(2012) 11 PAT CK 0074

Patna High Court

Case No: Criminal Miscellaneous No. 17392 of 2011

M/s. Baron Kalin Pharmaceuticals (India) Pvt. Ltd.	APPELLANT
Vs	
The State of Bihar and Others	RESPONDENT

Date of Decision: Nov. 30, 2012

Acts Referred:

- Drugs and Cosmetics Act, 1940 - Section 18(a)(i), 27(d)

Citation: (2013) 3 PLJR 83

Hon'ble Judges: Shivaji Pandey, J

Bench: Single Bench

Advocate: Avinash Kumar and Ajit Kumar, for the Appellant; Ram Naresh Rai, for the Respondent

Final Decision: Allowed

Judgement

@JUDGMENTTAG-ORDER

Shivaji Pandey, J.

In this case petitioner is challenging the order dated 13th January, 2006 by which the Chief Judicial Magistrate, Madhubani has taken cognizance u/s. 18(a)(i) read with Section 27(d) of the Drugs and Cosmetics Act, 1940 (hereinafter, in short, referred to as the "Act") in G.O. Case No. 154 of 2005, T.R. No. 802 of 2010. It appears that the Inspector of Drugs, Madhubani filed the present case stating therein that on 26th November, 2001, the Contemporary Inspector of Drugs, Madhubani, Smt. Sarita Kumari inspected the shop M/s. Vishnu Drug Agency, Lokha Bazar and collected the sample of "Kalizyme" liquid having quantity of 200 ml, Batch No. KL291 and sent the same to the Government Analyst, Bihar Drug Central Laboratory, Patna, after analysis submitted the report contained in Memo No. 144 dated 20th February, 2002 holding being of not standard quality. The Contemporary Inspector of Drugs, Madhubani Smt. Santa Kumari u/s 18A of the Act, Vide Letter No. 123 dated 8th

March, 2002 and Letter No. 159 dated 4th April, 2002 (Reminder) asked M/s. Vishnu Drugs Agency, Lokha Bazar to disclose the name and address of the person from whom he acquired the drugs. M/s. Vishnu Drugs Agency Letter No. 203 dated 24th April, 2002 disclosed, the said drug was acquired by it from Jai Ma Kali Pharmaceuticals, Jalan Market Bazar, Darbhanga. The Contemporary Inspector of Drugs, Madhubani Smt. Sarita Kumari vide Letter No. 203 dated 24th April, 2002 asked M/s. Jai Ma Kali Pharmaceuticals, Darbhanga to disclose the name and address of the person from whom he acquired the drugs and u/s 18A of the Act, vide Letter No. 489 dated 10th August, 2002, declared M/s. Baron Kalin Pharma (India) Pvt. Ltd, Patna as a manufacturer of Drug (Kalizyme Liquid) and one portion of the sample was handed over to manufacturer as per Section 23(4)(iii) of the Act.

2. The Contemporary Inspector, Smt. Sarita Kumari vide Letter No. 542 dated 1st October, 2003 informed the State Drug Controller, Bihar, Patna regarding all the steps taken in this matter and requested to give further direction in this matter. In pursuance thereof, the Drug Controller vide letter No. 148(15) dated 5th March, 2006 the State Drug Controller, Bihar ordered to file prosecution against M/s. Baron Kalin Pharma (India) Pvt. Ltd., Patna.

3. The present Inspector Rajesh Kumar Gupta, vide letter No. 291 dated 11th August, 2005 and Letter No. 365 dated 21st September, 2005 asked the explanation from Proprietor of the Company but no reply was received. Hence, having no way out, the present case has been filed against the Company.

4. Learned counsel for the petitioner submitted that the filing of the complaint petition and the order of cognizance is bad in law and in support of his contention, has submitted the following facts:

5. The premises was inspected on 26th November, 2001 by the Inspector of Drugs, Madhubani Smt. Sarita Kumari and the sample of Kalizyme liquid was taken. The expiry date of that sample was February 2002 which is apparent from pages 19 and 21 of the petition (Part of Annexure-1). From that document it shows that the syrup was manufactured in March 2001 and the expiry date was February 2002. He has further submitted that the sample which was obtained was sent for analysis to the Government Laboratory or 15th October, 2001 i.e. after 19 days of collection of aforesaid drug. The test was conducted on 20th February, 2002 and the syrup was found below standard. For the first time, the report alongwith the sample was sent to the petitioner Company on 10th August, 2002 i.e. after expiry period.

6. Counsel for the petitioner submits that as per the provision of Drugs and Cosmetics Act, the report of the Laboratory was required to be served on the petitioner 28 days prior to the expiry date of the syrup but the syrup alongwith the report was received by the petitioner on 10th August, 2002 i.e. much after the expiry date. He further submitted that as per Sections 23(3) & (4) of the Act, it was duty of the Inspector to have served the same alongwith report before its expiry. The idea

behind this is that the manufacturer will have the opportunity to contest and challenge the report submitted by the Government Analyst and in case of failure the whole prosecution and the order of cognizance is bad in law being violative of Sections 23 and 25 of the Act. It has further been submitted that the quality of an item can be guaranteed upto the date of expiry and no one can vouch the sustainability its standard beyond the expiry period and in support of his contention, he has relied on the judgments reported in Medicamen Biotech Ltd. and Another Vs. Rubina Bose, Drug Inspector, and the order passed in Cr.W.J.C. No. 295 of 2009. (M/s. Growmed Pharmaceuticals vs. The State of Bihar and Others).

7. Counsel for the State has submitted that there is no illegality in the order of cognizance as the Inspector of Drugs had collected the drugs as per the provisions of the Act which was sent to the Government Laboratory, returned with the report that it was of substandard. It has been submitted that the complaint case could not have filed against the petitioner, unless Inspector would have been sure as to who was the manufacturer of the drug only then the report was sent alongwith the sample which was found below the marks, thereafter the present case has been filed.

8. Counsel for the State submits that there is no illegality on the part of the Inspector or the court in taking cognizance under the provisions of the Act. In reply, it has been submitted that it is an undisputed fact that the sample was made available to the petitioner after expiry period and the petitioner had no opportunity to challenge the veracity of the test conducted by the Laboratory and stated, when opportunity of challenging the test report was not given, the cognizance is bad in law as the Hon''ble Supreme Court and this Court are of the view that the manufacturer should have been given reasonable opportunity to challenge the test report otherwise it would be violation of Sections 23 and 25 of the Act.

9. It would appear from the counter affidavit that the sample alongwith report in Form 13 was sent to the manufacturer on 10th August, 2002 i.e. after long period of its expiry, which denies the right of the manufacturer to challenge the authenticity of the sample.

10. In order to appreciate the controversy it will be appropriate to consider the provisions of Sections 23(3) & (4) of the Act which are as follows:--

Section 23(3) Where an Inspector takes a sample of a drug (or cosmetic) for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he willfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked: Provided that where the sample is taken from premises whereon the drug (or cosmetic) is being manufactured, it shad be necessary to divide the sample into three portions only:

Provided further that where the drug (or cosmetic) is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug (or cosmetic) be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary sealing them.

Section 23(4) states that in case '' the sample is taken from the premises of the manufacturer, the same would be divided into only three parts, otherwise the same would be divided into four parts. The provisions thus enjoins upon the respondents to remit a sample of the seized items to the person from whose premises it is collected as well as to the manufacturer and to the court concerned beside tendering a sample for being sent to the Analyst for chemical examination.

11. As per Section 23 of the Act, the Inspector will take sample from the Drug Store and would divide in three parts or in four parts. The provisions obliges upon the opposite party No. 2 to send the samples to the Laboratory for test, one sample each would be kept for the Court, shop and manufacturer. Sample alongwith the report would be sent in the event report goes wrong so that the manufacturer would have an opportunity to challenge the test report.

12. The service of the report alongwith the sample before the date of expiry is not an empty formality rather it is mandate of law to give opportunity to the manufacturer to challenge the report, if any, submitted by the analyst.

13. The Supreme Court in the case of M/s. Medicamen Biotech Ltd. was considering the similar situation wherein in Para-18 it has been held as follows:--

It cannot be gainsaid, therefore, that the respondents in these appeals have been deprived of their valuable right to have the sample tested from the Central Insecticides Laboratory under sub-section (4) of Section 24 of the Act. Under sub-section (3) of Section 24 report signed by the Insecticides Analyst shall be evidence of the facts stated therein and shall be conclusive evidence against the accused only if the accused do not, within 28 days of the receipt of the report, notify in writing to the Insecticide Inspector or the court before which proceedings are pending that they intend to adduce evidence to controvert the report. In the present cases the Insecticides Inspector was notified that the accused intended to adduce evidence to controvert the report. By the time the matter reached the Court, the shelf life of the sample had already expired and no purpose would have been served informing the Court of such an intention. The report @ page SC 1943 of the Insecticide Analyst was, therefore, not conclusive. A valuable right had been conferred on the accused to have the sample tested from the Central Insecticides Laboratory and in the circumstances of the case the accused have been deprived of that right, thus, prejudicing them in their defence.

14. In these circumstances, Hon''ble Supreme Court held that the High Court was right in concluding that it would be an abuse of the process of the court if the

prosecution continued against the accused persons and held, the criminal case was rightly quashed and upheld the order of the High Court and dismissed the appeal.

15. The Court was of the view that as the report alongwith the sample was not handed over to the accused persons before its expiry, thereby valuable right was taken away.

In that case the complaint case was filed after expiry of the life period of the drug and the plea was taken, the accused of that case evaded the service of drug was held to be of no substance as the case could have been fifed one month earlier to the expiry of the drug.

16. In this respect, reliance can be further placed in the case of Core Healthcare Limited Vs. The State of Bihar and Others, , particularly paragraph 18 which reads as under--

18. Therefore it is incumbent upon the Inspector while purporting to carry on inspection, test and analysis of the drug in question, to send a notice either to the petitioner Company or to its agent mentioned in paragraph 5 and also to send a sample of the same. A report has also to be sent to either the petitioner Company or its Agent mentioned in paragraph 5 of the writ petition. Admittedly the said procedure has not been followed. Therefore, the entire procedure relating to seizure and analysis and test of the drugs in question have been made in a manner which is not contemplated in law.

17. In view of the aforesaid facts and circumstances, the present order of cognizance is not sustainable in law as the sample was served upon the petitioner after expiry of the drug which was subject matter of seizure and as he could not get an opportunity to challenge the report submitted by the Govt. Analyst before any forum and thereby he was deprived of valuable right to challenge as has been provided under Sections 23 and 25 of the Act. Accordingly, the order of cognizance is quashed and the petition is allowed.