(1992) 06 P&H CK 0012

In the Punjab And Haryana At Chandigarh

Case No : Civil Writ Petition. No. 6882 of 1998

Systopicalabo Ratoribs Private Limited — APPELLANT

Vs

Dr. Prem Gupta, Drugs Controller (India), New Delhi and others — RESPONDENT

Date of Decision : 03-06-1992

Acts Referred:
Constitution of India, 1950 — Article 14, 19, 226
Drugs and Cosmetics Act, 1940 — Section 26A, 5, 7

Citation : AIR 1993 P&H 28

Hon'ble Judges : M. Rama Jois, C.J;J.L. Gupta, J

Bench : Division Bench

Advocate : Mr. A Mohunta, Mr. J.K. Sibal and Miss Swaran Kohli, for the Appellant; Mr. Jagdev Sharma, Addl. A.G., for the Respondent

Judgement

M. Rama Jois, C. J.—In all these petitions presented under Art. 226 of the Constitution, the petitioners have questioned the legality of the notification issued by the Central Government dated November 3, 1988, under S. 26A of the Drugs and Cosmetics Act, 1940, (hereinafter referred to as ''the Act''), insofar as it bans the manufacture and sale of the fixed dose combination steroids on the ground that it is arbitrary and, therefore, not authorised by S. 26A of the Act, and also violative of Arts. 14 and 19(1)(g) of the Constitution.

2. The brief facts of the case as stated in the Writ Petition No. 6882 of 1988 are these. The petitioner is a company incorporated under the Companies Act, 1956. Inter alia it carries on the business of preparation, manufacture, sale and distribution of drugs and pharmaceutical products. Some of the formulations which are being manufactured by the company are Cortomine tablets; Cortomine Forte tablets and Beta-Asmatide tablets. These tablets are combinations of steroid with other drugs. The petitioner company had secured necessary licence for manufacturing the above formulation. The Central Government by notification dated November 3, 1988, issued under S. 26A of the Act, has banned the manufacture and sale. Fixed dose combination of corticosteroids with any other

drug for internal use, as also fixed dose combination of chloromphenicolo with any other drugs for internal use. Questioning the legality of the said notification, the petitioners have presented the petition.

3. The pleas of the petitioners are as follows :--

That the question as to whether fixed dose combinations containing steriods should be allowed to be manufactured or not had been the subject matter of consideration by the Central Government on the basis of the opinion tendered by the Drugs Technical Advisory Board (for short ''the Board''), and on the basis of the said opinion, the Central Government had issued an earlier notification under S. 26A of the Act on July 23, 1983, and in the said notification, though fixed dose combination of steroids for internal use was banned, the formulation made for treatment of asthama was not banned. The fixed dose combinations which are being manufactured and sold by the petitioner company are those meant for the treatment of asthama, and there was no basis or justification for the Central Government to impose ban on the said fixed dose combinations which are meant for the treatment of asthama, and, therefore, the notification was liable to be struck down as arbitrary and, therefore violative of the fundamental rights of the petitioner guaranteed under Arts. Hand 19(1)(g) of the Constitution.

4. In the written statement filed on behalf of the Union of India, it is stated that the DTAB in its meeting held on 31-12-1981 gave a considered opinion for imposing a ban on fixed dose combinations of steroids for internal use for treatment of ailments other than asthama and in the opinion furnished it was expressly stated that the question of banning fixed dose combinations even for the treatment of asthama required further examination, and, that it was in view of this opinion that the Central Government had issued the notification dated July 23, 1983. It is further stated that the Technical Advisory Committee in its 40th meeting held on April 22, 1988, after due consideration of the matter, had given the opinion that a total ban should be imposed on fixed dose combinations containing steroids including the com- binations meant for the treatment of asthama. It is further stated that it was on the basis of the technical opinion so rendered that the Central Government had issued the notification under S. 26A of the Act and, therefore, it can neither be contended that it was arbitrary and therefore not authorised by S. 26A of the Act nor can it be said to be violative of Arts. 14 and 19(1)(g) of the Constitution.

5. Shri J. K. Sibal, Senior Advocate, appearing for the company contended that apart from the material on which the earlier order of 1983 was passed banning certain combinations containing steroids except for the treatment of asthama, there was no material on the basis of which the Central Government has or could have acted and issued the impugned notification under S. 26A of the Act and, therefore, the impugned notification amounted to unreasonable restriction on the fundamental right of the petitioner to carry on the business guaranteed under Art. 19(1)(g) of the Constitution and was also violative of Art. 14 of the Constitution as it was a clear case of arbitrary exercise of power under S. 26A of

the Act.

6. The learned counsel for the respondents submitted that the proceedings of the Board which have been produced clearly indicated that the Board had not given any opinion in 1981 to the effect that the fixed dose combinations containing steroids for the treatment of asthama was not harmful and, therefore, its manufacture and sale should be banned. On the other hand, he submitted that a reading of the proceedings of the DTAB of 1983 would indicate that the committee had reserved its opinion in so far it related to the fixed dose combination containing steroids meant for the treatment of asthama and wanted to investigate further into the matter. He submitted that the Board after further consideration of the matter advised the Central Government to ban fixed dose combinations containing steroids even for the purpose of treatment of asthama and the Central Government was satisfied on the basis of the advise so tendered that ban should be imposed on the manufacture of such items and accordingly, notification under S. 26A of the Act, was issued. It was also submitted that there was no merit in the submission of the counsel for the petitioner that the notification was arbitrary or that it was violative of Arts. 14 and 19(1)(g) of the Constitution. In support of the contention, the learned counsel for the respondents relied upon the judgment of the Andhra Pradesh High Court in Writ Petition No. 3632 of 1986, decided on December 22, 1988, a true copy of which has been produced, in which the validity of the notification issued in 1983 was upheld on the ground that the said notification was issued by the Central Government accepting the advise tendered by the Board. He also relied upon thejudgment of the Madras High Court in Writ Petition No. 16023 of 1988 (Micro Labs (P) Ltd. v. Union of India), decided on June 11, 1991, a true copy of which has been produced, in which the validity of the notification impugned in this writ petition itself was upheld.

7. Now we proceed to consider the validity of the rival contentions. The relevant provisions of the Act are : Section 5 empowers the Central Government to constitute Drug Technical Advisory Board to advise the Central Government or the State Government Section 7 of the Act provides for constitution of the Drugs Consultative Committee (The committee for short), to advise the Central Government the State Government and the Board, on any matter tending to secure uniformity throughout the country in the administration of the Act. These provisions reads :--

5. The Drugs Technical Advisory Board -- (1) The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Government on Technical matters arising out of the administration of this Act and to carry out other functions assigned to it by this Act. (2) The Board shall consist of the following members, namely :--

(i) the Director-General of Health services, ex-officio who shall be the Chairman;

(ii) the Drugs Controller, India, ex-officio;

(iii) the Director of the Central Drugs Laboratory, Calcutta, ex-officio;

(iv) the Director of the Central Research Institute, Kasauli, ex-officio;

(v) the Director of the Indian Veterinary Research Institute, Izatnagar, ex-officio;

(vi) the President of the Medical Council of India, ex-officio;

(vii) the President of the Pharmacy Council of India, ex-officio;

(viii) the Director of the Central Drugs Research Institute, Lucknow, ex-officio;

(ix) two persons to be nominated by the Central Government from among persons who are in the charge of drugs control in the States;

(x) one person to be elected by the Executive Committee of the Medical Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian University, or a college affiliated thereto;

(xi) one person, to be elected by the Executive Commitee of the Medical Council of India, from among teachers in medicine or therapeutic on the staff of an Indian University or a college affiliated thereof;

(xii) one person to be nominated by the Central Government from the pharmaceutical industry;

(siii) one pharmacologist to be elected by the Governing body of the Indian Council of Medical Research;

(xiv) one person to be elected by the Central Council of the Indian Medical Association;

(xv) one person to be elected by the Council of the Indian Pharmaceutical Association;

(xvi) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government.

3. The .nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election :

Provided that the person nominated or elected, as the case may be, under cl. (ix) or Cl. (x) or Cl. (xi) or Cl. (xvi) of sub-section (2) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board.

(4) The Board may, subject to the previous approval of the Central Government, make by-laws fixing a quorum and regulating its own procedure and the conduct of all businesses to be transacted by it.

(5) The Board may constitute sub-committees and may appoint to such sub-

committees for such period, not exceeding three years, as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.

(6) The function of the Board may be exercised notwithstanding any vacancy therein.

6. The Control Drugs Laboratory xxxxx

7. The Drugs Consultative Committee.-

(1) The Central Government may constitute an advisory committee, to be called "the Drugs Consultative the Drugs Technical Advisory Board or any matter tending to secure uniformity throughout India in the administration of this Act.

(2) The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned.

(3) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure."

As can be seen from S. 5 of the Act, the Board is required to be constituted by the Central Government under that section. Its Chairman is the Director General of Health Services and the members are all technical experts having special knowledge about the properties, qualities and usefulness or otherwise of the drugs manufactured and used for treatment of ailments. The Drugs Consultative Committee constituted under S. 7 of the Act consists of two representatives of the Central Government to be nominated by the Govt. and one representative of each State to be nominated by the State Government concerned. S. 26A of the Act inter alia, empowers the Central Government prohibit the manufacture, sale or distribution of any drug if it is satisfied that the use of such drug is likely to involve any risk to human being or it does not have the therapeutic value claimed or purport to be claimed in it and that it is in public interest to prohibit the manufacture, sale or distribution of such drugs.

7. On December 31, 1981, a meeting of the Drugs Consultative Committee constituted under S. 7 of the Act was held in which inter alia the question relating to the undesirable effect of fixed dose combination of steriods was considered. The relevant portion of the proceedings read;

"In his opening remarks the Chairman observed that the purpose of this special meeting was to consider the recommendations of the Sub-committee specially constituted at the 21st meeting of the Drugs Consultative Committee held in 1979 to weed out irrational/harmful formulations. The sub-committee had held three meetings in Bombay. The Chairman mentioned that he had attended the first meeting of the Subcommittee to suggest the guidelines on which the sub-committee could work, but the second and third meetings were not attended by

him as he felt that being Chairman of the Drugs Consultative Committee he should not associate himself with the decisions of the sub-committee. He also added that it was necessary to take an early decision on the recommendations of the sub-committee in view of the publicity which this sub-committee has received. He had therefore, called this special meeting of the Drugs Consultative Committee to take a decision on the recommendations of the Sub-committee."

Mr. Sane briefly described the procedure adopted by the Sub-Committee in compiling the report. He stated that the experts had worked out norms and guidelines for scrutiny Of fixed dose combinations which are also in accordance with the W.H.O. guidelines. He made a point that while in the first meeting the sub-committee had considered weeding out irrational/harmful fixed dose combinations in phases depending on the extent to which they were considered irrational or harmful, subsequently the sub-committee had felt that such phasing was not necessary and in the interest of consumer protection it was thought that a decision should be taken whether such fixed dose combinations would be allowed to continue in the market or should be weeded out. He stated that the justifications for weeding out specific combination have also been spelt out in the report.

Thereafter, the Board considered the subject in its meeting held on 31-12-1981. The relevant portion of the reconsideration reads :

"4. Steroid Combinations :

Fixed combination of steroids with other drugs for internal use should not be allowed.

However, the Board felt that so far as combination of steriods with other drugs for the treatment of Asthama are concerned there are a need for examining the matter in further details and getting wider medical opinion in the matter. The Board therefore, felt that such combination may continue for the present."

Accepting the above advise the Central Government issued the notification dated 23-7-1983. Relevant portion of the notification reads :

"G.S.R. 578(E) -- Whereas the Central Government is satisfied that the use of the drugs specified in the Table below is likely to involve risk to human beings of the said drugs do not have the therapeutic value claimed or purported to be claimed for them or contain ingredients and in such quantity for which there is no therapeutic justification and it is necessary and expedient in the public interest so to do;

Now, therefore, in exercise of powers conferred by S. 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture and sale of the said drugs, namely

TABLE

1. Amidophrine

xx xx xx xx xx xx

14, Fixed does combinations of Steroids for internal use except combination of Steroids and other drugs for the treatment of Asthama.

This notification has been in force from July 1983. From these proceedings of the Board dated 31-12-1981 it is clear that the Board had reserved its opinion relating to the question of imposing ban on fixed does combination of steroids even for the purpose of treatment of asthama. Therefore, it is not correct to say that any opinion was tendered to the effect that such fixed dose combinations were not harmful and, therefore, they could be allowed to be manufactured and sold. The respondents have produced the proceedings of the Board held on April 22, 1988. The relevant portion of the report reads :--

"Item 25 : Review of fixed dose combination of chloramphenicol and streptomycin and fixed dose combination of cortiocos-teriod : with other drugs for systemic use.

The Board agreed that the fixed dose . combination of chloramphenicol and streptomycin should not be allowed to be marketed.

After exchange of views amongst the members it was agreed that the fixed dose combinations of corticosteroids with other drugs for use jn asthama should be banned because asthama therapy is a long term therapy and corticosteroids are reported to cause more harm than good to the patients. The Board approved that the entry No. 14 appearing in the notification GSR No. 578(E) dated 23-7-1983 may be suitably amended."

The Central Government has accepted the advise tendered by the Board and issued the impugned notification.

8. The question for our consideration is : whether it can be said that the Central Government has acted arbitrarily or the opinion tendered by the Board was arbitrary and without any material whatsoever?

9. As can be seen from the provisions of Section 5 of the Act, the composition of the Board is such it consists of persons who are technical experts, on various topics concerning the composition and properties of various ingredients used in manufacture of drugs and also experience about the good or bad effects of the manufactured drugs used for curing the different types of diseases. The Committee constituted under S. 7 consists of the representatives of the Central Government and one representative from each State nominated by the Central Government. As can be seen from the proceedings of the Board dated 22-4-1988, it is expressly stated that after the exchange of views amongst the members, each of whom is an expert on the subject-matter, they agreed that ban should be imposed on corticosteroids with other drugs for use in asthma also. The Board has clearly stated that the use of corticosteroids with other drugs for use in asthma therapy caused more harm than good to the patients as it was a long term therapy. The formation of that opinion is preceded not only by

consultation with experts, but also consideration of the opinion of the Committee. We are of the view that the advise tendered by the Board consisting of experts, who have special knowledge and experience in respect of different kinds of drugs their special knowledge and experience and the opinion formed after due exchange of views in itself ensures that the opinion given by the Board has a rational basis and constitutes sufficient basis for the Central Government for satisfying itself to issue the impugned notification in exercise of its power under S. 26A of the Act. When such a high powered body consisting of experts arrive at such a decision after due consideration and exchange of views, we have to presume that the advise tendered is good in the absence of any basis to characterise it as arbitrary. In this case there is no material or basis to discard the opinion formed and the advise tendered by the Board. Therefore, as the Central Government has exercised its power u/s 26A of the Act on the advise tendered by the Board, we are unable to agree that the impugned notification is illegal, arbitrary or violative of Articles 14 and 19(1)(g) of the Constitution. The notification has a rational basis and has a clear nexus with the object sought to be achieved by Section 26A of the Act, and it also amount to a reasonable restriction in the interest of the general public as permitted by clause (6) of Article 19. In this regard we are in respectful agreement with the view taken by the Madras High Court in Micro Lab''s case (supra) and we respectfully disagree with the view taken by the Bombay High Court in Unichem Laboratories Ltd. and Another Vs. Union of India (UOI), .

10. For the reasons aforesaid, we make the following order;

The writ petitions are dismissed. There shall, however, be no order as to costs.

11. Petition dismissed.

