IN THE HIGH COURT OF JUDICATURE AT MADRAS

Dated: 01.07.2022

Coram:

THE HONOURABLE MR.JUSTICE N.SATHISH KUMAR

Crl.O.P.No.11230 of 2022
and Crl.M.P.Nos.6456 & 6457 of 2022

1.M/s.Centurion Laboratories
(A Unit of Centurion Remedies Pvt. Ltd.,)
rep. by its Director Mr.Ambalal Vanarsidas Patel

2.Ambalal Vanarsidas Patel
Managing Director of M/s.Centurion Laboratories
... Petitioners/Accused

Vs.

State represented by
Drugs Inspector Perambur Range
Zone-II, Chennai 600 006 ... Respondent /Complainant

PRAYER: Criminal Original Petition filed under Section 482 of Criminal Procedure Code, to call for records in C.C.No.719 of 2008 pending on the file of the X Metropolitan Magistrate Court, Egmore and quash the same.

For Petitioners : Mr.AR.L.Sundaresan, Senior Counsel
for Mr.T.D.Selvan Babu

For Respondent : Mr.A.Gokulakrishnan
Additional Public Prosecutor

O R D E R

This Criminal Original Petition is filed under Section 482 of Criminal Procedure Code to call for records in C.C.No.719 of 2008 for the offence punishable under Section 18(a)(i) r/w 17 (c) of the Drugs and Cosmetics Act, 1940, and 27(d) of the said Act, pending in the X Metropolitan Magistrate Court at Egmore and quash the same.

2.The case of the prosecution is that the sample of multivitamin tablets was given for a test analysis by the Drug Inspector on 27.11.2006 from E.S.I. Dispensary II, Perambur. The sample was sent to the Government Drugs Testing Laboratory, Chennai for analysis of drugs and a report was issued indicating that the nature of the drug was not of standard quality and misbranded as the sugar coating was not present in the tablets.

3.Hence, it is the contention of the complainant that after collecting the details of the manufacturer, show cause notice dated 23.04.2007 was issued to the Medical Officer, Centurion Laboratories along with a copy of the report. Despite the subsequent reminders, no reply is forthcoming from the petitioners, hence the complaint.

4.Mr.AR.L.Sundaresan, the learned Senior Counsel would submit that samples in respect to the vitamin tables contained all the ingredients of the vitamins, which is not in dispute. The only contention of the complaint is that sugar coating was not found during the test. It is the further contention of the learned Senior Counsel that when the report analysis was sent to the petitioners, the same was replied indicating their intention to adduce evidence u/s.25(3) of the Drugs and Cosmetics Act, 1940. Despite their request to send it to the Central Government Laboratory, the samples were not sent to the Central Government Laboratory. On the contrary, the complaint has been lodged on 18.09.2007, that is after the shelf life of the drugs was over. Hence the rights of the petitioners have been defeated.

5.Learned Senior Counsel also brought to the notice of this Court that as per the guidelines of National Formulary of India, the vitamin tablets' sugar coat is not a mandatory one and the tablets contained the necessary ingredients as per the guidelines itself. Therefore, when the National Formulary of India itself does not prescribe any sugar, the prosecution is not maintainable.

6.Learned Additional Public Prosecutor would submit that three show cause notices were issued to the petitioners indicating the nature of the report. However, no reply was forthcoming from the petitioners. Therefore, prosecution has been initiated. The petitioners have not taken any steps to adduce evidence within 28 days as required u/s.25(3) of the Act. Therefore, the learned Additional Public Prosecutor would submit that the complaint cannot be quashed.

7.Heard Mr.AR.L.Sundaresan, the Senior Counsel and Mr.A.Gokulakrishnan, the learned Additional Public Prosecutor for the respondent.

8.The prosecution has been mainly laid on the ground that the vitamin tablets manufactured by the petitioner is sub-standard since sugar is not identified during the test. The analysis report further shows that the tables having average weight and containing necessary ingredients which is not in dispute. Whereas the only defect pointed out in the analysis report is that sugar has not been identified. Therefore, it is the contention of the prosecution that it is misbranded and liable to be prosecuted.

9.Though it is the contention of the learned Additional Public Prosecutor that show cause notices have been issued on 23.04.2007, 21.05.2007 and 24.08.2007 and no reply is forthcoming from the petitioners. Whereas when the question was posed to the respondent whether the analysis report was sent to the petitioner, the respondent neither could produce any materials to show that the analysis report has been sent nor could file an acknowledgment. It is fairly submitted by the learned Additional Public Prosecutor that no acknowledgment is available on record. Whereas, the petitioners vide reply dated 30.10.2007 categorically stated that they have received the letter personally only on 30.10.2007 and also denied the analysis report and sought to adduce evidence in contravention to the report of the Government Analyst, Chennai and also requested the respondent to send the sample to the Central Drug Laboratory, Kolkata. This letter has been prepared on 30.10.2007. Despite the same, the report has not been sent to the Central Drug Laboratory, Kolkatta.

10.Be that as it may, it is relevant to note that the main crux of the charge is that there was misbranding u/s.17(c) of the Drugs and Cosmetics Act, 1940. Contrary to the lab test. It is relevant to extract Section 25(3) of the Drugs and Cosmetics Act, 1940;

> 25 (3) : Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken (or the person whose name, address and other particulars have been disclosed under Section 18-A has, within twenty-eight days of the receipt of a copy of the report, notified in writing

the inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in contravention of the report.

11.On a perusal of the Sub Section 25(3) of the above Act, it makes it very clear that the report of the Government ought to have been sent to the petitioners and after receipt of such report, the petitioners / accused shall within a period of 28 days of the receipt of a copy of the report notify in writing to the Inspector or to the Court in respect to the sample that intends to adduce evidence in contravention of the report. There are no materials available with the respondent to show that the report was immediately sent and acknowledgment to that effect is also not available as admitted by the learned Additional Public Prosecutor.

12.When such being the case, the letter dated 30.10.2007 makes it clear that the very accused have sent a reply with an intention to adduce a contra evidence. Besides, they have also sought for examining the sample by Central Government Laboratory. Despite such request, the sample was not sent to the laboratory. Section 25(3) has also given two options to the accused. Firstly, the accused can either seek further analysis by the Central Government Laboratory by the inspector himself or else they can make a request to the Court to send the sample. When there are two options available u/s.25 (3) of the said Act, the present petitioners have exercised their first option, requested the inspector himself to send the sample to the Central Government Laboratory.

13.Further, it is also to be noted that to exercise the second option before the Court, the right of the accused to have such a sample analysed by the Central Government Laboratory is already lost by passage of time. Admittedly, the complaint was filed on 18.12.2007, after the expiry of the said drug. The complaint itself clearly indicates the expiry date of the multivitamin tablets in the month of November 2007. Therefore, when the shelf life of the drug is already expired, the accused rights to exercise the second option has become redundant. As no useful purpose would be served when the mandatory procedure is not followed and the right of the accused guaranteed under Section u/s.25 (3) of the said Act to get the sample tested got defeated. Hence, no purpose would be served in keeping the complaint pending and proceeding it further is nothing but a futile exercise.

14.It is also to be noted that in the guidelines for taking action and samples of Drugs declared spurious or not of standard quality, the guidelines framed u/s.33 (P) of the Act category (C) of the guidelines narrates the following:

Category (C) (Minor defects):

Drugs manufactured by the licensed manufacturers found not of standard quality because of defects arising out of minor variations in quality. Such defects may arise because of inadequate pre-formulation development studies, lack of in process controls exercised by the manufacturer or unsuitable conditions under which drugs are stored or transported. Examples of some such the defects are as under:

(i) Broken or chipped tablets

(ii) Presence of spot / discolouration / uneven coating.

(iii) Cracking of emulsions.

(iv) Clear liquid preparations showing sedimentation.

(v) Change in colour of the formulation.

(vi) Slight variation in net content.

(vii) Formulations failing in weight variation.

(viii) Formulations failing to respond to the colour test.

(ix) Isolated cases of presences of foreign matter.

(x) Labelling error including nomenclature mistake, Rx, Nrx, Red Line, Schedule H. Caution, Colour etc.

15.On a perusal of the above guidelines further, it makes it very clear that the State Drug Control Organisation for uniform implementation of the provision of the Drugs and Cosmetics Act and Rules made thereunder. While implementing new provisions, the State Regulatory Authorities should ensure that the law is implemented in a comprehensive way. In order to effectively use the said instrument of law, it is necessary to have Standard Operative Procedures set in each State to examine and process various violations of the provisions of the Act. The State Drug Central Organizations should have internal mechanism of checks and balances to ensure that law abiding manufacturers and sellers of drugs are not harassed or put to a disadvantageous position. Care should be taken that while violations with criminal intent or gross negligence leading to serious defects are dealt with heavy hand, the violations

involving minor variations in quality by licensed manufacturers are resolved through administrative measures.

16.The above guidelines also stipulate that the prosecution must be only for serious violations.

17.Subject to the above, this Criminal Original Petition stands allowed. The complaint taken on file in C.C.No.719 of 2008 for the offence punishable under Section 18(a)(i) r/w 17 (c) of the Drugs and Cosmetics Act, 1940, and 27(d) of the said Act, pending on the X Metropolitan Magistrate Court at Egmore is hereby quashed. Consequently, the connected miscellaneous petitions are closed.

Sd/-
Assistant Registrar(CS-V)

// True Copy //

Sub Assistant Registrar

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To

1.The X Metropolitan Magistrate,
Egmore, Chennai.

2.Drugs Inspector Perambur Range
Zone-II
Chennai 600 006

3.The Public Prosecutor
High Court of Madras
Chennai 600 104

Crl.O.P.No.11230 of 2022
&Crl.M.P.No.6456&6457/2022

CA(CO)
CB(21/07/2022)