HIGH COURT OF JUDICATURE AT HYDERABAD
FOR THE STATE OF TELANGANA AND THE STATE OF ANDHRA PRADESH

*THE HONOURABLE Dr. JUSTICE B. SIVA SANKARA RAO

+ **Crl.P.No. 11424 of 2018**

%31.12.2018

#Between:

M/s Biogenetic Drugs Private Limited
and another ...Petitioners/A.1 and A.2

AND

The State of Telangana
Rep. by its Public Prosecutor
and another ..... Respondents

!Counsel for the petitioners : Sri K. Rajanna,

Counsel for the respondents : Public Prosecutor

<Gist :

>Head Note:

?Cases referred:

1 2018 Crl.L.J.2883

2 (2014) 2 SCC 62

3 (2008) (7) SCC 196

THE HONOURABLE Dr.JUSTICE B.SIVA SANKARA RAO

Criminal Petition No.11424 of 2018

ORDER :

The petitioners are A.1 and A.2 viz: M/s Biogenetic Drugs Private Limited represented by the Authorised signatory, Updesh Yadav and Mukta Goyal, Director, M/s Biogenetic Drugs Private Limited. The 2nd respondent M.Vijaya Gopal-Drug Inspector, Kadapa is the complainant, on whose complaint, the learned Judicial First Class Magistrate/Special Mobile Magistrate Court, Kadapa(for short, 'the JFCM'), taken cognizance by allotting C.C.No.10 of 2015 against the petitioners, dt.21.06.2013 by citing 6 witnesses including for the offences punishable u/Sec.18(a)(i) read with Sec.16, and punishable under Section 27(d) of Drugs and Cosmetics Act, 1940(for short, 'the Act') and Section 18(B) punishable u/sec.28(A) of the Act.

2. The complainant-Drug Inspector is having jurisdiction over entire State of Andhra Pradesh vide G.O.Ms.No.335, Health Medical & Family Welfare (L2), dt.24.11.2011 and is empowered to launch prosecution under Section 32 of the Act and is a public servant.

3. The contents of the complaint are that on 05.03.2008, L.W.1-the complainant visited the Drugs Store-Joint Director, Insurance Medical Services, Sankarapuram, Kadapa, (for short, the JD, IMS') and picked up drug SIMTIL tablets, B.No.01097-TH67 Mfg.date.09/2007, Exp.date.08/2009 Mfg. Lic.No.MNB/ 05/150, Mfg by Biogenetic Drugs Pvt.Ltd.Jham Nagar, Baddi-District, Solan (H.P.)174103-the 1st petitioner for the purpose of analysis/test from Medical Stores of JD, IMS, by issuing Form-17, as per the provisions of Section 23 of the Act. Further for L.W.5-K.Dhanalakshmi-Pharmacist, refused the same to receive, issued Form-17-A dt.05.03.2008 to that effect. The LW1-complainant forwarded one sealed portion of the sampled drug to the Government Analyst, Drugs Control Laboratory,

Hyderabad along with memo in original Form-18 bearing No.SA/24/DI/CDP/2008, dt.05.03.2008 and also forwarded specimen impression of the seal used separately as per provisions of the Act. On 23.08.2008, the LW2-Drug Inspector, Kadapa received from the Government Analyst, certificate of analysis/test in Form-13 bearing No.2604/DCL/2008 dt.22.07.2008 declaring the sample drug as "Not Of Standard Quality" as defined in the Act and Rules made thereunder for the reason that the sample does not meet the labelled claim in respect of "Simvastatin" drug content and forwarded the copy of the report to the JD, IMS, vide Rc.No.586/DI/NN/KDP/2008 dated 23.08.2008 as per the provisions of the Act. The JD, IMS in his letter RC.No.861/Stores/JDIMS/08, dt.30.06.2008, stated that SIMTIL Tablets, B.No.01097-TH67 was purchased from M/s Sri Sai Krishna Marketing Associates, Hyderabad vide invoice No.VAT 41209,dt.28.12.2007 and in his letter Rc.No.308/stores/08,dt.29.08.2008 issued order to all in charge Medical Officers of ESI Dispensaries in Rayalaseema region and including Nellore to return said (simvastatin) as not of standard quality drug. The L.W.2 also deposited as per section 23(4) (ii) of the Act, and Rules 1945, third portion of the sample and certificate of analysis to M/s Sri Sai Krishna Marketing Associates, Hyderabad vide Letter Rc.No.586/DI/NN/KDP/2008, dt.01.09.2008 in reply in their letter stated that they purchased 25x10x10 tablets of SIMTIL tablets, B.No.01097-TH67 from M/s S.R.R. Enterprises, Vijayawada vide invoice No.TIL-403,dt.22.12.2007. Then the LW2 issued a notice vide letter Rc.No.586/DI/NN/KDP/2008,dt.22.10.2008 to M/s S.R.R Enterprises, Vijayawada, who in their letter dated 07.112008 stated that they purchased 60x10x10 tablets of SIMTIL Tablets B.No.01097-TH67 from M/s S.M.S. International Company, Hyderabad vide invoice No.MD9, dt.26.10.2007.

4. The LW3-K.Anil Kumar, Drug Inspector issued a notice vide letter Rc. No.586/DI/NN/KDP/2008,dt.17.12.2018 to M/s SMS International

Company, Hyderabad, as per the provisions of the Act. On 24.01.2009 the LW3 received a letter dt.12.01.2009 from M/s SMS International Company, Hyderabad stating that they purchased 240x10x10 tablets of SIMTIL Tablets, B.No.01097-TH67 from M/S Medi one (India), Bangalore vide invoice No.00031,dt.23.10.2007, 00039,dt.06.11.2007 and 00048,dt.17.11.2007. Then LW3 issued a notice to Medi One(India), Bangalore vide Rc.No.586/ D1/NN/KDP/2008,dt.24.01.2009 as per the provisions of the Act. On 10.02.2009 the LW3 received a letter from M/S Medi One (India) Banglore dt.04.02.2009 stating that they purchased 976x10x10 tablets of SIMTIL Tabllets, B.No.01097-TH67 from M/S Tablets (India)Limited, Chennai vide invoice No 27. dt.16.10. 2007. LW3 issued a notice to M/s Tablets(India) Ltd. Chennai, vide Rc.No.586/DI/NN/KDP/2008,dt.10.02.2009 as per the provisions of the Act. On 21.02.2009 the L.W.3 received a letter dt.18.02.2009 from M/s Tablets(India) Ltd. Chennai who in their letter stated that they purchased 976x10x10 tablets of SIMTEL Tablets, B.No.01097-TH67 from M/S Biogenetic Drugs Pvt.Ltd, Jharmajri, Baddi, vide invoice No.0434, dt.10.10.2007. L.W.3 issued a notice to M/s Biogenetic Drugs Private Ltd., Baddi-the 1st petitioner vide Rc.No.586/DI/NN/KDP/ 2008, dt.21.02.2009 to submit (i) Raw material, manufacturing and analytical records of the said batch drug, (ii) Distribution particulars of the said batch drug (iii) Constitution and other related particulars of the firm (iv) technical staff responsible for manufacturing and analysis of the SIMTIL tablets, B.No.01097-TH67 (v) copy of manufacturing/sale license as on date of manufacturing (vi) permission given by the licensing authority to manufacturing SIMTIL tablets, B.No. 01097-TH67 (vii) Name and Address of the responsible person for the purpose of Section 34 of the Act and (viii) any relevant information.

5. On 24.03.2009 L.W.3 received a letter dt.04.03.2009 from M/s Biogenetic Drugs Pvt. Ltd. Baddi, in that they ordered to the M/s Tablet

India Limited to stop further sale of the said batch and recall all unsold stocks lying in the market and requested to send the sealed sample portion for their conformation of genuineness of sample. As no reply was received from the 1st petitioner, a remainder notice and as a reply to the letter received L.W.3 issued a notice to the 1st petitioner vide letter Rc.No.586/ DI/ NN/ KDP/ 2008,dt.24.03.2009 to approach the I Addl.JFCM court Kadapa and pay requisite fee as per schedule-B of the Act, for causing the sample to send to the Director, Central Drugs Laboratory, 3, Kyd street, Calcutta for analysis. On 08.05.2009 L.W.3 received a letter dt.24.04.2009 from the 1st petitioner, requesting for the sealed sample portion for finding genuineness of the sample. On the same day, the L.W.3 sent a letter to the 1st petitioner stating that the sample portion was already supplied to the M/S Sri Sai Krishna Marketing Associates, Hyderabad and a sealed portion of sample drug was deposited in the I Addl.JMFC court, Kadapa on 31.03.2009.

6. LW3 submitted the sealed portion of the sampled drug as per section 23 (4) (ii) of the Act and prayed the Court to forward the same to the Director, Central Drugs Laboratory, 3, K Y D street Calcutta as required u/ s 25(4) of the Act, along with original Form-17, original Form-13, letter of company, office copy of Form-18 with covering letter and copy of letter addressed to the company dt.24.03.2009. The AJFCM court received the sealed sample portion on 31.03.2009 and issued CPR item No.176/ 2009 dt.22.08.2009.

7. On 20.05.2011 L.W.4-Surendranath Sai Drugs Inspector, Kadapa, Drugs Inspector, sent a letter to the State Drugs Controller, Health and Family welfare Department, Himachal Pradesh, requesting for constitution particulars of the 1st petitioner but no reply was received.

8. On 22.08.2007 L.W.7-K.V.Ramanamurthy, Drug Inspector, Kadapa received a letter from State Drugs Controller, along with Memorandum of Association of the 1st petitioner. The sealed portion of the samples are all

drugs within the meaning of Section 3(b) of the said Act. As per Sec.18(a)(i) of the said Act, no person shall himself or by any other person on his behalf manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute-(i) Any drug which is not of a standard quality, or is misbranded, adulterated or spurious and the said offence is punishable under Section 27(d) of the Act. As per Section 18(b)-Every person holding a licence under clause(c) of Section 18 shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act and the said offence is punishable u/sec.28-A of the Act.

9. The averments of quash petition in impugning cognizance order are that 1st petitioner is manufacturer of various varieties of drugs as specified in the license and selling to various parts of the country as recommended by the Registered Medical Practitioners, on the purchase orders, placed by the wholesale dealers and their Head office in Chennai, to their office at Bangalore in respect of particular batch SIMTIL-20 along with other drugs was supplied to one M/s Tablets(India) Limited, No.22, North Terminus Road, Tolgate, Chennai-600081, Tamilnadu, to their branch at Bangalore vide invoice dt.10-10-2007(Ex.P.5). As per the precautionary conditions enumerated in the medicines, the purchaser should store the required medicines in a dry and dark place. The 2nd respondent did not verify as to where the retailer purchased the said drug 'SIMTIL-20' nor of they have maintained precautionary measures for the reasons best known to the 2nd respondent. It is alleged in the complaint that the drug SIMTIL tablets manufactured by the 1st petitioner was detected substandard quality as per the report of the Government Analyst, vide report No.2604/DCL/2008, dt.22.07.2008(Ex.P.7) wherein the presence of 'Assay for Simvastain'

was found to be 15.7mg and wherein the claim of 'Assay for Simvastain' is 20 mg. However, as per the same report, at column No.4, the permissible limits of presence of Assay for Simvastain is between 108 to 20%whereas, as per the test report, the presence of Assay for Simvastain is 15.7mg., which is happened to be depending on the storage conditions of the Stockists who purchased from the 1st petitioner and blaming the 1st petitioner company is nothing but abuse of process of law. Once the date of expiry of manufacturing of the product comes into effect, question of re-sending to analyst report does not arise at all, as it becomes redundant. If the subject drug is not stocked in a dry and dark place as per the precautionary conditions, naturally the standard of subject drug will loose its standard and for that the 1st petitioner not to be blamed for the mistakes committed by the Stockists, either at distribution point or at the retail outlets. Leaving the stockists without filing any complaint against them as they are local and influenced persons and involving the manufacturer as scape goat is nothing but abuse of process of law. Initially the complaint filed by the 2nd respondent in C.C.No.10 of 2015 was dismissed by the learned JFCM, Kadapa on 08.06.2015(Ex.P.8) and questioning the same, the Crl.R.C.No.24 of 2017 filed by the 2nd respondent, was allowed by the Principal Sessions Judge, Kadapa vide orders,dt.29.12.2017 by restoring the complaint on file(Ex.P.9). The 1st petitioner deposited Rs.1000/- for sending the sample to Central Lab and the same was pending. In the meantime, the complaint was dismissed for default. But the particular batch sample which was said to be collected by the 2nd respondent was expired and therefore question of sending for Central Lab, did not arise at all. Hence, the acts of the 2nd respondent are clear abuse of process of law.

10. The learned counsel for the petitioner reiterated the same. It is the submission of the learned Public Prosecutor that at the time of the sample taken the drugs are stored in a closed rock at room temperature at

23 centigrade and for the claim of the tablets must contain Assay for Simvastain USP 20mg, between 18 to 22, it was found only 15.7 mg. The pendency of the case was as per the letter addressed by the Drug Inspector, Kadapa to the State Drugs Controller, Himachal Pradesh on 20.05.2011 for want of constitution particulars of the 1st petitioner in requesting to furnish at an early date and thereafter received memorandum and certificate of corporation of M/s Biotech and Form-13 filed with Registrar of Companies showing from 15.05.2006 Mukta Goel is Director in the place of Prakash Goel, vacated as Director.

11. Heard both sides and perused the material on record.

12. The main contention of the learned counsel for the petitioners is once there is a bar of limitation to the allegation of the drug not in confirmation with the standards required with prescribed punishment u/sec.27-(d) of the Act and u/sec.468 CrPC, the limitation is three years from the date of seizure of the drug, if not prescribed within two years by filing final report to take cognizance, the proceedings no way survive as held by the Jharkhand High Court in M/s Galpha Laboratories Limited, Mumbai Vs. State of Jharkhand[1], relying upon the expressions of the Apex Court in Sarath Mathew Vs IOCVD[2], where it is stated the date is date of filing the complaint and not the subsequent taking of cognizance. It is the contention therefrom of the seizure was undisputedly on 05.03.2008. The complaint filed was on 21.06.2013 though cognizance taken subsequent to that. Thus, the complaint filed beyond three years from the date of seizure on 05.03.2008 of the drug. So far as the offence under Section 27-D of the Act for the alleged sub-standard of the drug concerned, barred by limitation. So far as the offence u/sec.18(b) punishable u/sec.28(a) of the Act concerned, the punishment provided is upto one year or with a fine not less than Rs.20,000/- or with both. Thereby for which limitation is only one

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[1] 2018 Crl.L.J.2883
[2] (2014) 2 SCC 62

year. On both the counts as the complaint is hopelessly barred by limitation under Sec.468 of CrPC as per the expression of the Jharkhand High Court supra, the petition is to be allowed by quashing the proceedings.

13. It is leave apart shell life of the sample already expired and continuation of proceedings no way just as held by the Apex Court in M/S. Medicamen Biotech Ltd. Vs. Rubina Bose, Drug Inspector[3].

14. In the result, the Criminal Petition is allowed by quashing the proceedings against the petitioners/A.1 and A.2 in C.C.No.10 of 2015 on the file of the Judicial Magistrate of First Class/Special Mobile Magistrate Court, Kadapa, and they are acquitted. The bail bonds of the petitioners/A.1 and A.2 shall stand cancelled.

Miscellaneous petitions pending if any, shall stand closed.

Dr. B.SIVA SANKARA RAO J,

Date:31.12.2018

Note: L.R.Copy to be marked. Yes.
b/o. Vvr

[3] (2008) (7) SCC 196