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BEFORE THE MADURAI BENCH OF MADRAS HIGH COURT

DATED : 17.12.2024

CORAM

THE HONOURABLE **MR.JUSTICE N.ANAND VENKATESH**

Crl.O.P(MD)No.10379 of 2019
and
Crl.M.P(MD)Nos.6513 and 6514 of 2019

1. M/s.Hindustan Syringes and Medical Devices Limited,
174, 178/25, Ballabgarh,
Faridabad, India - 121004,
Represented by its
Senior General Manager,
Mr.Rajan Khosla.

2. Rajan Khosla
Senior General Manager of
M/s.Hindustan Syringes and Medical Devices Limited,
174, 178/25, Ballabgarh,
Faridabad, India - 121004.

3. Rajiv Nath
Joint Managing Director of
M/s.Hindustan Syringes and Medical Devices Limited,
174, 178/25, Ballabgarh,
Faridabad, India - 121004.

... Petitioners

Vs

Drugs Inspector Nagercoil - I Range,
O/o. the Drug Inspector
23 G/2f, Hindu College Road,
Chettikulam, Junction Nagercoil.

... Respondent



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PRAYER: Criminal Original petitions have been filed under Sections 439 (1) (b) of the Code of Criminal Procedure, to call for the records relating to the proceedings in connection with STC No. 105 of 2019 on the file of Learned Judicial Magistrate No. II, Nagercoil and Quash the same.

For Petitioners : Mr.P.T.Ramesh Raja

For Respondent :Mr.S.Ravi
Additional Public Prosecutor

ORDER

This petition has been filed challenging the proceedings in STC No. 105 of 2019 pending on the file of the learned Judicial Magistrate No. II, Nagercoil.

2.The respondent filed a private complaint stating that the subject drug namely viz. Dispovan sterile single use needles (hereinafter referred to as a drug) was drawn for analysis by the Drug Inspector on 19.12.2017 from M/s.JMJ Surgicals. The same was sent for analysis to the Government Analyst. A report was submitted, dated 15.05.2018 by the Analyst stating that the sample does not confirm to requirements for sterility.

3.After the receipt of the above report, a show cause notice was issued to M/s.JMJ Surgicals along with the report. On receipt of the show



cause notice, the said JMJ Surgicals gave a reply stating that the drug was purchased from M/s.Essar Agencies. Hence a fresh show cause notice was issued to Essar Agencies along with the report. On receipt of the same, the said Essar Agencies informed that the drug was purchased from A1.

4.On receipt of the above reply, a show cause notice was issued to the petitioners dated 25.06.2018 along with the report and the petitioners were called upon to explain the contravention of the provisions of the Act for having manufactured and sold drug which is not of standard quality. The petitioners on receipt of the show cause notice submitted a reply, dated 09.07.2018. The petitioners took a stand that the probable cause for the failure in the sterility test was due to damage in the primary pack during the storage by the Government Analyst of Biological Control, Chennai or due to some external contamination during testing.

5.On receipt of the reply from the petitioners, a proposal was submitted before the competent authority seeking for sanction to prosecute the petitioners. The sanction order, dated 31.10.2018 was issued by the Director of Drugs Control, Chennai. Pursuant to the same, the private complaint was filed against the petitioners for the offence under Section



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18(A)(i) of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as Act) punishable under Section 27(d) of the Act.

6.The above quash petition was originally heard by this Court and by an order, dated 29.08.2022, the petition was dismissed. Subsequently, a clarification petition came to be filed in Crl.M.P(MD)No.11086 of 2023 and this Court passed the following order on 07.08.2023:

"This petition has been filed to recall the order passed by this Court in Crl.O.P (MD).No.10379 of 2019 dated 29.08.2022.

2. The main Criminal Original Petition was dismissed by this Court on 29.08.2022.

3. The learned counsel for the petitioners has brought to the notice of this Court that the factual mistake was committed by this Court that in the order it has been stated that the expiry period of the drug is October, 2023 and the order was passed in the year of August 2022 and the liberty was granted to the petitioners to workout their remedy as per Section 25(4) of the Drugs and Cosmetics Act.

4. The learned counsel for the petitioner submitted that actually the expiry period of the drug even as per the case of the prosecution is October 2022 and not October 2023 and the same was also verified by the learned Additional Public Prosecutor.

5. The learned Additional Public prosecutor appearing for the respondent submitted that the expiry period is October 2022.

6. Since the factual mistake has been committed by this Court, the order passed in Crl.O.P(MD).No.10379 of 2019 dated 29.08.2022 is hereby recalled. Accordingly, this Criminal Miscellaneous Petition is allowed.

7. Registry is directed to list the Crl.O.P(MD).No.



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10379 of 2019 for fresh hearing."

7.Pursuant to the above order, the matter was listed for final hearing before me.

8.Heard the learned Counsel appearing on either side.

9.The main ground that was urged by the learned Counsel for the petitioners is that the petitioners after the receipt of the show cause notice, clearly stated that they do not agree with the test report of the Government Analyst and that they are challenging the same and therefore, they want to get the portion of the sample to be tested at the competent laboratory. It is the grievance of the petitioners that in spite of the petitioners specifically requesting for testing the sample before the competent laboratory, which is the Central Government laboratory, the respondent has not chosen to send the sample and as a result, a valuable right that was available to the petitioner under Section 25(4) of the Act was deprived.

10.In answer to the above submission, the learned Additional



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Public Prosecutor submitted that the shelf life of the drug was up to February 2022 and in the instant case, even when the show cause notice was issued to the petitioners, the copy of the report of the Government Analyst was sent to the petitioners. That apart, the third portion of the sample was also sent to the petitioners in order to enable the petitioners to get the sample tested in the Central Government laboratory. However, the petitioners instead of testing the same in the Central Government laboratory, had chosen to test it in some other laboratory and the test report was also relied upon. He further submitted that the sanction was granted in the year 2018 and the private complaint was filed in the year 2019 and even at that point of time, the petitioners could have filed an application before the concerned Court and requested for sending the sample to the Central Government laboratory in line with the right given under Section 25(4) of the Act. The petitioners did not choose to exercise this right. Therefore, the petitioners cannot be allowed to turn around and make an allegation against the respondent as if the respondent had deprived the petitioners from sending the sample to the Central Government laboratory.

11. In reply to the above submission, the learned Counsel appearing for the petitioners relied upon the judgment of the Apex Court in



Medicamen Biotech Limited and another Vs. Rubina Bose, Drug

Inspector reported in (2008) 7 SCC 196. The petitioners relied upon paragraph No.18 in that judgment, which is extracted hereunder:

"18. In Unique Farmaids's case (supra) which was a case under the Insecticides Act which has provisions analogous to Section 25(4) of the Act, the court found that the accused had indeed made a request to the Inspector for sending the sample for re-testing within the prescribed time limit and as this request had not been accepted an important right given to an accused had been rendered ineffective on which the proceedings could be quashed. This is what the Court had to say:

"12. It cannot be gainsaid, therefore, that the respondents in these appeals have been deprived of their valuable right to have the sample tested from the Central Insecticides Laboratory under sub-section (4) of Section 24 of the Act. Under sub-section (3) of Section 24 of the act signed by the Insecticides Analyst shall be evidence of the facts stated therein and shall be conclusive evidence against the accused only if the accused do not, within 28 days of the receipt of the report, notify in writing to the Insecticide Inspector or the court before which proceedings are pending that they intend to adduce evidence to controvert the report. In the present cases the Insecticides Inspector was notified that the accused intended to adduce evidence to controvert the report. By the time the matter reached the Court, the shelf life of the sample had already expired and no purpose would have been served informing the Court of such an intention. The report of the Insecticide Analyst was, therefore, not conclusive. A valuable right had been conferred on the accused to have the sample tested from the Central Insecticides Laboratory and in the circumstances of the case the accused have been deprived of that right, thus, prejudicing them in their defence.

13. In these circumstances, the High Court was right in concluding that it will be an abuse of the process of the court if



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the prosecution is continued against the respondents, the accused persons. The High Court rightly quashed the criminal complaint. We uphold the order of the High Court and would dismiss the appeals."

*We find that this judgment helps the case of the appellant rather than that of the respondent because in spite of two communications from the appellant that it intended to adduce evidence to controvert the facts given in the report of the Government Analyst, the fourth sample with the Magistrate had not been sent for re-analysis. The observations in *Amery Pharmaceuticals's* case (supra) are also to the same effect. We find that the aforesaid interpretation supports the case of the appellants inasmuch they had been deprived of the right to have the fourth sample tested from the Central Drugs Laboratory. It is also clear that the complaint had been filed on the 2nd July 2002 which is about a month short of the expiry date of the drug and as such had the accused appellant appeared before the Magistrate even on 2nd July 2002 it would have been well nigh impossible to get the sample tested before its expiry.*

12.This Court has carefully considered the submissions made on either side and the materials available on record.

13.The only legal ground that has to be considered by this Court is as to whether the petitioners were deprived of their right to send the sample for further testing before the Central Government laboratory and therefore, the proceedings against the petitioners is vitiated.



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14. The sample of the drug was taken on 19.12.2017 and the report of the Government Analyst is dated 15.05.2018. This report states that the drug is not of standard quality. Ultimately, the authority was able to ascertain that it is the petitioners, who had manufactured and sold the drug and hence a show cause, dated 25.06.2018 was issued to the petitioners. While issuing the show cause notice, the petitioners were also informed about the result of the Government Analyst and a copy of the same was also sent to the petitioners and all the particulars were sought for from the petitioners. Apart from that, the third portion sample was also sent to the petitioners, which is quite evident from the materials available before this Court. The petitioners on receipt of the same, gave a reply and in that reply, the petitioners questioned the report of the Government Analyst and expressed that the sample has to be tested by a competent authority. This would mean that the petitioners wanted the sample to be tested by the Central Government laboratory.

15. The petitioners utilized the third sample that was sent to them and it was tested in a private laboratory and the test report was also relied upon by the petitioners.



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16.The short issue that arises for consideration is as to when the petitioners had expressed their mind that the sample has to be tested by the Central Government laboratory, the respondent, by not sending that sample to the Central Government laboratory, has really deprived the valuable right that was available to the petitioners under Section 25(4) of the Act.

17.It is now too well settled that the right available under Section 25(4) of the Act is an invaluable right which cannot be deprived. If that right is deprived, that by itself becomes a ground to interfere with the proceedings.

18.The purpose of sending the sample to the Central Government Laboratory is to enable the concerned person to challenge the report of the State Government Analyst. The judgment that has been relied upon by the learned Counsel for the petitioners and many of the other judgments on similar lines, are cases where the sample is not sent to Central Government Laboratory and by the time the case ends up in the Court, the shelf life comes to an end and thereby the concerned person is deprived of the important right given to him under the Act.



19. When the above judgments are applied to the facts of the present case, it is seen that the shelf life of the drug was up to February 2022 and it is evident from the analysis report submitted by the Government Analyst. Hence this right is available till the shelf life of the drug is available. The petitioners expressed their mind that they want to challenge the report of the Government Analyst and they wanted the sample to be sent for further analysis. Admittedly, the respondent did not send the sample for further analysis. However, the respondent had sent the third portion sample to the petitioners as early as on 25.06.2018. When this sample was received by the petitioners, it ought to have been sent to the Central Government Laboratory, instead the petitioner had chosen to send it to some private Laboratory. Even thereafter, after the summons was served on the petitioners in the private complaint, in the year 2019, the petitioners had an opportunity to send the sample for further analysis by making a request before the Court as provided under Section 25(4) of the Act. The petitioners did not choose this option also. The quash petition was filed before this Court on that ground. Thus, it is quite apparent that for the period from 2018 to February 2022, the petitioners had the opportunity to send the sample for analysis to the Central Government Laboratory and for reasons best known to the petitioners, it was not sent. Just because, the respondent



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did not send the sample for analysis to the Central Government Laboratory, that by itself did not prevent the petitioner from sending the sample for analysis since such a right is given to the petitioners under Section 25(4) of the Act. If the petitioners did not utilise that opportunity, the petitioners cannot be permitted to turn around and put the blame on the respondent as if an important right has been deprived.

20. In the light of the above discussion this Court holds that the right to send the sample for analysis to Central Government Laboratory was very much available and the petitioners did not utilise the said right. Hence this Court holds that the right under Section 25(4) of the Act was not deprived to the petitioners by the respondent but on the other hand it is the petitioners who deprived themselves the right available for them by not sending the third sample for the period from 2018 to 2022.

21. This Court does not want to go into the other issues raised by the learned Counsel for the petitioners since they are all factual in nature and it requires appreciation of evidence. Hence the petitioners are permitted to raise all the other grounds before the Court below and the same shall be considered on its own merits and in accordance with law.



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22. In the result, this criminal original petition stands dismissed and there shall be a direction to the Court below to dispose of the case in S.T.C.No.105 of 2015 within a period of three months, from the date of receipt of a copy of this order. Consequently, connected miscellaneous petitions are closed.

23. After the order was passed, the learned Counsel for the petitioners requested this Court to dispense with the appearance of the petitioners. Considering the said request, the presence of the petitioners is dispensed with and the petitioners shall be present before the Court below at the time of questioning under Section 313 (1)(b) of Cr.P.C and at the time of passing of the final judgement and as and when required. The Counsel representing the petitioners shall cross examine the witnesses on the same day they are examined in chief and shall co-operate for the completion of the proceedings within the time frame fixed by this Court.

17.12.2024

Internet : Yes
Index : Yes/No
NCC : Yes/No
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1.The Judicial Magistrate No.II,
Nagercoil.

2.The Drugs Inspector Nagercoil - I Range,
O/o. the Drug Inspector
23 G/2f, Hindu College Road,
Chettikulam, Junction Nagercoil.

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



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N.ANAND VENKATESH, J.

LR

Crl.O.P(MD)No.10379 of 2019

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