IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on : 05.04.2019
Pronounced on : 28.06.2019

CORAM

THE HONOURABLE MR.JUSTICE M.NIRMAL KUMAR

Crl.O.P.No.23190 of 2013
and
M.P.No.1 of 2013

1.M/s.Kwality Pharmaceuticals Pvt. Ltd.,
Rep. by its Managing Director
Mr.Ramesh Arora,
Vill.Nag Kalan, Majitha Road,
Majitha – 143 601,
Punjab.

2.Ramesh Arora,
Managing Director,
M/s.Kwality Pharmaceuticals Pvt. Ltd.,
Vill.Nag Kalan, Majitha Road,
Majitha – 143 601,
Punjab. ... Petitioners/Accused Nos.1 & 2

Vs.

State of Tamil Nadu,
Rep. by its Drug Inspector,
Mayiladuthurai Range,
Office of the Drugs Inspector,
Room No.13, II Floor,
Salam Mansion,
27B, Town Extn.,
Mayiladuthurai – 609 001. ... Respondent/Complainant

PRAYER: Criminal Original Petition filed under Section 482 of the Code of Criminal Procedure, to call for the records connected with Spl.C.C.No.8 of 2012 on the file of the Court of District and Sessions Judge at Nagapattinam and quash the same.

For Petitioners: Mr.N.Viswanathan

For Respondent : M/s.S.Thankira
Government Advocate (Crl. Side)

O R D E R

This Criminal Original Petition is filed to quash Spl.C.C.No.8 of 2012 pending on the file of the Court of District and Sessions Judge at Nagapattinam.

2.The petitioners herein are the accused Nos.1 and 2 in Spl.C.C.No.8 of 2012, who are facing trial for the offences under Section 18(a)(i), punishable under Section 27(d) and Section 18-B, punishable under Section 28-A of the Drugs and Cosmetics Act, 1940 (hereinafter referred as "the Act")

3.The case of the prosecution is that on 16.04.2009, the Drugs Inspector, Myladuthurai Range, notified under Section 21 of the Act visited the Government Primary Health Centre, Nallur, Nagai District, drawn samples of the impugned drug namely Multivitamin Tablets NFI, B.No.T1054, M/D:12/2008, E/D: 11/2010, Manufactured by: KWALITY PHARMACEUTICAL (P) LTD., 6th Mile Stone, Village Nag Kalan, Majitha Road, Amritsar – 143 601, as per Form 17 with due acknowledgment. The drawn samples were sent for analysis to the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai. The Government Analyst vide Report dated 12.01.2010 as per Form-13 gave a report as samples does not conform to label claim with respect to the content of vitamin A (39.41%) and B1 (53%).

4.On receipt of the analytical report, the complainant on 02.02.2010 sent a copy of the analytical report in Form 13 and protocol of analysis as per Section 25 (2) of the Act to the Medical Officer, Primary Health Centre, Nallur, Nagai District to disclose the name of the supplier of the subject "Not of standard quality" drug, as per Section 18 A of the Act and requested to furnish the purchase, stock on hand etc. The Medical Officer informed that the impugned drug was received through voucher No.87/09 dated 20.02.2009 from the office of the Deputy Director of Health Services, Nagapattinam. In turn the Deputy Director by letter dated 22.03.2010 had disclosed that the impugned drug was acquired from Tamil Nadu Medical Service Corporation, District Ware House, Tiruvarur in invoice No.1235/NG dated 25.01.2009 of M/s. KWALITY PHARMACEUTICAL (P) LTD. The Ware House incharge by letter dated 05.04.2010 had informed and furnished the particulars.

5.On receipt of the above said information, the respondent/complainant sent a show cause memo dated 13.04.2010 to the petitioner calling for explanation for the contravention of Section 18 (a) (i) of the Act for having manufactured and sold a "Not of standard quality drug." Further requested the petitioners to furnish the following particulars:

"1.Xerox copy (attested) of drug licenses, renewal certificate, with endorsement of the products held by them.

2.True/Xerox attested copy of memorandum and Article of Association for the firm.

3.Name, age, father's name, permanent address, residential address of the Directors and Managing Director of the M/S. KWALITY PHARMACEUTICAL (P) LTD., Vill. Nag Kalan, Majitha Road, Majitha – 143 601.

4.Name, age, father's name, residential address, permanent address, of the person or persons responsible for conduct of the business of the company of M/S. KWALITY PHARMACEUTICAL (P) LTD., Vill. Nag Kalan, Majitha Road, Majitha – 143 601.

5.Total quantity of subject "Not of standard quality drug" manufactured.

6.Stock on hand (not to be disposed off)

7.Distribution details, Bill No. to whom sold, quantity sold, amount charged, true copy/ Xerox copy (attested) of the sales bill to be furnished.

8.True/ Xerox copy (attested) of Raw material register of subject drug.

9.True/ Xerox copy (attested) of Raw material Analytical report and finished product Analytical report of the subject drug.

10.True/ Xerox copy (attested) of Batch manufacturing record of the subject drug.

11.True/ Xerox copy (attested) of Results of tests applied for the container and packing materials of the subject drug.

12.True/ Xerox copy (attested) of Master formula record of the subject drug.

13.True/ Xerox copy (attested) of standard operating procedures for manufacturing and analysis.

14.True/ Xerox copy (attested) of Records of in-process controls in each stage of manufacturing of the subject drug.

15.True/ Xerox copy (attested) of stability test report of the subject drug."

6.The petitioners were furnished with analytical report and protocol of analysis in Form 13 as per section 25(2) of the Act. The third portion of the sealed sample was sent to the manufacturer as per Section 23 (4) (3) of the Act so as to adduce evidence on the report of the Government Analyst (Drugs), Drugs Testing Laboratory, Tamil Nadu. The petitioners had sent

a reply disputing Government Analyst report. The petitioners failed to furnish the particulars as to the show cause memo. Therefore, on 31.07.2010, the complainant sent another show cause memo to the accused under Section 18B of the Act for not having furnished the relevant particulars called for. In the mean while, the complainant as per Section 25(4) of the Act had sent the sample portion of the drug to the Central Drugs Laboratory through Court on its own motion. Thereafter, the complainant on 20.08.2010, had submitted the proposal for prosecution to the Director of Drugs Control Tamil Nadu, Chennai through proper channel, seeking for necessary sanction to prosecute the accused.

7.The sanction order was issued by the Director of Drugs Control Tamil Nadu, Chennai on 02.11.2010 through the Assistant Director of Drugs Control, Thanjavur Zone. Thereafter, complaint was lodged before the Chief Judicial Magistrate, Nagapattinam, as C.C.No.74 of 2010 against the petitioners for the offences under Sections 18 (a) (i) of the Act for having manufactured sale and sold a "Not of standard quality drug", namely Multivitamin Tablets, which is punishable under Section 27(d) of the Act and Section 18B of the Act for having not furnished the records called for in the show cause memo, which is punishable under Section 28-A of the Act.

8.In the meanwhile, the respondent/complainant received the test analysis report from the Central Drugs Laboratory, Kolkatta. As per the Central analysis report, the samples were found to be spurious drugs, as defined under Section 17B (d) of the Act. On receipt of the report, the Drug Inspector filed a petition before the Chief Judicial Magistrate Court, Nagapattinam to alter the Section 18(a)(i) as 17B(d) under Section 216 of Cr.P.C. The case was transferred to the Special Court/Court of Session, Nagapattinam for trial, the case was taken on file as S.C.No.8 of 2012. Challenging the same, the above quash petition is filed.

9.The first petitioner is the company and the second petitioner is it's Managing Director. They contended that the alleged offence is said to have committed on 16.04.2009 and the amendment to Section 32(2) of the Act came into force only on 10.08.2009 and hence, the case ought to have been tried by the learned Chief Judicial Magistrate, Nagapattinam and not by the Sessions Judge/Special Court, Nagapattinam.

10.Further contented that there is no whisper in the complaint to rope in the second petitioner, the Managing Director of the first accused company having committed the alleged offence with his knowledge, consent or connivance, which could be attributable to any negligence leading to the

commission and his complicity in the offence and as per Section 34, the second petitioner cannot be mechanically roped in as an accused. Further contended that even before getting the analytical report from the Central Drugs Laboratory, Kolkatta dated 03.12.2010, the sanction was obtained on 02.11.2010. The date of manufacture of the impugned drug was on December 2008 and the expiry date was on November 2010. The sample of the impugned drug was under control and custody of the respondent/complainant for more than 1½ years before the sample was sent to the Central Drugs Testing Laboratory, Kolkatta on 12.11.2010 and the report is dated 03.12.2010, which is after the expiry date of the impugned drug.

11.Further contended due to improper storage of the impugned drug under unpredictable climatic conditions and exposure under unsuitable temperature, there is every possibility that the impugned drug would have lost its potency and became unfit for usage. When the impugned drug itself has become unfit for usage, the question of subjecting it for testing, moreso when the Drug was about to expire defies the purpose and therefore no credence could be given to the report of the Central Drugs laboratory.

12.Further submitted that the samples drawn from the Primary Health Centre, Nallur, Nagapattinam and dispatch of the same to the Government Analyst, Chennai, the procedure as contemplated under the Act and Rule was not followed. The Government Analyst had not specified which of the test and method prescribed under the official pharmacopoeia had been carried out on the sample on hand. The protocol in testing the drug has not been followed. The mandatory provisions and Rules have not been followed in this case. The impugned drug has been tested one day before its date of expiry. They further questioned the Government Analyst and the Central Analyst at Chennai and Central Drugs Testing Laboratory, Kolkatta of non application of mind. Further submitted that the impugned drug is only multivitamin, which does not partake the characteristics of a drug and therefore no test and method prescribed under the official pharmacopoeia will apply. Further contended that the Government Analyst conveniently omitted to take note of the formula as prescribed in the Patent or Proprietary medicine and proceeded to test the sample not provided under the official pharmacopoeia of India or any other country. They questioned the sanction order on the ground that it had been mechanically given without proper application of mind. Further questioned the jurisdiction under Section 22 of the Act. Further it was vehemently argued that the Multivitamin tablet is not a drug, it is a food supplement. Therefore, the Drug and Cosmetics Act will not apply. Hence, on these grounds sought quashing of the complaint.

13.The learned counsel for the petitioners relied upon the following citations:

"1.Rajendra Kumar Vs. P.K.Das reported in 1998 Drugs Cases is on the point of sanction.

2.M/s. Vishal Pharmaceuticals and another Vs. State of Madhya Pradesh reported in 1999 Drugs Cases 363 is on compliance of Rule 4 & 6 and Section 25 of the Act.

3.M/s. Wheezal Laboratories Pvt. Ltd. and others Vs. State of M.P. reported in 2002 Drugs Cases 595 is on the point of jurisdiction.

4.Merind Limited Vs. State of H.P. & Others reported in 2007 Drugs Cases (DC) 518 is on the point of vicarious liability.

5.Dr.D.V.Srikanth, M/s. Hippo Labs Pvt. Ltd. and others Vs. State of A.P. reported in 2004 Drugs Cases (DC) 349; in support of second accused contention that he has been made an accused under Section 34 of the Act without materials; and

6.Bimal Kumar Kundu and Sudip Ghosh Vs. State of West Bengal reported in 2005 (1) CHN 548."

14.The Government Advocate (Crl. Side) representing the respondent/complainant vehemently opposed the quash petition and filed a detailed typed set of papers enlisting the Gazette notification and other document. The respondent/complainant, is authorised under the Act. The samples were drawn and forwarded for Government Analysis. Sanction was obtained from the Director of Drugs Control, Chennai. Further contended that all the statutory provisions have been followed in this case. The petitioners supplied the medicines to Tamil Nadu Medical Services Corporation through Invoice No.1235/Ng dated 25.01.2009, which was supplied to Primary Health Centre, Nallur from where the samples were drawn. The statutory forms and other documents contains the particulars of multivitamin tablets, license No., batch No., manufactured date, expiry date, manufacturer particulars and other relevant particulars which are not disputed by the accused.

15.From the Government analysis report it is seen that the samples were found sealed intact and identical with the specimen impression of the seal. Further detail of the analysis along with the protocol of analysis have been furnished to the accused. The show cause memo dated 13.04.2010, the particulars and proof was called for 15 items. Though it is admitted by the petitioners to have received the same, they have not furnished the particulars which is an offence as per the Act. Without

furnishing the particulars the petitioners cannot question the analysis report and the procedure of investigation. The accused failed to comply with the statutory compliance as per Act.

16.Further in this case, proper sanction has been obtained, prosecution has been lodged against the first and second accused. The second petitioner being the Managing Director of the first petitioner cannot feign ignorance and seek immunity under Section 34 of the Act. From the Analysis report of the Central Drugs Laboratory Report, which is a conclusive evidence of the facts, it is found that the drug is a spurious drug under Section 17B (d) of the Drugs and Cosmetics Act, 1940. Hence, the case has been transferred to the Sessions Court/Special Court as per the Act. The petitioners cannot have any umbrage on the point of jurisdiction. Due to the pendency of the above Criminal Original Petition, the trial in this case has been stalled from the year 2012 and hence, prayed this Court to dismiss the quash petition.

17.Considering the rival submissions and on perusal of the records, it is seen that the respondent complainant is a notified Inspector as per Section 21 of the Act and had followed all the statutory provisions as per Act and Rule while drawing the samples and forwarded the same to Government Analyst. Further the Analyst report with Batch No, protocol of Analysis have been forwarded to the respondent along with a portion of the sample drug. Show cause memo calling for particulars have been sent which was received by the respondent. The petitioner failed to submit the documents as per the show cause memo dated 13.04.2010. The second petitioner had signed and sent a reply dated 23.04.2010, as Managing Director of the first petitioner. In the reply petitioner had challenged the manner of Analysis and had requested for report under Section 25 (4) of the Act, which has been done in this case. The petitioners failed to submit the doubts as per show cause memo dated 13.04.2010. Hence, show cause memo dated 31.07.2010 for contravention of Section 18-B was sent. The petitioners willingly not produced records, registers, other documents, relating to manufacture, sale, distribution etc. In all the statutory forms and communications, the particulars of the drug are found. The Government Analyst has found the Drug to be "Not of Standard Quality" by report dated 12.01.2010. The Central Drugs Laboratory received the samples from the Court and conducted the Test on the Drug from 23.11.2010 to 29.11.2010 and gave its Analysis report dated 03.12.2010. "The sample is considered to be spurious under Section 17 B (d) of the Drugs and Cosmetics Act, 1940". Finding the Drug spurious which is punishable under Section 27 of the Act, is triable only by the Court of

Sessions/Special Court, the case has been transferred to the Special Court. The citation relied by the petitioners are not relevant to the facts of this case.

18.This Court on the submission of either side and on perusal of the material facts finds that this mandatory provisions has been followed and investigation has been carried out properly. Sanction was obtained and thereafter the complaint has been filed. In view of the same, there is no merits in this petition. Hence the quash petition is dismissed. However, it is made clear that whatever have stated above or observed should not be considered as opinion regarding merit of the main case and the concerned Court at appropriate stage would act in accordance with law and arrive at its own conclusion and would not be guided by the observations made by this Court in this quash petition.

Sd/-
Assistant Registrar(CS VI)

//True Copy//

Sub Assistant Registrar

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To

1.The District and Sessions Judge,
Nagapattinam.

2.The Drug Inspector,
Mayiladuthurai Range,
Office of the Drugs Inspector,
Room No.13, II Floor,
Salam Mansion,
27B, Town Extn.,
Mayiladuthurai - 609 001.

3.The Public Prosecutor,
High Court, Madras.

+2cc to Mr.N.Viswanathan, Advocate Sr.53851

Crl.O.P.No.23190 of 2013
AND
M.P.No.1 of 2013

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