
(1999) 07 CAL CK 0055
In the Calcutta High Court
Case No : M.A.T. No. 2705 of 1997

Drug Controller General of India and Another	APPELLANT
Vs	
West Bengal Small Scale Manufacturers Association and Others	RESPONDENT

Date of Decision : 27-07-1999

Acts Referred:

Constitution of India, 1950 — Article 14
Drugs and Cosmetics Act, 1940 — Section 26A

Citation : AIR 2000 Cal 133

Hon'ble Judges : S.B. Sinha, Acting C.J.; M.H.S. Ansari, J

Bench : Division Bench

Advocate : Bidyut Kr. Roy, for the Appellant; Ajay Kumar Gupta and Amal Kumar Mitra, for the Respondent

Final Decision : Allowed

Judgement

1. The instant appeal is directed against a Judgment and order dated 14-2-97 reported in West Bengal Small Scale Pharmaceutical Manufacturer's Association and others Vs. Union of India and others, passed by a learned Single Judge in C.O. No. 5043 (W) of 1996 whereby and whereunder the Notification No. G.S.R.-793 (E), issued u/s 26A of the Drugs and Cosmetics Act, 1940 (in short the Act) and published in the Gazette dated 13th December, 1995 was quashed and set aside.

2. By the impugned Notification dated 13th December, 1995 a prohibition on manufacture, sale and distribution of fixed dose combination of Hydroxyquinoline group of drugs with any other drug, except for preparations meant for external use, was imposed.

3. The impugned Notification has been issued in exercise of the power vested in the Central Government u/s 26A of the Act which reads as under :--

"Power of Central Government to prohibit manufacture, etc. of drug and cosmetic

in public interest.-- Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, prohibit the manufacture, sale or distribution of such drug or cosmetic."

4. The contention of the respondents-writ petitioners assailing the impugned notification was that except reproducing the language of Section 26A of the Act, the impugned Notification does not specify the ground on which the Central Government arrived at a satisfaction that the manufacture, sale and distribution of fixed dose combination of Hydroxyquinoline group of drugs with any other drug, except for preparations meant for external use was required to be prohibited in the public interest.

5. The above contention found favour with the learned single Judge in quashing the impugned notification. The Ld. single Judge observed that there was nothing on record to show that any expert committee was constituted to examine the matter in consultation with the manufacturers of the drugs in question and directed that the order under appeal shall remain in abeyance for a period of two months from the date thereof to enable the Central Government to consider the matter afresh in accordance with the principles of natural justice and administrative fair play. It was further directed that while reconsidering the matter, the Central Government should take the assistance of a committee of experts which should give the representative of the manufacturers of the drug in question, including the petitioners a reasonable opportunity of hearing and placing relevant research papers and documents.

6. While giving directions for hearing the appeal expeditiously an interim order staying the operation of the Judgment under appeal was passed on 3-2-99.

7. It is the case of the Drug Controller General of India, appellant before us, that before issuing the final notification the matter was referred to before the Technical Sub-Committee of Drugs Technical Advisory Board whereby the Technical Sub-Committee has recommended the case for external use after examination of various fixed dose combination of Hydroxyquinoline group of drugs with any other drug. It is the submission of the appellant that the Sub-Committee is a statutory body which may advise the Central/ State Government for implementation of the Act. The recommendations made by the said Sub-Committee were accepted by the Central Government and thereafter the impugned notification was issued in exercise of the power vested in it u/s 26A of the Act.

8. It is the further submission of the Ld. Counsel for the appellant that the impugned notification was issued as a measure of carrying out the directions of

the Supreme Court of India made on 17-11-1994 in W.P. (C) No. 698/93. The Ld. Counsel for the appellant has referred to and relied upon an earlier order of the Supreme Court dated 12-2-97 whereby the Supreme Court accepted the recommendations made in the report of Dr. Bajaj for constitution of a core group.

9. Reliance has also been placed upon the order of the Supreme Court dated 17-11-1994 wherein the submissions of learned Additional Solicitor General were accepted and the Supreme Court considered it appropriate to permit the Advisory Board to constitute a Technical Sub-Committee for the purpose of expediting its work. It is the submission of the Ld. Counsel for the petitioner that the Technical Sub-Committee so constituted, at its meeting held on 23rd May, 1995 made the following suggestions :--

"The members had agreed to amend the existing item No. 13, GSR 578(E) dated the 23rd July, 1983 which reads as follows:--

"Fixed dose combination of halogenated hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery and for external use only."

10. This amendment was considered necessary as in the last meeting which was held on 15th February, 1995, it was decided by majority of the experts that clloquinol group of drugs (halogenated hydroxy-quinolines) can only be indicated as rational for the treatment of non-dysenteric amoebic colitis and for syst passers and clloquinol or any derivative of clloquinol should alone be administered for the treatment of diarrhoea and dysentery and not any fixed dose combination.

11. The member had agreed that this Item No. 13 of GSR 578(E) 23-7-1983 require amendment in light of the discussion of the experts and clloquinol group of drugs should alone be marketed for restricted indications as amended above and for external use only. However, for the exact language of this notification, the members will give a thought to it and write back to the secretariat."

12. In short, it is the submission of the appellant that the impugned Notification was based upon the recommendations of the said Technical Sub-Committee.

13. On the other hand, the submission of the respondent which has been found favour with the learned trial Judge was that prior to issuance of the impugned notification, the principles of natural justice had not been complied with. It has further been contended that despite the fact that an opportunity had been granted to the authorities by the Ld. trial Judge to issue an appropriate notification, no action thereupon had been taken.

14. Drugs and Cosmetics Act, is a complete code in itself. The said Act lays down procedures before a notification u/s 26A of the Act can be issued. An order issued u/s 26-A of the Act by the Central Government would be in exercise of its legislative power. When such legislative power is exercised, the question of complying with the principles of natural justice would not arise. Furthermore

satisfaction of the Central Government to the effect as to whether drug should be prohibited or not on the ground that the same is injurious to public health is essentially a matter dealing with a policy decision, and, thus, compliance of the principles of natural justice must be held to be excluded in such a situation.

15. A notification completely prohibiting manufacture and sale of drug is not either violative of Article 14 of the Constitution of India or Article 19(1)(g) thereof. See *Systopic Laboratories (Pvt.) Ltd. Vs. Dr. Prem Gupta and others*, .

16. In *Vincent Panikurlangara v. Union of India*, reported in : [1987]2SCR468 , the Apex Court has held that the question of banning a Drug is of National importance.

17. *Unichem Laboratories Ltd. and Another Vs. Union of India (UOI)*, upon which reliance had been placed by the respondent herein does not lay down any law in absolute term. In the said decision the question as to whether issuance of a notification in terms of Section 26-A being legislative in nature or not, was not raised. Assigning of a reason is a part of principles of natural justice. Unless a statute clearly provides for assignment of reason, no reason is required to be assigned unless the order visits the concerned persons with civil consequences. A policy decision adopted by the State may affect a particular person or a group of persons but such a policy decision being necessary in the public interest, requirements to comply with the principles of natural justice must be held to be excluded.

18. According to the respondents, the requirements laid down under the provisions of Section 26-A of the Act have been complied with. Assuming that the same had not been complied with, the writ Court in a given case may refuse to exercise its jurisdiction keeping in view in larger public interest.

19. In *Re. P.P. Raja Reddy*, one of us held that issuance of writ of certiorari or mandamus is a discretionary remedy.

20. In any event, it was not a case where a writ application could have been entertained by way of a public interest litigation in view of the aforementioned decision in *Vincent Panikurlangara v. Union of India* reported in, : [1987]2SCR468 .

21. For the reasons aforementioned we are of the opinion that it was not a fit case in which the learned trial Judge ought to have allowed the writ application.

22. Although several documents had now been placed before us as regards compliance of the provisions of the Act we are of the opinion that appeal being a continuation of writ petition, this Court while exercising its jurisdiction for issuance of a writ of or in the nature of mandamus in public interest can take into consideration other and further documents which had not been produced by the appellants before the learned trial Judge. It is also well settled that the appeal being a continuation of a writ proceedings; the Court in terms of the principles laid down in Section 107 read with Order 7, Rule 7 of the Code of Civil

Procedure, can grant appropriate relief.

23. For the reasons aforementioned we are of the opinion that the impugned judgment and order cannot be upheld which is set aside accordingly. The appeal is allowed but in the facts and circumstances of this there will be no order as to costs.