicated in dryness associated with leprosy and clofazimine. It contains a precaution and warning against application in large quantities as it contains keratolytic moisturizing agent that have potential to cause irritation and stinging sensation; it is not to be used near eyes and mucous membranes. The dosage and administration is indicated that thin layer of the cream should be applied to the affected area (emphasis supplied) once or twice daily and in case of severe dry skin conditions three times application may be required.

13. From the above it is clear that product finds use for the treatment of skin disorder in human beings like ichthyosis vulgaris. So far as the therapeutic properties of the product are concerned it is seen that in the affidavit of Dr. Rakesh Seth, a Consultant Dermatologist of Bombay produced by the appellants, it has been stated that urea is the active ingredient for treatment ichthyosis and dry skin conditions. An emollient with urea when applied to the skin attracts moisture from

the atmosphere and hydrates the skin in addition to preventing water loss from the skin to the atmosphere, whereas, says the Doctor, ordinary moisturising creams only prevent water loss from the skin to the atmosphere. The affidavit further avers that the British Pharmacopoeia mentions urea as a pharmacological ingredient. According to the affidavit lactic acid the order ingredient, is also a natural moisturising agent which helps easy penetration of topically applied cream into the skin and it hydrates the skin. The therapeutic properties of urea and lactic acid have been useful in treatment of disease such as ichthyosis and dry skin condition. Similar affidavits have been filed from two other Doctors who also say that the product is not cosmetic. The affidavits have to be given due consideration as they are from medical practitioners in dermatology and certain authorities have also be cited for the averments made therein. The Supreme Court in the BPL case (supra) has also observed in that case that affidavits cannot be discarded by saying they are identically worded. It cannot be said in this case that all the 3 Affidavits are identically worded. The affidavits serve the purpose of showing that the product has properties which would differentiate it from ordinary moisturising cream. The Commissioner (Appeals) has referred to Hawley's Condensed Chemical Dictionary' to say that urea finds other uses including in cosmetics.

He has also found from a paper furnished by the appellants, 'Uses of Urea in Cosmetology' as indicating use of urea in cosmetic preparation like moisturising cream. However, it has to be borne in mind that the ingredients of the product having other uses will not make the product not a medicament if it satisfies the definition thereof. There is evidence to show that urea is contained in the product in therapeutic quantity. Further, in the paper 'uses of urea in cosmetology' it is stated. "For cosmetic purposes, concentrations of 4 to 10% urea are considered sufficient to induce the desired effects. It must be borne in mind that urea is quite difficult to incorporate into cosmetically acceptable PREPARATIONS". In the same paper there is a Table 'Indications for use in dermatology wherein it is given that urea alone (10%) for atopic eczema psoriasis vulgaris and other scaly diseases, senile skin and other dry skin states, ichthyosis. There are also uses of urea in combination for other skin disorders given therein. It would appear therefore that 10% urea is a therapeutic quantity in a formulation to treat skin disorders like ichthyosis. Also it is found that in the Indian Pharmacopoeia 1996, it has been

indicated that urea cream contains urea in a suitable basis with usual strength 10% w/w.

This would then indicate that it cannot therefore be said that the product in question has only subsidiary curative or prophylactic value.

It has already been noted that the indication on the label as well as the product literature show that the goods are used to treat dry skin conditions of the human skin and is prescribed by the doctors for the purpose.

14. Therefore, the product satisfies the definition of medicament in the sense that it is comprising of ingredients which have been mixed together for therapeutic or prophylactic use. There is nothing in the label or the literature of the product which would support a conclusion that it is to be applied to the human body or any part thereof for cleansing, beautifying or promoting attractiveness so as to be called a cosmetic product. Moisturex is more a product in the nature of a medicament for the cure of dry skin conditions in human beings, than a preparation for the care of the skin. As a medicament, the product gets excluded from Heading 33.04 as per wording of that Heading. In this view of the matter, since Heading 33.04 CETA does not merit equal consideration along with Heading 30.03, the question of preferring the latter heading in numerical order in the Tariff, in terms of Rule 3(c) of Interpretation Rules of the Tariff, does not arise. In the result, it is held that it will be appropriate to classify product moisturex under sub-heading 3003.10 of CETA, 1985. The impugned order is set aside, and the appeal is allowed.

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