(2001) 04 KL CK 0038

In the High Court Of Kerala

Case No : O.P. No. 5382 of 1998

Uni-San Pharmaceuticals — APPELLANT

Vs

Union of India and Others — RESPONDENT

Date of Decision : 09-04-2001

Acts Referred:
Constitution of India, 1950 — Article 19(1)(g), 19(f)
Drugs and Cosmetics Act, 1940 — Section 26A, 28(3)

Citation : (2001) 1 KLJ 822

Hon'ble Judges : R. Rajendra Babu, J

Bench : Single Bench

Advocate : M.C. Sen, Parvathi A. Menon, M.P. Sreekrishnan and S. Prakash, for the Appellant; K.M. Jamaludheen, (ACGSC), for the Respondent

Final Decision : Dismissed

Judgement

R. Rajendra Babu

1. The petitioners Uni-San Pharmaceuticals, Hyderabad, and M/s. Pharma Traders, Jews Street, Ernakulam, filed this O.P. for quashing Ext. P1 notification issued by the 1st respondent u/s. 26A of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the Act) prohibiting the manufacture, sale and distribution of fixed does combination of Hydroxyquinoline group of drugs with any other drug except for preparations meant for external use and also for quashing Ext. P2 complaint filed by the 4th respondent before the J.F.C M. Court-II, Kochi, for violation of Sec. 26A punishable u/s. 28(3) of the Act. The 1st petitioner is a proprietory concern engaged in the manufacture and sale of drugs by virtue of a licence issued by the Director of Drugs Control Administration, Government of Andhra Pradesh, Hyderabad, and the 2nd petitioner is engaged in the purchase, storage, sale and distribution of drugs. The 1st petitioner was manufacturing various drugs including "maxaquin" tablets with the following formula:

Metronidazole I.P. 200 mg.

D1 - iodohydroxy quinoline IP-250 mg.

D1 Cyclomine Hydrochloride BP. 5 mg.

Colour - Tartrazinc

The first respondent by Ext. P1 notification dt. 30-12-95 prohibited 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. Ext. P1 notification was issued without applying the mind and without getting the opinion of an expert committee as envisaged u/ S. 26A of the Act and it was only a verbatim reproduction of Sec. 26A of the Act. There was no consultation by the Drugs Technical Advisory Board or the Drugs Consultative Committee or any sub committee appointed by the 1st respondent before Ext. P1 notification was issued and Ext. P1 was issued without constituting any expert committe and the entire matter has been dealt with perfunctorily and in an abrupt manner and as such Ext. P1 was illegal, arbitrary and violative of natural justice and is liable to be set aside. Ext. P2 complaint was filed by the 4th respondent alleging violation of Ext. P1 notification and as Ext. P1 notification is nonest and void, the complaint also is liable to be quashed.

2. Respondents 1 and 2 filed a counter affidavit contending that Ext. P1 notification was issued by the Central Government by virtue of the power conferred u/s. 26A of the Act after a thorough examination by a technical sub committee constituted for the said purpose and by the Drug Technical Advisory Board. The decision taken by the above Board was informed to the Supreme Court in Writ Petition 698/1993 filed by Drug Action Forum was weeding out irrational and harmful drugs. Therefore, if at all aggrieved by Ext. P1 notification, the petitioners have to approach the Supreme Court in the above case. The business activities of the petitioners are carried out on the basis of a licence issued by the Director of Drugs Control Administration, Government of Andhra Pradesh, and the petitioner cannot claim protection under licence issued by the State Government for the manufacture and sale of Mexaquin tablets since the manufacture and sale are subject to the provisions of Sec. 26A of the Act. Ext. P1 notification was issued on the basis of the recommendations made by the sub committee for Drug Consultative Committee entrusted with weeding out of irrational and harmful drugs and with the approval of the Drug Technical Advisory Board (DTAB). The fixed dose combinations of Hydroxyquinoline group of drugs were banned in the year 1983 except for preparations which are used for diarrhoea/disentry and for external use. The observations contained in WHO reports were also considered by the sub committee and the DTAB. A public interest litigation under WP. 698/93 was filed by the Drug Action Forum before the Supreme Court praying for the ban of drugs and combinations including Hydroxyquinoline in the country and after examining various submissions made by the interveners and the Government, the Supreme Court by order dt. 17-11-94 directed the Government of India that the list of drugs that would be submitted by the petitioner therein be examined by the DTAB within a period of

three months. The list of drugs submitted included Dy-Hydroxyquinoline. The reports were duly placed before the Supreme Court through affidavits filed by Government. Consequently Ext. P1 notification was issued banning the above combination of medicine. Respondents 3 and 4 are the agencies who are implementing the orders passed by the respondents. Ext. P1 notification was issued by virtue of the powers conferred u/s. 26A of the Act and it is not liable to be set aside as violative of the fundamental rights as alleged.

3. The 4th respondent filed a counter raising similar contentions as those raised by respondents 1 and 2. It was further contended that the drug was banned because the use of the drug has been associated with severe neuro toxicity. In Japan the epidemic development of Subacute Myelo -Opticoneuropathy was associated with the ingestion of normal or high dose of Cloioquinel which is a hydroxyquinoline group of drug. Later in 1970 the above medicine was banned in Japan. Similar toxic effects had been reported from other countries and hydroxyquinoline derivations have been banned worldwide including India. Even after the notification the petitioner was continuing the manufacture and distribution of the above medicine and accordingly a case has been taken against the petitioners and it is pending before the JFCM Court, Kochi, as CC 795/97. No reasons are there for quashing the above complaint.

4. A reply affidavit also has been filed by the petitioners traversing all the contentions raised in the counter.

5. Heard the learned counsel for the petitioners, the standing counsel for respondents 1 and 2 and the Govt. Pleader for R3, 4 and 5.

6. One of the contentions raised by the petitioners was that Ext. P1 notification was issued without giving an opportunity to the petitioners of being heard and as such it has violated the principles of natural justice. It was further argued that there was no consultation by the Drugs Technical Advisory Board or the Drugs Consultative Committee or any sub committee appointed by the 1st respondent before the notification was issued and it was violative of the fundamental rights guaranteed by the Constitution of India. The learned Govt. Pleader submitted that Ext. P1 notification was issued on the basis of the recommendations of the sub committee constituted in accordance with the provisions of law and the administration of the above medicine was found to have adverse effects. It was further submitted that the ban of the above drug and its combinations had been imposed after hearing all the parties concerned and in accordance with the directions of the Supreme Court in Writ Petition No. 698/93. The Supreme Court in Vincent Panikurlangara Vs. Union of India (UOI) and Others, held that injurious drugs should be totally eliminated from the market and that the Union of India should come forward with a declaration of its drug policy at an early date. In the above cited decision the Supreme Court has considered all the aspects of the case after hearing the manufacturers as well as other persons interested and held:

The Central Government on the basis of the expert advice can indeed adopt an approved national policy and prescribe an adequate number of formulations which would on the whole meet the requirement of the people at large. Obviously, instant attention has to be bestowed to keep abreast of the changing situations and make proper and timely amends. While laying the guidelines on this score, injurious drugs should be totally eliminated from the market. Great care in this regard has to be taken. Such drugs as are found necessary should be manufactured in abundance and availability to satisfy every demand should be ensured.

There it was further held:

Having regard 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 the petitioner has prayed, we must at the outset clearly indicate that a judicial proceeding of the nature initiated is not an appropriate one for determination of such matters.

Further it was held that the ban of the production of certain medicines which are found to be harmful to the health of the citizens was not violative of Art. 19(f) of the Constitution of India. In Systopic Laboratiries (Pvt.) Ltd. Vs. Dr. Prem Gupta and others, a similar notification banning the production of certain medicines were issued by the Government invoking Sec. 26A of the Act was challenged before the Supreme Court. Therein the Supreme Court held that the prohibition which has been imposed by the impugned notification on the manufacture and sale of certain drug did not impose an unreasonable restriction so as to be violative of the right guaranteed under Art. 19(1)(g) of the Constitution. Ext. P1 notification had been challenged by some of the manufacturers before the High Court of Calcutta in West Bengal Small Scale Pharmaceutical Manufacturers Association and others v. Union of India and others (1997 (2) CWN 67). There a single Bench of the High Court of Calcutta found that the impugned notification cannot be justified under the provisions of Sec. 26A of the Act and accordingly the above notification was quashed. A Division Bench of the Calcutta High Court set aside the above order of the Single Bench in M.A.T. 2705/1997 dt. 27-7-99 and the constitutional validity of the notification was upheld. Similar contentions had been raised before the above court challenging the notification. In fact the notification was issued after the matter being referred before the Technical Sub Committee of the Drugs Technical Advisory Board and on the basis of the recommendation of the Sub Committee. The manufacture, production and sale of the medicine had been banned by Ext. P1 notification after complying with all the statutory formalities and also considering the adverse effects. Whether the drug should be prohibited or not on the ground that it was injurious to the public health is essentially a matter dealing with the policy decision of the State and hence the above decision cannot be challenged as violative of the principles of natural justice. As laid down by the Supreme Court in Vincent Panikurlangara Vs. Union of India (UOI) and Others, the matters for consideration are relating to the

technical and specialised matters relating to therapeutic value and the harmful side effect of drugs which are to be decided not by judicial proceedings of this nature, but by the appropriate and competent forums. Hence I do not find any reasons to quash Ext. P1 notification as prayed for and this petition has only to be dismissed.

In the result this petition is dismissed.

