
(1995) 12 MAD CK 0024

In the Madras High Court

Case No : Writ Petition No. 16679 of 1995 and W.M.P. No. 26487 of 1995

Bahola Laboratories

APPELLANT

Vs

Union of India (UOI) and Others

RESPONDENT

Date of Decision : 06-12-1995

Acts Referred:

Constitution of India, 1950 — Article 14, 19, 226

Drugs and Cosmetics Act, 1940 — Section 12, 3, 33, 33C, 5

Citation : (1997) 57 ECC 172

Hon'ble Judges : Raju, J

Bench : Single Bench

Final Decision : Dismissed

Judgement

Raju, J.—The above writ petition has been filed for the following reliefs:--

1. To issue a writ of declaration, or any other order or direction in the nature of a writ, declaring Rule 106-B of the Drugs and Cosmetics Rules,

1945, inserted by G.S.R. 108-E dated 22.2.1994 as ultra vires, unconstitutional and violative of Articles 14 and 19(1)(g) of the Constitution of

India and contrary to the provisions of Drugs and Cosmetics Act, 1940.

2. The petitioner is a manufacturer of homoeopathic medicine and claims to be as such from the year 1975. It is also claimed that homoeopathic

medicines are manufactured as per the standards laid down by the Homoeopathic Pharmacopoeia of India, that the petitioner is holding a valid

licence issued under Rule 85-B of the Drugs and Cosmetics Rules, 1945, hereinafter referred to as "the Rules" to manufacture homoeopathic

medicine, that the licence is being renewed from time to time and that the current licence is valid upto 31.12.1996. The petitioner also claims to

have obtained the licence under , Rule 139-A of the rules and the same was

being renewed from time to time and the validity of the current licence is upto 31.12.1996. The further claim of the petitioner is that they are also manufacturing various medicines such as mother tinctures, dilutions, ointments, tablets, liquid preparations and eye preparations and that the mother tinctures is prepared by powdering a herb and mixing the same with nine parts of 95% ethyl alcohol in the manner set out in detail, which in my view, is not necessary to be referred to in such greater detail for the purpose of appreciating the grievance of the petitioner. The relevant fact that requires to be mentioned is that a dilution is said to be prepared by adding mother tincture with 89% of ethyl alcohol in the manner prescribed by the Homoeopathic Pharmacopoeia, that the sales of the petitioner is more than 60 lakhs per annum and 60% of the same is of mother tinctures and dilutions. The next fact that requires to be noticed is that all these years, the mother tinctures and dilutions are sold in a container of 540 ml, and the same is used to be sold to dealers, who in their turn, should also have a licence under Rule 57-C of the Rules. A general claim is also made that the entire industries generally pack mother tinctures and dilutions in bottles of 450 ml. for the reason that it will be most convenient for the manufacturers as also for the dealers and so far, there had been no complaint against the petitioner by anybody. The occasion for the filing of the above writ petition is said to be the letter dated 25.8.1994 communicated by the 5th respondent intimating the petitioner about the amendments to the rules of which Rule 106-B of the Rules is one which is being challenged now.

3. Rule 106-B of the Rules which is under challenge reads as hereunder:--

106-B. Prohibition of quantity and percentages:-- No homoeopathic medicine containing more than 12% alcohol v/v. (ethyl alcohol) shall be packed and sold in packing or bottles of more than 30 millilitres, except that it may be sold to hospitals/dispensaries in packings or bottles of not more than 100 millilitres.

The said rule is challenged on the following grounds:--

(i) Though the rule in question directly affects those dealings in manufacturing the homoeopathic medicine, the same has not made in consultation

with the Board relating to the homoeopathic medicine and as a matter of fact, there is no such Board consisting of or taking case of the interest of

the homoeopathic medicine. This, it is stated, is violative of the provisions contained in Section 33 of the Act;

(ii) The mere publication of the draft rule in the Gazette, according to the petitioner, would not amount to proper and sufficient compliance with the

statute and that in addition to such publication in the Gazette, the same must be made available to the petitioner also. It is stated that though the final

rule has been communicated, there was no attempt on the part of the respondents or the rule-making authorities to communicate the draft of the

rules to elicit their opinion and the impugned rule is vitiated on that account also. To support the said claim, reliance is placed on the decision of a

learned single Judge of this Court reported in 1984 Writ L.R. Summary of Judgments (Extracts) page 88 [Asia Tobacco Company Ltd. Vs.

Union of India and Others, which, it is stated, has subsequently been confirmed also in Writ Appeal, W.A.No. 1051 to 1053 of 1984 dated

10.7.1989 [reported as Union of India Vs. Asia Tobacco Co. Ltd.,].

(iii) The rule of the nature in question, according to the petitioner, cannot be made applicable or framed so as to bind or affect the manufacturer of

homoeopathic medicine and if at all the rule could have been so devised or the rule could be enforced only against those who are dealers in the

medicine in question and not the manufacturers. It is stated that the rule cannot be justified also as one pertaining to the prescription of standards

since, according to the petitioner, the prescription with reference to the quantity in which it has to be packed has relevance to the measure and not

the standard of the medicine and consequently, the same is liable to be struck down as violative of Articles 14 and 19(1)(g) of the Constitution of

India;

(iv) The rule of the nature, on the face of it, has been made with particular relevance and application only to the homoeopathic medicine and not

with reference to the other categories of medicines and, therefore, it constitutes hostile discrimination in so far as the homoeopathic medicine is

concerned and, therefore, violative of Article 14 of the Constitution of India.

4. Mr. N.R. Chandran, learned Senior Counsel, appearing for the petitioner, reiterated the above contentions at the time of hearing to substantiate

the grievance of the petitioner.

5. I have carefully considered the submissions of the learned Senior Counsel

appearing for the petitioner in the light of the relevant rules and the materials made available as also the judgment relied upon and I am of the view that they do not merit countenance by this Court. The fact that similar writ petitions, challenging the validity of the rules, have been admitted or entertained in other High Courts in any view, is no legitimate ground to mechanically admit the present writ petition in this Court, de hors the legality or the tenability of the grounds of challenge. So far as the ground of challenge No. 1 referred to above is concerned, based on the absence of a separate Board for homoeopathic medicine to justify the making of a rule governing the same after consultation with the said Board, I am of the view that to accept such a plea would be doing violence to the language of the provisions of the Act as also the relevant rules. No doubt, Section 12 as also Section 33 of the Drugs and Cosmetics Act, 1940, hereinafter referred to as "the Act" contemplate consultation with the Board while making the relevant rules under the respective Chapters contemplated under those provisions. The Act contains a definition in Section 3(aa) defining the "Board" as meaning in relation to ayurvedic, siddha or unani drug, the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board constituted u/s 33-C of the Act and in relation to any other drug or cosmetic, the Drugs Technical Advisory Board constituted u/s 5. It is not the case of the learned Senior Counsel for the petitioner that there was no such consultation with such Drugs Technical Advisory Board. There is nothing in the provisions of Sections 9, 12 or Section 33 warranting the consultation with only a particular Board dealing with the particular nature of medicine particularly in the teeth of the definition of the "Board" in respect of the drugs other than ayurvedic, siddha or Unani drug. As a matter of fact, Rules also appears to have been made as early as in the year 1964 under the caption, "Sale of Homoeopathic Medicines" only after consulting the Drugs Technical Advisory Board, and there is no legal infirmity in the same. The first ground of challenge, therefore, fails.

6. So far as the publication of the draft rule in the gazette and making it available to the persons aggrieved are concerned, the submission of the learned Senior Counsel is that it is not enough that it is published in the gazette, but it should be made available individually also by service thereof to enable them to make their objections as the copies of the final rule made and

published came to be served on the petitioner. This proceeds, in my view, on a misapprehension of the scope and purport of the requirements relating to the publication itself. It is not the rule-making authority which has served the final rule on the petitioner or for that matter any of the other manufacturer. It is only the enforcing authorities, though perhaps not required in law in order to make the manufacturers or dealers alive to their obligations, thought fit to serve the communication by way of abundant caution and information. There is no specific provision in the Act or the Rules warranting any individual service of either the draft rule or the rule as finally made on any one of the manufacturers or dealers of any medicine. The reliance placed upon the judgment reported in 1984 WL.R. -- Summary of Judgments (Extracts) Page 88: Asia Tobacco Company Ltd. Vs. Union of India and Others, is wholly inappropriate. I take it that the said judgment, as claimed by the learned Senior Counsel, has been affirmed by a Division Bench. Be that as it may, the ratio of the said Judgment does not in any manner help or assist the learned Senior Counsel for the petitioner to vindicate the grievance of the nature raised in this case. In the case under consideration in 1984 Writ L.R. -- Summary of Judgments (Extracts) page 88: Asia Tobacco Company Ltd. Vs. Union of India and Others, , it was held that a mere printing of a notification in the Official Gazette, without making it available for circulation at the Sales Depot for sale to the public, was held to be not sufficient compliance with the requirement of publication. There can be no difficulty in understanding the ratio of the said decision. Publication would not be complete if merely it is claimed to be published but the copies of such publication are not issued for sale in the respective Sales Depots of the Government Gazettes. It was found therein that there was no attempt to make available for sale the gazette copies of publications containing the notification of withdrawal of exemption by rescinding the previous notification. The grievance of the petitioner in this case is not such, as was projected before the learned single Judge deciding the above case. In the case before me, the claim is that it is not enough if the draft of the rules are published in the gazette but the draft should be served individually on those concerned or may be affected also to enable them to file their objections to the rules. As noticed earlier, neither the provisions of the Act

nor the rules made thereunder contemplates any such personal service of the draft notification of the rules published in the gazette nor the decision

referred to above supports such a claim. In this case, the preamble to the final rule published indicates meticulously the procedure adopted for

publication and the subsequent events which transpired thereafter before actual finalisation. This procedure, as found stated to have been followed,

in my view constitutes sufficient compliance with the provisions pertaining to the rule-making powers of the competent authority and I do not see

any infirmity involved in not communicating individually the draft rules for the information of the petitioner or anybody similarly placed. The second

ground of challenge also, therefore, fails. Equally untenable is the plea that the rule under challenge could be and ought to be made so as to govern

or to be enforced against the dealers only and not against the manufacturers who, it is claimed, manufacture the drug or medicine concerned in

bulk. This also, in my view, proceeds upon a total misapprehension of the object of the rules as also the scope and purport of the rules.

7. The provision engrafted in Rule 106-B of the rules under challenge is so comprehensive as to cover both the manufacturer and the dealer. It is

futile, having regard to the object and purport of the rule, to contend that such rule can be made applicable only to the dealer and not to the

manufacturer. Though the manufacturer manufactures the drug or medicine concerned in bulk, it is he who also makes it and packs them in a

saleable condition and puts them into market either by himself or through his dealers or agents and the mischief sought to be prevented by the

prohibition concerned be effectively negotiated and dealt with unless it is, as the rules stand at present so comprehensive and binds both the

manufacturer and the dealer. I do not see any logic or reason in the challenge made on this ground to the impugned rule. The plea that the

stipulations relating to packing will be "" comprehended only in fixing the measures and not the standards also does not merit countenance. The

manufacture and sale of medicine can be regulated and controlled both with reference to the standards and the manner and method of packing and

the wisdom or expediency of the requirement in this regard are not matters which should concern the Court unless it is demonstrated before this

Court that grave injustice or prejudice is caused by such prescription and that any of the legally protected rights are violated. In this case, though it

is claimed that it is easy and convenient both for the manufacturer and the dealer to pack it in the quantity of 450 ml. as has hitherto been done, as to how the said stipulation really affects the petitioner-manufacturer or the dealers or it impedes his/their business is not demonstrated with any precision or clarity and that, therefore, I do not see any legal grievance whatsoever substantiated in the submission made in this regard. As the rule stands, it appears, even on a cursory reading, that the object of the rule-making authority is to prevent abuse of the drug concerned containing alcohol of more and above than a prescribed percentage for other than genuine and medicinal purposes by imposing a restriction in the manner of its package and that, in my view, no exception could be taken to the reasonableness of the measure. The plea based on Articles 14 and 19(1)(g) of the Constitution, therefore, fails and shall stand rejected.

8. The final ground of challenge that no such prohibition or restriction has been engrafted in respect of the other medicines except homoeopathic medicine and that the differential treatment is discriminatory in nature and constitutes violation of Article 14 of the Constitution of India also does not appeal to me. The different categories of medicine form basically a different class by themselves and if as a matter of policy to prevent any abuse, the competent rule-making authority has resolved to impose a restriction or prohibition of the nature in respect of only a particular class or category of even homoeopathic medicines, which, in my view, is just and reasonable, it cannot be contended by the petitioner that unless similar or the same type of restriction is imposed in respect of the medicines or drugs of different or other Pharmacopoeia also, it would lead to hostile discrimination. Since each drug or medicine pertaining to different Pharmacopoeia, forms a class by themselves, the plea of hostile discrimination cannot be said to be either genuine or acceptable. The question as to which category of medicine or class of drug requires what category or manner of treatment to prevent any abuse are mere matters of policy over which unless for strong or extraordinary or exceptional reasons on grounds of unreasonableness or arbitrariness involving violation of fundamental rights are not normally undertaken by the Courts for adjudication in proceedings under Article 226 of the Constitution of India.

9. For all the reasons stated above, the writ petition shall stand dismissed.

Consequently, the writ miscellaneous petitions shall also stand dismissed.