

(2003) 06 PAT CK 0024
In the Patna High Court
Case No : C.W.J.C. No. 5178 of 2003

Universal Drug House Pvt. Ltd.

APPELLANT

Vs

State of Bihar and Others

RESPONDENT

Date of Decision : 30-06-2003

Acts Referred:

Drugs and Cosmetics Rules, 1945 — Rule 66, 66(2)

Citation : AIR 2004 Patna 86 : (2003) 3 BLJR 1756 : (2003) 3 PLJR 771

Hon'ble Judges : Aftab Alam, J

Bench : Single Bench

Final Decision : Allowed

Judgement

Aftab Alam, J.—Heard Mr. S.S. Asghar Husain, Senior Advocate appearing for the petitioner and Mr. J.D. Singh, Government Pleader No. 1 representing the State.

2. The petitioner is a company engaged in manufacture, sale and distribution of drugs, medicines and pharmaceutical products. It has its manufacturing unit in West Bengal where it holds a licence to manufacture drugs for sale issued by the Director of Drugs Control, West Bengal. The petitioner has its sale out-let(s) in this State and it holds a licence to sell, stock or exhibit or offer for sale or distribute drugs issued by the Regional Licensing Authority in this State, The licence permits the petitioner to sell, stock etc. 51 different items indicated in the licence.

3. This writ petition is filed challenging the order passed by the licensing authority (the Regional Licensing Officer, Drugs Control Administration, Patna Division, Patna) under his memo No. 674, dated 20-5-2003 (Annexure 4) cancelling the licence issued to the petitioner. The cancellation order is passed in exercise of power under Rule 66 of the Drugs and Cosmetics Rules, 1945.

4. The petitioner was given a show cause notice, dated 12-4-2003 (Annexure 3) with regard to certain irregularities found in course of an inspection of its business premises on that date. The irregularities in regard to which the

petitioner was directed to show cause with reference to two specific items out of the 51 items covered by its licence. One was a patent syrup called Ocimal Linctus with Codeine and the objection of the Drug authorities was that in the preparation of this syrup two Ayurvedic ingredients, namely, Vasaka and lobelia were also used in combination with Allopathic compounds. A combination of allopathic compounds with Ayurvedic, Sidha or Unani ingredients was prohibited in terms of a notification, dated 23-7-1983 issued by the Central Government under Sections 26A of the Drugs and Cosmetics Act. The other irregularity in regard to which the petitioner was asked to show cause was with reference to the sale price of Parafen tablets. In Bihar the maximum retail price of these tablets was fixed at Rs. 6.04 paise plus excise duty for a leaf of ten tablets. But the packed strips of the tablet found at the petitioner's premises had Rs. 10.00 printed as the maximum retail price of each leaf of ten tablets.

5. The petitioner gave its reply to the show cause on 23-4-2003. In the show cause, it was stated with regard to Ocimal Linctus with Codeine that in the licence, dated 23-12-1992 issued by the Drugs Controller, West Bengal (for manufacture of drugs), this preparation with Vasaka and lobelia as its ingredients was included in the list of approved medicines. It was further stated that a renewed drug licence (upto 31-12-2006) was received by the petitioner on 17-2-2003 in which this preparation was deleted and the petitioner had made an application for a fresh licence omitting vasaka and lobelia from the formula of the preparation and it hoped to get the necessary permission within a week from the date of filing of the show cause. It was further stated that the patent syrup found in course of inspection was manufactured before the issuance of the renewed licence on 17-2-2003. The petitioner further expressed its willingness to withdraw the stock from sale in this State and to take it back to West Bengal where the sale of this preparation was not prohibited.

6. As regards Parafen tablets, a plea was taken that the cost of production was higher than the maximum retail price fixed by the State Government and the petitioner was willing to withdraw these tablets from sale in Bihar and to send them back to West Bengal for sale there.

7. The licensing authority found the petitioner's explanation unsatisfactory and consequently issued the impugned order cancelling the petitioner's licence in its entirety.

8. Opposing the writ petition Mr. J.D. Singh, G.P.I submitted at the outset that Rule 66(2) provided for an appeal against an order of cancellation of licence. He submitted that it was open to the petitioner, in terms of Rule 66(2), to file an appeal against the impugned order and this writ petition, according to him, was not maintainable as the petitioner had a statutory remedy available to him by way of appeal.

9. On the other hand, Mr. S.S. Asghar Hussain submitted that even assuming that there were some irregularities in the sale of two specified items, namely, the

patent syrup Ocimal Linctus with Codeine and parafen tablets, the action of the licensing authority in cancelling the licence as a whole and with regard to all the 51 items was so patently unreasonable and arbitrary that it called for an intervention by a writ Court and hence, the petitioner may not be relegated to the appellate authority. Learned counsel further submitted that though the irregularities in regard to the two specified items (Ocimal Linctus with Codeine and parafen tablets) were purely technical, he would not seek any relief from this Court with regard to those two items and would take the matter before the appellate authority. But the licence with regard to other 49 items may be directed to be restored as in the facts and circumstances of the case the cancellation of the licence in regard to the other items was wholly unjustified and without any basis. In support of his submission, he relied upon a recent decision of this Court in Wyeth Lederle Ltd. Vs. State of Bihar and Others, . Mr. Husain submitted that in the case of Wyeth Lederle Limited, this Court had directly intervened on a writ petition and had also cautioned the licensing authority against cancelling the licence as a whole for a minor violation in regard to one of items of the licence.

10. I find substance in the submissions of Mr. Husain. It may be noticed that in course of inspection the drug authorities noticed two irregularities, one relating to the preparation called Ocimal Linctus with Codeine and the other with the pricing of parafen tablets. The irregularities in regard to these two specified items are made the basis for cancellation of the entire licence. It is true that a single violation of the licence or a contravention of the licence with regard to any one of the items covered it may be so grave and serious as to justify the cancellation of the entire licence with regard to a number of other items as well. But all violations may not necessarily lead to cancellation of the licence as a whole. A technical or minor violation in regard to one or some of the items covered by the licence may not, in all cases, justify cancellation of the whole licence covering many other items in regard to which there is no violation of any kind. It cannot be lost sight of that the cancellation of the licence in its entirety would amount to, as in this case, a forcible shutting down of a long standing business of in licence. Whether the licence would be liable to cancellation partly or wholly would depend upon the facts and circumstances of each case. But the point to be emphasised is that the power to cancel licence must be exercised with proper discretion and not mechanically or arbitrarily.

11. At this stage, it would be apposite to take a look at Rule 66 (1) of the Drugs and Cosmetics Rules which is reproduced below:

"66(1) The licensing authority may, after giving the licensee an opportunity to show cause why such an order should not be passed by an order in writing stating the reasons, therefore, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or Rules

thereunder."

12. It is to be noted that the provision of the rule itself envisages a partial suspension/revocation of the licence in respect of the items with reference to which the violation(s) was committed.

13. I am supported in the view taken by me by the decision in Wyeth Lederle Limited (supra).

14. On hearing counsel for the parties and on going through the writ petition, the impugned order and the counter-affidavit, it appears to me that in the facts and circumstances of the case the licensing authority acted mechanically and without a proper application of mind in cancelling the entire licence of the petitioner. In this case having regard to the fact that till 17-2-2003 the patent preparation with two Ayurvedic ingredients was in the list of approved substances in the manufacturing licence issued in favour of the petitioner by the licensing authority in West Bengal, the irregularities alleged against the petitioner with regard to the two specified items under its licence do not appear so grave or serious as to render the entire licence liable to cancellation.

15. Therefore, the impugned order in so far as it cancels the petitioner's licence as a whole and with regard to the items other than Ocimal Linctus with Codeine and parafen tablets is quashed and the licensing authority is directed to restore the petitioner's licence with regard to its other items.

16. It may be noticed here that on behalf of the petitioner submissions were also advanced to show that there were no irregularities in regard to Ocimal Linctus with Codeine and parafen tablets and in any event the irregularities were not such as to justify the cancellation of the licence in even in regard to these two items. But, as the matter in regard to these two items has to be examined by the appellate authority, I am not inclined to take note of the petitioner's submissions on this issue or to express any opinion on it.

17. It is accordingly directed that with regard to cancellation of the licence in respect of Ocimal Linctus with Codeine and parafen tablets, it will be open to the petitioner to prefer an appeal u/s 66(2) of the Rules. In case such an appeal is preferred within one month from today, the appellate authority shall not reject it on the grounds of delay alone.

In the result, this writ petition is allowed to the extent indicated above but with no order as to costs.