IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 29.07.2021

CORAM

THE HONOURABLE MR. JUSTICE M.DHANDAPANI

Crl.O.P.No.2148 of 2018
and
Crl.M.P.Nos.817 & 818 of 2018

1. M/s.Biogenetics Drugs Pvt. Ltd.,
   Represented by its Directors,
   Mr.Mukut Bihari Goyel,
   Mrs.Mukta Goyel & Mr.Vibhor Goyel

2. Mukut Bihari Goyel,
   Director,
   M/s.Biogenetics Drugs Pvt. Ltd.

3. Mukta Goyel,
   Director.

4. Vibhor Goyel,
   Director,
   M/s.Biogenetics Drugs Pvt. Ltd. .. Petitioners

Vs.

Union of India,
represented by Drugs Inspector,
Office of the Deputy Drugs Controller (India),
South Zone, 2nd Floor,
Shastri Bhawan Annex,
Chennai - 600 006. .. Respondent

PRAYER: Criminal Original Petition filed under Section 482 of the Code of Criminal Procedure, to call for the records in STC No.48 of 2017 pending before the Judicial Magistrate, Arakkonam and quash the same.

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

For Respondent : M/s.P.Ayya Swamy
Central Government Standing Counsel

O R D E R

This Criminal Original Petition has been filed to call for the records in STC No.48 of 2017 pending before the Judicial Magistrate, Arakkonam and quash the same.

2. The case of the petitioner is that the respondent had drawn a sample of Diclofenac Sodium Tablets IP 50mg Batch (Manufacturing Date December 2013 and Expiry Date November 2016) from M/s. Government Hospital, Arakkonam, manufactured by the petitioner on 28.03.2014. In furtherance the respondent sent one sealed portion of the sample to the Government Analyst, Central Drugs Testing Laboratory, Chennai for analysis. On 02.06.2014, the respondent received the Test Report dated 30.04.2014 in Form 13, declaring that the Sample is Not of Standard Quality, for the reason that the sample does not confirm to the IP (Indian Pharmacopaie) with respect to test for ''Disintegration''. Thereafter, the respondent issued a letter dated 10.07.2014 to Deputy Drugs Controller, Ghaziabad for investigation, based on which the Assistant Drugs Controller (I), Sub Zone, Chandigarh, forwarded a Joint Investigation report dated 22.07.2014, along with letter dated 12.08.2014 for having carried investigation in the petitioner's company, wherein it was found that the petitioner firm had valid manufacturing license and the same was also renewed and has valid product permission from State Licensing Authority and also reported that the sample was within the specification with respect to disintegration test. While being so, the respondent had initiated Manufacturer level Investigation in advance on 10.07.2014 itself and issued a show cause notice dated 01.10.2014 to the 1st petitioner, seeking an explanation for contravention of Section 18(a)(i) of the Drugs and Cosmetics Act, for manufacturing of a non-standard quality drug. However, the respondent has not considered the report of the Joint Inspection Team or its finding or the reply of the 1st petitioner dated 22.07.2014 given to the Joint Inspection Team stating that there is no manufacturing defect and the result could be due to moisture content because of storage conditions. The petitioner did not agree with the report of the Government Analyst and requested to either refer the matter to the Himachal Pradesh Drugs Controller for administrative action or to send the third portion of the sample lying with him to the Appellate Laboratory, Central Drugs Laboratory, Kolkatta, for reanalysis with respect to disintegration test under Section 25(3) of the Drugs and Cosmetics Act, 1940. However, the respondent, without considering the petitioner's reply dated 22.07.2014, filed the complaint, after expiry of the shelf life period of the drugs. Challenging the same, the present petition is filed.

3. The learned Senior Counsel appearing for the petitioner submitted that it is an undisputed fact that the

sample was lifted from the Government Hospital on 28.03.2014 and the respondent complainant issued a show cause notice on 01.10.2014 and the petitioner has also challenged the report of Regional Laboratory and requested to send the sample to Central Drugs Laboratory, Kolkatta. However without considering the said request, the respondent has issued a show cause notice on 01.10.2014 and filed the impugned complaint on 14.01.2017. It is the submission of the learned senior counsel for the petitioner that sample drugs, which was lifted, was manufactured in December 2013 and the shelf life of the drug expired on November 2016. The petitioner's request for sending portion of the sample to the CDRL, Calcutta, as per the provisions of the Act, which was not entertained, thereby the valuable right of the petitioner under Section 25(3) of the Act was lost. It is the submission of the learned senior counsel for the petitioners that it is incumbent upon the respondent to file a complaint before the competent Court within the period of shelf life of the drug samples, and beyond the shelf life, if any complaint is filed, the same cannot be taken cognizance of, in view of the fact that the test samples loses its nature and therefore, the filing of the complaint and taking cognizance thereof beyond the period of limitation is unsustainable. Further the petitioner was denied opportunity to exercise its right under Section 25(4) of the Drugs and Cosmetics Act, 1940 and, therefore, the present complaint is wholly unsustainable and, accordingly, prays for quashment of the complaint.

4. The learned Senior Counsel relied upon the decision of this Court reported in CDJ 2020 MHC 1315 (M/s.Alfred Berg and Co.(I) Pvt., Ltd., rep by its Director, Kamalesh K Jain and another Vs. Tamil Nadu State rep.by Senior Drugs Inspector, Villupuram Range, 1999 (8) SCC 190 (State of Haryana Vs. Unique Farmaid (P.) Ltd., and Others), 2017 SCC OnLine Supreme Court 632 (Laborate Pharmaceuticals India Ltd. & Ors. - Vs - State of T.N.).

5. Per contra, learned Government Advocate (Crl. Side) appearing for the respondent, referring to the counter affidavit submitted that on inspection of the Government Hospital by the respondent, drug sample was lifted by the respondent by following the due procedures contemplated under the Drugs and Cosmetics Act and the same was sent for analysis, which revealed that the sample was of non-standard quality as defined under the Act and the complainant Office has sent a letter dated 10.07.2014 to the Deputy Drugs Controller (India), CDSCO, North Zone, Ghaizabad, to carry out an investigation and the respondent also received a joint investigation report dated 22.07.2014 wherein it was concluded that action may be initiated on the petitioner Company as per 'Guidelines for taking action on samples of Drugs declared spurious or not of standard

quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008. Since the sample was not of standard quality, the respondent has issued Show Cause notice dated 01.10.2014, however, the respondent has not received any evidence based communication from the petitioner within twenty eight days of the receipt of a copy of the report, notified in writing by the Inspector as per Section 25(3) of the said Act and therefore, criminal prosecution was launched against the petitioner as per established procedures and on the filing of the complaint, the trial court took cognizance of the same. It is the further submission of the learned Government Advocate that necessary sanction was also obtained vide order dated 16.12.2015 and the complaint was filed on 04.01.2017, which is well within the time and not barred by limitation. Accordingly, he prays for dismissal of the present petition.

6. Heard the learned counsel appearing for the petitioner as well as the learned standing counsel appearing for the respondent and also perused the available materials.

7. The facts in the present case are not in dispute that admittedly the respondent made inspection in the Government Hospital, Arakkonam and after disclosing their identity, they drew the samples of Diclofenac Sodium Tablets IP 50 mg, manufactured by the petitioner and thereafter divided them separately and sent one sealed portion of the sample to the Government Analyst, Central Drugs Testing Laboratory, Chennai on 28.03.2014. The respondent complainant received the test report from the Government Analyst, Chennai, on 02.06.2014 and found that the sample is not of standard quality as defined under the said Act. Thereafter, the respondent has issued a letter dated 16.06.2014 to the Chief Pharmacist, Government Hospital Arakkonam, to disclose the name and address of the person from whom the drug was acquired. In reply, the Medical Superintendent of the said Government Hospital, vide communication dated 30.06.2014, informed the petitioner's name. After completing the formalities, the respondent has lodged a complaint for criminal prosecution on 04.01.2017.

8. It is not in dispute that the shelf life of the drug is between December 2013 and November 2016. The moot point raised by the learned senior counsel for the petitioners is that not only the petitioners right u/s 25 (3) of the Act stood curtailed by not sending the sample for analysis to the Central Drugs Laboratory, Kolkata, but the initiation of the complaint and cognizance having taken of the same, is beyond the period of three years and, therefore, the same is hit by the period of limitation and no cognizance can be taken by the court below.

9. For better appreciation of the case on hand, it is relevant to extract Section 25 (3) and (4) of the said Act:

"25.Reports of Government Analysis:

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 18A] 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.

4. Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in contravention of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused: cause the sample of the drug [or cosmetic] produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein."

9. A perusal of the above provision makes it clear that as per Sections 25 (3) and (4) of the said Act, if the sample has already been tested or analyzed in the Central Drugs Laboratory, on the request of the person under Sub Section 3, once intention is for adducing evidence, which is in contravention of a Government Analyst's report, the Court may, of its own motion, or in its discretion, at the request either of the complainant or the accused, cause the sample of the drugs produced before the Magistrate under Sub Section 4 of Section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and send its report in writing signed by or under the authority of the Director of the Central Drugs Laboratory of the result thereof, and such report shall be conclusive evidence of the facts stated therein.

10. However, in the present case it is not disputed that initial test was conducted by the Government Analyst, Chennai. However, it is the case of the petitioners that request was made vide their letter dated 22.7.21 to send the third portion of the sample, being held by the respondents for being analysed at the Central Drugs Laboratory, Kolkata. However, the request of the petitioners seems to have not been acceded to.

11. It is not in dispute that Court, of its own motion, or on the request of the petitioners, on taking cognizance, could send the samples for analysis to the Central Drugs Laboratory, Kolkata. But, it is to be pointed out that the cognizance has been taken by the court not only well after the period of limitation of three years, but beyond the shelf life of the product. In such a backdrop, the valuable right of the petitioner, provided u/s 25 (3) and (4) of the Act has been defeated by the act of the respondents in not filing the complaint well within the period of limitation and within the shelf life of the product. The decisions relied on by the learned senior counsel for the petitioners are in direct assistance to the case of the petitioners and stand squarely attracted, as the complaint itself has come to be filed well after the expiry of the shelf life of the drug.

12. Therefore, not only on the period of limitation in instituting the complaint, but also due to the non-compliance of the provision envisaged u/s 25 (3) and (4) of the Act, the complaint resulting in cognizance by the Court has severely caused prejudice to the petitioner and, therefore, the case on the file of the court below cannot be allowed to survive.

13. The delay in launching the prosecution and also denial of the right of the petitioners to have the sample tested at the Central Drugs Laboratory, Kolkata, enures to the benefit of the petitioners and, therefore, this Court is of the considered opinion that the prosecution launched against the petitioners / accused deserves to be quashed and the petition deserves to be allowed.

14. Accordingly, this Criminal Original Petition is allowed and the proceedings in S.T.C.No.48 of 2017, on the file of the Judicial Magistrate, Arakkonam, is hereby set aside. Consequently connected miscellaneous petitions, if any, are closed.

Sd/-
Assistant Registrar(CS VII)

//True Copy//

Sub Assistant Registrar

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To

1.The Judicial Magistrate,
Arakkonam.

2.The Public Prosecutor,
High Court, Madras.

+1cc to P.Ayyaswamy, Advocate Sr No.37344

Crl.O.P.No.2148 of 2018
and
Crl.M.P.Nos.817 & 818 of 2018

RSV (CO)
PR (16/09/2021)