IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on : 11.04.2017

Pronounced on : 21.04.2017

Coram

THE HONOURABLE Mr. JUSTICE M.VENUGOPAL

Crl.O.P.No.27614 of 2016 in
Crl.A.Sr.No.40728 of 2016

State rep. By
The Public Prosecutor,
High Court, Madras - 600 104.
(Drugs Inspector, Salem-I Range,
Office of the Asst. Director of Drugs,
Salem - 5.) ... Petitioner/Appellant/Complainant

V.

1.M/s.Alfred Berg & Co. (I) Pvt. Ltd.,
No.C-28, SIDCO Pharmaceutical Complex,
Alathur, Chennai - 603 110.

2.Thiru.Kamlesh Jain,
S/o. Kanthilal Jain,
The Director cum Person-in-charge
of Day to Day Business,
No.C-28, SIDCO Pharmaceutical Complex,
Alathur, Chennai - 603 110. ... Respondents/Accused

Prayer: Petition filed under Section 378(3) of the Criminal Procedure Code, praying to grant leave to file the appeal against the Judgment of the acquittal of the Respondents/Accused (A1 & A2) passed by the Court of the Judicial Magistrate No.III, Salem in C.C.No.347/ 2016, dated 29.02.2016.

For Appellant : Mr.K.Madhan
Government Advocate (Crl. Side)

For Respondents: M/s.R.Anitha

ORDER

Preface:

The Petitioner/Appellant/Complainant has preferred the instant Criminal Original Petition praying for 'Grant of Special Leave' to prefer an Criminal Appeal in Sr.No.40728 of 2016 before this Court as against the Judgment of Acquittal passed by the Learned Judicial Magistrate No.III, Salem in C.C.No.347 of 2006 dated 29.02.2016.

2.The trial Court, while passing the impugned Judgment in C.C.No.347 of 2006, on 29.02.2016, at paragraph 13, had, among other things, observed the following:

> "... In the present case, the accused in view of the provisions of sub-section (3) of section 25, informed the complainant within 28 days from the date of receipt of the report his intention to adduce evidence in controversion of the said report of the Government Analyst. However, because of the failure on the part of the complainant to take prompt appropriate steps in this regard, the petitioner was deprived of his valuable statutory right which has affected the prosecution adversely.
>
> In the instant case, the Drug Inspector, inspite of the receipt of the intimation from the complainant company on 13.12.2004, did not do anything at all and allowed it to lapse which ultimately resulted in denial of opportunity to the petitioners for getting the part of the sample of the drug re-analysed from the Central Drugs Laboratory, Calcutta which, in fact, has further resulted in depriving the petitioners from exercising their valuable statutory right which, goes to the root of the matter and adversely affects the prosecution. It is no doubt true that the report of the Government Analyst continues to be the evidence in a case of the facts contained therein. However, the right of the accused to get the sample analysed from the Central Drugs Laboratory, Calcutta is a valuable right since the certificate of Central Drugs Laboratory supersedes the report of the Government Analyst and is treated as conclusive evidence of its contents."

and consequently held that because of the expiry of the life period of the product or because of the failure of the Complainant to take measures to send the sample for retesting well within time, the valuable right of the Accused (Respondents) to prove his innocence was lost and ultimately, dismissed the Complaint as not maintainable and dismissed the same, thereby acquitting the Respondents/Accused under Section 248(1) Cr.P.C.

Petitioner's Submissions:

3.The Learned Government (Crl. Side) for the Petitioner/ Appellant/State contends that the Respondents/Accused, in their letter dated 08.10.2004 submitted to the Director of Drugs Control, had stated that they would make arrangement as per Law to send their portion of the sample for analysis to Central Drugs Laboratory, Calcutta.

4.It is represented on behalf of the Petitioner/Appellant/ Complainant that the trial Court should have appreciated the fact that the Respondents (Accused) had not at all denied the receipt of the Show Cause Memo dated 24.09.2004 and further they had not replied to P.W.1 vide letter dated 13.12.2004 for the Show Cause Memo and the reminder dated 07.12.2004 sent by P.W.1.

5.Proceeding further, the Learned Government (Crl. Side) for the Petitioner/Appellant projects an argument that the trial Court should have taken into account an important fact that the Respondents/Accused had adduced the Test Report of the Government Analyst in Form - 13 only under his letter dated 13.12.2004 sent to P.W.1 and the said letter was received by P.W.1 on 24.12.2004. Therefore, it is the stand of the Petitioner/Appellant that the Petitioner/Appellant had failed to controvert the Government Analyst Report within 28 days and controverted the Report of the Government Analyst pertaining to the present case after 90 days of the receipt of the memo issued by P.W.1. As such, a plea is taken by the Petitioner/Appellant that the Respondents/ Accused had lost their rights in this regard.

6.The Learned Government Advocate (Crl. Side) for the Petitioner/Appellant emphatically submits that the Government Analyst, Drugs Testing Laboratory in Form - 13 dated 08.07.2004 is a conclusive evidence in the subject matter in issue. Further, the Respondent/Accused had submitted a reply to the Director of Drugs Control, Chennai dated 08.10.2004 and marked only a copy to P.W.1.

7.The Learned Government Advocate (Crl. Side) for the Petitioner/Appellant contends that the trial Court had committed an error by giving benefit to the Respondents/Accused and acquitted them, which is not correct per se in the eye of Law.

Respondents' Pleas:

8.In response, the Learned Counsel for the Respondents/ Accused submits that for the Show Cause Notice issued by the Director of Drugs Control dated 03.09.2004 which was received by the Respondents on 01.10.2004, the Respondents/Accused had issued a reply dated 08.10.2004 whereby they had disagreed with the Test Report of the Government Analyst, Drugs Testing Laboratory, Chennai and expressed their willingness to have the sample tested at CDRL, Calcutta as enshrined under Section 25(3) & (4) of the Drugs and Cosmetics Act, 1940.

9.The Learned Counsel for the Respondents brings it to the notice of this Court that the Respondents had expressed their willingness to have the drug tested in CDRL, Calcutta within 25 days from the date of receipt of Show Cause Notice and further, the Petitioner/Appellant had filed the Complaint, the shelf life of the drug had expired and that the Respondents/Accused had lost their valuable right as per Section 25(3)&(4) of the Drugs and Cosmetics Act, 1940 to have the drug tested in CDRL, Calcutta.

10.Moreover, it is the stand to the Respondents that the lower Court had dismissed the Complaint filed by the Petitioner/Appellant in C.C.No.347 of 2006 dated 29.02.2016 and in fact, the Petitioner to cover up the lapses had sought the 'Grant of Special Leave', before this Court by filing the instant Criminal Original Petition which is to be dismissed in limini.

11.The Learned Counsel for the Respondents draws the attention of this Court to the fact that the expiry date of the tablet was in the year 2005 and that the sanction to prosecute the Respondents/Accused was obtained only on 01.09.2006 for reasons best known to the Petitioner.

12.It is projected on the side of the Respondents/Accused that the trial Court had analysed the pros and cons of the oral evidence of witnesses on the side of the Prosecution and looked into the relevant Exs.P1 to P18 and also the M.O.1 and came to a resultant conclusion that because of the expiry of the life period of the product (tablet) or because of the failure of the Complainant (Petitioner/Appellant) to take measures to send the samples for retesting well within the time, the Respondents/Accused had lost their accrued valuable rights to prove their innocence and dismissed the Complaint by acquitting the Respondents/Accused which does not require any interference in the hands of this Court at this distance point of time.

13.The Learned Counsel for the Respondents/Accused to lend support to the proposition that the Respondents/Accused had lost their rights under Section 25(3) of the Drugs and Cosmetics Act,

1940 and Section 25(4) of the Act, because of the delay in filing the Complaint and therefore, the Complaint of the Petitioner/Appellant before the trial Court in C.C.No.347 of 2006 is to be quashed, cites the decision of the Hon'ble Supreme Court in Medicamen Biotech Limited and another V. Rubina Bose, Drug Inspector, (2008) 7 SCC 196, wherein it is held as under:

> "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 the 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 complaint had been filed. Likewise, requests for retesting of drug had been made by the appellant in August/September 2001 and there is absolutely no reason as to why complaint could not have been filed earlier and 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 quashing of proceedings against them."

Petitioner's Reply:

14.By means of reply, the Learned Government Advocate (Crl. Side) for the Petitioner/Appellant contends that after completion of the detailed investigation based on the Report of the Government Analyst, necessary sanction order was obtained from the Directorate under R.Dis.No.11633/IW2/2004[54], dated 09.08.2006 which is a mandatory one and in fact, the Complaint filed before the trial Court by the then Drugs Inspector, Salem for the contravention of Section 18(a)(i) of the Drugs and Cosmetics Act, 1940 by the Respondents/ Accused, which was taken on file in C.C.No.347 of 2006.

15.The Learned Government Advocate (Crl. Side) for the Petitioner/Appellant/State submits that P.W.1 had strictly followed the mandatory provisions of the sampling procedure under Section 23 r/w Rule 57(2) of the Drugs and Cosmetics Rules, 1945 while drawing sample. Added further, it is the categorical stand of the Petitioner/Appellant that the Respondents/Accused had not at all denied the receipt of Show Cause Memo dated 24.09.2004 of the then Drugs Inspector, Salem and that they had not replied to the aforesaid Show Cause Notice and therefore, reminder for the said Show Cause Notice was issued on 07.12.2004 and that the Respondents/Accused had replied on 13.12.2004 and in that Reply, they had not denied the substandard drugs [vide Test Report No.03993-D/2003-04, dated 08.07.2004 of the Government Analyst], but they denied the

spurious drugs as per Ref. No. Test Report No.00798-D/2004-2005, dated 08.09.2004 of the Government Analyst, Chennai.

16.The core contention advanced on behalf of the Petitioner/ Appellant is that the Respondents/Accused had failed to controvert the Report of the Government Analyst within 28 days, within the limitation period and questioned the Report of the Government Analyst in the present case after 90 days of the receipt of the Memo issued by P.W.1. Therefore, it is the stand of the Petitioner/ Appellant that the Respondents/Accused had lost their rights under Section 23(3) of the Drugs and Cosmetics Act and that the Report of the Government Analyst, Drugs Testing Laboratory in Form – 13 vide Ref. No.03993-D/2003-04, dated 08.07.2004 is the conclusive evidence.

Narration of Evidence of P.W.1 to P.W.3:

17.Before the trial Court, in the main case, P.W.1 (serving as Salem Circle Medical Inspector in 2004) had deposed that on 23.03.2004 he went to the Government Mohan Kumaramangalam Medical College Hospitals and Medical Stores and Enalapril Maleate Tablets measuring I.P. 2.5. mg., and that the manufacture date was October 2003 and the expiry date of the tablet was September 2005 and further that the name of the Manufacturer Alferd Berg & Company India Private Limited Alathur, Chennai and he separated the 200 Tablets into four portions and keeping each 50 tablets in a cardboard box and closed the same by tying with thread on four sides and sealed the same and gave a Sample No.GS/S.L.M.1/20/ 2004 dated 23.03.2004. In the said four boxes, he had affixed his signature and also obtained the signature of the Chief Druggists of the Pharmaceutical Depot and after taking the tablets for the purpose of analysis in Form 17 and later on 23.03.2004 he prepared Form 18 for sending the tablets along with a portion of a sample to the Chennai Government Analyst and sent the same through parcel and that Ex.P3 was Form 18 and as per the Government Analyst Report dated 08.07.2004, the aforesaid I.P. Standard was a substandard one.

18.Further, it is the evidence of P.W.1 that the important missing component in Enalapril Maleate was found at 1.67 mg. instead of 2.5 mg. and it was at 66.8% and the said Report Ex.P4 was received on 15.07.2004 and later, he sent a registered notice to the Medical Store of the Mohan Kumaramangalam Medical College Hospital on 16.07.2004 for asking details from whom the aforesaid tablets/medicine were purchased and also sent a Report – Ex.P5 to the Hospital and on 21.07.2004 a reply was sent that the medicines were purchased from TNMC, Salem Government Firm which was received on 09.08.2004 and the explanation letter of the Pharmaceutical Officer was Ex.P6 and he issued Ex.P7 – Notice to the in-charge of the Medical Store of the Hospital

calling for explanation as to the receipt of the tablets and that the Tamil Nadu Medical Service Corporation Limited gave a reply on 04.09.2004 stating that the Tablets (North Arcot District at Vellore) was received through TNMC Firm and the said reply letter with enclosures was Ex.P8 (series) and Ex.P9 was the letter asking for explanation for the purchase of medicines for the North Arcot District TMLC Firm under Section 18(a) viz., Ex.P9 and that Ex.P10 was the reply dated 17.09.2004 from the Vellore TMLC to the effect that the aforesaid tablets were received through Delivery Challan 1071 dated 30.09.2004 from the Manufacturer Alfred Berg Company India Private Limited and a Show Cause Notice was issued on 24.09.2004 to the Manufacturer of the Tablets as to why action should not be taken under Section 18(a)(1) of the Drugs and Cosmetics Act for manufacturing a substandard drugs and also sought certain details like the firms medicines manufacturing licence, copies of registers and the medicine, tablets, the Analyst Report and on 28.10.2004 as per Section 23(4) (111) of the Drugs and Cosmetics Act, he sent one sample (third portion) to the said Firm through Registered Parcel - Ex.P12 and since no reply was replied, he issued a reminder - Ex.P13 on 07.12.2004 and the said Company/Firm issued an explanation for his Memo Notice dated 24.09. 2004 by stating that they were not accepting the Government Analyst Report and for sending another portion of the tablet for the purpose of obtaining Analyst Report from the Kolkatta Central Drugs Laboratory, they had informed that they were take necessary steps for sending the samples to the Central Drug Laboratory and Ex.P14 (series) - Letter together with enclosures.

19.It is the further evidence of P.W.1 that the 1st Respondent /A1 had not taken any steps through the trial Court or any other Court for resending the Analyst Report to the Central Drugs Laboratory and that the aforesaid Enalapril Maleate drug percentage was 66.8% and that for proceeding against the Respondents/ Accused Ex.P16 – Letter was sent by him to the Director of Drugs Control, Chennai and out of the four portions which he took for sample, the 4th portion viz., M.O.1 is producing by him before the Court and that the further proceedings of the case was undertaken by one Kunasekaran.

20.It is the evidence of P.W.1 (in cross examination) that on 28.10.2004 one portion of the sample drug taken, was sent to the Manufacturer as per Section 23(4)(3) of the Drugs and Cosmetics Act and further that, a reminder was sent on 07.12.2004 and that on 23.03.2004 he had taken the drugs for sample and on that day itself he had sent the same which was received by the Government Analyst on 29.03.2004 and that the Analyst Report dated 08.07.2004 was received by them on 14.07.2004 and that the expiry date of the drug sent for examination was September 2005 and that during March 2006 he got

transferred and till such time, Sanction Order was not received.

21.P.W.2 in his evidence had deposed that when he was working as Drugs Inspector, he received a Sanction Order on 01.09.2006 from the Director of Drugs Control to file a case against the Manufacturer of the Drugs and its Managing Director Kamlesh Jain (R1 and R2) and that the said Sanction Order was Ex.P17.

22.P.W.3 in his evidence had deposed that he retired in the year 2005 after serving as Government Analyst at the Medical Store and on 29.03.2004 he received a letter together with 18 Enalapril Maleate sample through Tapal from P.W.1 (Selvaraj) for the purpose of carrying out investigation and that the drugs sample name, batch name, manufacturing date, expiry date, manufacturer detail and his address were compared with the letter given by P.W.1 and that the sample tablet was properly kept under custody from the date of receipt of the same at the Laboratory till the carrying out of examination and that the details given over the sample (given by the manufacturer) (i) Enalapril Maleate Tablets I.P. 2.5 mg., B.No.3871003-M and the manufacturing date was October 2003 and the expiry date was September 2005. Further, the address of the Manufacturer was given as M/s.Alfred Berg & Company (I) Private Limited, No.C-28, SIDCO Pharmaceutical Complex, Alathur, Chennai – 603 110 and over the sample tablet, it was mentioned as Tamil Nadu Government Supply.

23.P.W.3 adds in his evidence that in the examination/ analysis, it was found out that in each tablets, Enalapril Maleate was only at 1.6 mg. and as per Table, in every tablet should contain 2.5 mg. Enalapril Maleate and the said Enalapril Maleate Drug in each Tablet should be at the level of 2.25 mg. to 2.75 mg. But, in the said tablet/drug, 1.67 mg., viz., 66.8% Enalapril Maleate alone was found and his Analyst Report was Ex.P18 and his Analyst Report dated 08.07.2004 was issued by him and the same was sent to the Drugs Inspector through Tapal and in fact, a Report was given as one of 'NOT OF STANDARD QUALITY' in Form – 13, Report No.3993 – D/2003/ 04.

24.P.W.3 proceeds to state in his evidence that if there was any objection to their Report within 28 days from the date of the Government Analyst Report, the Report could be obtained by sending the sample to the Central Drugs Laboratory at Kolkatta and in this regard, the concerned person has a right and it was correct to state that before expiry of the tablet period for carrying out Analyst Report, the tablet could be sent to the Central Drugs Laboratory.

Act's Purpose:

25.At the outset, this Court pertinently points out that the prime object of the Act is to prevent sub-standards in drugs, presumably for maintaining high standards of medical treatment. As a matter of fact, that would certainly be defeated if the necessary concomitants of medical or surgical treatment were allowed to be diluted: the very same evil which the Act intends to eradicate would continue to subsist, as per decision of the Hon'ble Supreme Court in Chimanlal Jagjivandas Sheth V. State of Maharashtra, AIR 1963 SC 665.

26.The main object of Drugs and Cosmetics Act, 1940 and the Rules made thereunder is to regulate manufacture of drugs to maintain standard or quality drugs for sale and distribution as a drug, as per decision Medley Pharmaceuticals Limited V. Commissioner of Central Excise and Customs, Daman, (2011) 2 SCC 601. Further, the Drugs Act, 1940 was enacted to regulate import, manufacture, distribution and sale of drugs and cosmetics, as per decision State of Bihar V. Shree Baidyanaath Ayurved Bhawan (P) Ltd., (2005) 2 SCC 762.

27.In reality, the Drugs and Cosmetics Act, 1940 is a pre-constitutional Act. The Legislature of all provinces passed a resolution in terms of Section 103 of the Government of India Act, 1935 to regulate import, manufacture, distribution and sale of Drugs and Cosmetics, as per decision Director of Drugs Control V. Pijush Kanti Ghosh, (2006) 1 Calcutta Head Notes 172.

Analysis:

28.It is not in dispute that a Show Cause Notice dated 24.09.2004 was addressed to the M/s Alfred Berg & Co. (India) Pvt. Ltd., No.1, Hunters Road, P.B. No.3529 Choolai, Chennai - 600 112 by the Drugs Inspector, Salem-I Range, inter alia, stating as under:

> '.... On investigation M/s T.N.M.S.C., Ltd., Vellore disclosed vide there letter dated 17.9.04 that the acquired said drug from Alfred Berg & C., (India) Pvt. Ltd. No. Hunters Road, Choolai, Chennai under delivery Challan No.1071 dated 31.10.2003.
>
> Hence M/s Alfred Berg & Co., (India) Pvt. Ltd., are hereby directed show cause why action should not be taken against them for the contravention of Section 18(a)(i) of the Drugs and Cosmetics Act, 1940 for having been manufactured and sold a NOT OF STANDARD QUALITY drug, namely Enalapril Maleate Tablets I.P. 2.5 mg., B.No.3871003.

Further they are directed to furnish a following records to the undersigned along with their explanation.

1) Copy of the drug licence along with endorsement for the said product.
2) Copy of the memorandum of article.
3) Name, Age, Fathers name and residential address of the all the directors.
4) Name and address of the person who is responsible for day-to-day business.
5) Total quantity manufactured and it's distribution details.
6) Copy of Batch manufacturing record.
7) Copy of the test reports of all the raw materials used and finished products.
8) Balance quantity of drugs if any.

Further they are directed not to dispose the balance quantity of the drugs if any until further orders.'

and sought their explanation and particulars within 5 days from the date of receipt of memo and further, it was informed that the 3rd portion of the sealed sample would be sent separately.

29.It comes to be known that the 1st Respondent/A1 viz., M/s.Alfred Berg & Co. (I) Pvt. Ltd., by means of letter dated 08.10.2004, addressed to the Director of Drugs Control, Chennai – 600 006, had observed as follows:

".. Firstly, please be informed that your letter No.015321/1W73/NSQ-234-04-05 dt. 16.9.04 says that the said product is spurious because it contains 23.2% of Enalapril Maleate and balance other substances. The Govt. Analyst repot in Form 13 bearing No.00758-D/2004-05 has declared as spurious stating that it contains starch and Dicalcium Phosphate. It says firstly that it is "Not of standard quality" and subsequently says it is "spurious".

Now the same batch has been analysed by the same Govt. Analyst and issued the report no.03993-D/2003-04 in Form 13. In this report they have stated that the product contains 66.8% of Enalapril Maleate and declared "Not of standard quality" in respect of assay.

The same batch has been analysed by the same Govt. Analyst and issued another report bearing no.03284-D/2003-04 in Form 13. In this report they state that the product contains 69.02% of Enalapril maleate and declared "Not of standard Quality" in respect of Assay.

Similarly the Govt. Analyst has tested the same product but of different batch no. It may be seen that all the reports in Form 13 are not consistent. Every test report is different from others.

Finally in the report no.00798-D/2004-05 filmsy tests are carried for starch and Dicalcium Phosphate) and superceded her authority by declaring the product "Not of Standard" as well as "spurious". The Drugs & Cosmetic Act has clearly defined "Standard of quality" under Section 16 and "Spurious Drugs" under Section 17 B.

It is universal act that starch and Dicalcum Phosphate is used in most of the tablets as excepients without which it is difficult to compress the tablets. We firstly firmly disagree and wish to contest the declaration of the product "Spurious"

We give the details as required by you.

1.We have recalled the available stock of this batch with TNMSC.

2.Stock in hand is nil and we have not received any stock till now.

3.The full quantity is sold to TNMSC.

4.The photocopy of analytical report of finished product is enclosed.

5.The Batch size is 20 lacs. The date of Manufacturing is Oct 2003 and Date of Expiry is September 2005. The product was released on 29.06.04.

We further inform you that we disagree with the test result of the Govt. Analyst and hence decided to contest the same. We are making arrangement as per Law to send our portion of the sample for analysis to Central Drugs Laboratory, Kolkatta. Please bear with us till then and oblige."

30.In fact, on 13.12.2004, the 1st Respondent/Company, had, inter alia, stated as under:

"... Further be informed that we are not accepting the test result of the Govt. Analyst. The same batch had been analysed by the same Govt. Analyst the samples of which were received from different Drugs Inspector. We are in the process of filing a petition in the court of law to send one portion of sample to CDRL, Kolkatta as per the provision in Drugs & Cosmetics Act & Rules. We will keep you informed as soon as the report is received from

CDRL, Kolkatta. We also apologise for delay in reply because we though that the copy of our letter dt. 8.10.2004 will be answering your queries in Show Cause Notice. Please bear with us and oblige."

31.It appears that on 29.12.2004, the Drugs Inspector, Salem I Range had addressed a communication to the Director of Drugs Control, Tamil Nadu, Chennai - 6, seeking permission to prosecute the Respondents/Accused for the contravention of Section 18(a)(i) of the Drugs and Cosmetics Act, 1940 for having manufactured and sold a Not Of Standard Quality Drug, Enalapril Maleate Tablets I.P., B.No.3871003, which is punishable under Section 27(d) of the Drugs and Cosmetics Act, 1940. The Director of Drugs Control, Chennai through letter dated 09.08.2006 addressed to the Drugs Inspector, Salem I Range had accorded sanction to him to prosecute - (i)The Firm M/s Alfred Berg & Co. (I) Pvt. Ltd., C.28, Sidco Pharmaceutical Complex, Alathur 603 110 represented by its Director Kamlesh Jain, (ii) Kamlesh Jain, the Director cum person in charge of day to day business of M/s Alfred Berg & Co.(I) Ltd., Alathur 603 100. In fact, the Petitioner/Appellant/State represented by Drugs Inspector, Salem I Range had filed a Complaint under Section 32 of the Drugs and Cosmetics Act, 1940 for the offences under Section 18(a)(i) of the Drugs and Cosmetics Act, 1940 punishable under Section 27(D) of the said Act against the Accused for having manufactured a Not of Standard Quality Drug Enalapril Maleate Tablets I.P. Batch No.3871003.

32.It is to be borne in mind that Section 18(a)(i) under the caption 'Prohibition of manufacture and sale of certain drugs and cosmetics' deals as under:

"18.From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf -

(a){Substituted by Act 68 of 1982, S.14 for certain words (w.e.f. 1-2-1983)} [manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,] or distribute -

{Substituted by Act 68 of 1982, for Cls. (i), (ii) and (ii-a) (w.e.f. 1.2.1983)} [(i) any drug which is not a standard quality, or is misbranded, adulterated or spurious;"

33.Section 18-A of the Drugs and Cosmetics Act, 1940 refers to 'Disclosure of the name of the manufacturer', etc. Section 19 of the Act speaks of 'Pleas'. Section 20 of the Act mentions 'Government Analysts'. Section 22 of the Act relates to 'Powers to Inspectors'. Section 24 of the Act pertains to 'Persons bound

to disclose place where drugs or cosmetics are manufactured or kept'. Section 25 of the Drugs and Cosmetics Act, 1940 refers to 'Reports to Government Analysts'.

34.Indeed, Rule 44 of the Drugs and Cosmetics Rules, 1945 speaks of 'Qualifications of Government Analyst'. Rule 45 deals with 'Duties of Government Analysts'. Rule 46 pertains to 'Procedure on receipt of sample'. Rule 47 relates to 'Report of result of test or analysis'. Rule 56 refers to 'Form of intimation of purpose of taking samples'. Rule 57 deals with 'Procedure for despatch of sample to Government Analyst'.

35.As a matter of fact, the conclusiveness mentioned in Section 25(3) of the Drugs and Cosmetics Act is to be read in juxtaposition with the individuals referred to in the sub-section. To put it differently, if any of the individuals who receives a copy of the Report of the Government Analyst fails to notify his intention to adduce evidence in controversion of the facts mentioned in the report within a period of 28 days of the receipt of the notice, then, such report of the Government Analyst could become conclusive evidence regarding the facts stated therein as against such individuals. However, in respect of an Accused like the Manufacturer, who is not entitled to be supplied with a copy of the Report of the Government Analyst, he should have the liberty to challenge the correctness of the facts stated in the report by resorting to any other modes by which such facts can be disproved. He is also entitled to avail the remedy mentioned in sub-section (4) of Section 25 of the Act by making a request before the Court to send the other portion of the sample remaining in the Court to be tested at the Central Drugs Laboratory.

36.It is to be remembered that a Court of Law is not under compulsion to send the sample to be tested in case if the request is made after an inordinate delay. It is only for that purpose that a discretion has been conferred on a Court of Law to decide whether such sample should be sent to the Central Drugs Laboratory on the basis of request. Once the sample is tested at the Central Drugs Laboratory and a report as per Section 25(4) of the Act is filed into Court, the conclusiveness mentioned in that sub-section would become incontrovertible one, as per decision of the Hon'ble Supreme Court in Amery Pharmaceuticals V. State of Rejesthan, reported in AIR 2001 S.C. 1303.

37.At this juncture, a mere running of the eye over the ingredients of Section 25(3) of the Act unerringly points out that within 28 days of the receipt of the copy of the Government Analyst Report, a person whom the sample was taken is to notify in writing to 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.

38.It cannot be brushed aside that the procedure under sub-section (2) to (4) of Section 25 is available only to the person from whom the sample is taken or to the person whose name is disclosed under Section 18-A of the Drugs and Cosmetics Act, 1940. Despite a service of copy of Analyst Report, if the Manufacturer had not notified the Inspector within the specified period that he intended to adduce evidence in controversion of the Report, then, his right to get the sample tested by the Central Drugs Laboratory, Kolkatta gets extinguished, the Report of the Analyst would become a conclusive evidence.

39.It is to be relevantly mentioned that the onus of proof viz., an option to controvert Report of Government Analyst is to be exercised within the period of 28 days is on an individual who questions the report. Indeed, the report becomes conclusive and criminal proceedings initiated under the Drugs and Cosmetics Act, 1940 cannot be challenged on the basis of delay even though the expiry date of drug had gone by in the meantime, as per decision of the Hon'ble Supreme Court in Glaxosmithkline Pharmaceuticals Limited and another V. State of Madhya Pradesh, (2011) 13 Supreme Court Cases 72.

A Panoramic View of Case Laws:

40.It is to be pointed out that the entire quantity or atleast sufficient quantity should be sent for analysis as per decision of the Hon'ble Supreme Court in Gauntar Edwin Kircher V. State of Goa, Secretariat Panaji Goa, 1993 3 SCC 145.

41.As a matter of fact, under the Drugs and Cosmetics Act, a search or seizure by a Drugs Inspector is equated to a search or seizure under the authority of a warrant. It is not necessary for a Drugs Inspector to record his reasons for carrying out a search, as per decision Public Prosecutor V. Mahaveer Pd, 1972 CRI.L.J, 1546 (AP).

42.At this stage, this Court worth recalls and recollects the decision of the Hon'ble Supreme Court in Ram Shankar Mistra V. State of U.P., (1980) 1 Supreme Court Cases 255, wherein it is held as under:

> "The words 'unless sample has been tested or analysed in the Central Drugs Laboratory' with which Section 25(4) starts, clearly indicate that the provision under Section 25 (4) for sending it to the Director of Central Drugs Laboratory, the other one being sending it direct to the Government Analyst and the Director as contemplated under the first part of Section 25(1). Therefore, there is no

prohibition under the Act or the Rules barring the Inspector from sending the sample direct to the Director."

43.Also, this Court aptly points out the decision of the Hon'ble Supreme Court in T.A.Krishnaswamy V. State of Madras reported in AIR 1966 Supreme Court 1022, whereby and whereunder, it is observed and held as under:

"Rule 46 of the Rules mad under the Act and Form 13 contemplate analysis and test as two different things for otherwise both words would not have been mentioned, nor the word "or" been put between them. It is true that the rule and form require the protocols of a test should be stated but they do not require any protocols to be stated in the report of an analysis.

Thus where the Government analyst carried out only an analysis to find out the quantities in which components were contained in drug and gave only result of analysis without standing protocols of test, it was held that the report was in the prescribed form and was fully admissible in evidence. Even if the sample was sent to him both for test and analysis, the failure of the analyst to carry out the test would not prevent the report of the result of the analysis from being admitted in evidence."

44.Apart from the above, this Court relevantly quotes the decision in M/s.Zim Laboratories, Bombay and others V. State of Maharashtra, 1999 CRI.L.J. 2903 at special page 2907 at paragraphs 18 & 19, it is laid down as follows:

"18. In the present case, the petitioner-accused in view of the provisions of sub-section (3) of section 25, informed the complainant within 28 days from the date of receipt of the report his intention to adduce evidence in controversion of the said report of the Government Analyst. However, because of the failure on the part of the complainant to take prompt appropriate steps in this regard, the petitioner was deprived of his valuable statutory right which has affected the prosecution adversely.

19. In the instant case, the Drug Inspector inspite of the receipt of the intimation from the petitioner Company 011 18-6-1994, did not do anything at all and allowed the time to lapse which ultimately resulted in denial of

opportunity to the petitioners for getting the part of the sample of the drug re-analysed from the Central Drugs Laboratory, Calcutta which, in fact, has further resulted in depriving the petitioners from exercising their valuable statutory right which, in my opinion, goes to the root of the matter and adversely affects the prosecution. It is no doubt true that the report of the Government Analyst continues to be the evidence in a case of the facts contained therein. However, the right of the accused to get the sample analysed from the Central Drugs Laboratory, Calcutta is a valuable right since the certificate of Central Drugs Laboratory supersedes the report of the Government Analyst and is treated as conclusive evidence of its contents. In that view of the matter, in my opinion, the impugned order is not just and proper and the same is devoid of substance and misconceived."

45.Moreover, in the decision State of Haryana V. Brij Lal Mittal and others, (1998) 5 Supreme Court Cases 343 at special page 344, it is observed as follows:

"The right to get the sample examined by the Central Drugs Laboratory through the Court before which the prosecution is launched arises only after the person concerned notifies in writing the Inspector or the Court concerned (here the latter clause did not apply for the prosecution was set to be initiated) within twenty eight days from the receipt of the copy of the report of the Government Analyst that he intends to adduce evidence in controversion of the report. The complaint and its accompaniments (which include correspondences that took place the Inspector and the manufacturers) clearly disclose that on February 19, 1991 the Inspector served the original copies of the Analyst's report upon the Managing Director of the manufacturers along with two letters asking for their comments. They further disclose that receiving no reply from the manufacturers the Inspector again wrote a letter on March 6, 1991 directing them to reply to his letters dated February 19, 1991 and asked whether they wanted to take benefit of the provisions of Section 25(3) of the Act. Inspite thereof the manufacturers did

> not exercise their right (much less within 28 days from the date of the receipt of the report of the Government Analyst i.e. February 19, 1991); and, on the contrary, in their letter dated April 8, 1991 annexed to the complaint), sent in response to the letter dated March 6, 1991, asserted, that their quality control department examined and tested samples of the two drugs and found that they complied with the test of sterility. It must, therefore, be said that consequent upon their failure to notify the Inspector that they intended to adduce evidence in controversion of the report within 28 day, not only the right of the manufactures to get the sample tested by the Central Drugs Laboratory through the Court concerned stood extinguished but the report of the Government Analyst also became conclusive evidence under sub-section (3). The delay in filling 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."

46.Further, in the decision of the Hon'ble Supreme Court (Three Judge Bench) in Damodar S.Prabhu V. Sayed Babalal H., AIR 2010 Supreme Court 1907 wherein it is observed that 'In case of acquittal by the Judicial Magistrate of First Class the complainant could appeal to High Court under Section 378(4) Cr.P.C. and for Special Leave to Appeal to Supreme Court under Article 136 of the Constitution of India'.

47.As far as the present case is concerned, the 1st Respondent /A1 had addressed a letter dated 08.10.2004 to the Director of Drugs Control, Chennai - 600 006, inter alia, stating that '.... they disagree with the test result of the Government Analyst and hence decided to contest the same' and further they made it clear they were making arrangement as per Law to send their portion of the sample for analysis to Central Drugs Laboratory, Kolkatta.

48.However, it appears that the Respondents/Accused pursuant to their letter dated 08.10.2004 had not moved their little fingers to take necessary steps for sending their portion of the sample for analysis to the Central Drugs Laboratory and the omission in this regard is certainly not a favourable

circumstance in their favour, as opined by this Court. Besides this, although the 1st Respondent/A1, had addressed a letter dated 08.10.2004 [for the letter of the Drugs Inspector, Salem I Range dated 24.09.2004] to the Director of Drugs Control, Chennai [with a copy being marked to the Drugs Inspector, Salem Zone), among other things, mentioning that they were making arrangement as per Law to send their portion of the sample for analysis to Central Drugs Laboratory, Kolkatta, the reply of the 1st Respondent/A1 was well within two weeks and therefore, the plea of the Petitioner/Appellant/ Complainant that the Respondents/Accused had failed to adduce the Government Analyst Report within 28 days limitation period, is incorrect in the eye of Law and the same is out rightly negatived by this Court.

49.As a matter of fact, as per Section 25(3) of the Drugs and Cosmetics Act, 1940, the Inspector or the Court before which any proceedings in respect of the sample are pending the concerned person within 28 days of the receipt of a copy of the Government Analyst Report, should inform that he intends to adduce in evidence in controversion of the Report. However, in the present case before us, the 1st Respondent/A1 through its Director, the 2nd Respondent/ A2 had informed the Director of Drugs Controller, Chennai with a copy being marked to the Drugs Inspector, Salem Zone. In this connection, this Court significantly points out that although the letter dated 08.10.2004 of the 1st Respondent/A1 was addressed to the Director of Drugs Control, Chennai – 6, yet, the Drugs Inspector, Salem Zone [viz., the Complainant before the trial Court] was informed to send their Company sample for analysis to Central Drugs Laboratory, Kolkatta, in effect, the Petitioner/Appellant/ Complainant (Drugs Inspector, Salem I Range) was aware of the intention of the Respondents/Accused that they were making arrangements as per Law to send their portion of the samples for analysis to Central Drugs Laboratory, Kolkatta.

50.It appears that the Respondents/Accused had not taken any efforts to send their sample portion for analysis to the Central Drugs Laboratory, Kolkatta and in this regard, there is no proof. Moreover, in the present case, the Appellant/Complainant had not made a request before the trial Court to send the sample of the drug to be sent for test/analysis to the Central Drugs Laboratory, Kolkatta. The Court also on its own motion or on its own discretion, had not taken any efforts in sending the sample of the drug to be sent for test or analysis to the Central Drugs Laboratory.

51.One cannot brush aside an important fact that a sample of Enalapril Maleate I.P. 2.5 mg., B.No.3871003-M/dt October 2003, E/Dt. September 2005, manufactured by M/s Alfred Berg & Co.(I) Pvt. Ltd., Alathur (1st Respondent/A1) was drawn for analysis by the then Drugs Inspector from the Medical Stores, Government

Mohan Kumaramangalam Medical College Hospital, Salem on 23.03.2004 under Form 17 and the sample was reported as 'NOT OF STANDARD QUALITY' by the Government Analyst Drugs Testing Laboratory, Chennai – 6 through her Test Report dated 08.07.2004 for the reasons that the sample does not conform to I.P. Specification in respect of Assay (context of Enalapril Maleate is only 66.8%) etc. The Sanction Order to prosecute the Respondents/Accused for controversion of Section 18(a)(i) of the Drugs and Cosmetics Act, 1940 was obtained on 01.09.2006 under Ref. No.11633/Iw2/2004 (54) dated 09.08.2006. There appears to be a delay of more than 2 years & five months in not obtaining a Sanction Order to prosecute the Respondents/Accused.

52.Apart from that, even though a copy of the order dated 08.10.2004 addressed by the 1st Respondent/A1 to Director of Drugs Control, Chennai – 6 was sent to the Drugs Inspector, Salem Zone, it appears the Petitioner/Appellant/Complainant had not taken any steps (as Complainant) to cause the sample of the drug to be tested by the Director of Central Drugs Laboratory, especially, when the Respondents/Accused had not taken action as per Law to send their portion of the sample for analysis to Central Drugs Laboratory, Kolkatta, even the trial Court on its own motion as per Section 25(4) of the Drugs and Cosmetics Act, 1940 had not made any endeavour to cause the sample of the drug produced before it under sub-section (4) of Section 23 to send the same for test or analysis to the Central Drugs Laboratory, Kolkatta. In any event, looking into the facts of the case from any angle, this Court is of the earnest view that the right of the Respondents/Accused to get the sample tested or analysed from the Central Drugs Laboratory, Kolkatta is a valuable right which cannot be taken away in Law much against their interest and therefore, this Court comes to a resultant conclusion that owing to the failure of the Petitioner/Appellant/ Complainant's part in not taking necessary steps to send the sample for retest or analysis in time, the Respondents/Accused had acquired a valuable right in their favour to establish their innocence which they lost the same and therefore, this Court holds that the trial Court was correct in dismissing the Complaint and acquitting the Respondents/Accused in terms of Section 248(1) Cr.P.C. which, in the considered opinion of this Court, does not suffer from any material or patent illegalities in the eye of Law. Consequently, the Petition filed by the Petitioner/Appellant/Complainant seeking 'Grant of Special Leave' fails.

53.In fine,the Criminal Original Petition is dismissed.

-s/d-
Assistant Registrar(CSV)

True Copy

Sub-Assistant Registrar

Sgl

To

1.The Judicial Magistrate-III,
Salem.

2.The Public Prosecutor,
High Court, Madras.

3.The Section Officer,
Criminal Section
High Court, Madras.

Crl.O.P.No.27614 of 2016 in
Crl.A.Sr.No.40728 of 2016

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aa28/04/2017