

IN THE COURT OF THE JUDICIAL MAGISTRATE OF FIRST CLASS,
KAMAREDDY

PRESENT: - Smt. M. Kiran Mahi,
Judl. Magistrate of First Class,
Kamareddy

Dated this the 14th day of February, 2018

C.C. No. 326 of 2010

Between:-

The State through Drug Inspector, Kamareddy.

...Complainant

// And //

A1: T. Jamuna Naidu, Proprietrix, M/s. Restech Parma, B-184 & 185,
pipdic, Industrial Estate, Mettupalyam, Puducherry – 605009.

A2: M/s. Restech Parma, B-184 & 185, PIPDIC, Industrial Estate,
Mettupalyam, Puducherry – 605009.

...A1 and A2.

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This case coming before me on this the 22nd day of January, 2018 for hearing and disposal in the presence of APP for the State and Sri M.A. Muqueem, Advocate for the accused and after hearing and having stood over for consideration, this Court delivered the following:-

J U D G M E N T

The Drug Inspector, Kamareddy filed this case against A1 and A2 for the offence U/s. 18(a)(i) r/w 16 of Drugs and Cosmetics Act, 1940 punishable U/s. 27 (d) of Drugs and Cosmetics Act, 1940.

2. The brief facts of the case are that Pw1 is the Drug Inspector of Kamareddy, inspected M/s. Lalitha Sai Medicals, D.No. 5-63-504,

A1-Rasheed Complex, Kamareddy and took up sample of Leofenac-SP tablets, B.No. LFS-001, Mfg Date May, 2009, Exp date April, 2011 manufactured by A2 company/M/s. Restech Parma, B-184 & 185, PIPDIC, Industrial Estate, Mettupalyam, Puducherry – 605009 for analysis and sent it to the Government Analyst, Drug Control Laboratory, Hyderabad. The Government Analyst in his report under Form-13 declared that the sample drug was not of standard quality and does not meet the labeled claim in respect of Serratiopeptidase content. Pw1 served copy of Government Analyst Report to M/s. Lalitha Sai Medicals and requested to disclose the source of supply of drug . M/s. Lalitha Sai Medicals gave reply that the drug was supplied by EMAR Health Care, Door No. 11-12-23. 2nd floor, Road No. 1, Income Tax Colony, SRK Puram, Saroornagar, Hyderabad under Invoice No. 25 dated 29-06-2009, Invoice No. 94 dated 06-08-2009, Invoice No. 115 dated 21-08-2009 and Invoice No. 401 dated 04-11-2009 along with particulars of the drug. Pw1 addressed a letter to M/s. EMAR Health Care enclosing the sealed portion of sample drug along with Form-13 with a request to disclose the source of supply and to provide necessary documents. In response M/s. EMAR Health Care on 24-03-2010 enclosed a copy of purchase Invoice No. RP-042 dated 17-06-2009. Pw1 addressed a letter to A2 company to disclose the source of supply and to furnish documents and A2 company gave

reply confirming the sale of subject drug and challenged the Government Analyst Report. Pw1 deposited the second sample portion of the drug in this Court with a request to forward the sample to Central Drug Laboratory, Calcutta for analysis. The Director, Central Drug Laboratory has declared in his report that the said sample was "Not of standard Quality" as the sample does not confirm to IP with respect to the Assay of Serratiopeptidase was found to be 7.73 mg as to the labeled claim of 15 mg. A1 being the Proprietrix of A2 firm and A1 and A2 manufactured and sold the drug which is "Not of standard Quality". Therefore A1 and A2 contravened the provisions for the the offence U/s. 18(a)(i) r/w 16 of Drugs and Cosmetics Act, 1940, punishable U/s. 27 (d) of Drugs and Cosmetics Act, 1940.

3. After filing the charge sheet, this Court has taken cognizance of offence U/s. 18(a)(i) r/w 16 of Drugs and Cosmetics Act, 1940, punishable U/s. 27 (d) of Drugs and Cosmetics Act, 1940 against A1 and A2 and proceeded with.

4. Copies of case documents were furnished upon A1 and A2 provided U/s. 207 Cr.P.C and charge there upon was framed against them for the offence U/s. 18(a)(i) r/w 16 of Drugs and Cosmetics Act, 1940, punishable U/s. 27 (d) of Drugs and Cosmetics Act, 1940 against

A1 and A2 read over and explained to them in Telugu, to which they pleaded not guilty and claimed to be tried.

5. At the time of trial Special Vakalat Holder reported for A1 and A2 in the Court. During the course of trial prosecution examined Pws 1 and 2 and got marked Exs.P1 to 16.

6. Accused when examined U/s 313 Cr.P.C, explaining the incriminating circumstances appearing against them in the evidence of prosecution witnesses, they denied the same and reported no evidence on their behalf.

7. Heard the arguments of the learned APP and the learned counsel for A1 and A2.

8. Now, the point for determination is whether the prosecution could prove the offence U/s. 18(a)(i) r/w 16 of Drugs and Cosmetics Act, 1940, punishable U/s. 27 (d) of Drugs and Cosmetics Act, 1940 against A1 and A2 beyond all reasonable doubt?

9. **POINT:-**

Learned Counsel for the accused contended that the Drug Inspector had committed breach of sec.21 of Drugs and Cosmetics Act as PW1 failed to prove that he is the Local Area Drugs Inspector of Kamareddy and is competent to lift the sample of drug from the shop of PW2.

10. The main point urged on behalf of accused are firstly, the prosecution is liable to be quashed for want of valid notification from the State Government as envisaged under the provisions of the Act. Learned APP Submitted that PW1 is notified Drug Inspector for the entire State of Andhra Pradesh and renotification every time they are transferred is not mandatory as they are posted only within the State. She relied upon the decision reported in *State of Maharashtra Vs Ghanshyam K.Zaveri and another, Bharat Damodhar Kale Vs State of A.P.* wherein the Hon'ble Apex Court observed that a narrow interpretation confining the operation of the notification to a part of Andhra Pradesh would defeat the public purpose for which the notification is issued. It is contended by the learned Learned counsel for accused that PW1 has no jurisdiction over the place from where samples said to have been lifted and as per the provisions of the Act, there should be notification from the State Government, prescribing local limits of the area, for which, the Drug Inspector is appointed. It is contended that G.O. filed along with complaint would only refer to the appointment of the Drug Inspector and the local area is not mentioned in it.

11. **Whether appointment of Drug Inspector is limited to particular area and not for whole of the State ?**

The appointment of Drug Inspector is made under the provision of Drugs and Cosmetics Act,1940, for the implementation of the controlling and regulating of drugs in various manners. Section 21 of the Act provides for appointment of Drug Inspector, the provision of which is couched in a manner to limit the territorial jurisdiction of the Drug Inspector and not uncontrolled. Besides the territorial limitation of the state boundaries, it also imposes the condition as to area of operation of the Drug Inspector.

The provision of section 21 is reproduced as under:

Inspectors.

(1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such person as it thinks fit, having the prescribed qualification, to be Inspectors for such areas as may be assigned to them by the Central Government or State Government, as the case may be.

12. From above provision, it is clear that the DI is appointed for such areas as may be assigned to them. These words "such areas" is of paramount importance. The words used in the section give impression that such areas means something less than the whole state. It may be more than one area but it may not be for the whole state. If the legislature had the intention to have appointment of the DI for the whole state it would have provided the wordings in a different way.

The imposition of condition in the section 21 clearly states that appointment must be for the areas and can not be for the whole state.

The imposition of the condition further necessitates fixing the responsibility of the DI for the act done. As of today, the state has a tendency to appoint the Drug Inspector for whole of the state by Gazette Notification and then keep on transferring them at the whims and fancies of the Drug Controller by an Office Resolution. The practice is seemed to be devoid of any merit. When law prescribes the appointment of Drug Inspector by Gazette Notification for such areas, then it does not lie with the Drug Controller to transfer the Drug Inspector by passing an official resolution after obtaining administrative order or confirmation. That the provision of Section 21 of the Drugs and Cosmetics Act, 1940, makes it abundantly clear that the post of Drug Inspector is a very vital public post with wide range of powers to take samples and seize the samples and prosecute the persons for selling adulterous, spurious and sub-standard quality drugs. In view of such vital powers conferred by Section 21 of the Drugs and Cosmetics Act, 1940, on such Drug Inspectors, the said Section clearly mandates that the Central Government or the State Government may issue notification in Official Gazette so as to appoint such Drug Inspectors for such areas as assigned to them. The intention of the legislature is very clear from the said Section 21 of the Drugs and

Cosmetics Act, 1940, that the appointment of such a person holding such an important post as a Drug Inspector, especially in the interest of public health, obviously will have to be notified in the Official Gazette and that the said notification should indicate the area in which the said Drug Inspector can exercise his powers. Infact, Section 21 does not say that the publication of notification in Official Gazette is discretionary. If one were to look at the wording of the said Section carefully, the Central Government or the State Government may appoint such qualified persons as the Drug Inspectors as it thinks fit. In fact, the wording of the said Section 21 shows that there is coma after the word 'may' and not before the said word, so as to construe that the issuance of the notification in the Official Gazette is discretionary. Taking into account all the purposes and objects of the Act and the powers conferred on the Drug Inspector who is the vital authority to initiate the prosecution, the appointment of Drug Inspector can only be through an Official Gazette Notification and not otherwise. Such a notification should also indicate the area in which such a Drug Inspector can operate and exercise his powers, and the same should not be left to conjectures and surmises of the public. Taking into account all the purposes and objects of the Act and the powers conferred on the Drug Inspector who is the vital authority to initiate the prosecution, I hold that the appointment of Drug Inspector can

only be through an Official Gazette Notification and not otherwise. I am also of the opinion that such a notification should also indicate the area in which such a Drug Inspector can operate and exercise his powers, and the same should not be left to conjectures and surmises of the public.”

13. Learned Counsel for accused relied upon the decision reported in *1986 Crl.L.J.2037 A.K.Roy and another vs State of Punjab and others* wherein the Hon'ble Apex Court observed that where a power is given to do a certain thing in a certain way, the thing must be done in that way or not at all. Other modes of performance are necessarily forbidden. They further relied on the decision reported in *M/s.Gaba Pharmaceuticals, Hyderabad Vs State of Andhra Pradesh 2007(2) Crimes 358 A.P.High Court* wherein our Hon'ble High Court observed that the government has to issue notification duly notifying the area where inspector could discharge his duties. He also relied on the decision reported in *Johnson & Johnson Ltd., H.P.& another 2015(2) ALD (Crl) 457 T.S&A.P.High Court* wherein it was held that provisions of Act requires State Government to issue notification appointing Drugs Inspector and prescribing local limits of area, for which drugs inspector is appointed, *State of Maharashtra Vs Chandawarkar and others 1999 Crl.L.J 4449 Bombay High Court* observed that a person cannot claim to be appointed as a Drug Inspector for a particular area

when no official gazette notification is issued appointing him as a Drug Inspector for that area, *M/s.Channakesha Bandage and others Vs State of Andhra Pradesh* wherein it was held that entire proceedings is illegal and improper if the notification duly notifying the area under which Drug Inspector was authorised to discharge his duties is not filed.

14. In the instant case, admittedly, there is no Official Gazette Notification appointing PW1 as a Drug Inspector for Kamareddy area. In view of the aforesaid, very serious infirmity, which goes to the root of the matter, it is held that PW1 has no authority whatsoever to act as the Drug Inspector of Kamareddy area. When the statute very clearly provides a particular mode of appointment, the State cannot deviate from the said mode. Thus, the State can appoint the Drug Inspector only by means of publishing in Official Gazette and mentioning therein the area in which they are entitled to empower and also specifying therein the products with which they can analyse and test. In case the Government Resolution is adopted it shall be published in the Official Gazette while transferring the Drug Inspector. The practice of appointment of Drug Inspector for the whole of the State and thereafter transferring the Drug Inspector to other areas at the whims and fancies of the administration is not proper. Mere passing of order by the controlling authority or the administration will not suffice and if

the mode of government resolution is taken then also it is incumbent upon the State to publish it in the Official Gazette. It will not be open for the Drug Inspector to act throughout the state without any limitation and conditions. However in view of the decision rendered by Hon'ble Apex Court, a narrow view cannot be taken and the notification issued by Government of A.P., was to comply the requirement of the Central Act, 1954, this Court finds that in larger interest, the notification issued by the government is applicable to the entire State of A.P. Hence this point is answered in favour of the prosecution.

15. Second contention raised on behalf of accused is that whether the Government Analyst is validly appointed in pursuance of the provisions of section 20 of the Drugs and Cosmetics Act, 1940, and if not, his analysis report has no sanctity in law and the same cannot be acted upon or relied upon.

16. Section 20 of the Drugs and Cosmetics Act, 1940 provides that the State Government may, by notification in Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas in the State and in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.

17. The above provision also makes it clear that the Government Analysts having the prescribed qualifications can be appointed by the State Government by the notification in the Official Gazette. The said notification should also specify the area in which the said Analyst is required to exercise his powers and should also specify the drugs or classes of drugs or the cosmetics or the classes of the cosmetics in respect of which the said Analyst is entitled to analyse.

18. Learned Counsel for the accused relied upon the decisions reported in *Ram Shanker Misra Vs State of U.P. (1980) 1 SCC 255* wherein the Hon'ble Apex Court observed that section 20 empowers the State Government and Central Government by notification in appropriate cases to appoint persons having prescribed qualification to be Government Analysts; *1999 Crl.L.J. 44449 State of Maharashtra Vs R.A.Chandrawarkar and others* wherein the Hon'ble Bombay held that the appointment of Government Analyst is invalid if the notification appointing government analyst does not specify area wherein he can operate and analyse; *Criminal Appeal No.285 of 2010 A.P.High Court K.Rama Rao and others Vs State of Andhra Pradesh* wherein it was held that provisions of section 20 and 21 of the Act are mandatory.

19. Considering the clear wording of section 20 of the Drugs and Cosmetics Act, 1940, there is no doubt that the provisions therein are

mandatory and thus, the State must publish in an Official Gazette the appointment of the Government Analyst specifying therein the area wherein the Government Analyst can operate and also specifying therein the products with which the Government Analyst can test and analyse. Specifically, the State can appoint the Government Analysts only by publication of Government Gazette Notification as contemplated under section 20 of the Drugs and Cosmetics Act, 1940, and not otherwise. Since no such notification is filed, it is difficult to ascertain if the person who issued the analyst report is the Government Analyst and for which area and for which products. Hence this Court holds that the prosecution failed to establish that the person who issued the analysis report is appointed as a Government Analyst validly and properly as per the provisions of section 20 of the Drugs and Cosmetics Act, 1940.

20. The third point that arises for consideration is whether the analytical report issued is proper and reliable. The Learned Counsel for accused relied upon the decision reported in *1999 CrI.L.J.44449 State of Maharashtra Vs R.Chandrawarkar and others* wherein the Hon'ble Bombay High Court held that if the report of Public Analyst is made later, it will cease to have evidentiary value; *1986 Drugs Cases 150 State Vs M/s.Scotch Pharmaceutical Works Madras* wherein the Hon'ble Madras High Court observed that if the protocols test is

included, it is not conclusive evidence without oral testimony of the Analyst.

21. Hon'ble Apex court in *Dhian Singh vs Municipal Board, Saharanpur reported in 1970 AIR 318* held that it is not necessary that the report of the Public Analyst should contain the mode or particulars of analysis or the test applied. But it should contain the result of analysis, namely, data from which it can be inferred whether the article of food was of or was not adulterated. Relying on that judgment Hon'ble Apex Court in *Glaxosmithkline Pharmaceuticals Ltd.,* again held "It is a settled legal proposition that report of the analyst is conclusive. It means that no reasons are needed in support of conclusion given in the report, nor it is required that the report should contain the mode or particulars of the analysis."

Hence the Analyst report is found valid and proper.

22. It is also contended by the Learned counsel for accused that whether the sample of the drug was stored at a temperature below 25 degree celsius and if the potency of the drug has been reduced. Learned APP submitted that the drug was stored in the refrigerator.

23. PW1 deposed that the subject drug is antibiotic and comes under schedule C(1) of the Rules. Since the drug is prescribed in Schedule C(1), it has to be kept in cool place with temperature between 10

degree celsius to 25 degree centigrade. PW1 deposed that at the time of alleged offence, his office was not equipped with air condition and the shop from where the subject drug was lifted was not air conditioned. He also deposed that he did not note down the temperature of the shop when the sample was lifted. It appears PW1 has not taken any precautions to maintain the storage temperature of the drug till it was sent for analysis. In such circumstances, there is every likelihood of the drug being deteriorated. Counsel for the accused relied upon the decision reported in *State of Maharashtra Vs R.A.Chandrawarkar and others* wherein the Hon'ble Bombay High Court observed that when the sample drug is not stored in permissible temperature, there is possibility of its potency getting reduced . In the present case as it is observed that PW1 failed to establish that the subject drug was stored in cool condition, there is every possibility that the potency of the drug has been reduced and there by deviating from the standards required. Hence this point is also answered against the prosecution.

24. The next point to be considered is whether Rule 46, 57, 4 and 6 of Rules has been complied ?

It is the contention of the Learned counsel for accused that PW1 did not send a copy of memorandum and specimen impression of the seal to Government Analyst of the State Laboratory or to the Director

Central Drugs Laboratory and hence there is breach of Rule 57 and Rule 4. That PW1 admitted in his cross examination that after sending sample to the Government Analyst, he did not send anything to the Government Analyst till the analytical report is received from the Government Analyst. Further PW1 did not depose that he send the portion of samples to Government Analyst for analysis either through registered post or by hand. PW1 failed to file the acknowledgment card or the postal receipt to show that the portion of sample drug was sent to Government Analyst. There is no evidence to show that the seals on samples were compared with Form 18 sent separately containing specimen impression and seals. Hence PW1 did not comply Rule 57 and 46 and caused serious prejudice to the accused. Counsel for accused relied upon the decision reported in *1979 Cr.L.J.530 Bombay High Court between State of Maharashtra Vs J.S.Ujawan* wherein the Hon'ble Bombay High Court observed that under Rule 46, the Government Analyst is bound to furnish to the inspector the full protocols of the tests applied. Rule 46 and 57 being mandatory, must be strictly observed and cannot be left to conjectures and surmises. Counsel for accused further relied upon the decision reported in *The State of Delhi Vs Hukam Chand 2008 Cr.L.J.(NOC) 503* wherein the Hon'ble Delhi High Court observed that report of Government Analyst does not specify whether the Government Analyst has compared the

seal on sample bottles with specimen seal impression sent to them separately and hence the benefit of doubt must be given to the accused. Considering the aforesaid facts and circumstances, this Court finds that there is no material to substantiate the contention of non-compliance of Rule 46 or Rule 57 of the Drugs and Cosmetics Rules, 1945. Hence this point is also answered against the prosecution.

25. The next point to be considered is whether the prosecution could explain the difference between the two analytical reports issued by Government Analyst and by the Director Central Drug Laboratory.

26. As per Ex.P5 analytical report of Government Analyst, the sample does not confirm to claim with respect to Assay of Serratiopeptidase. But as per Ex.P15 the analytical report issued by Director, Central Drug Laboratory, Kolkata, it is declared that the sample does not confirm to the claim with respect to Assay of Serratiopeptidase. PW1 could not explain the cause for variation in the two reports. Accused challenged the said report and petition u/sec.25(3) of Drugs and Cosmetics Act was allowed by this Court and sample was sent to Central Drug Laboratory, but while sending it Central Drug Laboratory, PW1 filed Ex.P13 letter of advice and same was sent to Central Drug Laboratory along with sample drug. In column 6 of Ex.P13, PW1 asked Central Drug Laboratory to analyse

only in respect of Assay of Serritiopeptides only and not other components. The sample drug was not completely analysed and if analysed, there would have been variations in respect of other components. The same caused serious prejudice to the accused. Counsel for accused relied upon the decision reported in *Girdhari Lal Vs State of Rajasthan and others 2006(2) Crimes 221 Rajasthan High Court* wherein the Hon'ble Rajasthan High Court observed that on account of difference in reports of two expert bodies, one by State Laboratory and another by Central Laboratory, the benefit should go to the accused and deserves to be acquitted. It is found that the Government Analyst and Central Drug Laboratory gave two different opinions and when PW1 could not explain the reason for difference in the reports, it can be opined that the accused is entitled for benefit of doubt.

27. The last point to be considered is whether there was breach of Section 23(3) of the Drugs and Cosmetics Act. Learned APP submitted that PW1 followed the procedure prescribed under section 23 and forwarded one sealed portion of the sample to the Government Analyst Drugs Control Laboratory, Hyderabad on 26-10-2009. Learned Counsel for accused contended that PW1 did not divide the samples into four equal portions and sealed those portions effectively and put the seal of the person from whom sample was lifted. Counsel for

accused relied upon the decision reported in *1986 Cr.L.J.2037 A.K.Roy and another vs State of Punjab and others* wherein the Hon'ble Apex Court observed that where a power is given to do a certain thing in a certain way, the thing must be done in that way or not at all. Other modes of performance are necessarily forbidden. PW1 has denied the same but there is no evidence by PW1 or PW2 that they obtained the seal of the person from whom it was lifted. It could not be understood as to what prevented PW1 from following the procedure laid down in the Act. PW1 is found to have deviated from the procedure laid down in the Act thereby causing prejudice to the accused.

28. In view of the discussions made supra, it is found that the accused is entitled for benefit of doubt.

29. **In the result**, A1 and A2 are found not guilty for the offence U/s. 18(a)(i) r/w 16 of Drugs and Cosmetics Act, 1940 punishable U/s. 27 (d) of Drugs and Cosmetics Act, 1940 and accordingly they are acquitted U/s. 248(1) Cr.P.C. The bail bonds of A1 and A2 shall stand cancelled after expiry of appeal time.

Typed and corrected by me on my personal laptop and pronounced by me in open Court on this the 14th day of February, 2018.

Judl. Magistrate of First Class,
Kamareddy

Appendix of evidence
Witnesses examined on behalf of

For Prosecution

PW1: G. Prasad/Complainant/Investigating Officer
PW2: K. Sudarshan/Witness

For Defence:-

-Nil-

Exhibits Marked

Ex.P1: Transfer Proceedings
Ex.P2: G.O.Ms. No. 117
Ex.P3: Copy of Form-17
Ex.P4: Memorandum in Form-18
Ex.P5: Analyst Report along with covering letter.
Ex.P6: Office copy of the letter
Ex.P7: Reply letter along with purchased and sales bills signed by Pw2
Ex.P8: Letter
Ex.P9: Reply letter containing four invoices and one letter
Ex.P10: Office copy of letter along with acknowledgement
Ex.P11: Reply letter dated 26-04-2010 from Restec Pharma
Ex.P12: Official memorandum of this Court
Ex.P13: Letter of advice and covering letter
Ex.P14: Attested copy of analyst reported
Ex.P15: Original Form-2 along with covering letter of Director, Drug Control Laboratory
Ex.P16: Original cash receipt

Material Objects Marked

Nil

Judl. Magistrate of First Class,
Kamareddy

IN THE COURT OF THE JUDICIAL MAGISTRATE OF FIRST CLASS
AT KAMAREDDY

CALENDER AND JUDGMENT OF CASE TRIED BY JMFC,
KAMAREDDY

C.C. No. 326 of 2010

Name of the police station. : Drug Inspector, Kamareddy
Crime No. of offence. :
Description of the accused. : T. Jamuna Naidu and another
Date of offence. : 23-10-2009
Date of Complaint : 23-10-2009
Date of apprehension : -
Date of commencement of trial. : 18-02-2014
Date of closure of trial. : 22-09-2014
Date of sentence or order. : 14-02-2018
Explanation for delay or remarks. : ----
Findings. : Not guilty
Sentence/Order : Acquitted

Judl. Magistrate of First Class,
Kamareddy

To:-
The Hon'ble I-Addl. Dist. & Sessions Judge,
Nizamabad

