IN THE HIGH COURT OF JUDICATURE AT BOMBAY
CRIMINAL APPELLATE JURISDICTION
WRIT PETITION NO.2777 OF 2024

M/s. C.B.Healthcare and Ors. ... Petitioners
versus
Union of India … Respondent

Mr. Nitin Bhasin with Mr. Vishal N. Nevshe, for Petitioners.
Mr. Anilkumar Singh i/by Mr. D.P.Singh, for Respondent – Union of India.
Mr. K.C.Shinde, APP for State.

CORAM: N.J.JAMADAR, J.

RESERVED ON : 11 DECEMBER 2025
PRONOUNCED ON : 24 MARCH 2026

JUDGMENT :

1. Rule. Rule made returnable forthwith, and, with the consent of the learned Counsel for the parties, heard finally.

2. By this Petition under Article 227 of the Constitution of India, the Petitioners seek to quash and set aside criminal prosecution initiated against the Petitioners in Special Case No.32 of 2021 before the Special Judge, Dadra and Nagar Haveli, Silvasa, for an offence punishable under Section 27(d) of the Drugs & Cosmetics Act, 1940 (the Drugs Act, 1940).

3. The background facts necessary for the determination of this Petition can be summerized as under :

3.1 The Petitioner No.1 is a Partnership firm. It is engaged in pharmaceutical manufacturing business. Petitioner Nos.2 to 5 are the

partners of Petitioner No.1. The Petitioner No.1 manufactures drugs at Baddi, District Solan, Himachal Pradesh. The Petitioner No.1 was holding a valid licence to manufacture FEXINOL-12 – Fexofenadine Hydrochloride Tablets IP.

3.2 Respondent-complainant is a Drugs Inspector appointed under the Drugs Act, 1940. Respondent claimed that, on 29 November 2016, he had visited and inspected the premises of Vinoba Bhave Civil Hospital's Central Medical Store at Silvasa, and, drawn a sample of FEXINOL-12, Batch No.CBT-400/16, manufactured by the Petitioner No.1. The said sample was purportedly drawn for the purpose of test and analysis by issuing Form No.17. On 30 November 2016, one portion of the sealed sample was allegedly sent by the Respondent to Government Analyst, Central Drugs Testing Laboratory, Mumbai, in Form No.18. The Respondent allegedly received a report in Form No.13 dated 6 July 2017 from the Government Analyst, opining that the sample was 'not of standard quality'.

3.3 Thereupon, Respondent issued a show cause notice along with one sealed portion of the sample, to the Central Medical Store, Civil Hospital, Silvasa, directing the store to stop usage / distribution and to disclose the name / address of the firm/ person from whom the said drug was obtained.

3.4 Eventually, the distribution chain of the subject drug was traced back to Petitioner No.1. A joint investigation was carried out by the Deputy Drugs Controller (I), CDSCO, Baddi Zone, alongwith State FDI Officials. A joint

investigation report dated 4 September 2017 was prepared. Thereafter, on 6 November 2019 sanction to initiate prosecution against the Petitioners was obtained from the Drugs Controller General of India.

3.5 Armed with the said sanction, the Respondent filed a complaint before the Special Judge at Silvasa on 28 September 2021. By an order dated 28 September 2021, the learned Special Judge, Dadra and Nagar Haveli, Silvasa, was persuaded to issue process against the Petitioners for an offence punishable under Section 27(d) of the Drugs Act, 1940.

4. The Petitioners have assailed the prosecution by raising a slew of exceptions. Firstly, in clear violation of Rule 45 of the Drugs Rules, 1945, there was an inordinate and unexplained delay in testing the samples. Secondly, there was non-compliance of the mandate contained in Section 23(4)(ii) of the Drugs Act, 1940, as the Respondent failed to send one portion of the sealed sample to the Petitioner No.1. Thirdly, on account of the breach of the provisions contained in Sections 23 and 25 of the Drugs Act, 1940, an invaluable right of the Petitioner No.1 to have the retesting of the sample was lost. Fourthly, the impugned order of issuance of process suffers from the non-application of mind, as the learned Special Judge has issued the process in a mechanical manner. Fifthly, in any event, the complaint is conspicuously silent about the specific role of Petitioner Nos.2 to 5 and on the basis of bald assertions in the complaint, they could not have been roped in by invoking the

provisions contained in Section 34 of the Drugs Act, 1940. Sixthly, the learned Special Judge could have not taken cognizance of the offence directly in view of the interdict contained in Section 193 of the Code of Criminal Procedure, 1973. Lastly, it was contended that, the Respondent No.1 being a Drug Inspector appointed by the Central Government had no authority to initiate action in view of the jurisdictional limits of the Central Drugs Inspector under the Drugs Act, 1940, and the Drugs Rules, 1945.

5. The Respondent has resisted the Petition by filing an affidavit in reply. Each of the contentions on behalf of the Petitioners were sought to be met point by point. In substance, Respondent has asserted that, there was neither any jurisdictional transgression nor procedural infraction on the part of the Respondent in initiating action against the Petitioners.

6. On the aspect of the alleged delay in testing the sample, it was contended that, since the reference standard and the impurity standard required to test the sample were not readily available, some time was consumed in procuring the reference and impurity standard, and, thereafter, testing the sample.

7. In regard to the alleged non-compliance with the provisions contained in Section 23(4)(iii) and the loss of right of retesting of the sample, the Respondent contended that the Petitioners did not avail the opportunity, despite service of notice under Section 18A, on 26 December 2017. The

Petitioners did not intimate that, they intended to adduce evidence in controversion of the report of the Government analyst within a period of 28 days of the receipt of copy of the report. Thus, it was not open for the Petitioners to now urge that their right of retesting was lost. The delay in filing the complaint was also sought to be accounted for by ascribing reasons.

8. In the light of the aforesaid pleadings and the material on record, I have heard Mr. Bhasin, learned Counsel for the Petitioners, and Mr. D.P.Singh, learned Special Counsel for the Respondent, at some length. Learned Counsel took the Court through the material on record.

9. The Petitioners seek quashment of the prosecution by raising multi-fold grounds, as enumerated above. Those grounds can be broadly classified in two parts. First, the infraction of the procedural requirements under the Drugs Act, 1940 and the Drugs Rules, 1945, by the Respondent and the other authorities under the Drugs Act, 1940. Second, the alleged infirmities in the prosecution, post the stage of the sanction for initiation of the prosecution, comprising of the lack of adequate averments in the complaint to rope in Petitioner Nos.2 to 5, the alleged non-application of mind by the learned Special Judge in issuing the process, and, in taking the cognizance of the offence directly without the case having been committed to the Special Court.

10. In the context of the challenge, this Court considers it appropriate to first deal with the grounds premised on the alleged non-compliance of the

provisions contained in the Drugs Act, 1940 and the Drugs Rules, 1945, as that constitutes the substratum of the challenge.

11. To start with the ground of delay in testing the sample, forcefully canvassed by Mr. Bhasin. On facts, there does not seem much controversy. The inspection was conducted and the sample was drawn on 29 November 2016. One portion of the sample was sent to the CDTL, Mumbai on 30 November 2016. Government Analyst, CDTL, issued a report of analysis in Form No.13 on 5 July 2017, opining that the sample was 'not of standard quality'. In the light of these facts, the aspect of consequences of delay in testing the sample deserves to be appreciated.

12. The Drugs Act, 1940 regulates the import, manufacture, distribution and sale of the drugs and cosmetics. Chapter IV of the Drugs Act, 1940 contains a fasciculus of the provisions under the caption 'Manufacture, Sale and Distribution of Drugs and Cosmetics'. Section 18 of the Drugs Act, 1940 prohibits the manufacture for sale or for distribution or sale or stock or exhibit or offer for sale or distribute any drug which is not of a standard quality or is misbranded, adulterated or spurious. Section 21 provides for appointment of Inspector. Section 23 confers powers on the Inspector, inter alia, to inspect any premises and take samples of any drugs or cosmetics. The procedure of Inspectors is regulated by Section 23. Section 25 deals with the analysis of the sample by the government analyst and the evidentiary value of the reports

of the government analyst.

13. Section 27 prescribes penalty for manufacture, sale etc., of the drugs in contravention of the provisions of Chapter IV. Section 32 of the Drugs Act, 1940 contains provisions in regard to the cognizance of the offences. Sub-section (2) of Section 32 declares that, save as otherwise provided in the said Act, no Court inferior to that of a Court of Session shall try an offence punishable under the said Chapter. Section 33 of the Act, 1940 empowers the Central Government to make rules for the purpose of giving effect to the provisions of the said Chapter.

14. In exercise of the powers conferred under Sections 6(2), 12, 33 and 33N of the Drugs Act, 1940, the Central Government has framed Drugs Rules, 1945. Part V of the said Rules deals with the Government Analysis, Inspectors, licensing authorities and Controlling Authorities. Rule 45 of the Drugs Rules, 1945, with which we are primarily concerned, reads as under :

> "**Duties of Government Analysts**
>
> (1) The Government Analyst shall cause to be analysed or tested such samples of drugs as may be sent to him by Inspectors or other persons under the provisions of Chapter IV of the Act and shall furnish reports of the results of test or analysis in accordance with these Rules within a period of sixty days of the receipt of the sample :
>
> Provided that where it is not possible to test or analyse the sample within the specified period, the Government Analyst shall seek extension of time from the Government giving

specific reasons for delay in such testing or analysis.

(2) A Government Analyst shall from time to time forward to the Government reports giving the result of analytical work and research with a view to their publication at the discretion of Government."

15. Under Rule 45, a duty is cast on the Government Analyst to analyse or cause to be analysed or tested the sample of the drugs and furnish report of the result of the test or analysis in accordance with the said rules, within a period of 60 days of the receipt of the sample. The imperativeness of this duty to analyse or test the samples and furnish report within the stipulated period is underscored by employing the word 'shall' in the first and second part of sub-rule (1) of Rule 45. Government Analyst is, thus, enjoined to test the sample and also furnish report within the stipulated period. On a plain textual interpretation, time for testing and furnishing the report also appears peremptory and the only outlet that is available for not adhering to the time-line is the action as envisaged by the proviso to sub-rule (1). The rule making authority was, alive to the fact that, in a given case, it may not be possible to test or analyse the sample within the specified period and, thus, an outlet was provided to the Government Analyst to seek extension of time from the Government, giving specific reasons for such testing and analysis. Again, the mandatory nature of the time limit is emphasisd by employing the phrase 'shall seek an extension of time', in the proviso to sub-rule (1) of Rule

45.

16. The object behind prescribing the time limit for the testing and furnishing the report of analysis is not far to seek. Delay beyond the specified period has the propensity to render the report of analysis suspect as the properties of the drugs may be lost due to the lapse of time rendering the report unworthy of credence.

17. In the aforesaid context, Mr. Bhasin would submit that, there was a clear contravention of the provisions of Rule 45, as the report of analysis was furnished after seven months from the date of receipt of sample. Reliance was placed on the judgments of this Court in the cases of **M/s. Quixotic Healthcare and Ors. V/s. State of Maharashtra and Ors.**[1] and **Swapnil and Ors. V/s. State of Maharashtra**[2].

18. In the case of **M/s. Quixotic Healthcare (supra)**, a learned Single Judge of this Court enunciated that, when the sample was tested after the expiry period, the result is bound to be 'not of standard quality'. There was no explanation by the laboratory about the delay in testing. Such report cannot be considered at all. Benefit of such lapse on the part of the laboratory should be given to the accused.

19. In the case of **Swapnil and Ors. (supra)**, another learned Single Judge of this Court, after noting the provisions of Rule 45, in the context of the

1 2020 ALL Mr (Cri.) 1880
2 2024 SCC Online Bom 2074

analysis of the sample after one year of its receipt, observed that the analysis of the sample within a period of 60 days was necessary to ensure the standard of quality for the purpose of the analysis and an accurate report. The delay in analysis of the sample violates the right of the accused to get the sample retested.

20. In opposition to this, Mr. Singh, banking upon the contentions in the affidavit in reply, sought to explain the delay by asserting that the sample could not be tested as the reference standard and impurity standard of the subject drugs were not readily available. Mr. Singh made an endeavour to salvage the position by canvassing a submission that, in the case of **M/s. Quixotic Healthcare (supra)**, the sample was analysed after the expiry of the drugs in question, and that is not the case at hand.

21. I am afraid to accede to this submission. As noted above, the provisions contained in Rule 45 of the Rules, 1945, are peremptory in nature. A host of factors come into play, where there is an inordinate delay in testing sample far beyond the specified period. The properties of the drugs may be lost. The sample may not be stored in a DTL in the standard condition in which the particular drug is required to be stored. Delayed analysis of the sample thus erodes the sanctity of the analysis. It is for this reason, a time frame has been stipulated for the testing. Had there been such difficulty in the analysis of the sample, as propounded by the Respondent, the Government

Analyst could have resorted to the proviso and sought extension of time. In the absence thereof, the explanation sought to be offered by the Respondent by way of an affidavit, is of no avail. The explanation for the delay, if at all there was any, should have come from the Government Analyst and that too in the manner envisaged by the proviso to Rule 45(1) and not by way of an affidavit of the Respondent. Any other interpretation would render the peremptory nature of sub-Rule (1) and the proviso thereto otiose. Thus, this Court finds substance in the submissions on behalf of the Petitioners that the delayed testing of the sample dents the prosecution.

22. This propels me to the non-compliance of the procedure mandated by Section 23 of the Drugs Act, 1940. The provisions of sub-section (3) of Section 23 are of relevance in the determination of the challenge mounted on behalf of the Petitioners. They read as under :

> **“23. Procedure of Inspectors**
>
> …….
>
> (3) Where an Inspector takes a sample of a drug or cosmetic for the purpose of test of analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked:
>
> Provided that where the sample is taken from premises

whereon the drug or cosmetic is being manufactured, it shall be necessary to divide the sample into three portions only :

Provided further that where the drug or cosmetic is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug or cosmetic be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows: -

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

(ii) the second he shall produce to the court before which proceedings, if any, are instituted in respect of the drug or cosmetic; and

(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A”

23. Sub-section (3) of Section 23 obligates the Inspector who has collected sample for the purpose of testing or analysis to divide sample into four portions and effectively seal and suitably mark the same. However, where the sample is taken from the place of manufacturer, sample shall be divided into three portions only. Under sub-section (4) of Section 23, the Inspector is enjoined to restore one portion of the sample to the person from whom he

takes it, send the second to Government Analyst for test and analysis and produce the third before the Court and send the fourth to the person, if any, whose name, address and other particulars have been disclosed under section 18A.

24. It would be contextually relevant to note that, under Section 18A , a duty is cast on every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, if so required, to disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.

25. The aforesaid obligation to send a portion of the sample is of material significance in the context of the right of the person whose name, address and other particulars have been disclosed under Section 18A, to notify in writing the Inspector or the Court that he intends to adduce evidence in controversion of the report.

26. In the case at hand, the material on record unmistakably indicates that the portion of the sample was not sent to the Petitioner No.1 – Manufacturer. From the perusal of the Notice under Section 18A of the Act, 1940, it becomes abundantly clear that the notice was addressed to M/s. Knoll Healthcare Pvt. Ltd., being the authorized supplier for the distribution or sale of the subject drug. A copy of the said notice was indeed marked to the Petitioner No.1 - M/s. C.B.Healthcare.

27. In response to the said notice, on 15 January 2018, the Petitioner No.1 called upon the Inspector to forward a sample portion to the Petitioner No.1. That request was not acceded to. It is not the case that the Drug Inspector was not aware of the manufacturer of the subject drug. Receipt for sample of drug under Form No.17A and the intimation to person from whom the sample was taken, clearly records that M/s. C.B.Healthcare – Petitioner No.1 was the manufacturer of the subject drug.

28. In the backdrop of aforesaid facts, the question that comes to the fore is, whether he service of notice on M/s Knoll Healthcare Pvt Ltd, the distributor alongwith the report of Government Analyst and a portion of the sample constitutes sufficient compliance of the mandate contained in Section 23(4)(iii) of the Drugs Act, 1940?

29. Mr. Singh asserted that, the Petitioner No.1 was not entitled to seek reanalysis of the sample, as the Petitioner had not notified the Inspector or Court that it intended to adduce evidence in controvention of the report. It was submitted that, in view of the provisions contained in sub-section (3) of Section 25 of the Drugs Act, 1940, a report signed by the Government Analysts is the conclusive evidence of the facts stated therein, in the absence of the action as envisaged by sub-section (3). The aforesaid submission, as a matter of principle of law, cannot be controverted. If a notice is served on the person whose name is disclosed under Section 18A of the Drugs Act, 1940

and there is a default on the part of such person to notify the Inspector or Court about his intention to adduce evidence in controversion of the report, the consequences, as adverted to by Mr. Singh, will entail.

30. In the case of **State of Harayana V/s. Brij Lal Mittal and Ors.**[3], the Supreme Court enunciated that, unless the requirement of sub-section (3) of Section 25 is complied with by the concerned person, he cannot avail of his right under sub-section (4). The observations in paragraph No.5 of the said judgment, read as under :

> "5. From a bare perusal of sub-section (3) it is manifest that the report of the Government Analyst 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 or other particulars have been disclosed under Section 18A (in this case the manufacturers0 has within 28 days of the receipt 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. Sub-section (4) also makes it abundantly clear that the right to get the sample tested by the Central Government Laboratory (so as to make its report override the report of the Analyst) through the court accrues to a person accused in the case only if he had earlier notified in accordance with sub-section (3) his intention of adducing evidence in controversion of the report of the Government Analyst. To put it differently, unless requirement of sub-section (3) is complied with by the person concerned he cannot avail of his right under sub-section (4)."

3 (1998) 5 SCC 343

(emphasis supplied)

31. In the case of **Amery Pharmaceuticals And Anr Vs State of Rajasthan,**[4] the Supreme Court, considered the challenge based on non-compliance with provisions contained in Section 23(4)(iii) of the Drugs Act, 1940, on the premise that the Inspector did not deliver one portion of sample to the manufacturer-Appellants therein. After considering the provisions of Section 25(2), (3) and (4), Section 23(4) and Section 18A of the Drugs Act, 1940, the Supreme Court held that the obligation of the Inspector is to give one portion of the sample to the person whose name, etc, have been disclosed as the person from whom the vendor acquired the drug. The requirement of the provision would stand complied with when the Inspector gives one portion of the sample to the person from whom he took the sample, and forward the second portion to the Government Analyst and the third portion to the Court (before which the prosecution is pending) and fourth portion to the person whose name and address, etc, were disclosed by the vendor. In a case where the drug or medicine has passed from the manufacturer to wholesaler (a distributor) and then to a retailer, the obligation of the Inspector (who takes the sample from a retailer) as for giving portions of the sample would end up by giving it to the retailer and also to the distributor (from whom the retailer bought the drug).

4 AIR 2001 SC 1303

32. Dealing with the submission on behalf of the manufacturer that, since a manufacturer is not entitled to get a copy of the report of the Government Analyst as of right (when the sample was taken from a retailer) the manufacturer would be disabled from challenging the correctness of the facts stated in the report and such deprivation would visit him with hard consequences as the facts stated in the report would become conclusive evidence against him and such procedure would be unfair and unreasonable besides being oppressive and in violation of Article 21 of the Constitution, the Supreme Court resorted to an interpretation of the statutory provisions that would avert the consequences of depriving an accused of any remedy against such evidence in the following words.

> "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. In other words, if any of the persons who receives a copy of the report of the Government Analyst fails to notify his intention to adduce evidence in controversion of the facts stated in the report within a period of 28 days of the receipt of the report, then such report of the Government Analyst could become conclusive evidence regarding the facts stated therein as against such persons. <u>But as for an accused, like the manufacturer</u>

> in the present case, who is not entitled to be supplied with a copy of the report of the Government Analyst, he must have the liberty to challenge the correctness of the facts stated in the report by resorting to any other modes by which such facts can be disproved. He can also avail himself of the remedy indicated in sub-section (4) of Section 25 of the Act by requesting the court to send the other portion of the sample remaining in the court to be tested at the Central Drugs Laboratory. Of course, no court is under a compulsion to cause the said sample to be so tested if the request is made after a long delay. It is for that purpose that a discretion has been conferred on the court to decide whether such sample should be sent to the Central Drugs Laboratory on the strength of such request. However, once the sample is tested at the Central Drugs Laboratory and a report as envisaged in Section 25(4) of the Act is produced in court the conclusiveness mentioned in that sub-section would become incontrovertible."
>
> (emphasis supplied)

33. In the facts of the case at hand, even if the Court were to proceed on the premise that Petitioner No.1, having not resorted to the mechanism of notifying in writing, the Drug Inspector or the Court that Petitioner No.1 intends to adduce evidence in controversion of the Report, discounting the fact that the Report of the Government Analyst was not served on Petitioner No.1, yet, an inference becomes inescapable that Petitioner No.1's remedy to have the sample of the drug re-tested was lost by sheer delay on the part of the Respondent in lodging the complaint.

34. The concomitant factors indicate that the right of the Petitioner No.1 to

have the sample retested, seems to have been defeated by the delay and inaction on the part of the Respondent. The subject drug was manufactured in the year September 2016. The date of expiry was August 2018. The complaint was lodged by the Respondent on 28 September 2021. By that time, a period of over three years has elapsed even from the date of expiry of the subject drug. The Petitioners could not have exercised the right to have the drug retested, even if the Petitioners wanted to, by requesting the Court to send the portion of the sample delivered to the Court by the Inspector. By the time, the complaint was lodged and the cognizance of the offence was taken, the subject drug had lost shelf life, nay three years ago. Thus, the Court could not have sent the sample for re-analysis by the Central Laboratory.

35. Reliance placed by Mr. Bhasin on the judgment in the case of **Laborate Pharmaceuticals India Ltd. and Ors. V/s. State of Tamil Nadu**[5] appears to be well founded. In the said case also, one part of the sample was not sent to the Appellant – Manufacturer and, instead, what was sent was only the report of the Government Analyst. In the backdrop of such facts, the Supreme Court enunciated that, when the part of the sample was not sent to the manufacturer, the manufacturer could not have got the same analysed even if it wanted to do so and, therefore, it was not in a position to contest the findings of the Government Analyst.

5 (2018) 15 SCC 93

36. In the case of **Laborate Pharmaceuticals India Ltd. (supra)**, the Supreme Court quashed the prosecution observing that the prosecution if allowed to continue would be a lame prosecution. The observations of the Supreme Court in paragraph No.8 read as under :

> "8. All the aforesaid facts would go to show that the valuable right of the appellant to have the sample analysed in the Central Laboratory has been denied by a series of defaults committed by the prosecution; firstly in not sending to the appellant manufacturer part of the sample as required under Section 23(4) (iii) of the Act; and secondly, on the part of the court in taking cognizance of the complaint on 4 March 2015 though the same was filed on 28 November 2012. the delay on both counts is not attributable to the appellants and, therefore, the consequences thereof cannot work adversely to the interest of the appellants. As the valuable right of the accused for reanalysis vested under the Act appears to have been violated and having regard to the possible shelf life of the drug we are of the view that as on date the prosecution, if allowed to continue, would be a lame prosecution."
>
> (emphasis supplied)

37. A profitable reference can also be made to the judgment of the Supreme Court in the case of **Medipol Pharmaceutical India Pvt. Ltd. V/s. Post Graduate Institute of Medical Eduation and Research and Anr.**[6], wherein in the context of the provisions contained in the Drugs Act, 1940, as well as Prevention of Food Adulteration Act, 1954 and the Insecticides Act,

6 (2021) 11 SCC 339

1968, and after adverting to its previous decisions in relation to the pari materia provisions, the Supreme Court expounded the purpose behind the insistence on the timely testing of the sample as the valuable right of the accused hinges upon the same. The observations in paragraph No.13 read as under :

> "13. Though the aforesaid judgments pertain to criminal prosecutions under the Drugs and Cosmetics Act, Prevention of Food Adulteration Act and Insecticides Act, yet, they lay down that a valuable right is granted to a person who is sought to be penalized under these Acts to have a sample tested by the Government Analyst that is found against such person, to be tested by a superior or appellate authority, namely, the Central Drugs Laboratory. These judgments lay down that if owing to delay which is predominantly attributable to the State or any of its entities, owing to which an article which deteriorates with time is tested as not containing the requisite standard, any prosecution or penalty inflictable by virtue of such sample being tested, cannot then be sustained. We have seen that on the facts of this case, the sample drawn and analyzed by the Government Analyst was delayed for a considerable period resulting in the sample being drawn towards the end of its shelf life. Even insofar as the samples sent to the Central Drugs Laboratory, there was a considerable delay which resulted in the sample being sent and tested 8 months beyond the shelf life of the product in this case. It is thus clear that the valuable right granted by Section 25 of the Drugs and Cosmetics Act kicks in on the facts of this case, which would necessarily render any penalty based upon the said analysis of the sample as void.

38. In conclusion, by the time the prosecution came to be initiated, the shelf life of the subject drug was over long back. Cumulatively, an invaluable right of the Petitioner No.1 to have the sample retested was defeated by a series of failures and inactions on the part of the Respondent. Resultantly, I am persuaded to hold that the continuation of the prosecution in the face of the aforesaid insurmountable infirmities would be an abuse of the process of the Court.

39. This takes me to the ground of challenge to the prosecution premised on the alleged procedural irregularities in the prosecution proceeding and non-application of mind by the learned Special Judge while issuing the process. Since this Court has come to the conclusion that there are grave procedural infirmities on the part of the Respondent on account of the non-compliance of the provisions of the Drugs Act, 1940 and the Drugs Rules, 1945, an elaborate consideration of the challenges on all these counts does not seem warranted. Two major points deserve brief consideration. First, the justifiability of the action of the learned Sessions Judge, to take the cognizance of the offence, directly. Second, the invocation of the principle of vicarious liability qua the Petitioner Nos. 2 to 6.

40. In regard to the action of the learned Special Judge of taking cognizance of the offence directly, there appears substance in the submission of Mr. Bhasin.

41. Section 32 of the Drugs Act, 1940 provides for cognizance of offences. Sub-Section (2) of Section 32 provides that, save as otherwise provided in that Act, no court inferior to that of a Court of Session shall try an offence punishable under Chapter IV. Section 193 of the Code of Criminal Procedure, 1973, contains an interdict against the Court of Sessions taking cognizance of any offence as Court of original jurisdiction unless the case has been committed to it by a Magistrate under the Code, except as otherwise expressly provided by that Code or by any other law for the time being force. Evidently, though sub-Section (2) of Section 32 begins with an inbuilt saving clause in the form of expression, “save as otherwise provided in this Act” yet, there is no provision in the Drugs Act 1940 which expressly provides for the Court of Session taking the cognizance of the offence punishable under the said Act directly. Nor Section 32(2) contains the usual expression, “notwithstanding anything contained in the Code of Criminal Procedure, 1973”, employed by the legislature where the Court of Session is empowered to take cognizance of the offences under the special enactments, without the case having been committed to it by a Magistrate.

42. What sub-Section (2) of Section 32 essentially provides is that, the trial of an offence under Chapter IV of the Drugs Act 1940 shall be before a Court not inferior to that of the Court of Session. The necessary corollary flowing from Section 4 of the Code, is that the rest of the provisions in the Code in

regard to taking of the cognizance of the offence, inclusive of the interdict contained in Section 193 of the Code against the Court of Session taking cognizance of the offence directly, are clearly attracted.

43. Mr. Singh, the learned Special Counsel for the Respondent, attempted to wriggle out of the situation by canvassing a submission that the Administrator of the U.T. of Damand and Diu And Dadra and Nagar Haveli, has published Notification to designate the “Principal District Judge”, Daman and Diu and Dadra and Nagar Haveli at Silvassa as Special Court and empowered him to try the case under the Drugs Act, 1940 and the Code of Criminal Procedure, 1973, for the area of UT of Daman And Diu And Dadra And Nagar Haveli. The said Notification, according to Mr. Singh, constitutes the saving envisaged by the expression, “save as otherwise provided” contained in sub-Section (2) of Section 32.

44. I find it difficult to accede to the aforesaid submission. I have perused the said Notification dated 17th June 2010. It is issued under Section 36AB(1) of the Drugs Act 1940 which came to be inserted by Act No. 26 of 2008, to provide for designation of one or more Special Courts for trial of offence relating to adulterated drugs or spurious drugs and punishable under clauses (a) and (b) of Section 13, sub-Section (3) of Section 22, clauses (a) and (c) of Section 27, Section 28, Section 28A, Section 28B and clause (b) of sub-Section (1) of Section 30 and other offences relating to adulterated drugs or

spurious drugs.

45. In the case at hand, the complaint is lodged for the commission of an offence punishable under Section 27(d) of the Drugs Act, 1940. Secondly, the said Notification even if the submission on behalf of the Respondent is taken at par, would not empower the Court of Session to directly take the cognizance of the offence as there is no provision in the Drugs Act, 1940 which provides for taking of cognizance of offence by the Court of Session directly.

46. A useful reference in this context can be made to the judgment of the Supreme Court in the case of **Union of India V/s. Ashok Kumar sharma and Ors.**[7], wherein the Supreme Court expounded the law, as under :

> "49. Section 32 of the Act undoubtedly provides for taking cognizance of the offence by the court only at the instance of the four categories mentioned therein. They are: (a) Inspector under the Act; (b) Any Gazetted Officer empowered by the Central or the State Government; (c) Aggrieved person; and (d) Voluntary Association. It is clear that the Legislature has not included the Police Officer as a person who can move the court. Before the matter reaches the court, under Section 190 of the CrPC, ordinarily starting with the lodging of the first information report leading to the registration of the first information report, investigation is carried out culminating in a report under Section 173. The Police Report, in fact, is the Report submitted under Section 173 of the CrPC to the court. Under Section 190 of the CrPC, the court may take cognizance on the

7 (2021) 12 SCC 674

basis of the police report. Such a procedure is alien to Section 32 of the Act. In other words, it is not open to the Police Officer to submit a report under Section 173 of the CrPC in regard to an offence under Chapter IV of the Act under Section 32. In regard to offences contemplated under Section 32(3), the Police Officer may have power as per the concerned provisions. Being a special enactment, the manner of dealing with the offences under the Act, would be governed by the provisions of the Act. It is to be noted that Section 32 declares that no court inferior to the Court of Sessions shall try offence punishable under Chapter IV. We have noticed that under Section 193 of the CrPC, no Court of Sessions can take cognizance of any offence as a Court of Original Jurisdiction unless the case has been committed to it by a Magistrate under the CrPC. This is, undoubtedly, subject to the law providing expressly that that Court of Sessions may take cognizance of any offence as the Court of Original Jurisdiction. There is no provision in the Act which expressly authorises the special court which is the Court of Sessions to take cognizance of the offence under Chapter IV. This means that the provisions of Chapters XV and XVI of the CrPC must be followed in regard to even offences falling under Chapter IV of the Act. Starting with Section 200 of the Act dealing with taking of cognizance by a Magistrate on a complaint, including examination of the witnesses produced by the complainant, the dismissal of an unworthy complaint under Section 203 and following the procedure under Section 202 in the case of postponement of issue of process are all steps to be followed. It is true that when the complaint under Section 32 is filed either by the Inspector or by the Authorised Gazetted Officer being public servants under Section 200, the Magistrate is exempted from examining the complainant and witnesses."

(emphasis supplied)

47. Section 34(1) of the Drugs Act, 1940 provides that where an offence has been committed by a company, every person who at the time of offence was committed, was in charge of and was responsible to the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

48. By a catena of decisions especially under the provisions of Section 141 of the NI Act, 1881, the provisions of which are pari materia Section 34 of the Drugs Act, 1940, it has been held that there is no universal rule that a director of a company was responsible for its every day affairs. It was necessary to aver as to how the director of the company was in charge of the day to day affairs of the company or responsible to affairs of the company. Of course, the position of the managing director or a joint managing director is materially distinct. By virtue of the office a managing director or joint managing director holds, he is supposed to be in charge of the affairs of the company and responsible for the conduct of the business of the company.

49. In the case of **Brij Lal Mittal (Supra),** with reference to the provisions of Section 34 (as it then stood), the Supreme Court observed as under:

> "8. … … …
>
> It is thus seen that the vicarious liability of a person for being prosecuted for an offence committed under the Act by a company arises if at the material time he was in-charge of and

was also responsible to the company for the conduct of its business. Simply because a person is a director of the company it does not necessarily mean that he fulfills both the above requirements so as to make him liable. Conversely, without being a director a person can be in- charge of and responsible to the company for the conduct of its business. From the complaint in question we, however, find that except a bald statement that the respondents were directors of the manufacturers, there is no other allegation to indicate, even prima facie, that they were in-charge of the company and also responsible to the company for the conduct of its business.

9. In **Municipal Corporation of Delhi Vs Ram Kishan Rohtagi ((1983) 1 SCC 1)** while dealing with the applicability of Section 17(1) of the Prevention of the Food Adulteration Act, 1954, which is in pari materia with Section 34(1) of the Act, on similar facts, this Court observed as under:

"15. So far as the Manager is concerned, we are satisfied that from the very nature of his duties it can be safely inferred that he would undoubtedly be vicariously liable for the offence, Various liability being and incident of an offence under the Act. So far as the Directors are concerned, there is not even a whisper not a shred of evidence nor anything to show, apart from the presumption drawn by the complainant, that there is any act committed by the Directors from which a reasonable inference can be drawn that they could also be vicariously liable. In these circumstances, therefore, we find ourselves in complete agreement with the argument of the High Court that no case against the Directors (Accused Nos. 4 to 7) has been made out ex facie on the allegations made in the complaint and the proceedings against them were rightly quashed."

50. In **Lalankumar Singh and Ors Vs State of Maharashtra,**[8] after adverting to the decision in the aforesaid case of **Brij Lal Mittal (Supra)** and the decisions rendered in the context of the provisions contained in Section 141 of the Negotiable Instruments Act, 1881, the Supreme Court enunciated that merely reproducing the words of the section without a clear statement of fact as to how and in what manner a director of the company was responsible for the conduct of the business of the company, would not ipso facto make the director vicariously liable.

51. In regard to the invocation of the vicarious liability of Petitioner Nos. 2 to 6 under Section 34, in the complaint, the allegation qua Petitioner Nos. 2 to 6 is that, they were directors of M/s. C.B.Healthcare (P1) and at the time of the manufacturing of drug in question were responsible to day to day activities of the business of the firm and release for distribution of the said drug batch number. In paragraph 19 of the complaint, it is further urged that Accused Nos. 2 to 6 (P2 to P6) did manufacture the subject drug for sale and distribution and sold, “not of standard quality” drug and they were in charge of and responsible to the conduct of the business at the premises of Accused No.1 at the relevant time when the subject drug was manufactured.

52. The aforesaid averments do not strictly satisfy the requirement of spelling out the role of the Petitioner Nos.2 to 6; as to how and in what

8 (2023) 236 Comp Cas 741.

manner the Petitioners Nos.2 to 6 were responsible for the conduct of the business of the firm. Yet, whether the aforesaid allegations in the complaint are sufficient to invoke the principle of constructive criminality under Section 341(1) of the Drugs Act, 1940, in the light of the view this Court has taken on the substantive challenge to the prosecution, need not be answered definitively. De hors the challenge to the initiation of the prosecution qua Petitioner Nos. 2 to 6 by invoking the provisions under Section 34(1) of the Drugs Act, 1940, this Court has come to the conclusion that the prosecution of Petitioner No.1-firm itself would amount to an abuse of process of the Court.

53. For the forgoing reasons, the Petition deserves to be allowed.

54. Hence, the following order:

ORDER

(i) The Writ Petition stands allowed.

(ii) The impugned order dated 28 September 2021 of issue of process against the Petitioners for the offence punishable under Section 27(d) of the Drugs Act, 1940 stands quashed and set aside.

(iii) The proceeding in Criminal Complaint, being Special Case No.32 of 2021, also stands quashed and set aside.

(iv) Rule made absolute to the aforesaid extent.

(N.J.JAMADAR, J.)