IN THE HIGH COURT OF JUDICATURE AT BOMBAY
CRIMINAL APPELLATE JURISDICTION

WRIT PETITION NO.2950 OF 2015
WITH
CRIMINAL APPLICATION No. 335 OF 2015
IN
WRIT PETITION No. 2950 OF 2015

Parenteral Drugs (India) Ltd and Ors. ...Petitioners

Versus

The State of Maharashtra, through
the Drug Inspector, Sindhudurg ...Respondent

WITH
WRIT PETITION No. 2951 OF 2015
WITH
CRIMINAL APPLICATION No. 334 OF 2015
IN
WRIT PETITION No. 2951 OF 2015

Manoharlal Umashankar Gupta and Ors. ...Petitioners

Versus

The State of Maharashtra, through
the Drug Inspector, Sindhudurg ...Respondent

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Mr.Nikhil Sakardande a/w. Mr.Ibrahim Merchant and Mr.Vijayesh Atre for the Petitioners in both the Petitions.
Mr.A.R.Patil, APP for the Respondent-State.

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CORAM : MRS. MRIDULA BHATKAR, J.
DATE : 23 APRIL 2019

JUDGMENT

1. These Petitions are directed against the order dated 4th April, 2015 passed by the learned Sessions Judge, Sindhudurg- Oros., thereby

dismissing Criminal Revision Application No. 18 of 2015 so also the order dated 24th September, 2014 passed by the learned Chief Judicial Magistrate, Sindhudurg-Oros in C.C. No. 42 of 2014, thereby issuing process against the petitioners.

2. Petitioner No.1 is a company and petitioner No.2 is a Director and petitioner No.3 is an Assistant Production Manager of the company in both the Petitions.

3. The petitioners/accused are facing prosecution under sections 18 (a) (i), 16, 18-B and 34 of the Drugs and Cosmetics Act, 1940 (for short, “the said Act”). The Drug Inspector from the office of the Assistant Commissioner, Food and Drugs Administration is an Authorized Officer to file a complaint.

4. Petitioner No.1 i.e., company is manufacturing the drug viz., compound sodium lactate injection IP. On 3rd August, 2012, the respondent had received a complaint from the Civil Surgeon, District General Hospital, Sindhudurg- Oros that the compound sodium lactate injection-IP B. No. 1D-431 manufactured by petitioner No.1 company was having white coloured fibrous substances, suspended in the injectable function and, therefore, the respondent visited the pharmacist's store and made an inquiry. Thereafter, he had drawn three samples from the pharmacist's store as per provisions of the said Act. After following the procedure of the said Act, one sample was

sent to the Government Analyst on 6th August, 2012. On 30th August, 2012, the respondent had received an analytical report of the said sample from the Government Analyst that the said sample of the drug was not of standard quality as defined in the said Act because “the sample is infested with fungus growth”. Thereafter, a notice under section 18A of the said Act was issued to the petitioners/accused and after having communication between the petitioners/accused and the original complainant, the complaint was filed on 10th September, 2014 before the Chief Judicial Magistrate, Sindhudurg. The process was issued on 24th September, 2014. Notice was received on 18th October, 2014, which was returnable on 24th November, 2014.

5. The issuance of process was challenged only on the law point that the order of issuance of process is defective for non-compliance of the procedure laid down under the said Act. Thus, a short issue is involved in this case whether the order of issuance of process is illegal for want of compliance under sub-sections 3 and 4 of section 25 of the said Act.

6. Mr.Sakharande, the learned Counsel for the petitioners/accused has pointed out that after receipt of the notice under section 18A of the said Act informing that the drug was not of standard quality, the petitioners/accused have communicated that they want to controvert the report of the Government Analyst. He has relied on letter dated 11th September, 2012

communicating non-acceptance of the report. The compliance of sub-section (3) of section 25 of the said Act shall be communicated within a period of 28 days of the receipt of a copy of the report. He has submitted that in the said letter, it was specifically mentioned that they want to carry out test on the other sample and obviously, for the purpose of adducing more evidence to challenge the report. In support of his submissions, he has relied on the judgment in the case of ***Northern Mineral Limited Versus Union of India and another*** reported in **(2010) 7 SCC 726.** He has submitted that the shelf life of the drug was expired on 31st October, 2014 and the complaint was filed before the learned Judicial Magistrate First Class, Sindhudurg on 10th September, 2014 and notices were issued to the petitioners/accused on 18th October, 2014 and the first date of appearance before the Court was 24th November, 2014. Thus, due to delay, the petitioners/accused could not get an opportunity to request the Court for sending sample drug for testing or analysis to the laboratory. In support of these submissions, on the point of filing complaint, he has relied on the following judgments :

(i) ***State of Haryana Versus Unique Farmaid (P) Ltd. and Others*** reported in ***(1999) 8 SCC 190;***

(ii) ***Medicamen Biotech Limited and another Versus Rubina Bose, Drug Inspector*** reported in ***(2008) 7 SCC 196.***

On the point of making vague allegations in the complaint against the Directors of the Company, he has relied on the judgment in the case of **Municipal Corporation of Delhi Versus Ram Kishan Rohtagi & others** reported in ***(1983) 1 SCC 1.***

7. Mr.Patil, the learned Public Prosecutor has supported the order of issuance of process passed by the learned Sessions Judge. He has relied on the affidavit dated 9th March, 2016 of Parvathy Sangameshwar Iyer, Assistant Commissioner, Food and Drugs Administration, Sindhudurg. He has submitted that the samples were collected at the time of inspection and one of the samples was sent to the laboratory. An analytical report dated 27th August, 2012 discloses that the drug sample was declared as “not of standard quality” as defined under the said Act and the reason was given “the sample is infested with fungus growth”. He has further submitted that the prosecution has complied with the provisions under sections 23 and 25 of the said Act. He has challenged the compliance of sub-section (3) of section 25 of the said Act made by the petitioners/accused. While discussing the language in the letter dated 11th September, 2012 about communication of non-acceptance of the report, Mr. Patil, the learned Public Prosecutor has forcefully argued that there is absence of evidence to show intention to controvert the report on the side of the accused. On relying sub-section (3)

of section 25 of the said Act and on comparing the letter dated 11th September, 2012 written by the petitioners/accused to the office of the Assistant Commissioner, Food and Drugs Administration, he has submitted that the letter does not fall under sub-section (3) of section 25 of the said Act and, therefore, sub-section 4 of the said Act cannot be attracted. He has stated that the petitioners/accused have lost their right under sub-section (4) of section 25 of the said Act requesting the Court to send the sample for re-testing. On receipt of the summons, in October itself, the petitioners/accused should have moved an application for sending the sample for re-testing. In support of his submissions, he has relied on the following judgments :

(i) ***Amery Pharmaceuticals and another Versus State of Rajasthan*** reported in ***(2001) 4 SCC 382;***

(ii) ***State of Haryana Versus Brij Lal Mittal and others*** reported in ***(1998) 5 SCC 343***;

(iii) ***Ram Shankar Misra Versus State of U.P.*** reported in ***(1980) 1 SCC 255.***

8. In the present case, the chronology of the events is not disputed. Admittedly, the factory was inspected on 3rd August, 2012 and thereafter, one sample was sent to the Government Analyst on 6th August, 2012. The report was received on 30th August, 2012 and the said report was

communicated to the petitioners/accused under section 18A of the said Act on 4th September, 2012. It is admitted that on 4th September, 2012, a letter was issued by the Drug Inspector to the petitioners/accused under section 18A of the said Act. It is also not disputed that on 11th September, 2012, the petitioners/accused sent a letter to the office of the Assistant Commissioner, Food and Drugs Administration (M.S.). The said letter according to Mr.Sakhardande, the learned Counsel for the petitioners/accused is an objection by the petitioners/accused under sub-section (3) of section 25 of the said Act.

9. Sub-section (4) of section 25 of the said Act gives right to the accused to get sample of the drug, which is produced before the Magistrate to be sent for test or analysis to the laboratory and, thereafter, it is mandatory on the Government Analyst to analysis the Court sample and shall send a report. If such report is sent, then that is to be treated as conclusive evidence of the facts stated therein. Thus, in a way, sub-section (4) of section 25 of the said Act is helpful to both the parties i.e., the accused as well as the complainant. It ensures the right of the accused to get sample retested when it is sent by the Court. Once that sample is produced before the Court and it is in the custody of the Court, then any possibility of tampering the said sample in the process of sending it from the Court to the laboratory and from the laboratory to the Court is done away. Once the

sample is retested and report in writing is sent by the Director of Central Drug Laboratory based on the said sample, then the said report is treated as conclusive proof of the facts stated therein. Thus, there is presumption of the facts provided under sub-section (4) of section 25 of the said Act, which is in favour of the prosecution.

10. However, compliance of sub-section (3) of section 25 of the said Act is a condition precedent for sending and getting the Court sample retested and, therefore, it is necessary to look into sub-section (3) of section 25 of the said Act. Though it says that the report of the Government Analyst shall be conclusive, however, it puts the rider that if a person from whom the sample is collected or the other person may be manufacturer and concerned with the drug expresses his intention to adduce evidence in controversion of the report within 28 days of the receipt of a copy of the report. On receipt of the report, it is necessary for the opposite party to inform the Inspector or the concerned authority that the report is not acceptable and the party wants to controvert it.

11. Sub-section 3 of section 25 of the said Act reads as under :.

> *"(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 controversion of the report".*
>
> (emphasis placed)

12. As per sub-section 3 of section 25 of the said Act, the opposite party has to fulfill the following things :

(i) There should be a written communication to the Inspector or the Court;

(ii) It should be within 28 days from the receipt of the copy of the report;

(iii) In the communication, the opposite party should mention his/ her intention to adduce evidence in controversion of the report.

13. Let me advert to impugned letter dated 11th September, 2012. It is a written communication of the petitioners/accused to the office of the

Assistant Commissioner, Food and Drugs Administration (M.S). The said letter is a reply to the notice under section 18 A of the said Act and it has referred to the report of the Government Analyst dated 27th August, 2012. The contents and the language used in the said letter is a matter of dispute and, therefore, it is necessary to see whether the letter manifests the intention of the petitioners/ accused to controvert the said report. For that purpose, the letter dated 11th September, 2012 is required to be reproduced :

> *"Dear Sir,*
>
> *This is with reference to your notice dated 4th September, 2012, regarding failure of our sample of Compound Sodium Lactate Injection supplied vide batch no.: ID-431, Mfg.Date 11-2011 drawn by Mr.S.P.Yadav (Drug Inspector), from the premises of District General Hospital, Sindhudurg, Sindhudurgnagari, M.S. and we are in the process of recalling the same.*
>
> *We would like to bring to your notice that we have physically checked the control sample and found it clear. We therefore request you to provide us with 4 bottles as per Section 18A read with Section 23 (4) of the Drugs and Cosmetics Act, 1940, to carry out the complete testing procedure, as the Drug Laboratory has only carried out the tests of 1 bottle.*
>
> *Also it should be noted that the said batch has been supplied to many places all over India and we have not received any complain on the quality of the same from anywhere.*
>
> *Thanking you".*

14. It is true that the said letter is not specifically worded that the petitioners/accused wanted to adduce evidence in contraversion of the report. However, in paragraph Nos. 2 and 3 of the said letter, the petitioners/accused have clearly sounded that they disagree with the report and they wanted to go for re-testing of other samples collected by them. So they have demanded those sample bottles to carry out complete test procedure. It is also informed that they have not received any complaint on the quality of the said drug from anywhere. It is not expected from the common man to express himself in the exact legal language, but it should be worded in such a manner that after reading the said communication, another common man should be able to understand that the report is not acceptable and party wants to controvert the said by placing some evidence.

15. In the present case, the petitioners/accused want to examine all the samples of four bottles, as in the report, only one sample is tested. It is also stated that their quality of drug is not challenged by anybody till today. Thus, protest is not ambiguous, but one understands that the party wants to controvert the report by adducing more evidence.

16. Thus there is compliance under sub-section (3) of section 25 of the said Act and, therefore, the petitioners/accused have every right to request

the Court for re-testing the sample, which was produced before the Court. When the petitioners/ accused appeared before the Court, the shelf life of the sample was expired on 30th October, 2012. The petitioners/accused had lost their right. Thus, there is non-compliance of sub-section (4) of section 25 of the said Act, which is very valuable right of the accused.

17. The case of ***Northern Mineral Limited*** *(supra)* was under Insecticides Act and the Supreme Court had dealt with an intention of the accused to adduce evidence in controversion of the report and had discussed sub-section 4 of section 24 of the said Act, which is pari materia to section 25 of the said Act. Paragraph 22 of the said order reads as under :

> *"22. From the language and the underlying object behind Sections 24 (3) and (4) of the Act as also from the ratio of the aforesaid decisions of this Court, we are of the opinion that mere notifying the intention to adduce evidence in controversion of the report of the Insecticide Analyst confers on the accused the right and clothes the court with the jurisdiction to send the sample for analysis by the Central Insecticides Laboratory and an accused is not required to demand in specific terms that the sample be sent for analysis to the Central Insecticides Laboratory. In our opinion the mere intention to adduce evidence in controversion of the report, implies demand to send the sample to the Central Insecticides Laboratory for test and analysis".*

18. In the case of ***Amery Pharmaceuticals and another*** *(supra),* the Supreme Court had considered sub-sections (3) and (4) of section 23 and sub-sections (3) and (4) of section 25 of the said Act. It was contended by

the party that the Inspector did not send or give one portion of the sample to the appellants and, therefore, the mandatory provision contained in section 23 (4) (iii) of the said Act was breached and, therefore, the Supreme Court held that if the accused wants to controvert the report of the analyst, which has presumptive, then it can be done by following proper procedure under sub-sections (3) and (4) of section 25 of the said Act. Thus, the samples kept with the vendor cannot be re-tested to challenge the report, but the samples, which are kept with the Court, are to be sent to the analyst after following proper procedure under sub-section (3) of section 25 of the said Act and, therefore, the Supreme Court dismissed the Appeal.

In view of the facts, this particular case is not helpful to the prosecution. However, in ***Amery Pharmaceuticals and another,*** the Supreme Court had discussed the law of interpretation of statutes and held that,

> *"25. In our view the court should lean to an interpretation as would avert the consequences of depriving an accused of any remedy against such evidence. He must have the right to disprove or controvert the facts stated in such a document at least at the first tier. It is possible to interpret the provisions in such a way as to make a remedy available to him. When so interpreted the position is thus: the conclusiveness meant in Section 25 (3) of the Act need be read in juxtaposition with the persons referred to in the sub-section".*

19. In the case of ***Brij Lal Mittal and others*** *(supra),* the Supreme Court had discussed sub-sections (3) and (4) of section 25 of the said Act. In the said case, copy of the report was communicated to the accused, but there was no communication from the party. Thereafter, the Inspector had specifically sent a letter informing that the party has right under sub-section (3) of section 25 of the said Act and whether party wanted to take benefit of the said provisions. However, the manufacturers did not exercise their right i.e., sending of letter within 28 days from the receipt of the letter and, therefore, the ratio laid down in the said case is not applicable to the present case.

20. In the case of ***Ram Shankar Misra*** *(supra),* the Supreme Court had described the procedure laid down under sub-section (4) of section 25 of the said Act. Hence, it is not applicable to the present case.

21. In the case of ***Unique Farmaid (P) Ltd. and Others*** *(supra),* an issue about the accused's right to get the sample tested from the Central Insecticides Laboratory under the Insecticides Act, 1963 was considered. The Supreme Court in paragraph 11 of the judgment had discussed the procedure laid down under the Insecticides Act. The procedure laid down under the Insecticides Act is similar to the Drugs and Cosmetics Act, 1940. Then in order to safeguard the right of the accused to have the sample

tested from Central Insecticides Laboratory, it is incumbent on the prosecution to file the complaint expeditiously so that the right of the accused is not lost. In the present case, by the time the respondents were asked to appear before the Court, expiry date of the insecticide was already over and sending of sample to the Central Insecticides Laboratory at that late stage would be of no consequence. On this point, the Supreme Court relied on the ratio laid down in the case of ***The State of Punjab v. National Organic Chemical Industries Ltd.,*** reported in ***(1996) 10 SC 480.***

In the case of ***Unique Farmaid (P) Ltd. and Others,*** similar situation had occurred when the matter reached the Court, the shelf life of the sample had already been expired and no purpose would have been served informing the Court intention of the accused to controvert the report. The Supreme Court also held that it is a valuable right conferred on the accused to have the sample tested from the Central Insecticides Laboratory and, therefore, denial of his right is prejudiced his defence.

22. In the case of **Medicamen Biotech Limited and another** *(supra),* the Supreme Court while deciding the matter under the said Act, had dealt with the procedure laid down under clause (i) sub-section (4) of section 23, sub-sections (3) and (4) of section 25 and section 27 of the said Act and especially with the context of delay in filing the complaint under section 27 of

the said Act. In the said case also, the sample was collected on 14th June, 2000 and the complaint under section 27 of the said Act was filed on 2nd July, 2002, and the shelf life of the sample drug was expired in the month of August, 2002. Thus, the Magistrate's sample could not be got tested within time as provided under sub-section (4) of section 25 of the said Act. The prosecution raised an objection that the appellant had never expressed a desire to controvert the report of the Drug Analyst. However, the Supreme Court while turning down this objection, considered the letter written by the accused to the Government wherein it is mentioned that they do not agree with the Government Analyst report that the sample is not of standard quality. The Supreme Court had accepted the case of the appellants and quashed the proceedings on the point that the appellants rights under sub-sections (3) and (4) of section 25 of the said Act were lost due to delay in filing complaint.

23. The learned Judge of the Sessions Court while passing order, had lost sight of the procedure laid down under sub-sections (3) and (4) of section 25 of the said Act and committed error in interpreting the letter and also the relevant provisions of the said Act. The order of issuance of process passed by the trial Court and the order passed by the learned Sessions Judge are illegal and not tenable in law. Hence, Rule is made absolute with the following order:

ORDER

The order dated 4th April, 2015 passed by the learned Sessions Judge, Sindhudurg-Oros in Criminal Revision Application No. 18 of 2009 so also the order dated 24th September, 2014 passed by the learned Chief Judicial Magistrate, Sindhudurg-Oros in C.C. No. 42 of 2014 of issuance of process are hereby quashed and set aside.

24. In view of disposal of both the Petitions, Criminal Applications do not survive and the same are accordingly disposed of.

(MRIDULA BHATKAR, J.)