(2012) 08 AP CK 0112

In the Andhra Pradesh High Court

Case No : Criminal Petition No. 6019 of 2012

M/s. Associated Biotech and 4 Others — APPELLANT

Vs

The State Government of A.P. — RESPONDENT

Date of Decision : 27-08-2012

Acts Referred:
Drugs and Cosmetics Act, 1940 — Section 16, 17B(d), 18(A), 18(a)(i), 18(B)

Citation : (2012) 2 ALD(Cri) 807 : (2013) 1 ALT(Cri) 34 : (2013) CriLJ 1069

Hon'ble Judges : Samudrala Govindarajulu, J

Bench : Single Bench

Advocate : Dilip Kumar Jaiswal, for the Appellant;

Final Decision : Allowed

Judgement

Honourable Sri. Justice Samudrala Govindarajulu

1. The petitioners 1 to 5/A-1 to A-5 are accused of offences punishable under Sections 27(d) of the Drugs and Cosmetics Act, 1940 (in short, the Act) for violation of Section 18(a)(i)/ 16 and schedule-II and punishable u/s 27(c) of the Act for violation of Section 18(a)(i)/ 17B(d) of the Act. A-1 is having approval to manufacture drug viz., Rabpraz from the Licensing Authority, Shimla and A-2 to A-5 are partners of A-1 firm. It is alleged that they are all responsible for the day-to-day activities of the firm. On 05.09.2008 Drugs Inspector, Mahaboobnagar District had drawn sample of Rabpraz tablets from G.M. Medical and General Stores, Atmakur by allegedly following procedure prescribed by law and forwarded sealed portion of the sample drug to the Government Analyst, Drugs Control Laboratory, Hyderabad under registered parcel. On 06.07.2009, analysis report of the sample drug is received in Form-13 from the Government Analyst declaring the sample as not of standard quality for the reason that the sample does not comply the Assay for Rabprazole Sodium as per STP (claim 20mg/ tablet, found 4.9 mg/tablet). On 03.12.2009, the incharge drugs inspector addressed notice to Proprietor of G.M. Medical and General Stores to disclose source of supply of the sample drug u/s 18(A) of the Act and to submit copy of

purchase invoice. On the same day, reply was received from the said proprietor that subject batch drug was purchased from Thirumala Pharma, Mahabubnagar through invoice dated 14.06.2008, along with enclosure of attested copy of purchase invoice. On the same day, the incharge drugs inspector notice u/s 18(A) and 22(1)(cca) of the Act to Thirumala Pharma, Mahabubnagar requesting to disclose source of the sample drug and to submit copies of purchase invoice. The drugs inspector also handed over a sealed portion of the sample drug and copy of analysis report to Partner of Thirumala Pharma u/s 23(4)(ii) and 25(2) of the Act. On 04.12.2009, reply was received from Thirumala Pharma stating that the subject batch drug was purchased from Neosun Biotech India Pvt. Ltd, Hyderabad vide invoice dated 07.06.2008 and from Sadguru Pharmaceuticals, Hyderabad vide invoice dated 05.03.2008. Attested copies of purchase invoices were also furnished. On 29.12.2009, incharge drugs inspector addressed letter to Neosun Biotech India Pvt., Ltd., Hyderabad under Sections 18(A), 18(B) and 22(1)(cca) of the Act to disclose source of supply and to submit purchase invoices. On 07.01.2010 reply was received from Neosun Biotech India Pvt., Ltd., stating that the subject drug was purchased from A-1 through invoice dated 31.07.2007, along with attested copy of purchase invoice and sale bill. On 12.01.2010, incharge drugs inspector addressed notice to Sadguru Pharmaceuticals, Hyderabad under Sections 18(A), 18(B), 22(1)(cca) of the Act to disclose source of supply of the sample drug. The said notice sent by registered post was returned unserved as left. On 02.02.2010, incharge drugs inspector, Mahabubnagar personally visited Neosun Biotech India Pvt., Ltd., Hyderabad and on enquiry found that 1000 strips of Rabpraz tablets were sold to Sadguru Pharmaceuticals by them through sales invoice dated 08.11.2007. On 11.02.2010, incharge drugs inspector addressed notice to A-1 u/s 18(B) and 22(1)(cca) of the Act to confirm the manufacture and sale of the sample drug and to submit details of manufacturing licences manufacturing and analytical records. On 22.04.2010, reply was received from A-1 stating that the product is already expired and it is not available in the market and their control samples found quality based over expiry. Hence, Assistant Director who is incharge drugs inspector, Mahabubnagar District filed complaint in the lower Court against A-1 to A-5 for punishing them under the above provisions for the alleged violations. The complaint was filed before the Magistrate on 04.08.2010. The Magistrate took cognizance and issued summonses to A-1 to A-5 by order dated 14.11.2011. Form 17 of the Drugs Inspector, Mahabubnagar contains details of sample taken in this case. The sample drug is from Batch No. AP75L73, manufactured in July, 2007 and date of expiry in June, 2009.

2. It is contended by the petitioners'' counsel that the analyst report in this case was received by Drugs Inspector on 06.07.2009 by which month the sample drug expired and the complaint was filed before the Magistrate thereafter on 04.08.2010 and the offences were taken cognizance by the Magistrate on 14.11.2011 and therefore, the petitioners/accused have lost their valuable right of sending second sample to the Central Drugs Laboratory for second analysis

and for revised report, challenging report of the Government analyst, Hyderabad. The relevant provisions of the Act on this aspect are Sections 25(3) and 25(4) which read as under:

25. Reports of Government Analysts:- ------

(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed u/s 18A has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst''s report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused cause the sample of the drug or cosmetic produced before the Magistrate under sub-section (4) of Section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority, of the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

3. u/s 25(3) of the Act, the accused has got right to receive copy of the analysis report of the Government Analyst and within 28 days of receipt of copy of such report, right to notify his intention in writing either to the Inspector or to the Court before which the proceedings in respect of the sample are pending to adduce evidence in controversion of the analysis report. In such an event, sub-section (4) of Section 25 of the Act makes it incumbent on the Court either suo motu or at the request of either of the parties to send another sample of the drug to the Central Drugs Laboratory for analysis and report. Under Sub-section (5) thereof, it is for the Court to direct either the complainant or the accused to bear expenses for the exercise under sub-section (4). The exercise under sub-section (4) of Section 25 of the Act could be of use in case quality life of the sample drug did not expire by then. In the present case, sample drug expired by June, 2009. Unfortunately, analysis report dated 26.06.2009 was received by the complainant on 06.07.2009 after expiry date of the sample drug. There is inordinate delay in analysing the sample by the Government analyst and sending report of analysis. It is left unexplained. On the same date of obtaining sample i.e., on 05.09.2008, the Drugs Inspector dispatched one part of the sample to the Government analyst for analysis along with necessary forms. The analysis report reads that sample was received by the Government analyst on 08.09.2008 itself. In spite of it, analysis of the sample drug could not be made and analyst report could not be prepared till 26.06.2009. All the events subsequent to the

date of receipt of analysis report become futile, as by the respective dates, quality life of the sample drug had expired.

4. Drugs Inspector could have taken steps u/s 18(A) of the Act immediately after obtaining the sample and sending the same for analysis and without waiting for receipt of the analysis report. Similarly, Drugs Inspector could have taken steps u/s 18(B) and 22(1)(cca) of the Act even before receipt of the analysis of report, as the Drugs Inspector obtained samples suspecting the drug to be of not standard quality and has reason to believe the same. Instead, Drugs Inspector took prolonged steps even after receipt of analysis report stage by stage. When there is label declaration giving manufacturer''s name as A-1 together with its address, there was no reason for the Drugs Inspector to wait till the end to address A-1 for information under Sections 18(B) and 22(1)(cca) of the Act. Thus, unnecessary delays could have been avoided by Drugs Inspector in case he acted swiftly after obtaining suspected drug sample and sending the same to the Government Analyst for analysing and even before receipt of analysis report. In any event, Drugs Inspector cannot be responsible for the delay in this case as analysis report was received by him from the Government analyst on 06.07.2009 after expiry date of the sample drug.

5. In Medicamen Biotech Limited V. Rubina Bose (2008) 3 SCC 20 of the Supreme Court it was held that the delay deprived valuable right under Sections 25(3) and 25(4) of the Act and it should necessitate quashing of the proceedings against the accused.

6. It is contended by the Additional Public Prosecutor that in order to send second sample to Central Drugs Laboratory for second analysis, the accused could have notified his intention in writing u/s 25(3) to adduce his evidence in controversion of the report of the Government analyst. Such expression of intention by notification in writing arises only in case the proceedings are started even before expiry date of the sample drug. In this case, the question of exercising option or notifying intention u/s 25(3) of the Act does not arise, as report of the Government analyst was received after expiry date of the sample drug. In such a case, the accused has no opportunity to notify his intention u/s 25(3) of the Act as even if such intention is notified, there is no subsistence of shelf life of the sample drug as the sample drug had already expired. In these circumstances, the accused suffered great prejudice as the accused is deprived of valuable right of defence of having opportunity to get correctness of analysis report of the Government analyst challenged. Hence, continuation of proceedings in the lower Court for further trial becomes futile exercise. Accordingly, the Criminal Petition is allowed quashing proceedings in C.C. No. 102 of 2011 on the file of Judicial Magistrate of the First Class, Atmakur, Mahabubnagar District.

