(1992) 04 P&H CK 0039

In the Punjab And Haryana At Chandigarh

Case No : Civil Writ Petition No. 7749 of 1991

Franklin Laboratories (India) Private Limited Pharmaceuticals Manufacturers — APPELLANT

Vs

Drugs Controller (India) showing his office at Director General of Health Services, New Delhi and others — RESPONDENT

Date of Decision : 02-04-1992

Acts Referred:
Constitution of India, 1950 — Article 14, 19
Drugs and Cosmetics Act, 1940 — Section 26

Citation : AIR 1993 P&H 107 : (1993) 103 PLR 222

Hon'ble Judges : Jawahar Lal Gupta, J

Bench : Single Bench

Advocate : Anand Chhibbar, S.C. Mohunta, P.C. Goyal, S.S. Nijjar, R.L. Gupta and Rameshwar Puri, for the Appellant; H.S. Giani, Senior Standing Counsel for UOI, Anand Swaroop Joginder Sharma, G.S. Virdi and Ajay Tewari for U.T. CHD., Jaswant Singh, for State of Haryana and S.S. Kang, D.G., for the Respondent

Judgement

1. This bunch of 17 petitions viz. C.W.Ps. Nos. 7749, 8393, 9409, 9418, 12222 to 12224, 12328, 12329, 12298, 12299, 13076, 13212, 13933, 14613, 18350 and 18887 of 1991 raise a challenge to the validity of the notification (s) issued by the Central Government banning the manufacture etc. of various fixed dose combinations of drugs. Learned counsel for the parties are agreed that these petitions can be disposed of by one common order. The facts as stated in C.W.P. No. 7749 of 1991 may be briefly noticed.

2. The petitioner herein is a Company engaged in production, sale and distribution of various drugs and pharmaceutical products. It is producing various sedative, anxiolytic, hypnotic, analgesic and antipyretic drugs in different combinations. It claims to have been granted the permission to manufacture various products included in Schedule ''X'' to the Act. It is claimed that these products are of great utility and therapeutic value to the patients. It is further claimed that the petitioner-Company has been licenced under the provisions of

the Drugs and Cosmetics Act, 1940, (hereinafter referred to as ''the Act"). It has been further mentioned that the Government of India had constituted a Drugs Consultative Committee which after thorough examination of the matter made its recommendations. The Central Government on examination of the proceedings of the Committee, issued a notification in the year 1983, by which the manufacture and sale of various drugs was banned. However, the medicines prepared by the petitioner were not mentioned in this notification.

3. On December 26, 1990, the Government has issued a notification by which the manufacture of fixed dose combination of various drugs has been banned. The validity of this notification has been challenged on the ground that it is wholly arbitrary and viola-tive of the principles of natural justice.

4. A written statement has been filed on behalf of the Union of India and the Drugs Controller by the Deputy Drugs Controller (India), It has been mentioned that there were lots of representations from the consumers associations questioning the rationale and safety of fixed combination drugs. Consequently, Parliament had in its collective wisdom incorporated Section 26A authorising the Central Government to identify such harmful drugs and to prohibit their manufacture, sale and distribution. The Drugs Consultative Committee constituted under the Act surveyed fixed combination drugs available in this country. According to the written statement definite guidelines, as envisaged in Section 26A of the Act were laid down and after thorough screening, the Consultative committee published the list of various drugs periodically. Further a Sub-Committee of the Drugs Consultative Committee consisting of Experts in Pharmacology and medicine screened the fixed dose combination drug available in this country and identified such drugs as were considered irrational and harmful. It is on the basis of the recommendations of the Sub-Committee that the Central Government finally issued the impugned notification. Reasons have also been given in the written statement to show that a combination of various drugs like diazepam or phonobarbitone with analgesic or antipyretic drugs is not more advantageous than individual drug therapy. It has been further mentioned that there is a possibility of the drug being misused and administered in combination even in a condition when it is not actually required. On these promises, the impugned notification(s) are sought to be sustained.

5. I have heard learned counsel for the parties. The primary contention raised by the learned counsel is that the impugned notification vitally affects the interests of the small scale units, like the petitioners, and they had a right to be heard before their freedom of trade as guaranteed under Article 19 of the Constitution could be curtailed. It has also been contended that the action is beyond the provision of Section 26A of the Act and suffers from the vice of arbitrariness. On the other hand, learned counsel for the respondents maintains that experts who are well-equipped, to deal with the technical matters have come to a conclusion that it is in the larger interests of the health of the nation that the manufacture of these drugs should be stopped. He maintains that the procedure as prescribed

under the law was followed and notices were duly published in the relevant journals by which the industry was afforded due and a reasonable opportunity to represent its view point. Learned counsel also maintains that the action is within the four corners of the provision of Section 26A of the Act.

6. Mr. Ajay Tewari, learned counsel for the Union Territory, Chandigarh has drawn my pointed attention to the decision of the Supreme Court in Vincent v. Union of India : AIR 1987 SC 990. He has pointed out that an Advocate had filed a petition for the withdrawal of 7000 fixed dose combinations of various products so that the approved standards essential for the maintenance of general health of the people could be maintained. Their Lordships had given positive directions to the Government to examine the matter and decide. It is in pursuance to the directions of the Apex Court that the matter was examined by the appropriate bodies and the impugned notifications were issued.

7. Presumably in pursuance to the directions of the Supreme Court. The Drugs Technical Board which consists of the Director General of Health Services and various other experts in the field of Pharmacology met on April 22, 1988. It considered the report of the Drugs Controller and also the question of the manufacture of fixed dose combinations of various drugs. Thereafter, the Drugs Controller gave wide publicity through Drug Manufacturers Associations about the intention of the Central Government to ban various irrational/harmful fixed dose combinations and invited the opinion from the drug manufacturers. The Associations published the letter of the Drugs Controller in their magazines inviting their representation before the Sub-Committee of the Drugs Consultative Committee. This Sub-Committee met on 6/7 October, 1988 at Badodara (Gujarat). The proceedings of this committee have been produced as Annexure R. 1 with the written statement. This Committee came to the conclusion that the fixed dose combination of various drugs deserved to be withdrawn. It further appears that the Drugs Consultative Committee met on September 13,1989 and considered the report of the Sub-Committee. Finally on March 9, 1990, the Drugs Technical Advisory Board concurred with the recommendations of the Drugs Consultative Committee and approved the weeding out of the fixed dose combination of drugs. This led to the issue of the impugned notification(s). On an examination of the sequence of events and the pleadings of the parties, I am satisfied that the Government of India as also the various bodies constituted under the Act had examined the matter before the final decision was taken.

8. Learned counsel maintain that the action is beyond the provision of Section 26A of the Act. The said provision inter alia contemplated that whenever "the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals.... does not have the therapeutic value .... 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." This is what precisely appears to have happened in the present case. Various bodies, constituted under

the Act, as noticed above, have come to the conclusion that the fixed dose combinations do not have therapeutic value. Accordingly, the Government has formed an opinion that it is not in public interest to allow the manufacture, sale or distribution of such drugs. This has resulted in the impugned ban. The action falls within the provision of Section 26A, and is not ultra vires the provision.

9. Learned counsel then claim that the petitioners had a right to be heard before the impugned order could have been passed. Factually, a perusal of the pleadings of the parties indicates that the Government of India had conveyed its intention to ban the manufacture and sale of certain fixed dose combination drugs through a notice issued by the Drugs Controller. This notice was published by the Associations in their magazines and the representatives of the Industry were invited to appear before the Sub-Committee of the Drugs Consultative Committee. Such representatives actually appeared before the Committee. This is obvious from a perusal of the proceedings of the Committee, a copy of which has been produced as Annexure R. 1 with the written statement. It would be noticed that with regard to combination of tranquillizers with anlagesics and antipyretics, the pharmaceutical industry was represented by M/s. Wyeth Laboratories, M/s. Nulife and M/s. Rock Pharmaceutical. Similarly, the representatives of the Industry had put forth their view point with regard to the various other combinations.

10. In a case, like the present one, this is neither practically possible nor is otherwise required by law that each manufacturer howsoever small and wheresoever located has a right to be heard. Broadly it is sufficient if the view point of the industry has been factually projected. For this purpose, not only an adequate opportunity was given, but it was even availed of. In such a situation. I am unable to hold that the action is violative of the principles of natural justice. In my view, these were adequately complied with.

11. An effort has also been made to show that the fixed dose combinations, as produced by the petitioners, are of great utility to the public at large. This, in my opinion, is a matter for experts to examine. Courts do not have the expertise or the knowledge to go into it. I am unable to go into the wisdom of the matter. However, on a perusal of the proceedings of the Committee, it is fairly clear that the view taken in rational and a possible one. In the exercise of writ jurisdiction, I am unable to find any infirmity therein.

12. Accordingly I find no merit in these petitions, which are dismissed as such. How ever, in the circumstances of the case, I make no order as to costs.

13. Petition dismissed.

