

Cyano Pharma Vs. Collector of Central Excise

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Court : Customs Excise and Service Tax Appellate Tribunal CESTAT Delhi

Decided On : Jul-17-1987

Reported in : (1987)(14)ECC227

Appellant : Cyano Pharma

Respondent : Collector of Central Excise

Judgement :

1. Heard Shri V. Lakshmi Kumaran, Advocate for the appellant and Shri A.K. Rajhans, JDR for the respondent.

2. The department's case is that the appellants produced Analgin Tablets, N.F.I. "which were not pharmacopoeial drugs and would therefore fall under Tariff Item 14E of the Central Excise Tariff. It has been held in the order appealed against that the Central Excise Tariff exempts only such of the pharmacopoeial preparations which are strictly in accordance with the approved formula. It is also held that for purpose of reference the pharmacopoeia relevant is the one recognized under Drug Control Act and Rules in the year relevant to production and not any edition which might have subsequently been recognised. The department therefore dismissed the claim of the appellant company that their product was in accordance with the 1979 edition of National Formulary of India (N.F.I.).

3. It has been held by the department that the product of the appellant company does not satisfy the prescribed requirement of usual strength of 0.5 gram of Metamizole per tablet, since, as per the details given on the carton of the product,

each tablet contained analgin 0.3 grams metamizole, and the indicated dosage is 0.3 gram to 0.6 gram or as directed by the Physician. It is also held by the lower authority that this indication of dosage is contrary to the dosage of 0.30 to 1 gram prescribed by National Formulary of India (N.F.I.).

4. The department also held that while the Analgin Tablets have been described as N.F.I, yet there is also reference to U.S.S.R.P. that is another Pharmacopoeia which "is against the recognised mode of manufacture of any pharmacopoeia medicine".

5. While passing his order the Additional Collector has noted that the Drug Controller had withdrawn permission granted to the manufacturer to produce the Analgin Tablets on the grounds that while in the Indian Pharmacopoeia 1966 supplement the minimum dosage prescribed is 0.5 gram the appellant had manufactured Analgin Tablets of 0.3 gram only. It was held that the preparation marketed by the appellant therefore was "sub-therapeutic".

6. It has further been held in the Order appealed against that examination of the cartons in which the analgin tablets were packed showed that they carried a symbol/monogram/label showing the name of the manufacturer prominently, establishing the proprietary nature of the medicine, bringing it within the definition of patent and proprietary medicines falling under Tariff Item 14E of the Central Excise Tariff.

7. Finally the Additional Collector has also held that the appellant company has failed to comply with the requirements of Rule 96 ZN(2) of the Central Excise Rules, 19H inasmuch the recognised abbreviation for the relevant pharmacopoeia does not appear immediately after the name of the drug on the carton.

8. In their Appeal, the appellants have submitted that they were manufacturing Metamizole (Analgin) N.F.I. Tablets duly authorised by the Drug Controller. The Government analyst M.P. had also declared the product to be conforming to National Formulary of India Standard vide his report No. 2072/72, dated 1st September, 1977. It is submitted that Analgin Tablets of 0.30 grams strength are covered under the second edition (1966) as well as the third edition (1979) of

National Formulary of India (at page 250 in both editions). Although the usual strength is given as 0.5 gram but the range of dose in both the editions of N.F.I, is clearly given as 0.3 gram to 1 gram.

9. It is also submitted that the Government had issued a clarification under letter M.F. (D.R. & 1) No. 42/22/69-CX.3, dated 10th July, 1974 that in case of preparations in respect of which pharmacopoeia lay down the usual strength and also specify the dose, preparations marketed within the dosage range specified shall be deemed to be pharmacopoeial.

It is submitted that this plea has been dismissed by the Additional Collector as not relevant without assigning any reason therefor.

10. It is submitted by the appellants that the Additional Collector was wrong in the assumption that if pharmacopoeial preparations are not strictly in accordance with the approved formula then they would be classifiable under Central Excise Tariff Item No. 14E. It is also submitted that the Additional Collector was wrong in holding that any particular edition of pharmacopoeia would not be "relevant" for deciding whether a particular product is or is not a pharmacopoeial preparation. It is pointed out that amendments to the pharmacopoeia are issued from time to time under Public Notices, and it is the date of issuing of such Public Notices which is relevant for the enforcement of the amendments. An edition is only a compilation of all such changes made since the Publication of the previous edition. If, it is submitted, a change is incorporated in 1979 edition it does not mean that such change did not exist before its publication.

11. Appellants contends that there is no basis for the view taken by the Additional Collector that it is against the "recognised mode of manufacture of pharmacopoeial medicines" that they should be covered by two or more pharmacopoeia. It is also submitted that it is a statutory requirement for the name of the manufacture to appear on the carton and this by itself would not attract classification under Central Excise Tariff Item 14E. This does not show that the appellant had a proprietary right in the medicine. The learned Advocate has in this connection relied on the decision of the Madras High court in the case of Union of India v. Indo-French Pharmaceutical Company 725. Finally, it is submitted that appellants are not at all

guilty of violating Rule 96 ZN(2) of the Central Excise Rules, 1944.

12. The facts of the case and the submissions made before us have been carefully considered. Item 14E of the Central Excise Tariff reads as under :- "14E. Patent or proprietary medicines not containing alcohol, opium, Indian hemp or other narcotics or other than those medicines which are exclusively ayurvedic, unani, sidha or homoeopathic.

"Patent or Proprietary medicines" means any drug or medicinal preparation, in whatever form, for use in the internal or external treatment of, or for the prevention of 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 their publications notified in this behalf by the Central Government in the Official Gazette, or which as 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.

'Alcohol', 'Opium', 'Indian Hemp', 'Narcotic Drugs' and 'Narcotics' have the meanings respectively assigned to them in Section 2 of the Medicinal and Toilet preparation (Excise Duties) Act.

In pursuance of the Explanation of Item 14E of the First Schedule to Central Excises and Salt Act, 1944 and of the Explanation to Item No. 28A of the First Schedule to the Indian Tariff Act, 1934 (32 of 1934) all editions of the following Pharmacopoeia, Formularies and other publications are notified for purposes of the said Explanation namely :- 13. It would be observed that in order to fall under Tariff Item 14E it is necessary that the drug or the medicinal preparations should not be specified in a monograph in a pharmacopoeia, formulary or other publication notified in this behalf by the Central Government. The case of the department is difficult to understand as it is nowhere contended that the impugned

product is not specified in a Pharmacopoeia, Formulary etc. In fact it is admitted that the product is specified in Indian Pharmacopoeia as well as National Formulary of India.

14. The Additional Collector has apparently accepted that the product of the appellant company is covered by the 1979 Edition of National Formulary of India. Similarly, it is not denied that it also stands covered by the 1966 Edition but the view taken by the department is that these editions "are not applicable during the relevant period".

This is not understandable in view of the fact that the Notification under Explanation to Item 14E of Central Excise Tariff itself says - clearly that all editions(emphasis applied) of the specified Pharmacopoeia, Formulary and other publications - and this includes the Indian Pharmacopoeia and National Formulary of India - are notified for purpose of the Tariff Item. In view of this the department's stand that the 1966 or the 1979 edition would not be applicable to the relevant period is not sustainable and has to be rejected.

15. We have also taken note of the clarification issued under the orders of the Government of India, Ministry of Finance (Department of Revenue Insurance) letter No. 42/22/69-CX.3, dated 10th July, 1974 which is reproduced below for ready reference : (1) In case of preparations where pharmacopoeia lays down the "Usual strength" and also specifies the dose, preparations marketed in the "Usual strength" or in a strength which falls within the dosage range specified shall be deemed to be Pharmacopoeial. In case where the dose or dosage range is not prescribed and only "Usual strength" is specified and a preparation is marketed in a strength higher than the "Usual strength", such preparation also should be considered as "Pharmacopoeial".

(2) Where Pharmacopoeia prescribes a dosage range for a preparation without specifying any "Usual strength", the preparation should be in a strength which shall not be lower than the lowest dosage given in the Pharmacopoeia.

(3) Where a preparation is marketed in a strength lower than the dose specified in the Pharmacopoeia and the manufacturer takes the plea that the preparation is

meant for paediatric use, evidence in support of marketing a preparation in lower strength should be adduced by the manufacturer. The, paediatric dosages given in the Indian Pharmacopoeia or the National Formulary of India should be considered as guidelines. In addition, the manufacturer of such preparations should also be required to show a distinguishing legend on the label reading "for use of children only".

(4) In the case of all the preparations covered by the Pharmacopoeias irrespective of whether the "Usual strength" is prescribed or not if the preparation is marketed in strength higher than the maximum dose prescribed, such a preparation should be considered a Pharmacopoeial preparation".

16. A perusal of the foregoing orders of the Government would show that there is no substance in the stand taken by the department that the impugned product cannot be treated as a pharmacopoeial preparations merely because it is being marketed in a strength which is lower than the "usual strength". It is clearly laid down that in case of preparations where pharmacopoeia lays down the usual strength and also specifies the dose range, preparations which fall within the dosage range shall be deemed to be pharmacopoeial. We have observed that these orders of the Government were brought to the notice of the Additional Collector who has not examined the appellant's defence in this regard at all and dismissed it as "not relevant". We feel that not only are these orders wholly pertinent but also fully applicable and cover the impugned products.

17. As regards the view taken by the Additional Collector that the impugned medicine is classifiable under Item 14E of Central Excise Tariff because the name of the manufacturer appears on the carton, this again remains un-substantiated. As the appellant company has stated, it is obligatory that the name of the manufacturer should appear on the carton. We are not convinced that in this case the name of the manufacturer has appeared on the carton in such a way as to indicate "a connection in course of trade between the medicine and some person having the right as proprietor or otherwise to use the name of mark with or without any indication of the identity of that person". The appellants have rightly relied in this connection on the decision of the Madras High Court in the case of Indo-

French Pharmaceutical Company (supra).

18. We have in the foregoing paras disposed of all the main arguments put forward by the department in favour of the impugned goods under Tariff Item 14E. There are certain other points which have been made in the order of the Additional Collector. For instance, it is submitted that the Analgin Tablets are described not only as N.F.I, but also as U.S.S.R.P. It is not at all shown before us how this would militate against the product being considered as a pharmacopoeial medicine. All that is required is that the medicine should be manufactured in accordance with the particular pharmacopoeia. If reference is also made to another pharmacopoeia it is not at all understood how such a product would cease to be a pharmacopoeial preparation.

19. The department has also not been able to establish charge that there has been any violation of Rule 96 ZN(2) of the Central Excise Rules, 1944. As far as we could observe the recognised abbreviation of the relevant pharmacopoeia does appear just below the name of the drug on the carton and this should suffice.

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