

(1981) 07 MAD CK 0025

In the Madras High Court

Case No : Writ Petition No. 1396 of 1977

S. Srinivasan (Died) and Others

APPELLANT

Vs

Assistant Collector of Central Excise, Tiruchirapalli and Others

RESPONDENT

Date of Decision : 20-07-1981

Acts Referred:

Drugs and Cosmetics Act, 1940 — Section 16, 18
Drugs and Cosmetics Rules, 1945 — Rule 2

Citation : (1982) 10 ELT 360

Hon'ble Judges : Nainar Sundaram, J

Bench : Single Bench

Advocate : K. Ramamurthi, for the Appellant; R. Thiagarajan, Senior Central Govt. Standing Counsel, for the Respondent

Judgement

Nainar Sundaram, J.—Dr. S. Srinivasan, hereinafter referred to as the original petitioner, who is no more and whose legal representative is

continuing the writ petition, manufactured and cleared Homoeopathic injections during the years 1965-66 and 1966-67. On the basis that

Homoeopathic injections which are administered by parenteral route could not be recognised as Homoeopathic medicines, which are excluded

from the burden of duty under Item 14-E of the First Schedule to the Central Excises and Salt Act, 1944, hereinafter referred to as the act, the

Homoeopathic injections cleared by the original petitioner during the years 1965-56 and 1966-67, were assessed to duty under the Act and

requisite demands were issued. Before confirmation of the demands, the original petitioner was directed to show cause and he had adequate

opportunity to make his representation. The original petitioner seemed to have filed his representation and along with it, he referred to certain

Authorities on Homoeopathic medicines to show that Homoeopathic injections administered by parenteral route, will come only under the category of Homeopathic medicines, so as to attract the exclusion set out in Item 14-E of the First Schedule to the Act. This was not accepted by the first respondent and the demands were confirmed. There was an appeal by the original petitioner to the second respondent and there again, the original petitioner was not successful and the second respondent rejected the appeal. The revision to the third respondent by the original petitioner did not prove fruitful. The third respondent rejected the revision by order dated 29-2-1977. In the present writ petition the orders of the respondents are being challenged.

2. Mr. K. Ramamurthi, learned counsel for petitioner on record, would submit that when eminent authorities in the Homoeopathic field have been brought to the notice of the respondents, they have not been specifically referred to and discussed by the respondents and the approach of the respondents in ignoring them in a summary manner is not commendable. The learned counsel has not endeavoured to place before me any of the scientific works, which would throw light on this question. As stated above, the grievance of the learned counsel is that the respondents have not even referred to these scientific works and discussed them before they proceeded to eschew the submissions of the original petitioner. This by itself cannot vitiate the orders of the respondents. Respondents 1 and 2 have, in fact, made reference to the reliance placed by the original petitioner on the various authorities on Homoeopathic system. Yet, in their own assessment, they have found no warrant to accept them. It cannot be stated that it is always incumbent on the respondents to discuss the authorities in extenso.

3. The respondents have categorically opined that Homoeopathic medicines, subject-matter of exclusion under Item 14-E of of the First Schedule to the Act cannot take in Homoeopathic medicines, which are administered parenteral route. The second respondent refers to the Drugs and Cosmetics Rules, 1945, for the purpose of holding that the Homoeopathic medicines cannot include medicines administered by parenteral route, Obviously, the reference is to Rule 2(dd) of the said Rules, which was added on in 1969. The said rule reads as follows -

Homoeopathic medicines include any drug which is recorded in Homoeopathic

provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homoeopathic literature of India and abroad and which is prepared according to the techniques of Homoeopathic pharmacy and covers combination of ingredients of such Homoeopathic medicines but does not include a medicine which is administered by parenteral route".

4. It must be pointed out that neither in the Act nor in the Rules framed thereunder, we get a definition of Homoeopathic medicines. The third respondent has placed reliance on the Drugs and Cosmetics Act, 1940, to hold that Homoeopathic drugs in India do not include the administration of Homoeopathic medicines by injection. This reliance cannot be stated to be wholly untenable and out of place. In the absence of definition of Homoeopathic medicines in the Act and the Rules framed thereunder, it will be in order to glean out the meaning from the relevant statute which deals with drugs. In *Messers Bakola Pharmaceutical Co. v. Union of India*, W.P. 3171 of 1973 - judgment dated 20-11-1973, Ismail J. as he then was, had occasion to consider the meaning of Homoeopathic medicines under the Drugs and Cosmetics Act, 1940. In that case, the right to manufacture Homoeopathic medicines, which are administered by parenteral route was withdrawn from the licence granted to the petitioner therein by the Drugs Controller, Madras. It must be stated that the petitioner therein was engaged in the business of manufacture of Homoeopathic medicines even since 1944 and after the Drugs and Cosmetics Act, 1940 came into force, it had been in receipt of licence in form 28 for the manufacture of Homoeopathic medicines which included injections also. The first contention put forth on behalf of the petitioner therein was, the definition of Homoeopathic medicines in clause (dd) of rule 2 of the Drugs and Cosmetics Rules, 1945, which came to be introduced only in 1969 is ultra vires, being outside the scope of the Drugs and Cosmetics Act. This contention was repelled by the learned Judge and it was held that the Drugs and Cosmetics Act, 1940, itself did not comprehend Homoeopathic injections or Homoeopathic medicines intended to be administered by parenteral route within the scope of the Homoeopathic medicines and consequently Rule 2(dd) of the said Rules is not outside the scope of the said Act and all that Rule 2(dd) of the Rules did was to make explicit what was

implicit in the said Act itself. The reasoning of the learned Judge is found in the following passages and they clearly indicate that even on consideration of the Homoeopathic pharmacopeia of the United States of America or the United Kingdom or Germany, the Homoeopathic medicines which are meant for administration by parenteral route cannot be included in the category of Homoeopathic medicines.

For the purpose of understanding the first of the arguments, it is necessary to refer to certain provisions of Drugs and Cosmetics Act, 1940, as

well as the Rules. The said Act has been enacted for the purpose of regulating the import, manufacture, distribution and sale of drugs and

cosmetics. S. 18 of the Act states that from such date as may be fixed by the State Government by notification in the Official Gazette in this behalf,

no person shall himself or by any other person on his behalf manufacture for sale, or sell, or stocks or exhibit for sale, or distribute any drug or

cosmetic which is not of standard quality. Section 16 of the Act defines the expression "standard quality" and states that for the purpose of

Chapter IV, the expression "standard quality" means in relation to a drug, that the drug complies with the standard set out in the Second Schedule.

The relevant entry in the Second Schedule is Entry 4-A, which was introduced on 19th March, 1966. That Entry is as follows -

Thus, it will be seen that Homoeopathic 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 Homoeopathic Pharmacopoeia of the United States of America or the United Kingdom or Germany for

the medicines included therein. It is admitted that Homoeopathic medicines which are meant for administration by parenteral route are included in

any of the above three Pharmacopoeias. Then, the next condition contemplated in Item 4-A is that where the particular medicine is not included in

any of the Pharmacopoeias, the standards must be as approved by the Central Government and displayed in the prescribed manner on the label of

the container. The Central Government in this case has not prescribed or approved any standard with regard to Homoeopathic injections or

Homoeopathic medicines meant for administration by parenteral route. Consequently, from the very provisions contained in the Second Schedule

read with Secs. 16 and 18 of the Act, it is clear that Homoeopathic injections or

Homoeopathic medicines intended for administration by

parenteral route are not within the scope of the Act itself. Clause 2(dd) of the Rules was introduced on 19-11-1969 and that rule states :-

(omitted)....

The first contention of Mr. Sivaramakrishniah is based on the assumption that the Act itself did not exclude Homoeopathic medicines meant for

administration by parenteral route and it is only the rule which excluded them and that therefore the said Rule is beyond the scope of the rule

making power of the authority under the Act. As I have pointed out already, the Act itself did not comprehend Homoeopathic injection or

Homoeopathic medicines intended to be administered by parenteral route within the scope of the Homoeopathic medicines and consequently Rule

2(dd) of the Rules is not outside the scope of the Act and all that Rule 2(dd) did was to make explicit what was implicit in the Act itself. Therefore,

I reject the first contention of the learned counsel for the petitioner as without substance.

5. Learned counsel expressed a grievance that the second respondent ought not to have relied on the definition of Homoeopathic medicines found

in rule 2(dd) of the Drugs and Cosmetics Rules, 1945, which came to be introduced only in 1969. As pointed out by Ismail J., as he then was, in

the above decision, the said rule made it explicit what was implicit the Drugs and Cosmetics Act, 1940. Learned counsel is not stating before me

that the meaning of Homoeopathic medicines ought not to have been gathered by reference to other relevant statutes and the Rules thereunder. As

stated above, in the absence of definition of Homoeopathic medicines in the Act and the Rules framed thereunder, no exception could be taken to

the approach of the respondents in relying on the Drugs and Cosmetics Act and the Rules made thereunder for the purpose of gleaning out what

could be Homoeopathic medicines. There was no attempt on the part of the learned counsel to place before me any other scientific works or

judicial precedents, which may persuade me to hold otherwise. I am not able to spell out any infirmity in orders passed by the respondents, so as

to compel me to interfere in writ proceedings. Accordingly, the writ petition fails and the same is dismissed. There will be no order as to costs.