(1982) 08 MAD CK 0020

In the Madras High Court

Case No : Writ Appeal No. 396 of 1977

Bahole Pharmaceuticals Co. — APPELLANT

Vs

Government of India and Others — RESPONDENT

Date of Decision : 31-08-1982

Acts Referred:
Central Excise Rules, 1944 — Rule 10

Citation : (1984) 2 ECC 233 : (1983) 12 ELT 728 : (1983) 2 MLJ 235

Hon'ble Judges : Venugopal, J;K.B.N. Singh, J

Bench : Division Bench

Advocate : M. Srinivasan for Rajagopalan, for the Appellant; K.N. Balasubramaniam, for the Respondent

Judgement

Venugopal, J.—The writ petitioner is the appellant before this Court. It is a propriety firm. It manufactured and cleared Homeopathic

injections during the period March 1961 to December 1966, without payment of any Excise duty. In December 1968, the Assistant Collector,

came to the conclusion that Homeopathic injections which are administered by parenteral route are not recognised as Homeopathic medicine and

hence they are not excluded from the purview of Patent or Proprietary medicines under Tariff Item No. 14E of the Central Excise Tariff.

Accordingly, the Homeopathic injections cleared by the appellant during the period 1st March 1961 to 31st December 1966, were assessed to

duty under Item No. 14E of the Central Excise Tariff, and two demands for Rs. 345.60 and Rs. 5365.14 were raised by the two notices issued on

6th December 1968. The Appellant resisted the demand contending that Homeopathic injections contain purely minute quantity of Homeopathic

medicines classified in the Homeopathic Pharmacopoeia of U.S.A. and they are to

be exempted from payment of excise duty under Tariff Item

14E. The Assistant Collector came to the conclusion that it has not been established that parenteral manner of administration of Homeopathic

medicine is a Homeopathic practice and the medicinal contents of the items manufactured are the same if not similar to allopathy, though the

dosages may be smaller or even minimal. The writ petitioner thereupon filed an appeal to the Collector of Central Excise and he held that

parenteral use of Homeopathic medicines in the form of injection is not recognised in the original treatises of Homeopathic system of medicines,

and such injections cannot, therefore, be treated as patent or proprietary medicines, so as to get the benefit of item 14E. The writ petitioner filed a

revision petition before the Government and it was rejected holding that Homeopathic practice does not include the administration of preparation

of Injections and hence they are not entitled to exemption as Homeopathic medicines. The appellant then filed a writ petition before this court and

the learned single Judge of this Court held that drawing succour from the amendment to Rule 2(dd) of the Drugs and Cosmetics Rules, 1945, the

authorities have come to the correct conclusion that Homeopathic medicine administered by parenteral route is not a patent or proprietary

medicine which is exclusively Homeopathic and the exemption provided under Tariff Item 14E is to available and the injections manufactured and

cleared have been correctly assessed to excise duty. Against this order of the learned single Judge, the present writ appeal has been filed.

2. The learned counsel for the appellant contended that Homeopathic injections administered by parenteral route are nevertheless Homeopathic

medicine and by its mere administration in a particular form, it does not cease to be a Homeopathic medicine. The learned counsel further

contended that Rule 2(dd) of the Drugs and Cosmetics Rules came to be introduced in the statue book, with effect from 6th December 1969 and

the definition is for the purpose of that Act, and it cannot be imported or used as an aid for interpreting Tariff Item 14E and the Rule also is not

applicable, as the sales of the injections have taken place long before the promulgation of the rule.

3. The learned counsel for the respondents contended that in view of Section 16 and 18 of the Drugs and Cosmetics Act, 1940, only those classes

of drugs specified in the Second Schedule can alone be manufactured according to the standard set out in the Schedule and Homeopathic medicine

administered by parenteral route is not mentioned in the schedule, and there is thus a total prohibition to manufacture the drug, and what is implicit

in the Act has been made explicit by introducing the amendment to rule 2(dd) with effect from 6th December 1969, and when the manufacture of

the drug itself is prohibited, the question of grant of exemption under Tariff Item 14E cannot arise for consideration.

4. Section 18 of the Drugs and Cosmetics Act, 1940 (hereinafter to be referred to as the Act) prohibits manufacture of any drug which is not of

standard quality. Section 16 of the Act defines the expression ''standard quality'' to mean that the drug should comply with the standard set out in

the Second Schedule. The Second Schedule sets out the class of drugs and the standard to be complied with for the manufacture of that drug. A

combined reading of Sections 16 and 18 and the Second Schedule, makes it clear that only those class of drugs with the specified standards, can

alone be manufactured in this country in accordance with the licence issued for that purpose. The Act and the Second Schedule, to begin with, first

classified patent or proprietary medicines and set out the standard to be complied with. Then, control over the manufacture and sale of Ayurvedic

(including siddha) and Unani drugs came to be introduced by the Amendment Act of 1964. On 9th December 1966 the Second Schedule

classified Homeopathic medicines and set out the standard to be complied with by the manufacturer. Thus, the Act starting with the proprietary and

patent medicines, introduced control over the manufacture, sale and distribution of Ayurvedic (including Siddha) and Unani medicines in 1964, and

the control was further extended to Homeopathic medicines in 1966. Homeopathic medicines came to be classified and standard is set out in item

4-A of the Second Schedule as under :-

For Homeopathic medicines not included in the Homeopathic Pharmacopoeia of the United states of America or the United Kingdom or Germany,

no standards have been approved by the Central Government as required under item 4-A of the Second Schedule. Since the appellant has not

established that Homeopathic injections administered by parenteral route are in accordance with the standards specified in the Homeopathic

Pharmacopoeia, of the three countries, the manufacture of Homeopathic injections is prohibited under the Act. This implicit prohibition contained in

the Act is made explicit by introducing rule 2(dd) of the Rules framed under the Act. Rule 2(dd) is as follows -

Homeopathic medicines include any drug which is recorded in Homeopathic provings or therapeutic efficacy of which has been established

through long clinical experience as recorded in authoritative Homeopathic literature of India and abroad and which is prepared according to the

techniques of Homeopathic Pharmacy and covers a combination of ingredients of such Homeopathic medicines by does not include a medicine

which is administered by parenteral route.

Rule 2(dd) is clarificatory in nature, clarifying what is already implicit in the Act. By relying on Rule 2(dd) to understand the meaning of

Homeopathic medicines, no retrospective operation of that rule is intended. This is what this court has held in the earlier writ petition No. 3171 of

1973 filed by the appellant. It, therefore, follows that Homeopathic injections administered by parenteral route are not Homeopathic medicines that

can fall under Tariff Item 14E.

5. The appellant''s case, as seen from the reply to the show cause notice, is that Homeopathic injections contain purely minute quantity of

Homeopathic medicines classified in the Homeopathic Pharmacopoeia of the U.S.A. thereby implying that it is manufacturing Homeopathic

injections according to the standards specified in the Homeopathic Pharmacopoeia of U.S.A. and falling within the purview of Sl. No. 4-A of the

Second Schedule to the Act. In the earlier writ petition No. 3171 of 1973 filed by the appellant, this court has held -

Thus, it will be seen that homeopathic medicines as contemplated by the Act must satisfy the test of being of the standard quality, namely, the

standard specified from time to time in the Homeopathic Pharmacopoeia of the United States of America or the United Kingdom or Germany for

the medicines included therein. It is admitted that Homeopathic medicines which are meant for administration by the parenteral route are not

included in any of the above three Pharmacopoeias.

The above finding of this Court has become final and conclusive. As person claiming the benefit of exemption under Tariff Item 14E, it is for the

appellant to establish that Homeopathic injections which are administered by parenteral route, are in accordance with the standards specified from

time to time in the Homeopathic Pharmacopoeia of the three countries. Since the appellant has failed to establish this basic requirement to get the

exemption under Tariff Item 14E, it is liable to pay excise duty. As Serial Number 4-A of the Second Schedule to the Act, came into effect from

19th March 1966, injections manufactured and cleared after 19th March 1966, are liable for excise duty. Since the scheme of the Act makes it

clear that the licensing procedure and control over the manufacture, sale and distribution of medicines were made applicable to Homeopathic

medicines only from 19th March 1966, the demand raised which is for the period from 1st March 1961 to 31st December 1966 should thus be

restricted only to the period 19th March 1966 to 31st December 1966.

6. The learned counsel for the appellant next contended that since the demand has not been made within a period of six months from the date when

the excise duty was short-levied, it is barred by limitation under Rule 10 of the Central Excise Rules, 1940. The plea is raised for the first time only

in the appellate court. If the plea was raised at the appropriate stage, the respondents would be in a position to establish how the extended period

of five years provided under the same rule would be applicable to this case. If the plea now raised by the appellant is permitted at this stage, the

respondents would be deprived of the opportunity of establishing how the extended period of limitation would apply in this case. The facts

necessary invoke the period of limitation should have been specifically pleaded by the appellant at the appropriate stage when the respondents

would have had the benefit to pleading and showing how the claim is not barred by limitation. Since that stage has already passed, we are not

inclined to permit the appellant to raise the plea of limitation at this stage.

7. The last plea of the learned counsel that the respondents, having allowed the appellant to clear the goods earlier, are now estopped from raising

the additional demand, has to be rejected as there is no estoppel against the statue.

8. In the result, the appeal is allowed in part to the extent indicated above. Parties to bear their own costs.

