(2001) 04 KL CK 0020

In the High Court Of Kerala

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

Uni-San Pharmaceuticals — APPELLANT

Vs

Union of India — RESPONDENT

Date of Decision : 09-04-2001

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

Citation : AIR 2002 Ker 72

Hon'ble Judges : R. Rajendra Babu, J

Bench : Single Bench

Advocate : M.C. Sen ParvathiA. Menon, M.P. Sreekrishnan and S. Prakash, for the Appellant; K.M. Jamaludheen, A.C.G.S.C., for the Respondent

Final Decision : Dismissed

Judgement

R.Rajendra Babu, J.—The petitioners Uni-San Pharmaceuticals, Hyderabad, and M/s. Pharma Trades, Jews Street, Ernakulam, filed this O.P. for quashing Ext. P1 notification issued by the 1st respondent under S. 26-A of the Drugs and Cosmetics Act, 1940 (hereinafter referred as the Act) prohibiting 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 and also for quashing Ext. P2 complaint filed by the 4th respondent before the J.F.C.M. Court-II, Kochi, for violation of S. 26-A punishable under S. 28(3) of the Act.

2. The 1st petitioner is a proprietary 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 Pradsh, Hyderabad, and the 2nd petitioner is engaged in he 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-Tartrazine"

The 1st 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 under S. 26-A of the Act and it was only a verbatim reproduction of S. 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 committee 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 void, the complaint also is liable to be quashed.

3. Respondents 1 and 2 filed a counter affidavit contending the Ext.P1 notification was issued by the Central Government by virtue of the power conferred under S. 26A of the Act after a thorough examination by the 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 for weeding our 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 petitioner 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 sicne the manufacture and sale are subject to the provisions of S. 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 Hydroxyquninoline 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 W.H.O. reports were also considered by the sub committee and the DTAB. A public interest litigation under W P 698/93 was filed by the Drug Action Forum before the Supreme Court praying for the ban of drugs and combinations including Hydroxy quinoline in the country and after examining various submissions made by the intervenors 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 month. 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 he 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 under S. 26A of the Act and it is not liable to be set aside as violative of the fundamental rights as alleged.

4. The 4th respondent filed a counter raising similar contentions s those raise 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 taxicity. In Japan the epidemic development of Subacute Myelo - Opticoneuropathy was associated with the ingestion of normal or high does of Clioquinel 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 petition was continuing the manufacture and distribution of the above medicine and accordingly a case has been taken against the petitioners and it is ending before the JECM Court, Kochi, as CC 795/97. No reasons are therefore quashing the above complaint.

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

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

7. 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 right guaranteed by the constitution of India. The learned Government 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 he parties concerned and in accordance with the directions of the Supreme Court in Writ Petition No. 698/93. The Supreme Court in Vincent panikulangara v. Union of India : AIR 1987 SC 990) 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 abovecited 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 time amends. While laying the guidelines on this score, injurious drug 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 is 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 S. 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 as to as to be violative of the right guaranteed under Art. 19(1)(g) of the Constitution.

8. Ext. P1 notification has been challenged by some of the manufacturers before the High Court of Calcutta West Bengal Small Scale Pharmaceutical Manufacturers Association & Ors.v. Union of India & ors. 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 S. 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 : AIR 1987 SC 990 (supra) 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 reasons to quash Ext. P1 notification as prayed for and this petition has only to be dismissed.

9. In the result this petition is dismissed.

