(1997) 02 CAL CK 0035

In the Calcutta High Court

Case No : C.O. No. 5043 (W) of 1996

West Bengal Small Scale Pharmaceutical Manufacturer''s Association and others — APPELLANT

Vs

Union fo India and others — RESPONDENT

Date of Decision : 14-02-1997

Acts Referred:
Drugs and Cosmetics Act, 1940 — Section 26, 5, 6, 7

Citation : AIR 1997 Cal 186

Hon'ble Judges : Altamas Kabir, J

Bench : Single Bench

Advocate : Gautam Chakraborty, Prasanta Kumar Dutta and Amalendu Mirta, for the Appellant; A.C. Maitra and M.P. Chakraborty, Shibdas Banerjee, Subrata Ghosh and Ms. Arati Dutta, for the Respondent

Judgement

1. The petitioner Nos. 1 and 3 claim to be Associations of manufacturers of drugs and pharmaceuticals in West Bengal, some of whom are engaged in the manufacture of different combinations of Iodoch-lorohydorxyquinoline with diastase and metronodazole for treatment of diarrhoea and dysentery under different brand names for about the last forty years. In this writ application they have challenged a Notification No. G.S.R. 793(E) issued by the Union of India and published in the Gazette of India Extraordinary in its issue of 13th December, 1995, prohibiting the manufactue, sale and distribution of fixed dose combination of Hydroxyquinoline group of drugs with any other drug, except for preparations meant for external use.

2. Appearing in support of the writ petition, Mr. Guatam Chakraborty submitted that the impugned notification dated 13th December, 1995, was a more or less verbatim reproduction of Section 26A of the Durgs and Cosmetics Act, 1940, hereinafter referred to as the "1940 Act", and reveals complete non-application of mind on the part of the Central Government authorities who were responsible for the issuance thereof.

3. Mr. Chakraborty submitted that the powers u/s 26A of the 1940 Act could be invoked in the public interest only when the Central Government was satisfied that the use of the drug in question was likely to involve any risk to human beings or animals or it did not have the therapeutic value claimed, or contained ingredients in such quantity for which there was no the-repeutic justification.

4. Mr. Chakraborty urged that in the instant case no material had been disclosed to show as to how the Central Government had arrived at such satisfaction before issuing the impugned notification. Mr. Chakraborty also pointed out that neither had any affidavit been filed on behalf of the Central Government nor had the records been produced which might have thrown some light on the matter.

5. Mr. Chakraborty then submitted that neither the petitioners and/or their members had been given a reasonable opportunity of hearing before the impugned notification was issued nor had an Expert Committee been appointed to make a proper assessment of the combination drugs in question upon consultation with the manufacturers thereof.

6. Mr. Chakraborty next urged that significantly no adverse report had been received from any quarter regarding the use of such combination drugs or that its use was injurious to human beings. In fact, the American Medical Association had in its Drug Evaluation Annual, 1995, observed that in treating invasive intestinal amebiosis, metronidazole is the drug of choice in combination with idoquinol or paromycin.

7. Mr. Chakraborty also referred to a report published in Current Therepeutic Research, volume 56, No. 7, in its July 1995 issue, in respect of a research undertaken by Searle (India) Ltd., a well-known manfuac-turer of the combination drug, wherein it was observed that the combination of the two above-mentioned drugs complement each other effectively to eradicate intestinal amebe-biosis.

8. Mr. Chakraborty submitted that Sections 5, 6 and 7 of the 1940 Act provided for the constitution of a Drugs Technical Advisory Board, the establishment of a Central Drugs Laboratory and an Advisory Committee to be called the "Drugs Consultative Committee", to advise the Central Government, State Governments and the Drugs Technical Advisory Committee on any matter tending to secure uniformity in administration of the Act throughout India.

9. In support of his submissions, Mr. Chakraborty firstly referred to a Single Bench decision of the Bombay High Court in the case of Unichem Laboratories Ltd. and Another Vs. Union of India (UOI), where the total ban imposed by the Central Government on Anabolic Steroid with a combination of vitamins was under consideration; In the said case, although an affidavit was affirmed on behalf of the Central Government, it was observed that the decision reached by the Committee of experts or the Board did not contain the reasons in support of the conclusions reached by the said committee or Board. Furthermore, as in the instant case, the notification issued by the Central Government did no more than

recite the required satisfaction. The learned Judge went on to hold that had the Central Government given its reasons for imposing the ban, the matter would have ended there; but in the absence of any such reason, the decision to impose a total ban on the drug could not be sustained.

10. Mr. Chakraborty also referred to the decision of the Hon''ble Supreme Court in Systopic Laboratiries (Pvt.) Ltd. Vs. Dr. Prem Gupta and others, , wherein a similar question relating to the prohibition on manfacture and also of fixed dose combination of corlicosteroids with any other drug for internal use was under consideration. Mr. Chakraborty submitted that in the said case, the Drug Consultative Committee appointed by the Central Government set up an Experts Sub-Committee for screening the formulations of drugs prevalent in the Indian market from the point of view of therapeutic rationale in order to remove irrational and harmful combination of drugs. Mr. Chakraborty pointed out that the Sub-Committee requested experts to attend its meetings and also decided that representative of the manufacturers should be given a hearing. Mr. Chakraborty also pointed out that the process initiated in 1979 with the setting up of the Experts Sub-Committee ultimately ended with the publication of the impugned notification on 3rd November, 1988, after an interval of about 9 years and after the proposal for introducing the ban had been deliberated upon and considered at all levels.

11. Mr. Chakraborty urged that despite the ban imposed, the manufacturers of the combination drugs were given another opportunity by the Hon''ble Supreme Court to approach the Technical Advisory Board with fresh materials in support of their claim for revocation of the ban on the manufacture and sale of fixed dose combination of corticosteroids with any drug for internal use for treatment of asthma.

12. Mr. Chakraborty submitted that in this case the matter had been dealt with perfunctorily and in completely abrupt manner, as reflected from the order itself, leaving the manufacturers with large stocks. Mr. Chakraborty urged that the ban imposed by the Central Government merited reconsideration by the Drugs Technical Advisory Board and the Central Government and till the matter was reconsidered, the members of the petitioner associations should be allowed to continue to manufacture and sell the fixed dose combination drugs, which are the subject matter of the impugned notification and the ban Imposed thereby.

13. Appearing for the Union of India, Mr. A. K. Moitra firstly submitted that since no affidavit had been separately affirmed on behalf of the Central Government, he was adopting the case made out in the affidavit affirmed on behalf of the Drugs Controller General of India.

14. Mr. Moitra submitted that the identical issue involved in this writ application was also at issue in a pending writ petition before the Hon''ble Supreme Court brought by Drug Action Forum, and the petitioners should seek their relief, if any, in the said proceedings:

15. Mr. Moitra urged that it had already been held by the Supreme Court that the benefit of the above drugs in containing paediatric diarrhoea is negative and a wide range of safe drugs was available for the said purpose.

16. Mr. Moitra then contended that adequate opportunity had been given to the Indian Drug Manufacturers'' Association before the final notification was published oh 13th December, 1995.

17. Mr. Moitra also contended that from the affidavit affirmed on behalf of the Drugs Controller it will be quite apparent that the Central Government had applied its mind to the matter and its decision was based on the objective satisfaction of the concerned authorities. It was only after such satisfaction was arrived at, after giving the Indian Drug Manufacturers'' Association adequate opportunity of representing their case, that a decision was taken resulting in the impugned notification.

18. Mr. Moitra also referred to the decision of the Hon''ble Supreme Court in the Systopic Laboratiries (Pvt.) Ltd. Vs. Dr. Prem Gupta and others, which had been referred to by Mr. Chakraborty, and placed a good deal of reliance thereupon.

19. Mr. Moitra submitted that in the said case the Expert Committee appointed by the Drugs Consultative Committee did not consider it necessary to conduct clinical trials before recommending withdrawal of the drug, but the Supreme Court was of the view that on such ground it could not be said that the Committee did not properly evaluate the material submitted by the manufacturers. Mr. Moitra submitted that the Supreme Court did not set aside the impugned ban but only referred the parties to the Drugs Technical Advisory Board in support of their claim for revocation of the. ban.

20. Mr. Moitra submitted that in line with the aforesaid decision, at best the matter could be sent back to the Drugs Technical Advisory Board for reconsideration.

21. Appearing for the Drugs Controller General of India, Mr. Shibdas Banergee submitted that the question of imposing a ban on the manufacture and sale of fixed dose combination of Hydroxyquinoline group of drugs with any other drug, was considered at length by the Technical Sub-Committee constituted by the Drugs Technical Advisory Board and adequate opportunities were given to the Indian Drug Manufacturers'' Association to place their objections before the Board before recommendations were made for imposing such ban.

22. Mr. Banerjee submitted that the pharmaceutical industry was duly represented in the Drugs Technical Advisory Board and was a party to the deliberations which ultimately led to the imposition of the impugned ban.

23. Mr. Banerjee urged that the therepeutic value of the above-mentioned combination drug in the treatment of amebiosis had been found to be not very effective and a wide variety of other medicines were available as substitutes.

24. Mr. Banerjee also indicated that the self-same question was pending before the Hon''ble Supreme Court and a report had been filed by the concerned respondents in the said proceedings regarding the prohibition of several fixed dose combination drugs, including lodochlorohydromyquinoline, dn the recommendation of the Drugs Technical Advisory Board.

25. Inasmuch as, the averments made in the affidavit affirmed on behalf of the Drug Controller General of India were not supported by any documents, the Court had granted several opportunities to the learned counsel appearing on his behalf to arrange for production of the records which would contain the details of the satisfaction arrived at by the, Central Government before issuance of the impugned notification. Mr. Banerjee, however, submitted that in spite of repeated attempts made in the matter the said records were not made available for production before the Court.

26. A copy of the writ petition pending before the Hon''ble Supreme Court was the only relevant document produced on behalf of the Drugs Controller General of India, from which Mr. Banerjee attempted to point out that the same question involved in this writ application was also under consideration in the case before the Supreme Court and the writ petitioners herein should, therefore, make an application for intervention in the said proceedings for an effective decision in the matter.

27. Mr. Banerjee drew the attention of the Court to the provisions of Section 5 of 1940 Act which provides for the constitution of the Drugs Technical Advisory Committee and urged that under clause (xii) of sub-section (1), provision had been made for a person to be nominated by the Central Government from the pharmaceutical industry to be a member of the said Board.

28. Mr. Banerjee urged that since the Board was of a widely representative character, the writ petitioners could have no grievance in respect of the decisions taken by it, including the impugned decision to ban fixed dose combination of Hydroxyquinoline group of drugs with other drugs, except for preparations meant for internal use.

29. In support of his submissions, Mr. Banerjee referred to the decision of the Hon''ble Supreme Court in the case of Vincent Panikarlangara v. Union of India, reported in : [1987]2SCR468 , wherein it was, inter alia, observed that it is not for the Court to lay down the drug policy of the Union of India.

30. In view of such observation, Mr. Banerjee submitted that no interference was called for with the impugned notification and the writ petition was liable to be dismissed.

31. Replying to Mr. Banerjee''s submissions, Mr. Chakraborty urged that the matter before the Hon''ble Supreme-Court related to use of the fixed dose combination of the Hydroxyquinoline group of drugs with other drugs for paediatric purposes. Mr. Chakraborty submitted that the ban imposed in such

circumstances had been duly implemented and the said drugs were no longer manufactured or distributed for paediatric purposes.

32. The main question which emerges for decision in this case is whether the ban imposed by the impugned notification dated 13th December, 1995, stands scrutiny u/s 26A of the Drugs and Cosmetics Act, 1940, which makes it quite clear that the precondition for exercise of the powers thereunder is the formation of opinion by the Central Government that the use of the drug is likely to involve risk to human beings or animals or it does not have the therapeutic value claimed or it contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest its manfuacture, sale or distribution is required to be prohibited.

33. For the sake of reference, the provisions of Section 26A of the 1940 Act are reproduced hereinbelow:--

"26A. 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 being for 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".

34. In the instant case, except for a bare and verbatim reproduction of the language of Section 26A the impugned notification does not specify the ground on which the Central Government arrived at a satisfaction that the manufacture, sale and distribution of the fixed dose combination of Hydroxtruinbline group of drugs with other drugs, except for preparations meant for external use, was required to be prohibited in the public interest.

35. As already indicated hereinabove, no affidavit has been filed by the Central Government and in spite of repeated opportunities having been given, even the relevant records were not made available to the Court. The affidavit filed on behalf of the Drugs Controller General of India is wholly inadequate and there is no supporting evidence for the little that has been stated therein. The decision to ban a drug which has been in use for a considerable length of time has serious consequences both for manufacturers and consumers. It would be against the principles of natural justice if a meaningful hearing was not given to the manfuacturers of the drug in question or to the representatives of the pharmaceutical industry before a decision was taken to impose such ban.

36. No material has been produced either on behalf of the Central Government or on behalf of the Drugs Controller General of India to show that the manufacturers of the drug in question or their representatives were ever given a hearing either by the Drugs Technical Advisory Board or the Drugs Consultative

Committee or any Sub-Committee appointed by the Board before issuance of the impugned notification of 13th December, 1995.

37. There is nothing on record to show that any Expert Committee was constituted to examine the matter in consultation with the manufacturers of the drug, as was done in the Systopic Laboratories'' case (supra).

38. In fact, the grounds for invocation of the powers u/s 26A of the 1940 Act are not spelt out with clarity in the impugned notification. As indicated herein before, the impugned notification only reproduces the wording of Section 26A of the 1940 Act without indicating under which of the grounds the Central Government was" satisfied that a ban was required to be imposed. In fact, that was one of the grounds which weighed with the learned Judge in the Unichem Laboratories Ltd. and Another Vs. Union of India (UOI), in quashing the impugned notification by which a total ban had been imposed by the Central Government on Anabolic Steroids with a combination of vitamins.

39. In the absence of such ground, which must form the basis of the satisfaction to be arrived at by the Central Government and any connected evidence to show the reasons which prompted the Central Government to issue the impugned notification, it must be held that the said notification does not stand scrutiny u/s 26A of the 1940 Act under which it was purportedly issued.

40. On the other hand, Mr. Chakraborty has referred to certain research material annexed to the writ petition which seems to indicate that metronidazole in combination with iodoquinal or paromycin is ideal for treatment of invasive intestinal amebiosis.

41. While it is not for the Court to lay down the Central Government''s drug policy, it can certainly probe into the decision-making process which culminated in the issuance of the impugned notification upon an allegation being made that the decision had been arrived at arbitrarily and unjustly and in violation of the principles of natural justice and administrative fair-play,

42. Since, except for purposes of paediatric use, there is no material to show that the fixed dose combination of Hydroxyquinoline group of drugs with other drugs is harmful to human beings and animals, and since the same is no longer used for pacdiatric treatment, and, inasmuch as, the impugned notification cannot be justified under the provisions of Section 26A of the 1940 Act, the, impugned notification dated 13th December, 1995, being Annexure "C" to the writ petition, is hereby quashed.

43. This order will, however, in the public intent remain in abeyance for a period of two months from date to enable the Central Government to consider the matter afresh in consonance with the principles of natural justice and administrative fair-play. While reconsidering the matter the Central Government should take the assistance of a Committee of Experts who should give the representatives of the manufacturers of the drug in question, including the

petitioners, a reasonable opportunity of hearing and placing relevant research papers and documents.

44. The writ application is disposed of in the above terms.

45. There will be no order as to costs.

If a certified xerox copy of this order applied for, the same should be supplied within a week of such application being made.

46. Order accordingly.

