BEFORE THE MADURAI BENCH OF MADRAS HIGH COURT
DATE ON WHICH RESERVED : 27.01.2021
DATE ON WHICH PRONOUNCED :17.02.2021
CORAM:
THE HON'BLE MR JUSTICE G.ILANGOVAN
Crl.O.P.(MD)No.15979 of 2017
and
Crl.MP(MD)No.10593 of 2017

1.M/s.Helios Pharmaceuticals, (Division of P.K.T.P Pvt Ltd),
Vill Malpur PO, Bhud, Baddi,
The Nalagarh Dist (H.P) - 173205
Rep by the Managing Director,
Rajinikant Prahaldbai Patel.

2.Rajnikant Prahaldbai Patel,
Managing Director,
M/s.Helios Pharmaceuticals, (Divison of P.K.T.P Pvt Ltd),
Vill Malpur PO, Bhud, Baddi,
The Nalagarh Dist (H.P) - 173205.

3.Nitinbhai Kanubhai Panchal,
Power of Attorney and Manufacturing Chemist of
M/s.Helios Pharmaceuticals, (Divison of P.K.T.P Pvt Ltd),
Vill Malpur PO, Bhud, Baddi,
The Nalagarh Dist (H.P) - 173205. ... Petitioners 1 to 3/Accused-1 to 3

Vs.

State rep by Drug Inspector,
Trichy II Range,
Trichy Zone,
Thillainagar,
Trichy-620018. ... Respondent/Complainant

Prayer: Criminal Original Petition filed under Section 482 Cr.P.C., to call for records in C.C.No.307 of 2017 on the file of the learned Judicial Magistrate No.I, Trichy and quash the same.

For Petitioners : Mr.N.R.Ilango
Senior Cousel for S.Ravi
For Respondent : Mr.M.Ganesan
Government Advocate (Crl.Side)

ORDER

This Criminal Original Petition has been to quash the proceedings in C.C.No.307 of 2017 on the file of the learned Judicial Magistrate No.I, Trichy.

2.The brief facts of the case is as follows:-

The first petitioner is a Public Company, incorporated under the provisions of the Companies Act, 1956 and engaged in manufacturing, supply and distribution of pharmaceutical products in

India as well as overseas. The second petitioner is the Managing Director of the Company and the third petitioner, the power of attorney and manufacturing chemist of the Company.

3.On 28.01.2015, a sample of CD ATO 20 (Atorvastatin tablets IP) Batch No.HEA0051, M/D July – 2015:, E/D June 2017 manufactured by the first accused Company was purchased by the complainant, who is the respondent herein for analysis from M/s.Sotheren Railway Hospital, Golden Rock, Trichy under Form 17, dated 28.01.2015. The sample was sent for analysis to the Government Analyst (Drugs), DTL, Chennai under Form 18 on 28.01.2015. It was found that the sample was declared as 'not of standard quality' by the Government Analyst on the ground that it does not conform to IP specification for Atorvastatin Tables.

4.According to the complainant, it is a violation under Section 18A of the Drugs and Cosmetics Act, 1940. So, a show cause notice was issued on 06.01.2017 to disclose the name and address of the person from whom the drug was purchased under Section 18E of the Act. Subsequent to that from 06.01.2017 to 27.02.2017 the respondent issued a notice to various persons to ascertain the details of the manufacturer. Finally, on 13.02.2017, he issued a notice to the first accused/Company under Section 23 (4) (III) and 25 (2) of the Act. But, that was returned. Thereafter, final report was filed on1 5.03.2017 to the Director of the Drugs and Control, Chennai. On 10.05.2017, the Director of the Drugs and Control, Chennai, called for the proposal and prosecution against the first petitioner. Thereafter, reminder No.2 was issued on 10.05.2017 since there was no residence, on 20.07.2017, a proposal was submitted for launching prosecution seeking sanction. On 16.08.2017, sanction was granted and thereafter, on 15.09.2017, the respondent filed a private complaint before the learned Judicial Magistrate, Trichy and the same was taken cognizance in C.C.No.307 of 2017.

5.Seeking quashment of the complaint, this Criminal Original Petition is filed mainly on the ground that as per Section 25 (3) and 25 (4) of the Act, the petitioner have right to get samples of the product retested by the Central Drugs Laboratory before the expiry of said product i.e., June 2017.

6.The complaint has been filed after the expiry of the shelf life of the drug. The expiry date of the drug is June 2017. But, the complaint was filed only 15.09.2017. The mandatory provision contained under Section 23(4) (ii) of the Act is not complied. So, right of the petitioner is affected.

7.His further contention is that the product must be stored under specified storage conditions as set out in its in the packaging and if not, it will automatically deteriorate. Since the product was stored with the dealers for more than 5 months, there

was every possibility of the product, got automatically deteriorate before the testing is done. The product changed many hands, such as, Thiru.S.Gurubarathi, the then Durgs Inspector, Trichy II Range from M/s.Southern Railway Hospital, Golden Rock, Trichy and thereafter, it was retained by the Government Analyst, (Drugs), DTL, Chennai-6 under Form 18 dated 28.12.2015. Moreover, the prosecution has been laid by taking recourse under Section 34 of the Act. But, how the petitioners 2 and 3 are liable is not stated. The petitioners 2 and 3 were not in management of the affairs of the Company at the relevant point of time. So, they cannot be prosecuted.

8.Heard both sides.

9.It is not necessary to elaborate the facts which led into the filing of C.C.No.307 of 2017 before the learned Judicial Magistrate, Trichy. It has been elaborately stated above. The only point, that was raised at the time of argument by the Senior counsel is that right under Section 25(3) and 25 (4) of retesting the drug was not available, since, the complaint was lodged, much after the expiry of the sample mentioned in the package as well as due to the delay, the right of retesting was lost. The petitioner would rely upon the number of judgment on this point.

10.The matter can be disposed of on short premise. So, before going into the argument, let Me reproduce the events in a chronological manner. On 28.01.2015, sample was taken by the complainant from Southern Railway Hospital. In the sample, the date of expiry is mentioned as June 2017. The sample was sent to the Analysist on 29.12.2015. The Lab Report was received on 26.01.2016 seeking manufacturing address. Memo was issued to the Southern Railway Hospital on 06.01.2017. After going through the process of ascertaining the address of manufacturer, memo was issued to the first accused Company on 13.02.2017 and complaint was filed on 15.09.2017 before the Trial Court.

11. So, the chronological events shows that much after the expiry of the product, package has been preferred by the complainant. This is the first aspect, which the learned Senior counsel for the petitioners wanted this Court to pay attention Straightway he would rely upon the judgment of the Hon'ble Supreme Court reported in **Medicamen Biotech Limited and Another Vs Rubina Bose, Drug Inspector (2008) 7 SCC 196.** In para 19 of the judgment, the relevant portion is extracted here under:-

> *"We find that there is no explanation as to why the complaint itself had been filed about a month before the expiry of the shelf life of the drug and concededly the filing of the complaint had nothing to do with the appearance of the accused in response to the notices which were to be issued by the Court after the complaint has been filed."*

12.In the concluding portion, the importance of filing the complaint much before the shelf life of the drug has been stated by the Hon'ble Supreme Court in the following words:-

> *" We are therefore, of the opinion that the facts of the case suggest that the appellants have been deprived of a valuable right under Sections 25(3) and 25(4) of the Act which must necessitate the quashing of the proceedings against them."*

13.So according to the Hon'ble Supreme Court filing of the complaint much before the expiry of the drug is necessary, So that, right available to the accused under Sections 25(3) and 25(4) can be availed. According to the Hon'ble Supreme Copurt, this is the valuable right, which is available to the accused and if there is any delay it will deprive the accused of exercising his valuable right.

14.No doubt, the substance composition of the product is also of serious concern of the public health. But, at the same time, the right available to the accused, which are statutory in nature, must also be properly adhered. If not, the criminal prosecution is liable to be quashed. Because penal provisions must be strictly construed. Every steps and procedure must be followed, properly.

15.Now, the question, which arises for consideration is ***whether any reasonable explanation is offered by the complainant for filing the complaint belatedly.*** Show cause notice was issued to the accused on 13.02.2017 as mentioned earlier. But it was returned as 'un served'. On 15.03.2017, final report has been presented to the Director of Drugs Control, Chennai. On 10.05.2017, the Director of Drugs Control, Chennai, called for proposal for prosecution against the first accused Company. Again, second show cause notice was issued on 10.05.2017, to the first accused Company. There was no response from the manufacturer. So, on 20.07.2017, a proposal was submitted for launching prosecution. On 16.08.2017, sanction for prosecution was granted. So, this is the explanation offered by the complainant. From this, it is seen that the sanction for the prosecution was granted, after the expiry of the shelf life period. So, this explanation, on the part of the complainant cannot be accepted as reasonable.

16.The next contention on the part of the accused is that there is a violation of Sections 25(3) and 25(4) of the Drugs and Cosmetics Act, 1940. Sections 25(3) and (4) of the Act reads as under:-

> *"**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 of the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

25(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 controversion 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 same 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"*

17.As per the above provision, right has been conferred upon the accused to express his intention to get the sample reanalysis within 28 days from the date of receipt of the copy of the analyst report. So, this is also a valuable right available to the accused. Section 25(2) of the Act, makes it obligatory on the part of the Inspector of Drugs to deliver one copy of the report to the person, whose name is disclosed under Section 18 (A) of the Act. 18 (A) makes it compulsory on the part of the person to disclose the name, address and other particulars of the person from whom the drug or cosmetics was acquired.

18.The next point arisea for consideration is ***whether this compulsory proceedure was adopted by the complainant***. So, in the complaint, it has been stated that a copy of Form-13 was enclosed as per Section 25(2) of the said Act and sample was also sent for analysis separately as per Section 23(4) (iii) of the said Act. The reminder was sent on 13.02.2017 and it was returned as 'un served' on 13.03.2017. So, it is seen that even though the mandatory provision under Section 25(2) was complied, filing of the complaint, after the expiry of the shelf life period, makes the complaint defective. The complainant cannot take advantage of the non service or non receipt of memo issued by the complainant, as per Section 25 (2) of the Act. This Court in a judgment reported in **Unicure (India) Pvt. Ltd. Vs State 2010 SCC online Mad 5946** has quashed the complaint by observing the following:-

"10.A Cumulative reading of the aforesaid provisions coupled with the decision of the Honourable Apex Court inMeidcamen Biotech Limited and another V.Rubina Bose, Drug Inspector reported in (2008) 7

SupremenCourt Cases 196, would unambiguously and unequivocally make the point pellucidly and palpably clear that well before the expiry of the shelf-life of the drug concerned, the complaint should be filed, then only the accused also could get the drug concerned retested by the Central Drugs Laboratory concerned. But, in this case, that test was conducted only by the Tamil Nadu Drugs Testing Laboratory and ot by the Central Drugs Labnoratory."

19.So, following the dictum laid by the Hon'ble Supreme Court and also this Court in the judgments cited above, this Court also of the considered view that the prosecution is liable to be quashed.

20.Accordingly, the proceedings in C.C.No.307 of 2017 on the file of the learned Judicial Magistrate No.I, Trichy, is quashed and the Criminal Original petition is allowed. Consequently, connected miscellaneous petition is closed.

Sd/-

Assistant Registrar

// True Copy //

/ /2021

Sub Assistant Registrar(CS)

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Note: In view of the present lock down owing to COVID-19 pandemic, a web copy of the order may be utilized for official purposes, but, ensuring that the copy of the order that is presented is the correct copy, shall be the responsibility of the advocate/litigant concerned.

To

1.The Judicial Magistrate No.I,
Trichy.

2.The Drug Inspector,
Trichy II Range,
Trichy Zone, Thillainagar,
Trichy-620018.

3.The Additional Public Prosecutor,
Madurai Bench of Madras High Court,
Madurai.

+1 CC to M/s.S.RAVI, Advocate (SR-6279[F] dated 19/02/2021)

Crl.O.P.(MD)No.15979 of 2017
and
Crl.MP(MD)No.10593 of 2017
17.02.2021

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