(1989) 23 ECR 473 : (1984) 17 ELT 27 : (1983) 140 ITR 158(1)

Bombay High Court

Case No: Misc. Petition No. 2489 of 1979

Gufic Laboratories and three others		APPELLANT
	Vs	
Union of India and three others		RESPONDENT

Date of Decision: Dec. 7, 1983

Acts Referred:

- Central Excises and Salt Act, 1944 - Section 36(2)

Citation: (1989) 23 ECR 473 : (1984) 17 ELT 27 : (1983) 140 ITR 158(1)

Hon'ble Judges: M.L. Pendse, J

Bench: Single Bench

Judgement

1. The petitioners are the manufacturers of patent and proprietary medicines falling under Tariff Item 14-E. The petitioners intended to manufacture "Analgin Injections" and on December 16, 1975 got the label approved as being a pharmacopoeial product. The classification list was also approved on December 22, 1975 under Tariff Item 68. The petitioners manufacture "Analgin Injection" as per the pharmacopoeia U.S.S.R. of the packing 5 ml. and submitted classification list under Tariff Item 68 on December 27, 1976 and the same was approved on the next day.

2. The Superintendent of Central Excise issued show cause notice dated June 3, 1977 and the petitioners were asked to show cause why a short levy of Rs. 4446.33 should not be recovered from them in respect of the clearance of Analgin Injection of 53465 units of 2 ml. and 30 ml. valued at Rs. 40268.64 cleared from their factory during the period May 1976 to January 1977. The petitioners sent their reply on June 10, 1977, inter alia, claiming that the Analgin Injections were manufactured as per the pharmacopoeia of U.S.S.R. and the product is described at Serial No. 57 on page 81 of the U.S.S.R. pharmacopoeia. The Assistant Collector, by his order dated June 28, 1977, held that the demand notice issued was correct and the claim of the petitioners that the Analgin

Injection falls in monograph 57 of U.S.S.R. Pharmacopoeia is not correct. The petitioners carried an appeal before the Appellate Collector of Central Excise and the appeal was allowed by order dated June 16, 1978. The Appellate Collector held Entry 57 in U. S. S. R. Pharmacopoeia spells "Analgin" as a powder but also gives the minimum and maximum dosages for various injections, viz. intravenous and intramuscular. The appellate authority also held that the Commissioner of Food and Drugs Administration of Maharashtra State has recognised "Analgin Injection" as submitted by the petitioners to form a Pharmacopoeial product. The Government of India served a show cause notice for reviewing the order of the Appellate Collector, on the petitioners, in exercise of the powers u/s 36(2) of the Central Excises and Salt Act, 1944 and by order dated July 30, 1979, it was held that the petitioners are liable to pay duty under Tariff Item 14-E as Analgin Injections do not fall under Monograph 57 of the U.S.S.R. pharmacopoeia. The order of the Government is under challenge in this petition field under Article 226 of the Constitution of India.

3. Entry 14E and the relevant portion of explanation I thereto is as follows :

"Item No. 14E - Patent or Proprietary Medicines

Explanation I - "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 a 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."

In pursuance of the Explanation to Item 14E, the Government issued Notification dated March 1, 1963 observing that the State Pharmacopoeia of the U.S.S.R. would be considered relevant to ascertain whether any drug or medicinal preparation is specified in the Monograph of the said pharmacopoeia. Monograph 57 refers to the subject of Analgin and description given thereunder is as follows :

"Description. A macroacicular, crystalline, odourless, bitterish powder, white or white with a barely visible yellowish tint. Rapidly decomposes in the presence of moisture. Aqueous solutions turn yellow on standing."

The maximum single does to be given orally is 1 grammes, while maximum daily does to be given orally is 3 grammes. It further recites that the maximum single does subcutaneously, intramuscularly or intravenously should be 0.5 gramme and the maximum daily does to be given is 1.5 grammes. The heading of Monograph 58 is "Tabulettae Analgin 0.5" and covers Analgin in tablets form.

4. Shri Gurusahani, learned counsel appearing in support of the petition, submitted that the conclusion of the Government of India that as there is a separate monograph for Analgin tablets, it clearly indicates that one monograph covers only one form of preparation of a particular drug is entirely incorrect and unsustainable. The learned counsel submitted that the fact that under monograph 57, the form of preparation of

injection and doses is provided is conclusive to establish that Analgin Injection would fall under Monograph 57. In my judgment, there is considerable merit in the submission of the learned counsel. In my Introduction to the State Pharmacopoeia of the Union of Soviet Socialist Republics, it is observed :

"The monographs on medicines end with the indication of their basic pharmacological action. This is not to be understood that the medicine in question possessed no other activity or has no other application."

In my judgment, it is obvious that Monograph 57 is not restricted only to the Analgin in powder form but also includes Analgin in injection.

5. Shri Desai, learned counsel appearing on behalf of the Department, very strenuously submitted that the fact that Analgin in tablet form is under a separate monograph i.e. Monograph 58 and as there is no separate monograph under which injection falls, it must be concluded that the Analgin injection does not fall under any of the Monographs. The learned counsel also relied upon the observation in the revisional order that there are separate monographs in the form of powder, tablets and injection in Pharmacopoeia. In my judgment, the submission is entirely misconceived. The fact that Analgin in tablet form is under a separate monograph is only indicative that Monograph 57 would not cover Analgin in tablet form and Analgin in any other form which can be given either orally or intravenously would fall under Monograph 57. The reliance of the revisional authority on certain other entries in Monographs 71 to 74 entirely irrelevant. The mere fact that in respect of some Drug or Medicinal preparations, injections are brought under a particular monograph, cannot lead to the conclusion that Analgin Injection does not fall under Monograph 57. The revisional authority has clearly overlooked that in a Taxing Statute, the construction must always be strict and while construing whether a particular drug comes under monograph of Pharmacopoeia, the benefit of doubt, if any, must go to the assessee. Once, it is concluded that the Analgin injections manufactured by the petitioners fall under Monographs 57, then it is not in dispute that the petitioners would not be liable to pay excise duty under Tariff Item 14E and the liability would be under Tariff Item 68. In my judgment, the revisional authority was clearly in error in disturbing the conclusion of the Appellate Collector of Central Excise and the revisional order requires to be quashed.

6. Accordingly, the petition succeeds and the rule is made absolute and order dated July 30, 1979 passed by the Additional Secretary to the Government of India and the Joint Secretary to the Government of India is set aside and that passed by the Appellate Collector of Central Excise and Customs, Bombay on June 16, 1978 is restored. In the circumstances of the case there will be no order as to costs.