IN THE HIGH COURT OF ANDHRA PRADESH, AMARAVATI

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CRIMINAL PETITION No. 13022 of 2014

Between:

J.P.N.Singh,
S/o.P.N.Singh, Aged about 34 years,
Occ:Director, M/s.Galpha Laboratories Limited,
R/o.Flat No.404, Valentine Tower No.1,
Film City Road, Pimplypada,
Goregaon, East Mumbai. ... Petitioner/A.2

And

The State of A.P., through Drug Inspector, Ongole,
Represented by Public Prosecutor, High Court of A.P.,
Amaravati. .... Respondent

DATE OF JUDGMENT PRONOUNCED**: 26-09-2023**

SUBMITTED FOR APPROVAL:

THE HON'BLE SRI JUSTICE DUPPALA VENKATA RAMANA

1. Whether Reporters of Local Newspapers may be allowed to see the judgment? Yes/No

2. Whether the copies of judgment may be marked to Law Reporters / Journals? Yes/No

3. Whether His Lordship wish to see the fair copy of the Judgment? Yes/No

DUPPALA VENKATA RAMANA, J

*** THE HON'BLE SRI JUSTICE DUPPALA VENKATA RAMANA**

+ CRIMINAL PETITION No. 13022 of 2014

% 26-09-2023

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! Counsel for Petitioner **:** Sri T.S.Anirudh Reddy

^ Counsel for Respondent **:** Asst.Public Prosecutor

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> Head Note:

? Cases referred:

1. 2008 SCC Online Pat 1307
2. MANU/AP/0111/2019
3. 2019 (2) ALT (Crl.) 329 (AP)
4. (1998) 5 SCC 343

This Court made the following:

HON'BLE SRI JUSTICE DUPPALA VENKATA RAMANA

CRIMINAL PETITION No.13022 of 2014

ORDER:

This Criminal Petition has been filed by the Petitioner/A.2 under Section 482 of the Code of Criminal Procedure, 1973 (for short "Cr.P.C") for quashing the proceedings in C.C.No.405 of 2012 on the file of the Court of II Additional Munsif Magistrate, Ongole, registered for the offence under Section 18(a)(i) read with Section 16 punishable under Section 27(d) of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as "the Act").

2. Heard Sri T.Pradyumna Kumar Reddy, learned Senior Counsel instructed by Sri T.S.Anirudh Reddy, learned counsel for the petitioner and learned Assistant Public Prosecutor for the respondent.

3. The brief facts of the case are as follows:

(i) A.1-firm, namely, M/s.Galpha Laboratories Limited, Thana, possessed drug manufacturing licence bearing No.L/06/256/MB, dated 27.06.2006, to manufacture the drugs for sale. The petitioner/A.2 is the responsible Director of the firm and A.3-O.N.Vaishy is the responsible person for the manufacturing activities of the firm at Baddi.

(ii) On 12.05.2009, the-then Drugs Inspector-N.Ramamoorthy(L.W.1) inspected Central Drug Stores, APHMHIDC, Ongole, in the presence of Pharmacist under Form No.17 as required under Section 23 of the Act and picked up the drug, namely "Amoxycillin" and Potassium Clavulanate Oral Suspension I.P., Clanoxy-200 Batch No.CNSF-90071B, Manufacturing Date 4/2009, Expiry Date 3/2011, manufactured by A.1 firm, seized four samples(drugs) separately under seal, and immediately sent one sealed portion of the said drug sample - Clanoxy 200, to the Government Analyst, Drugs Control Laboratory, Hyderabad *vide* Form No.18, through Registered Post for analysis. He also sent one copy of Form No.18 to the Government Analyst, Drugs Control Laboratory, Hyderabad, separately through Registered Post.

(iii) On 26.05.2010 the Drugs Inspector(L.W.1) received the Government Analyst Report dated 20.05.2010, declaring the sample drug is "not of standard quality" as defined under the Act and Rules framed thereunder for the reason that the sample does not meet the labelled claim in respect of the Clavulanic Acid content(found 3.59 mg/28.5 mg).

(iv) On receipt of the Government Analyst's Report, the Drug Inspector addressed a letter dated 26.05.2010 to the

Executive Engineer, Central Drug Stores, APHMHIDC, Ongole, under Section 18A of the Act with a request to disclose the source of acquisition of the sample drug along with a self-attested copy of purchase invoice. On 10.06.2010, the Drugs Inspector received a reply from the Executive Engineer stating that the sample drug was received *vide* Bill No.0911NS/11, dated 25.04.2009. On 30.06.2010 the Drugs Inspector addressed a letter to M/s.Galpha Laboratories Limited, Hyderabad(A.1) under Section 18A of the Act requesting to disclose the source of the acquisition of the drug and to furnish the self-attested Xerox copy of the purchase invoice. The Drugs Inspector received a reply dated 14.07.2010 from A.1-firm stating that "*they have manufactured, sold and distributed a standard quality drug namely Clanoxy-200 Suspension and the findings of the Government Analyst can be attributed to error in testing or improper storage*". In view of the above, they requested the Drug Inspector to take into consideration their submission and the background submitted above and not to take any action against them. In another letter dated 26.07.2010 received from the Authorized Signatory of A.1 Firm, it was stated that "*they have manufactured, sold and distributed standard quality of drug namely Clanoxy 200 dry syrup and the findings of the*

Government Analyst can be attributed to error in testing or improper storage" and requested not to take any action against them.

(v) On 16.09.2010 the Drugs Inspector addressed another letter to M/s.Galpha Laboratories Limited, Zirakpur requesting to disclose the source of supply and to furnish a self-attested Xerox copy of their purchase invoice. On 18.04.2011 the complainant received a reply from A.1-firm along with the manufacturing and analytical records, stating that A.3-O.N.Vaishy, Associate V.P-QA is the responsible person for the day-to-day activities of A.1-firm. On 25.06.2011, the Assistant Director, Drugs Control Administration, Hyderabad sent the constitution particulars of A.1-firm to L.W.2/Assistant Director, Drugs Control Administration, Ongole and further, "Clanoxy 200 Oral Suspension USP Batch No.CNSF-90071B, Manufacturing Date 4/09, Expiry Date 3/11, manufactured by the A.1 firm is a drug within the meaning of Section 3(b) of the Act and the said drug was declared as "Not of Standard Quality" by the Government Analyst, Drugs Control Laboratory, Hyderabad. Thus, the petitioner/A.2, A.1-firm and A.3 contravened Section 18(a)(i) read with Section 16 of the Act by manufacturing and selling of the "Not of Standard Quality Drug" Clanoxy 200

Suspension as described above, and thereby rendered itself liable for punishment under Section 27(d) of the Act.

(vi) Therefore, the Drugs Inspector filed a complaint under Section 32 of the Act before the Court of II Additional Munsif Magistrate, Ongole, and the same was taken on file and numbered as C.C.No.405 of 2012.

(vii) Aggrieved thereby, the petitioner/A.2 moved the present criminal petition under Section 482 Cr.P.C for quashing the proceedings initiated against him in the above C.C.

4. Learned counsel for the petitioner would submit that the petitioner/A.2 is not responsible for the day-to-day affairs of A.1-firm and the complaint does not disclose the said fact. He would further submit that the Drug Inspector picked up the sample of the drug on 12.05.2009, sent the same to the Government Analyst, Drugs Control Laboratory, Hyderabad and on 26.05.2010 received the Analyst's report dated 20.05.2010 and the complaint was filed on 03.08.2011 and the drug was manufactured in 04/2009 and expired by 03/2011 and by the time of filing of the complaint on 03.08.2011 the shelf-life of the drug was expired and therefore, the complaint is not maintainable. Further, he would submit that the Drug Inspector has drawn four samples at Central Drug Stores, APHMHIDC,

Ongole and one sample was sent to the Government Analyst, Hyderabad, the second sample is a retailer sample and the third sample has to be deposited in the Court. But, the third sample was not deposited before the Court and the complaint does not disclose the reasons for the same. He would further submit that compliance of the provisions of Section 25 of the Act is mandatory and non-supply of the Government Analyst's report to the petitioner before expiry date of the drug resulted in depriving his valuable right to test the sample drug by the Central Drug Laboratory, Kolkata. As such, the proceedings are vitiated and consequently, the complaint filed by the Drugs Inspector, Ongole, against the petitioner/A.2 is to be quashed. The Report of the Central Laboratory supersedes the State Laboratory Report. Therefore, he would pray for quashing of proceedings against the petitioner/A.2.

5. Learned Assistant Public Prosecutor would submit that the petitioner/A.2 submitted an affidavit on behalf of A.1-firm, dated 13.05.2008, stating that he is the Director and responsible for the day-to-day affairs of the Company. Therefore, the petitioner/A.2 is the person, who is responsible for the commission of offence of manufacturing the drug which is "Not of Standard Quality". Further, he would submit that on receipt

of the report from the Government Analyst, Hyderabad, under Section 25(3) of the Act, the Drug Inspector addressed a letter to the Executive Engineer, Central Drugs Stores and A.1-Firm. The Sr.Vice President of A.1-firm sent a reply dated 14.07.2010 and the Authorized Signatory of A.1-Firm sent a reply 26.07.2010 stating that the findings of the Government Analyst, Hyderabad, can be attributed to error in testing or improper storage and not to take any action against them and they never requested to send the sample drug to the Central Drugs Laboratory for analysis in exercise of their valuable right conferred under Section 25(4) of the Act. Therefore, the report of the Government Analyst becomes final. In this process, loss of their valuable right does not arise since the petitioner/A.2 has not requested the Drugs Inspector to send the sample drug to the Central Drugs Laboratory. He would further submit that the present complaint is filed within the stipulated time i.e., three years from the date of the State Analyst Report dated 20.05.2010. Further, he would submit that the matter requires trial to ascertain the truth or otherwise. He would further submit that there is no merit in the contentions raised by the petitioner/A.2 with regard to the violations under the Act. Therefore, he would pray for the dismissal of the criminal petition.

6. Now the point for determination is:

> *Whether there are any merits in this criminal petition to allow?*

POINT:

7. At the outset, it will be apposite to extract Section 25 of the Act. It reads as under:

> ***25. Reports of Government Analysts***.—
> *(1) The Government Analyst to whom a sample of any drug [or cosmetic has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.*
>
> *(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken [and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A], and shall retain the third copy for use in any prosecution in respect of the sample.*
>
> *(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 under section 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 contraversion 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.*
>
> *(5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct.*

8. From a bare perusal of Sub-Section (3) of Section 25 of the Act it is manifest that the report of the Government Analyst shall be the 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 or other particulars have been disclosed under Section 18-A] (in this case manufacturers) has, within 28 days of the receipt of the report notified in writing the Drugs 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. Sub-Section (4) also makes it abundantly clear about the right to get the sample tested by Central Drugs Laboratory(so as to make its report override the report of Analyst) through the Court.

9. In the instant case, the petitioner/A.2 has not taken any steps to send the sample drug to the Central Drugs Laboratory in exercise of his valuable right conferred under Section 25(4) of the Act, and instead of availing such right, the Sr.Vice President of A.1-firm sent a reply letter dated 14.07.2010 stating that they

have received the letter in R.C.No.SA/44/D1-OGL/2009, dated June 2010 along with the copy of the Government Analyst Report No.1400/DCL/2010, dated 20.05.2010. After going through the Government Analyst Report, they found that the sample of Clanoxy-200, Batch No.CNSF90071B has been declared to be "Not of Standard Quality" for assay of Clavulanic Acid. Further, he stated that they have manufactured the drug, sold and distributed standard quality drug namely Clanoxy 200 Suspension and the findings of the Government Analyst can be attributed to error in testing or improper storage and do not take any action against them and similarly, the Authorized Signatory of A.1-firm sent a reply dated 26.07.2010 stating that the findings of the Government Analyst Report dated 20.05.2010 can be attributed to error in testing or improper storage and not to take any action against them.

10. In the light of the above reply, it is clear that the petitioner/A.2 has not exercised his valuable right under the provision of Sub-Section (4) of Section 25 of the Act by making a request to send the sample drug to the Central Drugs Laboratory to override the report of the State Analyst. Therefore, it cannot be said that they lost their valuable right. As such, the

report of the State Analyst is the conclusive evidence of the facts.

11. The learned counsel for the petitioner/A.2 has relied on **Sulochna Devi Vs. State of Bihar[1],** wherein, the High Court of Patna held as follows:

> *"8. The manufacturer M/s.Pravin Pharma have also appeared and filed counter affidavit wherein they have sought to support the case of the petitioner of their having received the consignment containing the drug on 8.2.2000 and selling the same to the Superintendent on 24.2.2000 and that it had remained with the retailer for only 16 days. They have also sought to raise question regarding the storage conditions both in the hospital as also in the office of the Drug Inspector where the medicines had been stored and of the possibility of the medicines having been lost its originality due to improper storage conditions.*
>
> *9. From the submissions advanced by the respective parties a few things are highlighted which requires serious consideration. Firstly, that the petitioner was never given an opportunity to explain her stand before initiation of the proceeding as has been given to the manufacturer, secondly, the sanction for prosecution had been obtained from the Drug Controller only with respect to the petitioner who was the mere retailer. Thirdly, there is no explanation for the delay of four months in sending the sample for analysis and fourthly the storage conditions in the hospital as also the office of the Drug Controller has not been stated and finally no report of the analysis was supplied to the petitioner. Since there are no satisfactory answers by the State and the Drug Inspector to all these questions raised apparently the complaint case as also the cognizance appears to be an abuse of the process of the Court and has to be quashed."*

12. The learned counsel for the petitioner/A.2 has relied on another decision in **M.V.Srinivasa Rao Vs. State of A.P. and Ors.,[2]** wherein, this Court held as follows:

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[1] 2008 SCC Online Pat 1307

> *"19. The Apex Court in the judgment in Medicamen Biotech Ltd. v. Rubina Bose, Drug Inspector MANU/SC/7327/2008 : 2009 (1) ALT (Crl.) 71 (SC) : (2008) 3 SCC (Crl.) 20 held that there is no explanation as to why the complaint itself had been filed about a month before expiry of shelf life of the drug and concededly filing of the complaint had nothing to do with the appearance of the accused in response to the notices which were to be issued by the Court after the complaint had been filed. Likewise, requests for retesting of drug had been made by the appellants in August/September, 2001 and there is absolutely no reason as to why the complaint could not have been filed earlier and the fourth sample sent for retesting well within time. Facts of the case suggest that the appellants have been deprived of a valuable right under Sections 25(3) and 25(4) of the Act, which must necessitate the quashing of the proceedings against them.*
>
> *20. The analogy of the aforesaid judgment squarely applies to the present facts of the case on hand. By the time, the State Analyst report was furnished to the accused, the shelf-life of the drug in question already expired long back. Therefore, the accused lost his valuable right conferred on him by the Statute under Section 25(3) and 25(4) of the Act to test the correctness or genuineness of the report of the State Analyst by Sending the Drug in question for test and analysis by the Central Drugs Laboratory. Ergo, the proceedings initiated against the accused in C.C. No.448 of 2011 on the file of the Additional Judicial Magistrate of First Class, Chirala, Prakasam District, stood vitiated and they are liable to be quashed."*

13. Having regard to the facts of the case and the material available on record, this Court is of the opinion that the decisions referred to *supra* relied on by the learned counsel for the petitioner/A.2 are not helpful to the case of the petitioner/A.2. A given set of facts are different from the facts of the above cases. In the instant case, the sample drug was expired by 03/2011. The petitioner/A.2 has not exercised his valuable right conferred under Section 25(4) of the Act with a

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[2] MANU/AP/0111/2019

request to send the sample drug to the Central Drugs Laboratory. The State Analyst Report was furnished to the accused in the month of June 2010. By that time, the shelf-life of the drug was not expired, and the present complaint was filed on 03.08.2011. Therefore, the petitioner/A.2 would not have lost his valuable right conferred on him by the Statute under Section 25(4) of the Act. Therefore, there is no merit in the contentions raised by the learned counsel for the petitioner/A.2.

14. Now, another contention of the learned counsel for the petitioner/A.2 is that the petitioner/A.2 is not responsible for the day-to-day affairs of A.1-firm and the complaint does not disclose the said fact. A perusal of the affidavit given by petitioner/A.2, dated 13.05.2008 along with the instructions, filed by the Drugs Inspector would show that "*the petitioner/A.2 JPN Singh is the Director of M/s.Galpha Laboratories Limited and he is responsible for the day-to-day affairs and conduct of business of M/s.Galpha Laboratories Limited for the purpose of Section 34 of the Drugs and Cosmetics Act, 1940 to which M/s.Galpha Laboratories Limited and its Directors etc., are held liable for any act of omission punishable under the Drugs and Cosmetics Act, 1940……".*

15. In view of the affidavit given by the petitioner/A.2, it is clear that he was the Director of A.1-firm and responsible for the day-to-day affairs of A.1-firm. Therefore, there is no force in the contentions raised by the learned counsel for the petitioner/A.2 that he is nothing to do with the affairs of the A.1-firm.

16. Learned Assistant Public Prosecutor relied on a decision in **Parenteral Surgicals Ltd., M.P. and others Vs. State of A.P.,**[3] wherein, this Court held at Para No.7 as follows:

> *"7. By reading clause (4) of Section 25, what this court can understand is that the pre-condition for sending the sample for second analysis is what is said under clause (3) of Section 25, which is that the person receiving the copy of the report has to notify in writing to the Inspector or the court, that he intends to adduce evidence in contraversion of the report. In this case, after receiving the report copy, the petitioners have sent an intimation to the complainant, which is dated 9-7-2011. A reading of the copy of the said letter filed before this court shows that the petitioners have only explained the reason for the contamination, which resulted in the report coming out with the finding that the sample is contaminated, stating that it might be only due to invisible damage to bottles in transit or storage. It does not anywhere question the analyst report, either with regard to the genuineness or with regard to the correctness. When there is no attack made on the report on the said aspects, the report stands to be conclusive. As specified in Section 25(3) of the Act, no intention to adduce evidence in contraversion of the report can be gathered from a letter, which explains only the reason for the report coming out in the negative. The letter, unless it specifies, either impliedly or expressly, that the petitioners intend to adduce evidence in contraversion of the report, cannot be construed as a notification made in compliance of Section 25(3), that he intends to adduce evidence in contraversion of the report. When no such intention can be gathered by the court, the obligation laid on the court to send the sample on its own or*

[3] 2019 (2) ALT (Crl.) 329 (AP)

at the request of the complainant or the accused, for second sampling, does not come into operation."

17. The above-said decision is squarely applicable to the present set of facts. The petitioner/A.2 cannot be compelled to disclose the grounds on which he seeks to controvert the report. The burden of proof that the option was exercised within the prescribed period of 28 days, is on the petitioner/A.2 which assails a report of consequences of failure to exercise the option within time, and the report becomes conclusive. The criminal proceedings initiated under the Act cannot be challenged on the ground of filing of complaint after the expiry of the shelf-life of the drug. *Prima facie* from the complaint, it appears that the Drug Inspector sent the report of the State Analyst, dated 20.05.20 to the petitioner/A.2 within the time but the petitioner/A.2 did not file any application for re-analysis of the drugs within the time by availing Sections 25(3) & (4) of the Act, to the Director of the Central Drugs Laboratory, Calcutta, instead, he sent a reply not to take any action against them.

18. It is relevant to refer to the decision of the Hon'ble Apex Court in **State of Haryana Vs. Brij Lal Mittal and others**[4], wherein, at Para No.7, it was held as follows:

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[4] (1998) 5 SCC 343

> "*7……. The delay in filing the complaint till the expiry of the shelf-life of the drugs could not, therefore, have been made a ground by the High Court to quash the prosecution. It will not be out of place to mention that the manufacturers' right under sub-section (3) expired four months before the expiry of the shelf-life of the drugs. In view of the above discussion, the reasoning of the High Court for quashing the prosecution against the three respondents cannot at all be sustained.*

19. In the instant case, there is no apparent basis to conclude that the Government Analyst Report ought to be excluded from consideration without being tested at trial. Whether the petitioner's right to get the sample in question retested, is defeated or not, is a moot question that cannot be answered at this stage as the petitioner's/A.2's correspondence, as stated above, is, in fact, the defence of the petitioner/A.2 which is refuted and is thus, required to be tested at trial. Thus, there is no basis for this Court to opine at this initial stage of these criminal proceedings that the Government Analyst's Report must be outrightly rejected or the petitioner's statutory right to get the sample in question re-tested stands violated justifying the quashing of the proceedings arising out of the complaint.

20. Therefore, upon considering the entire material and for the reasons above stated and after following the principles of law, this Court does not find any abuse of process of the Court in continuation of the criminal proceedings against the

petitioner/A.2. Therefore, the criminal petition is liable to be dismissed.

21. Resultantly, the criminal petition seeking quashing of the proceedings in C.C.No.405 of 2012 on the file of the Court of II Additional Munsif Magistrate, Ongole, lacks merit and stands dismissed.

However, the petitioner/A.2 is at liberty to raise all the contentions before the trial Court at the time of trial. All the contentions of the parties on merits are left open. It is made clear that none of the observations contained herein shall have bearing on the trial of the main case and the trial Court shall independently arrive at its conclusion based on the material on record and the evidence rendered before it.

As a sequel, the miscellaneous petitions, pending if any, shall stand disposed of.

JUSTICE DUPPALA VENKATA RAMANA

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HON'BLE SRI JUSTICE DUPPALA VENKATA RAMANA

CRIMINAL PETITION No.13022 OF 2014

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