

IN THE HIGH COURT OF JUDICATURE AT MADRAS

RESERVED ON : 27.08.2020
PRONOUNCED ON : 13.10.2020

CORAM

THE HONOURABLE MR.JUSTICE M.NIRMAL KUMAR

Crl.O.P.No.19300 of 2014 and
Crl.M.P.No.1 of 2014

Sangita Gupta,
W/o.Dr.Briji Bandhu Gupta,
Managing Director,
M/s.Midas Care Pharmaceuticals Pvt. Ltd.,
B-16, MIDC, Waluj,
Aurangabad 431 136. Petitioner

Vs.

Union of India,
Represented by Drugs Inspector,
Office of the Deputy Drugs Controller (India),
Central Drugs Standard Control Organization,
South Zone, 2nd Floor,
Shastri Bhawan Annex,
Chennai 600 006. Respondent

PRAYER: Criminal Original Petition is filed under Section 482 of the Code of Criminal Procedure, to call for the records relating to C.C.No.2092 of 2014 on the file of the IV Metropolitan Magistrate, Saidapet, and quash the same.

For Petitioner : Mr.G.Sankaran

For Respondent : Mr.P.Ayyaswamy, CGSC

ORDER

The petitioner/A3 in C.C.No.2092 of 2014 facing trial before the file of the IV Metropolitan Magistrate Court, Saidapet, for offence under Section 18(a)(i) and 27(d) of the Drugs and Cosmetics Act, 1940, (hereinafter referred to as 'Act') has filed this quash petition.

2.The gist of the case is that there are totally three accused, of which A1 is the Company viz., M/s.Midas Care Pharmaceuticals Private Limited, Aurangabad represented by A2, A2 and the petitioner/A3 are the Directors of A1 company. On 25.04.2012, the Drugs Inspector, Central Drugs Standard Control

Organization (CDSCO), Chennai/respondent visited the premises of ESIC Hospital, K.K.Nagar, Chennai, drawn samples of FLUSAL-250 HFA Inhalation (Salmeterol and Fluticasone Propionate Inhalation IP) Batch No.IL 11168, quantity in net weight 4 X 02 X 7.2 gms, manufactured by A1. By following the procedures as per Section 23 of the Act, the respondent took samples and one sealed portion of sample was sent to the Government Analyst, Central Drugs Laboratory, Kolkata under Form 18, dated 26.04.2012. The Government Analyst, Central Drugs Laboratory, Kolkata vide test report No.32-10/2012-SS/DCA(S)-32/2381, dated 17.10.2012 had declared the sample is "Not of Standard Quality". On receipt of the test report, the respondent/Drug Inspector sent a communication dated 15.01.2013 to ESIC Hospital, K.K.Nagar, Chennai to disclose the name and address of the person, from whom the drug was acquired. A reminder dated 18.03.2013 was sent to ESIC Hospital, K.K.Nagar, Chennai. M/s.ESIC Hospital by letter dated 26.03.2013 intimated that they received the drug from M/s.Midas-Care Pharmaceuticals Private Limited, Papa Industrial Estate, 40 Suren Road, Andheri East, Mumbai.

3. Thereafter, the respondent/the Drug Inspector issued letter dated 26.03.2013 to M/s.Midas-Care Pharmaceuticals Private Limited, Papa Industrial Estate, 40 Suren Road, Andheri East, Mumbai to disclose the name and address of the person, from whom the drug was acquired by them. By letter dated 02.04.2013 it was informed that drug was manufactured from their factory located at B-16, M.I.D.C Waluj, Aurangabad. On 10.04.2013, the respondent issued notice under Section 18(a)(i) of the Act to A1 Company, who manufactured and sold the drugs of Not of Standard Quality and sent the copy of test report issued by the Government Analyst, Central Drugs Laboratory, Kolkata and third portion of sample as per Section 25(2) and 23(4)(iii) of the Act. A reply letter dated 03.05.2013 was sent by the accused informing that they intend to adduce the Analytical Report of the Government Analyst, CDL, Kolkata and intend to send the sample portion for test to the Director, CDL, Kolkata under Section 25(4) of the Act.

4. The respondent informed A1 Company by letter dated 15.05.2013 and 19.05.2013 directing A1 to bring the sealed sample of the drug received from the Drug Inspector and produce the same before the learned IV Metropolitan Magistrate, Saidapet for retesting of sample under Section 25(4) of the Act. The accused vide letter dated 30.05.2013 informed that they have utilised the third portion of sealed sample for analysis received and requested the Drug Inspector to take steps as per law. On 07.06.2013, the respondent sent a letter to the Department of Law and Justice, requesting to nominate a Central Government Counsel to take necessary steps to forward the available sample under Section 25(4) of the Act to appellate

CDL, Kolkata through concerned Court. The respondent received letter dated 26.06.2013 from Department of Law and Justice nominating one M.Damodaran, Senior Panel Counsel to conduct the case and to assist in sending the sample for testing at Appellate Lab CDL, Kolkata.

5.The respondent received letter dated 28.06.2013 from A1 Company informing that they will deposit the fees as prescribed under law. The respondent by letter dated 01.07.2013, requested the accused to appear before the learned IV Metropolitan Magistrate, Saidapet to take steps in forwarding the sample to the Appellate Lab, CDL, Kolkata. The accused failed to respond and appear before the Court, hence the sample could not be sent. The accused failed to avail their right within 28 days after receipt of letter dated 01.07.2013. Thereafter getting sanction for prosecution, on 26.12.2013, the case was filed before the concerned Court, against which the present petition.

6.The learned counsel for the petitioner/A3 submitted that A1 is the Company viz., M/s.Midas Care Pharmaceuticals Private Limited, Aurangabad represented by A2, A2 and the petitioner/A3 were the Directors of A1 company. The learned counsel further submitted that A2, expired long back on 23.05.1993 after demise of A2 the petitioner is the Managing Director of A1 Company from 15.09.1996 onwards. The sample of the drug taken by the respondent is FLUSAL-250 HFA Inhalation (Salmeterol and Fluticasone Propionate Inhalation IP) pertains to Batch No.IL 11168 from ESIC Hospital, K.K.Nagar, Chennai. The date of manufacture is December 2011 and the date of expiry is November 2013. The petitioner admit they had supplied the drugs viz., FLUSAL-250 HFA Inhalation to ESIC Hospital, K.K.Nagar Chennai. The Drug Inspector took samples on 25.04.2012, one portion of the sample was sent for analysis to Government Analyst, Central Drug Laboratory, Kolkata on 26.04.2012. The Government Analyst, Central Drug Laboratory, Kolkata by report dated 17.10.2012 declared the sample as Not of Standard Quantity, for the reason sample does not confirm to "Assay of Fluticasone Propionate". In order to ascertain the supply and manufacturer of the drug, the respondent sent a letter dated 15.01.2013 to the said Hospital. On 26.03.2013, the ESIC Hospital sent a letter informing that the drug was received from M/s.Midas Care Pharmaceutical Private Limited, Papa Industrial Estate, 40 Suren Road, Andheri East, Mumbai. Thereafter, the respondent sent a letter to M/s.Midas Care Pharmaceutical Private Limited, Papa Industrial Estate, 40 Suren Road, Andheri East, Mumbai, manufacturer of the drug as required under Section 18(a)(i) of the Act and the third portion of the sample to A1 company as required under Section 23(4) of the Act.

7.The learned counsel for the petitioner further submitted that Al Company notified that they intend to adduce evidence to contravene the report dated 17.10.2012 of the Government Analyst, Central Drugs Laboratory, Kolkata and requested the Drug Inspector to send available sample portion of the drug for test to the Director, Central Drugs Laboratory as per Section 25 (4) of the Act. The petitioner on 02.05.2013, informed that they are not agreeable to the content stated in the Government Analysis report dated 17.10.2012 and requested to send the sample portion available in the Court under Section 23(4)(ii) of the Act to the Director, Central Drug Laboratory as per Section 25(4) of the Act. Thus, the petitioner notified its intention to adduce evidence in contravention to the Government Analyst report dated 17.10.2012, by letter dated 02.04.2013 and 02.05.2013. Hence, the notification of adducing evidence against Government Analyst Report was well within the statutory period of 28 days. On 15.05.2013, the respondent accepting the petitioners intention for re-testing the sample under Section 25 (4) of the Act, directed the petitioner to produce the sealed sample of the drug received by the petitioner under Section 23 (4)(iii) of the Act before the concerned Metropolitan Magistrate.

8.The petitioner requested the respondent to forward the sample produced by the Court by the respondent under Section 23 (4)(ii) for retest to the Director, CDL under Section 25(4) of the Act. He further contended that the sample forwarded to the petitioner under Section 23(4)(iii) cannot be asked to be produced for testing under Section 25(4) of the Act. Hence, the letter dated 15.05.2013 is in contravention to the provisions of the Act. The petitioner had sent the sample received as per Section 25(4)(iii) from the respondent for re-testing, to a approved analyst laboratory M/s.Manish Analytical Laboratory Private Limited, Mumbai and received the test report that the Drug complies to the label claim and it is of standard quality vide test report No.F/13/0205/2013, dated 02.05.2013 and hence, even prior to the letter dated 15.05.2013 issued by the Drug Inspector to produce the sealed portion of the sample, the petitioner had already forwarded the sample for analysis to the approved laboratory Manish Analytical Laboratory Private Limited, Mumbai. This fact was informed to the Drug Inspector by letter dated 30.05.2013 by the petitioner and requested the Drug Inspector to take steps as per law to forward the drug sample available in the Court for retesting with the Drug CDL, Kolkata.

9.The petitioner received the letter of the respondent dated 01.07.2013, directing them to appear before the IV Metropolitan Magistrate, Saidapet for taking steps to send for retesting the

sample under Section 25(4) of the Act. The letter dated 01.07.2013 is ex-facie contrary to law and without jurisdiction. It is seen that the respondent obtained permission for prosecution from the Drug Controller General India, New Delhi as per letter dated 26.12.2013 and filed the present criminal complaint before the learned IV Metropolitan Magistrate, Saidapet February 2014. The respondent was aware that the drug was manufactured during December 2011 and date of expiry is November 2013. In violation of Section 23(4)(ii) of the Act, the respondent failed to forward the drug sample for retesting to the Director, CDL, Kolkata within its period of expiry, denying petition a vital right and defence. In this case, by not sending the sample for retesting to Director of Central Drug Laboratory, Kolkata as per Section 25(5) is denied and violated. This is despite the petitioner by letter dated 28.06.2013 informing that the necessary fees/charges shall be deposited by them.

10. In support of his contention, the learned counsel for the petitioner relied upon the citations:

- Medicamen Biotech Limited and another Versus Rubina Bose, Drug Inspector reported in (2008) 7 SCC 196.
- M/s. Embiotic Laboratories (P) Ltd., and Ors. Versus Drugs Inspector, Erode reported in 2013-2-LW(Crl)475.

11. Thus, the valuable right of the petitioner under Section 25(4) of the Act was deprived and denied hence, the complaint of the respondent is vitiated and liable to be quashed.

12. The learned Central Government Standing Counsel appearing for the respondent filed counter, typed set of papers and submitted that on 25.04.2012, the respondent visited the premises of ESIC Hospital and took samples of FLUSAL-250 HFA Inhalation. The date of manufacture of the drug is December 2011 and date of expiry is November 2013. He further submitted that the samples were taken as per Section 23 of the Act and one portion of the sample was sent to Government Analyst, Central Drug Laboratory, Kolkata on 26.04.2012. The report dated 17.10.2012 was issued by the Government Analyst, Central Drug Laboratory, Kolkata. Thereafter, the respondent issued a letter dated 10.04.2013 to A1 Company to explain the contravention of the provision of Section 18(a)(i) of the Act. The copy of the test report was issued by the Central Drugs Laboratory, Kolkata in Form -13 and third portion of sample was sent as per Section 25(2) and 23(4)(iii) of the Act to the petitioner. A reply was received by the respondent on 03.05.2013 that the petitioner intend to adduce and send the sample portion for test to the Director, CDL, Kolkata under Section 25(4) of the Act. Thereafter, on 15.05.2013 and 19.05.2013, the respondent directed the petitioner to appear before the learned IV

Metropolitan Magistrate, Saidapet for retesting the sample under Section 25(4) of the Act. A letter dated 30.05.2013 was received requesting that the second portion of the sample submitted to the Court to be forwarded to the Central Laboratory, Kolkata for retest as per law. On 07.06.2013, communication sent to the Department of Law and Justice, requesting to nominate a Central Government Counsel to prosecute the case and to take steps in forwarding Court sample under Section 25(4) of the Act to appellate CDL, Kolkata through the concerned Court. This steps to be taken at the instance of accused, who disputed the report dated 17.10.2012 of the Government Analyst Cental Laboratory, Kolkata. The respondent never disputed the report dated 17.10.2012, in fact the case of the respondent proceeded on the said report. Mr.M.Damodaran, Senior Panel Counsel was nominated to forward the sample for testing at Appellate Lab CDL, Kolkata. The respondent informed the petitioner to appear on 15.07.2013 before the IV Metropolitan Magistrate, Saidapet for forwarding the sample to CDL, Kolkata and to pay the necessary fee for the same. The petitioner received the letter of the respondent but failed to appear before the concerned Court.

13.The learned Central Government Standing Counsel further submitted that Mr.M.Damodharan, Senior Panel Counsel appeared before the concerned Court, on 15.07.2013 but none appeared on behalf of the petitioner and thereby, the petitioner foregone their right. Now, the petitioner cannot claim that the right of forwarding the sample to Appellate Lab CDL, Kolkata has been violated and thereby prejudice caused to the petitioner. On these factual matrix it is seen there is no violation of mandatory provision of law vitiating the proceedings. Further, on the contention of the petitioner that A2 passed away on 23.05.1993, and mechanically proceedings are initiated against a dead person cannot be accepted for the reason that the petitioner/A3 had not intimated or informed to the respondent in any of the communications about the death of A2. From the Ministry of Corporate Affairs records, it is seen that M/s.Sangithaa Brijbandhu Gupta is the Managing Director and M/s.Shivangi Brijbandhu Gupta and Mr.Nandan Brijbandhu Gupta are the Directors which is found now. The respondent by communication dated 26.03.2013 directed the petitioner to furnish the constitution of the accused firm and its details, for which a Memorandum and Articles of Association of Midas Care Pharmaceutical Private Limited was sent. From which, it is seen that the name of A2 and the petitioner/A3 were shown as Directors. The death of A2 was not inormed. The change in Directorship and constitution of A1 Company was not informed, which was within the knowledge of petitioner/A3, for the first time in this quash petition such stand has been taken by the

petitioner. The respondent will take necessary steps to bring the concerned Directors to represent the company as accused in this case as per Section 63 of the Code of Criminal Procedure.

14. Considering the submissions and perusal of the materials it is seen that in this case the Drug Inspector had conducted an inspection in ESIC Hospital, K.K.Nagar, Chennai, taken samples of FLUSAL-250 HFA Inhalation on 25.04.2012, sent a portion of the sample taken under Section 23(4)(ii) of the Act to the Government Analyst, Central Drug Laboratory, Kolkata. On 17.10.2012, the Central Drug Laboratory sent a report through Form 13, stating that the sample is Not of Started Quality, after receipt of the test report immediately on 15.01.2013 the Drug Inspector sent a letter to ESIC Hospital, K.K.Nagar, Chennai to disclose the name and address from whom the drug was acquired. A reply dated 26.03.2013 received from ESIC Hospital, K.K.Nagar informing that the M/s.Midas-Care Pharmaceuticals Private Limited, Mumbai, supplied the drug to them. Thereafter, the respondent had issued a letter dated 26.03.2013 to M/s.Midas-Care Pharmaceuticals Private Limited, Mumbai to disclose the name and address of the person from whom the drug was acquired. By reply dated 02.04.2013, they admitted that drug was manufactured from their factory located at B-16, M.I.D.C Waluj, Aurangabad. Thereafter, on 10.04.2013, the respondent issued a notice to M/s.Midas-Care Pharmaceuticals Private Limited, Aurangabad as per Section 18(a)(i) of the Act, along with copy of the test report issued by the Government Analyst, Central Drugs Laboratory, Kolkata through Form -13 and also Third portion of sample was sent as per Section 25(2) and 23(4)(iii) of the Act.

15. On 03.05.2013, the manufacturer sent a reply stating that they intent to send a sample portion for test to the Director, CDL, Kolkata as per Section 25(4) of the Act. The respondent by letter dated 15.05.2013 and 19.05.2013 directed the Drug Company/A1 to bring the sealed sample received by them from the Drug Inspector and produce the same before IV Metropolitan Magistrate, Saidapet, for the purpose of retesting of the samples under Section 25(4) of the Act. The manufacturer by letter dated 30.05.2013 by referring their letter dated 15.05.2013, requested the Drug Inspector to take steps to forward the sample available in the Court to the Central Laboratory which is contrary to the provisions of the Act. The Drug Manufacturing Company failed to appear before the IV Metropolitan Magistrate, Saidapet, take any steps to send the second sample available before the Court for retesting and thereby contributed for delay, knowing well the drug expiry period is by November 2013. Further by not appearing before the concerned Court to exercise their right. The petitioner had

foregone its right. The respondent sent a letter to the Department of Law and Justice, requesting to nominate a Central Government counsel to take necessary steps to forward the available sample under Section 25(4) of the Act to appellate CDL, Kolkata through concerned Court. The Department of Law and Justice authorised one M.Damodaran, Senior Panel Counsel, to take steps in forwarding the sample for testing at Appellate Lab CDL, Kolkata. The respondent received letter dated 28.06.2013 from A1 Firm informing that they will deposit the fees as prescribed under law which is unwanted. The respondent by letter dated 01.07.2013, requested the accused to appear before the learned IV Metropolitan Magistrate, Saidapet on 15.07.2013 to forward the sample to the Appellate Lab, CDL, Kolkata. The petitioner receiving the communication from the respondent, failed to appear before the concerned Court. Thereby forgoing his right, now cannot claim that the drug was not forwarded as per Section 25(4) of the Act. Thereafter, getting sanction for prosecution the case has been filed.

16. This Court finds that the petitioner having been informed to appear before concerned Court on 15.07.2013 to send the samples for Central Laboratory had forgone its right and now raising a plea that their right under Section 25(4) had been denied and violated. Further, it is seen that in this case the respondent immediately after taking the sample has sent the sample to the Government Analyst who is none other than the Central Laboratory, Kolkata. On 26.04.2012, they had given a report dated 17.10.2012 that drug is of Not of Standard Quality. On the above facts, the contention of the petitioner that their statutory right has been violated cannot be countenanced. Further the Central Laboratory has given analytical report that the drug is Not of Standard Quality though there is some anomaly on part of the respondent informing the manufacturer to bring third sample and to produce the same before the Court to forward the same for second test may not be proper. That alone would not vitiate the proceedings. The contention that the third samples had been sent to M/s.Manish Analytical Laboratory Private Limited and the report obtained from the lab confirms that the samples is of standard quality is a matter of fact which is disputed by the respondent. Hence it has to be decided only during the trial.

17. This Court finds that the points raised by the petitioner are factual in nature which are to be raised during the trial and not in the quash petition. The Hon'ble Apex Court in the case of Ram Sankar and Sate of Uttar Pradesh reported in (1980) 1 SCC 255, held that mode prescribed under Section 25(4) is one method of sending it to the Drug Inspector of the Central Drugs Laboratory, there is no prohibition under the Act or the Rules, barring the Inspector from sending the

sample direct to the Director, Central Drugs Laboratory. In this case the respondent, Drug Inspector had sent the sample to the Government Analyst, Central Drug Laboratory, Kolkata on 26.04.2012 and the report from Central Laboratory report dated 17.10.2012, finding the drug of the petitioner "Not of Standard Quality".

18. In view of the above observations, this Criminal Original Petition is dismissed. Considering the proceedings in C.C.No.2092 of 2013 is pending without any progress for the past seven years, due to the pendency of the Criminal Original Petition, the Trial Court is directed to give priority in disposal of the case within a stipulated period, preferably within a period of six months.

19. It is made clear that the observations and findings made herein are only for the purpose of disposal of this petition. The trial Court uninfluenced by this order is directed to proceed with the trial and decide the case on its own merits.

Sd/-

Assistant Registrar

//True Copy//

Sub Assistant Registrar

rst/vv2

To:

- 1.The IV Metropolitan Magistrate,
Saidapet.
- 2.The Drugs Inspector,
Union of India,
Office of the Deputy Drugs Controller (India),
Central Drugs Standard Control Organization,
South Zone, 2nd Floor,
Shastri Bhawan Annex,
Chennai 600 006.

+1cc to The Government Advocate, sr no.32815
+1cc to Mr.G.Sankaran, Advocate, sr no.34227

Cr1.O.P.No.19300 of 2014

SSI (CO)
RMP (27/11/2020)