(1989) 02 BOM CK 0050

In the Bombay High Court

Case No : Writ Petition No. 3554 of 1988

Roussel Pharmaceuticals (India) Ltd. APPELLANT

Vs

Union of India RESPONDENT

Date of Decision : 21-02-1989

Acts Referred:

Citation : (1989) 25 ECR 315 : (1989) 42 ELT 374

Hon'ble Judges : R.A. Jahagirdar, J

Bench : Single Bench

Judgement

1. By this writ petition the petitioners are challenging the validity of a notification dated 3rd November, 1988 issued by the Government of India under which the Government of India, in exercise of the powers conferred on it by Section 26A of the Drugs and Cosmetics Act, 1940, hereinafter referred as "the Act", has banned the manufacture of fixed dose combination of corticosteroids with any other drug for internal use.

2. The petitioners are manufacturers of a drug called "Cartasmyl", which is a fixed dose of combination of corticosteroids and bronchodilators. They contend that this drug is of great benefit to asthma patients. They also contend that the ban imposed by the aforesaid notification has been done without being properly satisfied, as required u/s 26A of the Act.

3. Few facts need to be mentioned. Sometime in the year 1980 the question of the rationality or otherwise of the various fixed dose combinations then available in the market began to exercise the mind of the Government. The then Drugs Controller, Dr. S. S. Gothoskar had invited the views of the manufacturer of drugs on the recommendations which had made by the Sub-committee of Drugs Consultative Committee for weeding out the unnecessary and irrational combinations. The industry, presumably, expressed its opinion on the same. The Government thereafter banned the fixed dose combinations of steroids for internal use, except the combination of steroids with other drugs for the treatment of asthma. The material, which has been brought on record by the

petitioners and which has not been controverted, shows that the then Drugs Controller, India, Dr. Gothoskar, had stated that there was evidence then when steroids are added to bronchodilators there is lesser dose of steroids required to allay bronchial spasm than when steroids are given alone causing thereby lesser side effects due to steroids. This amounted to saying that there was evidence of pharmacological synergism between corticosteroids and bronchodilators.

4. A petition under Article 226 of the Constitution of India, being Writ Petition No. 1701 of 1984, had been fixed in this Court challenging the order of the Government banning the manufacture of a drug called "Celestamine", which was a fixes dose combination of steroids with antihistaminics for the treatment of bronchial asthma. Lentin J. was sufficiently impressed that there was no material for banning the said drug. Therefore, rule was issued on the said petition and interim injunction restraining the Government from enforcing the ban was also granted. It ought to be noted that during the hearing of that writ petition on affidavit of Raghunath Prasad Hinnaria, Deputy Drugs Controller, had been filed. In that affidavit the Government had supported the use of the fixed dose combination of corticosteroids with bronchodilators on the ground that the said combination was useful for the treatment bronchial asthma. This was naturally consistent with the opinion expressed by Dr. Gothoskar referred to above.

5. It is contented by the petitioners that after 1984 nothing has which could have legitimately led the Government to impose the ban in November 1988. It is the contention of petitioners that the ban is based upon total non-application of mind and on total of absence of material which could form the basic of the satisfaction u/s 26A of the Act. Section 26A of Drugs and Cosmetics Act, 1940, which was inserted by Act 68 of 1982, is in the following terms :-

"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 is in the public interest it is necessary or expedient so to do, then, the Government may, by notification in the Official Gazette, prohibit the manufacture, sale or distribution of such drug or cosmetic."

It is obvious from the above provision that it is not merely the dangerous drugs which can be banned, drugs which do not have any medicinal value can also be banned. This is because a patient should not be persuaded to consume a drug in the hope that it is useful when in fact it is not useful. If a patient does such a thing, the cure eludes him and he might lose valuable time for controlling his disease. In the instant case, therefore, the ban would held to be justified if it is shown that the drug in question is injurious or is useless.

6. Mr. Desai, the learned Advocate appearing in support of petition, has invited my attention to large mass of medical literature on the basis of which he wants

me to hold that the banned drug is highly useful and is a boon to persons who are suffering from bronchial asthma. There are, on the other hand, certain observations in other medical literature which reduce the value of the opinion on which Mr. Desai relies. If there are two contrary views and if one of them commends itself to authority u/s 26A of the Act, then this Court would not normally interfere with the order passed u/s 26A. Mr. Dalal. The learned Advocate appearing for the Union of India, has invited any attention to some judgments of the Supreme Court which point to the limited jurisdiction of Courts while dealing with the opinion formed by the Government on the basis of expert view. In Pyarali K. Tejani Vs. Mahadeo Ramchandra Dange and Others, , it was pointed out that so long as the exercise of power is not smeared by bad faith, influenced by extraneous considerations, uninformed by relevant factors, and is within the limits of reasonableness, it became out of bounds for judicial re-valuation. It was the judicial function to enter the thicket of research controversy or scientific dispute where Parliament has entrusted the Central Government with the power, and therefore the duty, of protecting public health against potential hazards and the Central Government, after consultation with a high-powered technical body, has prohibited the use of a particular product. In the case before the Supreme Court the prohibition was saccharin and cyclamates. The prohibition had been based upon the opinion expressed by a specialist committee which has been constituted u/s 3 of the Prevention of Food Adulteration Act, 1954.

7. In Vincent v. Union of India : [1987]2SCR468 , the question arose as to whether the Court could direct the Government to ban some products. The petition before the Supreme Court as by way of public interest litigation and it has been urged that in view of medical opinion prevailing in certain quarters some products ought to be banned and the Government should be directed to ban the same. Having regard to the to the magnitude, complexity and technical nature of the enquiry involved in the matter and keeping in view the far-reaching implications of the total ban of certain medicines, for which appropriate direction was sought, the Supreme Court observed that a judicial proceeding of the nature initiated is not an appropriate one for determination of such matters. I am in agreement with the proposition that if, after considering the rival medical opinions in support of or against a particular drug, the authority accepts one opinion and proceeds to exercise its power u/s 26A of the Act, this Court would be hesitant to interfere with the exercise of that power. The question in this petition, however, is whether there was any material before the Government when it proceeded to pass the impugned order.

8. On behalf of the Government it is stated that the Drugs Technical Advisory Board constituted u/s 5 of the Act has, in its meeting held on 22nd April 1988, recommended fixed dose combination of corticosteroids with other drugs for use in asthma should be banned because asthma therapy is a long-term therapy and corticosteroids even in low doses when administered for longer periods are reported to cause more harm than good to the patients. Mr. Dalal says that this is the option of a high-powered body consisting of high functionaries as

mentioned in Section 5 of the Act. If the Government, therefore, acted on the basis of this opinion, this Court should not interfere with the action of the Government. He has also relied upon the affidavit of Raghunath Prasad Hinnaria, Deputy Drug Controller, filed for the purpose of opposing the admission of this petition. In this affidavit it has been mentioned that a paper giving the background of the Agenda Item 25 (regarding the banning of fixed dose combination of corticosteroids with bronchodilators) was before the Board and after considering the said paper the Board has given its decision. I have, with the assistance of Mr. Dalal, gone through the affidavit of Mr. Hinnaria, including the annexures thereto. In my opinion, the material which has now been disclosed does not show that there was any material before the Board while it considered the ban of the drug in question. It is true that there was a paper which gave certain background information about the drug in question, but it seems to be more in the nature of opinion. The members of the Board themselves do not seem to have been given the benefit of a particular information which could have them to take a view contrary to the view which had been taken earlier by the Drugs Controller. It has not been mentioned, for example, that any medical literature or the results of any clinical test were made available to the members of the Board who meet on 22nd April, 1988. While considering this question, one cannot forget the fact that the Government of India had taken a decision that the fixed dose combination of corticosteroids with bronchodilators was a good and effective drug for the treatment of bronchial asthma as early as in the year 1983. That view was re-affirmed by the Government in the affidavit of Mr. Hinnaria in Writ Petition No. 1701 of 1984 in this Court. Neither in the proceedings of the Board nor in the present affidavit of Mr. Hinnaria is there anything to show as to why the view of the Government has swung to the other extreme. Mr. Dalal says, and not without justification, that it is not necessary to mention in the minutes of the meeting the various materials that might have been considered by the members of the Board as long as indication is available that the said material has been considered and a decision on the same has been taken. I agree that mention need not necessarily be made in the minutes of the meeting as to what material had been considered by the Board at its meeting. But when challenged, it must be shown that certain relevant material had been placed before the Board and the Board had considered the same. Unfortunately, this has not been done in the instant case.

9. In fact the only question which arises in this petition is whether there was some material before the Board to take the view which it has taken. On 29th November, 1988 when this petition first came up for admission Mrs. Sujata Manohar, J. granted interim relief on the ground the material on record showed advantages of using the banned drug. Therefore the petition was adjourned more than once in order to enable the Government to file an affidavit showing that there was material before the Government which could legitimately form the basis of the satisfaction as per required u/s 26A of the Act before imposing the impugned ban.

10. It is also interesting to note the following to be found in the minutes of the Board meeting held on 22nd April, 1988 :-

"The Chairman welcomed the members attending the meeting and stated that meeting of the Board could not be held after December, 1984 because then Drugs Controller (India), Dr. S. S. Gothoskar retired in November, 85 and it took sometime for Government to appoint new Drugs Controller (India). Thereafter the term of the elected and nominated members of the Board had expired and it took time to reconstitute the Board. Since the reconstituted Board is meeting for the first time, the Chairman requested all the members to introduce themselves."

From this it appears that the members of this Board were new or, at any rate, were meeting as a Board for the first time. If there was a continuous review of the relevant material from the year 1980 and if, as a result of the exercise of that review, the Board had taken a particular view, that view would not be subject to a challenge under Article 226 of the Constitution. From the extract of the minutes of the meeting reproduced above, it seems to me that there was no such continuous review. If there was one, the material of that review is not shown to have been placed before the Board. It is not so mentioned in the minutes of the meeting. It has not been so asserted by Mr. Hinnaria in his present affidavit.

11. In view of the failure of the Government to demonstrate that the ban is based upon relevant material, a case is made out of issuing rule on this petition and also for granting interim relief. I am inclined to grant interim relief because from all the material which is before the Court and on the view taken by the Government itself in the year 1983, it is seen that the banned medicine is of benefit to persons who are suffering from bronchial asthma. The proper approach in such cases is that injurious medicines should not be allowed to be manufactured and distributed. Similarly, beneficial medicines should not be made unavailable. While proceeding to issue rule and grant interim relief, I would strongly urge the Government, even at this stage, to apply its mind afresh to the whole question in the light of the relevant material and hear all the persons concerned on this question and then take an appropriate decision. This can be done even before the hearing and final disposal of this petition.

A proper decision taken may prevent the use of any injurious medicine or it may remove the cloud which is hanging over the banned medicine.

12. Hence, rule, returnable on 12th June 1989. Interim relief in terms of prayer clause (e) (i) of the petition. Leterly to appear for a fixed date.

