HONOURABLE JUSTICE G. SRI DEVI

CRIMINAL PETITION No. 1769 of 2015

ORDER:

This Criminal Petition is filed under Section 482 Cr.P.C. seeking to quash the proceedings in P.R.C.No.2 of 2015 on the file of the I-Additional Judicial Magistrate of First Class, Khammam. A complaint came to be filed by the Drugs Inspector, Khammam Urban (hereinafter referred to as "the complainant"), under Section 32 of the Drugs and Cosmetics Act, 1940 (for short "the Act") against the petitioners/A-1 to A-3, for contravening the provisions of Sections 18 (a) (i) read with Section 16 of the Act punishable under Section 27 (d) of the Act and Section 17 B (d) of the Act punishable under Section 27 (c) of the Act.

The gist of the averments in the complaint would show that on 15.06.2019, the Assistant Director, Drugs Control Administration, Karimnagar District (hereinafter referred to as "Assistant Director") visited the shop of G.Purna Chandra Rao (LW.2) by name M/s. Sri Venkata Durga Pharmaceuticals, D.No.10-2-93/1, Bus Depot Road, Khammam and lifted 200 tablets of Asek-3D, B.No.DAD-0818, Mfg. dt. 01/2009, Exp.dt: 06/2010, Mfg. by M/s. Everest Formulations, Solan-173211 (H.P.) for test/analysis as per the procedure laid down under Section 23 of the Act. On 16.06.2019, the Assistant Director, forwarded one sealed portion of the sampled drug to the Government Analyst, Drugs Control Laboratory, Hyderabad along

with original memorandum in Form-18 through registered parcel, as per the provisions and procedures laid down under Drugs and Cosmetics Act, 1940 and Rules made thereunder, with a request to cause test or analysis of the said drug as per the standards of label claim. On 17.05.2010, the Assistant Director received the certificate of test or analysis in Form-13 in triplicate vide report No.398/DCL/2010 from the Government Analyst and the Government Analysit declared that the drug i.e., Asek-3D tablets, B.No.DAD-0818 as of "Not of Standard Quality" for the reason that "the sample does not meet the labeled claim in respect of serratiopeptidase content found 5.0 mg. against labeled claim 10.0 mg. (limit is 9 mg. to 11 mg.)", i.e., 50% of the label claim. On the same day, the Assistant Director served a notice under Section 18-A and 22 (1) (cca) of the Act to the Proprietor-cum-competent person of M/s. Sri Venkata Durga Pharmaceuticals, Khammam (LW.2), in person under acknowledgment, with a direction to disclose the source of supply and produce the registers and records of said drug along with copy of Government Analyst Report in Form-13 as required under Section 25 (2) of the Act. On 26.05.2010, the Assistant Director received a reply stating that the said drug was purchased from M/s. Pravallika Medi needs, Pharmaceutical Distributors, D.No.1-10-9/7, Sattenapalli Road, Narsaraopet, Guntur District vide Invoice Nos. VS 587, dated 11-04-2009, VS 2911, dated 08.06.2009 and VS 3906 dated 02.07.2009. It is also stated that they were not having stocks of the said drug and also with retailers to

whom they have supplied. On the same day, the Assistant Director forwarded a notice under Section 18-A and 22 (1) (cca) of the Act to M/s. Pravallika Medi Needs, Narsaraopet, Guntur District, by registered post, to disclose the source of supply of the said drug along with copy of Form-13 and one sealed sampled drug portion as required under Section 23 (4) (iii) of the Act and further instructed not to sell the said drug since it is declared as of "Not of Standard Quality" and instructed to call back the stock sold. On 07.06.2010, the Assistant Director received reply from M/s. Pravallika Medi Needs, Narsaraopet, Guntur District, stating that the said drug was purchased from M/s. De-Cross Labs (India) Private Limited, D.No.2-4-80/4, Medical Complex, Rajagarikota, Narsaraopet, Guntur District, vide Invoice No.DCL 78, dated 20.02.2009. They also stated that they were not having stock of the said drug. On the same day, the Assistant Director forwarded a notice under Section 18-A and 22 (1) (cca) of the Act to M/s. De-Cross Labs (India) Limited, Narsaraopet, Guntur District, by registered post, to disclose the source of supply of the said drug and further instructed not to sell the drug since it is declared as of "Not of Standard Quality" and instructed to call back the stock sold. On 22.06.2010, the Assistant Director received reply from M/s. De-Cross Labs (India) Private Limited, Narsaraopet, Guntur District, stating that the said drug was purchased from accused No.1 vide Tax Invoice No.786, dated 30.01.2009. They also stated that they were not having stocks of the said drug. On the same day, the Assistant Director, forwarded

notice under Section 18-B and 22 (1) (cca) of the Act to accused No.1, by registered post, with an instruction to confirm the manufacture and sale of the said drug and produce information regarding the manufacturing records, analytical records and distribution particulars and also instructed to produce attested photo copies of Drug Licences, name and address of the responsible person of the firm. On 09.07.2010, the Assistant Director received reply from accused No.1, stating that they would like to challenge the Government Analyst report as per Section 25 (4) of the Act and requested to send the said sample to Central Drugs Laboratory, Kolkata.

It is also stated in the complaint that as per the provisions of Section 25 (3) of the Act, "Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence to 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 under Section 18-A of the Act 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 contravention of the report". The person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under Section 18-A of the Act were not

challenged the Government Analyst report, where as the manufacturer challenged the Government Analyst report after the twenty eight days from the date of receipt of a copy of Government Analyst report along with one sealed sampled drug portion by the person whose name, address and other particulars have been disclosed under Section 18-A of the Act. It is also stated that as per Section 18 (a) (i) of the Act "No person shall himself or by any other person on his behalf, manufacture for sale or for distribution, or for sell, or stock or exhibit or offer for sale, or distribute any drug which is Not of Standard Quality, or is Misbranded, Adulterated or Spurious". Thus, the petitioners/A1 to A3 are responsible for manufacturing of "Not of Standard Quality" drug ie. Asek-3D Tablets, B.No.DAD-0818, Mfg. dt. 01/2019, Exp.dt: 06/2010. Hence, violated Section 18 (a) (i) read with Section 16 of the Act, punishable under Section 27 (d) of the Act. As per Section 17-B(d) of the Act "A drug shall be deemed to be spurious, if it has been substituted wholly or in part by another drug or substance". Thus, the petitioners/A1 to A3 have violated this provision by manufacturing the above drug by substituting wholly or in part by another drug or substance, because the content of Serratiopeptidase is only 50% of the labeled claim, hence, punishable under Section 27 (c) of the Act. Basing on the above allegations a complaint came to be filed. By an order dated 03.01.2015, the learned I Additional Judicial Magistrate of First Class, Khammam, has taken cognizance of the complaint against the petitioners/A1 to A3 for the offences punishable under

Sections 27 (d) and Section 27 (c) of the Act; registered as P.R.C.No.2 of 2015 and ordered for issuance of summons to the petitioners/ A1 to A3. Challenging the said order, the petitioners/A1 to A3 filed the present Criminal Petition.

Heard Sri Challa Dhanamjay, learned Senior Counsel appearing for Sri K.Sai Babu, learned Counsel for the petitioners/A1 to A3 and learned Additional Public Prosecutor appearing for the respondents.

It has been submitted on behalf of the petitioners/A1 to A3 that the order of the learned Magistrate in taking cognizance against the petitioners/A1 to A3 is contrary to law, weight of evidence against the probabilities of the case. The Magistrate has not considered the complaint filed by the complainant with documents 1 to 13 in a proper perspective and recorded his findings mechanically. The learned Magistrate erred in taking cognizance against the petitioners/A1 to A3 for an offence under Sections 27 (d) and 27 (c) of the Act, for violation of Section 17 B (d) of the Act punishable under Section 27 (c) of the Act, when the date of manufacture of the drug was 1/2009 and its expiry date was 06/2010; the Assistant Director has seized the drug on 15.06.2009 and sent it to analysis on 16.06.2009 and the Assistant Director received the report on 07.05.2010 stating that the drug is Not of Standard Quality, though the same was expired by 06/2010. The Assistant Director has given the intimation of analyst report to the

1st petitioner/A1 on 22.06.2010 and the complainant filed the complaint in the Court on 23.12.2013 beyond three years and six months and the learned Magistrate has taken cognizance on 03.01.2015 beyond the period of limitation, as such, the same is bad in law and the prosecution against the petitioners/A1 to A3 is not maintainable. In support of his contention, learned Counsel for the petitioners/A1 to A3 relied on the following judgments.

1. ***Medicamen Biotech Limited and another v. Rubina Bose, Drug Inspector***[1]
2. ***Laborate Pharmaceuticals India Limited and others v. State of Tamil Nadu***[2]
3. ***M.V.Srinivasa Rao, Prop: M/s. Essel Pharma, Solan v. State of Andhra Pradesh***[3]

Learned Additional Public Prosecutor would submit that all the objections raised on behalf of the petitioners are matter of evidence which have to be considered during trial and these aspects cannot be decided in a quash petition under Section 482 Cr.P.C.

Now, the point that would arise for consideration by this Court in this Criminal Petition is whether the proceedings in P.R.C.No.2 of 2015 on the file of the I Additional Judicial Magistrate of First Class, Khammam, initiated by the complainant against the petitioners/A1 to A3 for the offences punishable under Section 27 (d) and Section 27 (c) of the Act, can be quashed or not?

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[1] (2008) 3 SCC (Cri) 20
[2] (2019) 1 SCC (Cri) 717
[3] Crl.P.No.3948/2013, dated 18.07.2019 of AP High Court

In ***Laborate Pharmaceuticals India Limited and others case*** (2 supra), the Apex Court in Para Nos.6 and 8 held as under:

> "6. A reading of the provisions of Sections 23 (4) and 25 of the Act would indicate that in the present case the sample having been taken from the premises of the retailer had to be divided into four portions; one portion is required to be given to the retailer; one portion is required to be sent to the Government Analyst and one to the Court and the last one to the manufacturer whose name, particulars, etc. is disclosed under Section 18A of the Act. In the present case, admittedly, one part of the sample that was required to be sent to the appellant (manufacturer) under Section 23 (4) (iii) of the Act was not sent. Instead, what was sent on 22nd March, 2012 was only the report of the Government Analyst. When the part of the sample was not sent to the manufacturer, the manufacturer could not have got the same analyzed even if he wanted to do so and, therefore, it was not in a position to contest the findings of the Government Analyst. In the present case, the sample was sent to the Appellant-manufacturer on 10th August, 2012 and on 13th September, 2012 the appellant had indicated its desire to have another part of the sample sent to the Central Laboratory for re-analysis. This was refused on the ground that the aforesaid request was made much after the stipulated period of 28 days provided for in Section 25 (3) of the Act.
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> 8. All the aforesaid facts would go to show that the valuable right of the appellant to have the sample analyzed in the Central Laboratory has been denied by

> a series of defaults committed by the prosecution; firstly, in not sending to the appellant-manufacturer part of the sample as required under Section 23 (4) (iii) of the Act; and secondly, on the part of the Court in taking cognizance of the complaint on 4th March, 2015 though the same was filed on 28th November, 2012. The delay on both counts is not attributable to the Appellants and, therefore, the consequences thereof cannot work adversely to the interest of the Appellants. As the valuable right of the accused for re-analysis vested under the Act appears to have been violated and having regard to the possible shelf life of the drug, we are of the view that as on date the prosecution, if allowed to continue, would be a lame prosecution. Consequently and for the reasons alluded we are of the view that the present would be a fit case to interdict the criminal trial against the accused appellants. We order accordingly. Therefore, C.C.No.263 of 2015 pending on the file of the XV Metropolitan Magistrate, George Town, Chennai is hereby quashed. The appeal is allowed and the orders of the High Court is set aside."

In the instant case also, though the date of manufacture of the drug is January, 2009 and the expiry date of the said drug is June, 2010, notice under Section 18-B and 22 (1) (cca) of the Act was sent to the 1st petitioner/A1 on 22.06.2010 and on 09.07.2010, the 1st petitioner/A1 has given reply stating that they intend to challenge the Government Analyst report as per Section 25 (4) of the Act and also requested to send the said sample to Central Drugs Laboratory, Kolkata. Apart from that in the present case, cognizance was taken

on 03.01.2015 though the complaint was filed on 23.12.2013. According to the petitioners, the drug had lost its shelf life in the month of June, 2010 itself. Therefore, on the date when cognizance was taken, the shelf life of the drug in question had expired. Therefore, the petitioners/A1 to A3 have been deprived of a valuable right which was conferred on them by the Statute under Section 25 (4) of the Act to test the correctness or genuineness of the Government Analyst Report by sending the drug in question for test and analysis to the Central Drugs Laboratory.

Having regard to the principles laid down by the Apex Court in ***Laborate Pharmaceuticals India Limited*** (2 supra) and having regard to the aforesaid facts and circumstances of the case, continuation of the proceedings against the petitioners/A1 to A3 is nothing but an abuse of process of law.

Accordingly, the Criminal Petition is allowed and the proceedings against the petitioners/A1 to A3 in P.R.C.No.2 of 2015 on the file of the I Additional Judicial Magistrate of First Class, Khammam, are hereby quashed.

As a sequel thereto, miscellaneous petitions, if any, pending shall stand closed.

JUSTICE G.SRI DEVI

22.11.2019
gkv/Gsn

HIGH COURT FOR THE STATE OF TELANGANA
HYDERABAD