(2007) 09 PAT CK 0082

In the Patna High Court

Case No : Criminal Miscellaneous No. 17280 of 2005

M/s. Modern Laboratories — APPELLANT

Vs

The State of Bihar — RESPONDENT

Date of Decision : 18-09-2007

Acts Referred:
Drugs and Cosmetics Act, 1940 — Section 17(b), 18(a)(i), 18(a)(i)(2)(iv), 23, 25

Citation : (2008) 1 PLJR 470

Hon'ble Judges : S.C. Jha, J

Bench : Single Bench

Final Decision : Dismissed

Judgement

S.C. Jha, J.—Petitioner Arun Kumar Kharia, a partner of M/s Modern Laboratories, having its registered office at 45 Sector, D-2 Sanwar Road, Indore, Madhya Pradesh, has filed this application for quashing the order of cognizance dated 2.11.2004 passed in Complaint Case No. 3075(M)/ 2004 pending in the court of S.D.J.M., Patna, for his trial for commission of offence punishable under Sections 27, 17(b), 18(a)(i), (iv) of the Drugs and Cosmetics Act, 1940 (hereinafter to be referred to as ''the Act''). Cognizance has been taken on receipt of official complaint from Sri Vijay Kumar Gupta, Inspector of Drugs-cum-Chief Hospital Pharmacist, P.M.C.H., Patna, who is opposite party here.

2. Opposite party has filed a complaint against eight different manufacturers and suppliers of drugs for violation of the provisions of the said Act in which the name of this petitioner figures at Serial No. 3. The allegation in Para-10 of the complaint petition against this petitioner is that petitioner-firm manufactured Vitamin B Complex Tablets and supplied the same through accused No. 4 to Chief Medical Officer on 23.3.2003 and also received payment. The said medicine was also supplied to M.L.A. Hospital, Patna. On 5.7.2003 the complainant-O.P. inspected the M.L.A. Hospital and collected various samples of drugs for test/ analysis from the Store-keeper after observing all formalities, one portion of each sealed samples were received by the Store-keeper, in-charge of M.L.A.

Hospital and further sample was sent to the Government Analyst, Bihar Drug Control Laboratories, Agamkuan, Patna. On receipt of the test report dated 10.9.2004 it was revealed that drug concerned with petitioner''s Vitamin-B Complex was found not of standard. So, the petitioner who is accused No. 3 alongwith the supplier accused No. 4 are alleged to have violated the provisions of Sections 18(a)(i)(2)(iv) and have committed offence u/s 27(d) of the Act.

3. Heard learned counsel for the petitioner and learned Additional Public Prosecutor for the State.

4. It has been submitted that the petitioner has received summons in this case without any copy of the complaint petition. But on inspection of the case record, it was found that the Analyst has found Vitamin-B Complex Tablets contained five items, out of which one is Thiamine Hydrochloride which was found below the limits laid down in Schedule-V of the Act and Rules.

5. It has also been submitted that from the report of the Analyst, it would be evident that the Tablets were moisturised inside the strips and they were not sufficiently hard which breaks or a crawble easily. It has also been submitted that date of manufacture of the seized tablets is January, 2003, the date of expiry of which is December, 2004. The date of supply is 23.3.2003, date of test is 10.9.2004 and date of collection of sample is 5.7.2003. As per test report, permitted limit for standard quality in respect of Thiamine Hydrochloride is 90-110%. But after one and half year from the date of manufacture, the Analyst found it substandard below the permitted limit as 86.5%.

6. Learned counsel for the petitioner has, thus, submitted that there is non-observance of mandatory provisions of the Act as provided u/s 23 of the Act. The Drug Inspector on collection of sample was required to divide the sample into four portions and effectively seal with suitable mark. The fourth portion of the sample is required to be sent to the manufacturer whose name and address is printed on the strip. But in this case, no portion of the sample was sent to the manufacturer. In absence of such observance of the mandatory provisions of the Act, the report of the Analyst cannot be given finality for launching prosecution, case against the petitioner. Learned counsel for the petitioner has also given emphasis for non-compliance of Section 25(2) of the Act i.e. on receipt of report of the Government Analyst by the Inspector of Drugs, a copy of the same has to be delivered to the manufacturer as also to the person from whom the sample was taken. But no such statutory obligation has been discharged by the Drug Inspector. Moreover, the report of the Analyst is belated. Further submission is that the drug itself is likely to have been affected by several factors like mis-storage, close expiry of date etc. and in that context of the matter, Vitamin-B Complex Tablet cannot be said to be substandard after keeping for one year and nine months from the date of manufacture.

7. On the other hand, the learned Additional Public Prosecutor for the State has submitted that from the materials on record, it cannot be said that there is

noncompliance of the mandatory provisions as stipulated in the Act, rather samples have been collected by the Inspector of Drugs by observing necessary formalities, which were sent for chemical test to the approved Analyst of the Government without any delay. Such compliance and observance of necessary formalities on the part of the Drug Inspector are the subject matters of trial where the evidence is supposed to be led on behalf of the prosecution.

8. Learned Additional Public Prosecutor for the State has also referred Schedule ''P'' of the Drugs and Cosmetic Rules, 1945, depicting life period in months (unless otherwise specified) between date of manufacture and date of expiry at Serial No. 3, conditions of storage at Serial No. 4. It has been shown from Column Nos. 3 and 4 that period in months between the date of manufacture and date of expiry in respect of Thiamine Hydrochloride is 48 months and the conditions of storage is in a well closed container protected from light, in a cool place.

9. He has also submitted that there is compliance of Sections 23 and 25 of the Act and the trial court is competent to examine this aspect of compliance or noncompliance of Sections 23 and 25 of the Act at the trial stage itself for which there should not be interference in the impugned order.

10. In the facts and circumstances, components of Vitamin-B Complex Tablets, namely, Riboflavin & Niacinamide were also found deficient i.e. only 90.5% and 91.2% of claim i.e. deficient by 9.5% and 8.8% of the claim by the manufacturer. Of course, Thiamine Hydrochloride was found to be sub-standard i.e. beyond the prescribed limit, but it was also to be extent of 86.5% of claim which should have been in between 90% and 110% of the claim by the manufacturer.

11. Since, the place of storage has not been challenged and the subject matter is due for consideration in trial and all the components of Vitamin-B Complex Tablets manufactured by the Company-petitioner have been found deficient in the order of 13.5%, 9.5% and 8.8% of its claim, it would not be presumed at this juncture that it was not sub-standard in quality and for that the criminal prosecution launched against the petitioner cannot be quashed.

12. The period for expiry as stated above is 48 months in respect of Thiamine Hydrochloride. So, the contention of the learned counsel for the petitioner that there was every likelihood of losing the potential value of Thiamine Hydrochloride by one year and nine months from the date of its manufacture, is unacceptable at this stage. In the facts and circumstances, I do not find any reason to interfere with the impugned order, and this application is, thus, dismissed.

