

IN THE SUPREME COURT OF INDIA

CIVIL APPELLATE JURISDICTION

CIVIL APPEAL NO. 6988 OF 2003

Commissioner of Central Excise, Mumbai IV ...
Appellant (s)

Versus

M/s. Ciens Laboratories, Mumbai ...
Respondent (s)

WITH

CIVIL APPEAL NO. 4434 OF 2004

Commissioner of Central Excise, Thane-II ... Appellant (s)

Versus

M/s. Time Pharma, Mumbai ...
Respondent (s)

J U D G M E N T

KURIAN, J.:

1. 'Care or cure', is the clue for the resolution of the *lis* arising in these cases. If the product by name 'Moisturex' is held to be a medicament for cure, the decision goes in favour of the assessee and if the product is held to be one for care of the skin, the decision benefits the Central Excise. The

Tribunal has held in favour of the assessee and, thus, the Central Excise is in appeals.

2. The Central Excise Tariff Act, 1985 (hereinafter referred to as 'CETA') under Chapter 30 of the Schedule (2) deals with pharmaceutical products for the purposes of tariff. At the relevant time, if a product is held to be medicament, then, the rate of duty was 15% and, if not, 70%. Heading 30.03 deals with the medicaments including veterinary medicaments. The same reads as follows:

"Headin g No. (1)	Sub- headin g No. (2)	Description of goods (3)	Rate of duty (4)
30.03	3003.1 0	Medicaments (including veterinary medicaments) -Patent or proprietary medicaments, other than those medicaments which are exclusively Ayurvedic, Unani, Siddha, Homoeopathic or Bio-chemic."	15%

3. 'Medicaments' is defined under Note 2(i) under Chapter 30 which reads as follows:

"2. For the purposes of heading No. 30.03:

(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 uses; or

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

(Emphasis supplied)

4. 'Patent or proprietary medicaments' is defined under Note 2(ii) which reads as under:

"2(ii) '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:-

- (a) The Indian Pharmacopoeia;
- (b) The International Pharmacopoeia;
- (c) The National Formulary of India;
- (d) The British Pharmacopoeia;
- (e) The British Pharmaceutical Codex;
- (f) The British Veterinary Codex;
- (g) The United States Pharmacopoeia;
- (h) The National Formulary of the U.S.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.”

5. The Chapter Note has explained Heading No.30.03 as under:

“This heading covers medicinal preparations for use in the internal or external treatment or prevention of human or animal ailments. These preparations are obtained by mixing together two or more substances. However, if put up in measures, doses or in forms or packings for retail sale, they fall in **heading 30.04.**”

The heading includes :

- (1) Mixed medicinal preparations such as those listed in an official pharmacopoeia, proprietary medicines, etc., including those in the form of gargles, eye drops, ointments, liniments, injections, counter-irritant and other preparations not falling in **heading 30.02, 30.05 or 30.06.**”

Entry 33.04 dealing with cosmetics reads as follows:

“Headin g No.	Sub- headin g No.	Description of goods	Rate of duty
(1)	(2)	(3)	(4)
33.04	3304.0 0	Beauty or make-up preparations and preparations for the care of the skin (other than medicaments), including sunscreen and suntan preparations; manicure or pedicure	70%

		preparations.”	
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The Chapter Notes on this Entry has explained the products as under:

“33.04 - BEAUTY OR MAKE-UP PREPARATIONS AND PREPARATIONS FOR THE CARE OF THE SKIN (OTHER THAN MEDICAMENTS), INCLUDING SUNSCREEN OR SUN TAN PREPARATIONS; MANICURE OR PEDICURE PREPARATIONS.

3304.10 - Lip make-up preparations.

3304.20 - Eye make-up preparations.

3304.30 - Manicure or pedicure preparations.

- Other :

3304.91 - - Powders, whether or not compressed.

3304.99 - - Other

(A) BEAUTY OR MAKE-UP PREPARATIONS AND PREPARATIONS FOR THE CARE OF THE SKIN, INCLUDING SUNSCREEN OR SUN TAN PREPARATIONS

This part covers:

- (1) Lipsticks and other lip make-up preparations.
- (2) Eye shadow, mascara, eyebrow pencils and other eye make-up preparations.
- (3) Other beauty or make-up preparations and preparations for the care of the skin (other than medicaments), such as: face powders (whether or not compressed), baby powders (including talcum powder, not mixed, not perfumed, put up for retail sale), other powders and grease paints; beauty creams, cold creams, make-up creams, cleansing creams, skin foods (including those containing bees' royal jelly) and skin tonics or body lotions; petroleum jelly, put up in packings of a

kind sold by retail for the care of the skin; barrier creams to give protection against skin irritants; anti-acne preparations (**other than soaps of heading 34.01**) which are designed primarily to cleanse the skin and which do not contain sufficiently high levels of active ingredients to be regarded as having a primary therapeutic or prophylactic effect against acne; toilet vinegars which are mixtures of vinegars or acetic acid and perfumed alcohol.

Sunscreen or sun tan preparations are also included.

(B) MANICURE OR PEDICURE PREPARATIONS

This part covers nail polishes, nail varnishes, nail varnish removers, cuticle removers and other preparations for use in manicure or pedicure.

The heading does not cover:

(a) Medicinal preparations used to treat certain skin complaints, e.g., creams for the treatment of eczema (heading 30.03 or 30.04).

(b) Foot deodorants and preparations for treating nails or claws on animals (**heading 33.07**)."

(Emphasis supplied)

6. Entry 30.04 reads as follows:

"Headin g No.	Sub- headin g No.	Description of goods	Rate of duty
(1)	(2)	(3)	(4)
30.04	3004.0 0	Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters,	15%

		<p>poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for medical, surgical, dental or veterinary purpose.”</p>	
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7. The pharmaceutical contents of the product ‘Moisturex’ are as follows:

“Urea I.P. -10%
 Propylene Glycol I.P. -10%
 Lactic Acid I.P. -10%
 Liquid Paraffin I.P. -10%
 Cream Base.”

8. It is the contention of the learned counsel for the Central Excise-appellants herein that the product ‘Moisturex’ is mainly used for care of the skin and thus, they are to be classified as cosmetic or toilet preparations and are to be treated under Heading 33.04. It is further contended that even if such cosmetic products contain certain subsidiary pharmaceutical contents or even if they have certain subsidiary curative or prophylactic value, still, they are to be treated as cosmetics only. It is also contended that the

product is sold across or under the counter and the same can be purchased without prescription of a medical practitioner and hence it is not medicament.

9. On the other hand, it is submitted on behalf of the assessee that the very presence of pharmaceutical substances will change the identity of the product since such constituents are used not for care of the skin but for cure of certain diseases relating to skin. The container of the product has given the following indications for use:

“Ichthyosis vulgaris, Fissure foot, Dry Scaly Skin conditions”

10. In the product literature, the cream is indicated for any dryness of skin associated with winter, fissure feet, cracked nipples, in the treatment of pathological dry skin conditions and also for dryness associated with leprosy and clofazimine. Detailed discussion on the pharmaceutical content and its use for treatment of dry skin conditions of human skin is given at Paragraph 12 in **Time Pharma vs. Commissioner of Central Excise, Mumbai-II**¹, wherein the Customs, Excise and Gold (Control) Appellate Tribunal, West Zonal

¹ 1998 (99) E.L.T. 643 (Tri. Mumbai)

Bench, Mumbai held that the product is a medicament. Since there is no dispute as to the description of the product, the contents and the usage, we shall extract paragraph 12: -

“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 contain 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.”
(Emphasis supplied)

It is brought to our notice that the said decision has attained finality *qua* the assessee therein since the Special Leave Petition filed by the Central Excise was dismissed.

11. In the Chapter Note dealing with cosmetics, it is clearly provided that the preparations for the care of skin, beauty or make-up preparations are the ones covered by the Heading 33.04 for the care of the skin. The Note has specifically

excluded medicaments. Still further, in the Chapter Note under Heading 33.04(B) also, it is clarified that medicinal preparations used to treat certain skin complaints are to be covered under the Heading 30.03 (medicaments) or Heading 30.04 (products containing pharmaceutical substances used for medical, surgical, dental or veterinary purposes).

12. Thus, if a product comprises of two or more constituents which have been mixed or compounded together for therapeutic or prophylactic use, the same is to be covered by Heading 30.03. Urea, lactic acid, propylene glycol are pharmaceutical constituents as per as Indian Pharmacopoeia.

13. The contention that 'Moisturex' is a moisturizing cream used for softening the skin cannot be appreciated. As we have already discussed, the use of the cream is not for the care of the skin. 'Moisturex' is also not primarily intended to protect the skin from sun, tan or dryness, etc. On the other hand, it is intended for treating or curing the dry skin conditions of the human skin and for a few other skin complaints like fissure feet, dry scaly skin conditions,

ichthyosis, etc. The argument advanced on behalf of the Central Excise that use of urea or lactic acid or propylene glycol, etc., is only as subsidiary pharmaceutical constituents and, hence, they cannot be held out as having curative, therapeutic or prophylactic value, cannot also be appreciated. It is the presence of the ingredients of the pharmaceutical constituents which makes the difference and not the percentage of the ingredients as held by this Court in **Meghdoot Gramodyog Sewa Sansthan vs. Commissioner of Central Excise, Lucknow**². It was held that the composition and the curative properties would make the difference in the classification. If the product is composed of pharmaceutical constituents which have curative properties, the product is to be classified as medicament. To quote:

“6. The appellant has drawn our attention to the composition of the six products and the uses in respect of each of these six products. This has not been doubted by the Tribunal nor indeed by the Departmental authority. The composition and the curative properties being admitted, it was not open either to the Department or the Tribunal to hold that the items were cosmetics merely by reason of the outward packing.”

(Emphasis supplied)

² (2004) 174 E.L.T. 14 (S.C.)

14. Another contention advanced by the appellant-Central Excise is that the product is sold not under any medical prescription but the same is available across or under the counter and, hence, the same cannot be treated as medicament. This contention also has been rejected by this Court in **Commissioner of Central Excise, Calcutta vs. Sharma Chemical Works**³. To quote:

“12. ... Mere fact that a product is sold across the counters and not under a Doctors prescription, does not by itself lead to the conclusion that it is not a medicament. We are also in agreement with the submission of Mr. Lakshmikumarn that merely because the percentage of medicament in a product is less, does also *ipso facto* mean that the product is not a medicament. Generally the percentage or dosage of the medicament will be such as can be absorbed by the human body. The medicament would necessarily be covered by fillers/vehicles in order to make the product usable. It could not be denied that all the ingredients used in Banphool Oil are those which are set out in the Ayurveda text books. Of course the formula may not be as per the text books but a medicament can also be under a patented or proprietary formula. The main criteria for determining classification is normally the use it is put to by the customers who use it. ...”

(Emphasis supplied)

³ 2003 (154) E.L.T. 328 (S.C.)

15. In Puma Ayurvedic Herbal (P) Ltd. vs. Commissioner of Central Excise, Nagpur⁴, it was held that the purpose of cosmetic product is to improve the appearance of a person and for enhancing the beauty whereas a medicinal product or medicament is meant to treat some medical condition. It was also held that merely because a product is sold not under a doctor's prescription, the same does not cease to be a medicament. In both these cases, it was held that minimal presence of medicinal element does not detract the product from being classified as a medicament. To quote:

“20. It will be seen from the above definition of cosmetic that the cosmetic products are meant to improve appearance of a person, that is, they enhance beauty. Whereas a medicinal product or a medicament is meant to treat some medical condition. It may happen that while treating a particular medical problem, after the problem is cured, the appearance of the person concerned may improve. What is to be seen is the primary use of the product. To illustrate, a particular Ayurvedic product may be used for treating baldness. Baldness is a medical problem. By use of the product if a person is able to grow hair on his head, his ailment of baldness is cured and the person's appearance may improve. The product used for the purpose cannot be described as cosmetic simply because it has ultimately led to improvement in appearance of the

⁴ 2006 (196) E.L.T. 3 (S.C.)

person. The primary role of the product was to grow hair on his head and cure his baldness.

21. The extent or the quantity of medicament used in a particular product will also not be a relevant factor. Normally, the extent of use of medicinal ingredients is very low because a larger use may be harmful for the human body. The medical ingredients are mixed with what is in the trade parlance called fillers, or vehicles in order to make the medicament useful. To illustrate an example of Vicks Vaporub is given in which 98% is said to be paraffine wax, while the medicinal part i.e. Menthol is only 2%. Vicks Vaporub has been held to be medicament by this Court in *CCE v. Richardson Hindustan Ltd.* 1989 (42) ELT A100. Therefore, the fact that use of medicinal element in a product was minimal does not detract from it being classified as a medicament.

22. In order to be a medicinal preparation or a medicament it is not necessary that the item must be sold under a doctor's prescription. Similarly availability of the products across the counter in shops is not relevant as it makes no difference either way."

(Emphasis supplied)

16. In Union of India vs. G. D. Pharmaceutical Limited⁵, the Calcutta High Court considered the question as to whether the product 'Boroline' containing boric acid with zinc oxide would be a medicament or cosmetic. It was held that the very presence of the pharmaceutical constituents like boric acid and zinc oxide will make the product medicament and not cosmetic. We are in respectful agreement with the views taken in the above-mentioned decisions.

⁵ 1998 (100) E.L.T. 24 (Cal.)

17. We shall also refer to the decision in **Alpine Industries vs. Collector of Central Excise, New Delhi**⁶, wherein this Court despite a certificate from Army that the cream 'Lip Salve' is used for treatment of sore, inflamed, roughened and cracked lips, declined to include the same in the category of medicament. It has been found that the product is meant for the care of the lips and not for the cure of the skin, being a protective/preventive preparation for chapping of lips though it has an incidental use on cracked and chapped lips. To quote:

"7. We have gone through the pharmaceutical and medical literature produced before us in the course of hearing and which has been duly dealt with by the Tribunal in its minority and majority opinion. The certificate issued by the Army Authorities and the chemical ingredients of the product are not decisive on the question of classification of the product for levy of excise duty. It is firmly established that on the question of classification of product under Central Excise Tariff Act, "commercial parlance theory" has to be applied. It is true that the entire supply by the appellant of its product 'Lip Salve' has been to the Defence Department for use of military personnel but that would also not be determinative of the nature of the product for classifying it. It is not disputed that the product 'Lip Salve' is used for the care of the lips. It is a product essentially for "care of skin" and not for "cure of skin". It is, therefore, classifiable as a skin care cream and not a medicament. From the nature of the product and the use to which it is put, we do

⁶ 2003 (152) E.L.T. 16 (S.C.)

not find that the claim of the appellant is acceptable that it is primarily for therapeutic use. What we find from the material produced before the Tribunal is that essentially the product is a protective/preventive preparation for chapping of lips. It is not a curative product maybe that incidentally on cracked and chapped lips, it has some curative effect. It is also not denied that the product 'Lip Salve' is not suitable for use only for soldiers operating in high altitude areas but it is of use for every one as protection from dry, cold weather or sun rays. The product, therefore, essentially is protective of skin of lip. It is lip care product and not a 'medicament'. It is neither prescribed by any doctor nor obtainable from the Chemist or Pharmaceutical shops in the market."

(Emphasis supplied)

18. Similarly, in **Sunny Industries Private Limited vs. Collector of Central Excise, Calcutta**⁷, while considering the question as to whether the Ad-vitamin Massage Oil forte could be medicament, it has been held that the same not being used for cure of skin but for care of skin, it can only be classified under 33.04 as a skin care oil. To quote:

"11. From the aforesaid Chapter notes, it is clear that heading 33.03 would include products whether or not they contain subsidiary pharmaceutical or antiseptic constituents, or are held out as having subsidiary curative or prophylactic value and heading 33.04 would inter alia include the products specified therein and other preparations for use in manicure or chiropody and barrier creams to give protection

⁷ 2003 (153) E.L.T. 259 (S.C.)

against skin irritants. Therefore, the product mainly oil containing some A&D vitamins which is used for massage, even if it prevents ailment of rickets and treats the same, it cannot be held to be medicaments.”

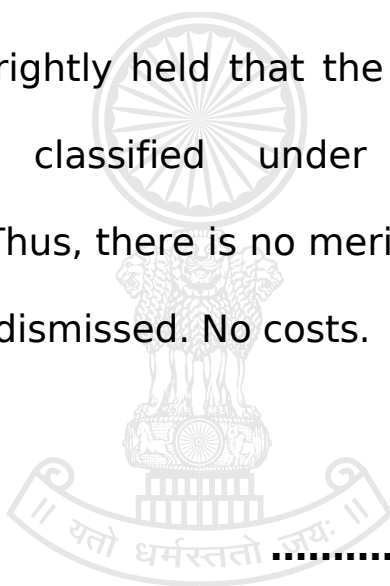
(Emphasis supplied)

19. Thus, the following guiding principles emerge from the above discussion. Firstly, when a product contains pharmaceutical ingredients that have therapeutic or prophylactic or curative properties, the proportion of such ingredients is not invariably decisive. What is of importance is the curative attributes of such ingredients that render the product a medicament and not a cosmetic. Secondly, though a product is sold without a prescription of a medical practitioner, it does not lead to the immediate conclusion that all products that are sold over / across the counter are cosmetics. There are several products that are sold over-the-counter and are yet, medicaments. Thirdly, prior to adjudicating upon whether a product is a medicament or not, Courts have to see what the people who actually use the product understand the product to be. If a product's primary function is "care" and not "cure", it is not a medicament. Cosmetic products are used in enhancing or improving 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.

20. In the case of 'Moisturex', there is no dispute that the said cream is prescribed by the dermatologist for treating the dry skin conditions and that the same is also available in chemist or pharmaceutical shops in the market. The cream is not primarily intended for protection of skin. The ingredients in the cream, the pharmaceutical substances do show that it is used for prophylactic and therapeutic purposes. The Central Excise Tariff Act has unambiguously clarified as to what is a medicament for curing an ailment relating to skin. Heading 33.04 dealing with beauty or make-up preparations and preparations for the care of the skin has specifically excluded medicaments. There is also an indication under the same entry that medicinal preparations used to treat certain complaints are to be provided under the Heading 30.03 (medicaments) or 30.04 (products containing pharmaceutical substances used for medical, surgical, dental or veterinary purpose).

21. Tribunals, the Customs, Excise and Gold (Control) Appellate Tribunal, West Zonal Bench at Mumbai in the first case and Customs, Excise and Service Tax Appellate Tribunal, West Zonal Bench at Mumbai in the other, having regard to the pharmaceutical constituents present in the cream 'Moisturex' and its use for the cure of certain skin diseases, have rightly held that the same is a medicament liable to be classified under the Heading 30.03 (medicament). Thus, there is no merit in these appeals. They are accordingly dismissed. No costs.



.....
.....J.
**(SUDHANSU JYOTI
MUKHOPADHAYA)**

JUDGMENT

.....J.
(KURIAN JOSEPH)

**New Delhi;
August 14, 2013.**