IN THE HIGH COURT OF JUDICATURE AT BOMBAY, NAGPUR BENCH, NAGPUR.

CRIMINAL APPLICATION (APL) NO.319 OF 2025

Mr.Ashwani Singla, s/o Desh Raj Aggrawal,
r/o 14, Aman Colony, near 22 No. Phatak,
Patiala (Service), Punjab 147 001. ….. Applicant.

:: V E R S U S ::

Government of India, through its Drugs Inspector,
Pushparaj Kumar Singh, aged 35 years, M.No.8224090507,
office of the Deputy Drugs Controller (India), Central Drugs Standard Control Organization (CDSCO), West Zone, 4th Floor, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai – 400008 (MS). ….. Non-applicant.

Shri Akshay Naik, Senior Counsel assisted by Shri Rohan Deo, Advocate for the Applicant.
Mrs.Mugdha Chandurkar, Counsel for the Non-applicant.

CORAM : URMILA JOSHI-PHALKE, J.
CLOSED ON : 14/07/2025
PRONOUNCED ON : 19/08/2025

JUDGMENT

1. Heard learned Senior Counsel Shri Akshay Naik for the applicant and learned counsel Mrs.Mugdha

Chandurkar for the non-applicant. Rule. Heard finally by consent.

2. The non-applicant is the original complainant appointed as Inspector under Section 21 of the Drugs and Cosmetics Act, 1940 and, therefore is authorized to initiate prosecution under the said Act.

3. The applicant is arraigned as accused No.2 in Complaint Case No.2450/2020 filed before learned Chief Judicial Magistrate at Nagpur. The applicant approached this court by way of this application under Section 482 of the CrPC by making following prayers:

> "(A) quash and set aside the criminal complaint and all proceedings being Regular Criminal Case No.2450/2020 pending before the learned Additional Chief Judicial Magistrate, Nagpur,

(B) Quash and set aside the order issuing process dated 21.10.2020 passed by the learned Additional Chief Judicial Magistrate, Nagpur against the applicant in Regular Criminal Case No.2450/2020,

(C) Quash, cancel and set aside the Non-Bailable Warrant purportedly issued by the learned Additional Chief Judicial Magistrate, Nagpur on 14th June 2024, and reissued on 21st August, 2024

(D) Stay the effect, operation and implementation of the order issuing process against the applicant dated 21st October 2020 as well as the non-bailable warrant issued in Regular Criminal Case No.2450 of 2020 by the learned Additional Chief Judicial Magistrate, Nagpur

during the pendency and final disposal of this application, and

(E) Stay all further proceedings in Regular Criminal Case No.2450/2020 pending before the learned Additional Chief Judicial Magistrate, Nagpur during the pendency and final disposal of this application."

4. Brief facts of the case are as under:

The non-applicant filed a complaint registered as Complaint Case No.2450/2020 filed before learned Chief Judicial Magistrate at Nagpur drug sample Enteric Coated Rabeprazole and Domperidone (sustained released) Capsules (Rabetroy-DSR) B.No.TPC16007 has been drawn by Dr.Kamal Halder on 23.9.2016 for testing and analysis under the provisions of Section 23 of the Drugs and Cosmetics Act, 1940 (the said Act). It is

claimed that the drug was manufactured by M/s.IBN Herbals which is a unit of Curetech Formulations Private Limited, and the sample thereof was drawn from a retail firm namely Ms/. Sidhivinayak Medical Agencies in presence of the said firm's proprietor Shri Harish Vaidya in Forms 17 and 17A. Out of that, one part of the sample was sent to the Government Analyst, the Central Drugs Testing Laboratory, Mumbai in Form No.18 along with covering letter. The sampled drug was manufactured in May 2016 and its expiry date was April 2018. It is further contended that the sample was forwarded to the Central Drug Testing Laboratory on 26.9.2016 which was received by the said centre on 29.9.2016. On 17.7.2017, the Government Analyst, the Central Drugs Testing Laboratory prepared its analytical report in Form No.13 and forwarded to the Drug Inspector in triplicate on the same day. As per the

analyst report, the sample in question "was not of standard quality" since it did not confirm with the claim regarding the testing of Assay of Rabeprazole.

5. After receipt of the analytical report, the non-applicant issued letter to Ms/. Sidhivinayak Medical Agencies seeking disclosure of the details of the firm from which sample drug was procured. By letter dated 26.7.2017 M/s.Sidhivinayak Medical Agencies disclosed by way of letter that the said drug was purchased from a supplier namely Triokaa Pharmaceuticals Limited. Accordingly, communication was issued to the said Triokaa Pharmaceuticals Limited on 9.11.2017 stating that it had purchased the sampled drug from manufacturer M/s. IBN Herbals on 13.8.2016.

6. Since the sample drug was not of a standard quality, a joint investigation was carried out by the

Drugs Inspector from Sub Zoje, Baddi, Himachal Pradesh at the premises of IBN Herbals. On 7.3.2015, the Drug Inspector issued communication to the Drugs Controller General of India seeking sanction for lodging prosecution against the manufacturing firm. Accordingly, the sanction was granted on 25.9.2018 and thereafter the complaint was lodged on 8.10.2020.

7. M/s.IBN Herbals rigorously tested drug and upon its analysis, it was found that the concerned drug confirms with the claim with respect to the Test Assay of Rabeprazole. Therefore, the applicant did not agree with the issuance of findings of the analyst report. But, since proceeding was not instituted by the complainant before learned Magistrate during the shelf life of the medicine, he was deprived of the invaluable right to challenge the analysis report. Therefore, the present

application is filed challenging the institution of the proceedings as well as issuance of process against the present applicant.

8. It is contended by the applicant that he has been arraigned as accused on the premise that he is Director of manufacturing unit of M/s. IBN Herbals. However, as per the joint investigation report one Mr.Sumit Singla was alleged to be proprietor of the manufacturing firm. The applicant was not incharge and looking after the day to day activities of the said firm. Moreover, IBN Herbals which is a unit of Curetech Formulations Private Limited, which is not made party to the criminal complaint. It is further contended that the IBN Herbals is not body corporate and therefore not the company as defined under Section 4 of the said Act and he is not Director of said IBN Herbals. The

applicant is only Director of Curetech Formulations Private Limited which has not been arraigned as accused. Therefore, the application is filed on the following grounds:

> "(i) in view of sub-sections 3 and 4 of Section 25 of the said Act, the accused has valuable right of challenging findings of the analysis report prepared by the government analyst or getting the same sampled drug analyzed. During delayed registration of the compliant, the applicant was deprived of his valuable right conferred under Section 25 of the said Act,
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> (ii) The government analyst though received sample on 29.9.2016, he prepared report on 17.7.2017 nearly ten months after receipt of the sample which is complete violation of Rule 45

of the said Act. In view of the said Rule 45, the government analyst is under obligation to analyze the sample in any case within 60 days of receipt of the sample,

(iii) The complaint ought to have been filed within a period of 3 years from the date of the analysis report. Therefore barred by the law of limitation, and

(iv) The vicarious liability cannot be fastened on applicant as he was not the person incharge and responsible of the day to day conduct of the business of the company. Merely because she is director of the company does not *ipso facto* establish that he was in fact responsible of the day to day business of the company. Except the statement of the complainant, there is nothing

on record to show that the applicant was incharge and was responsible for the day to day activities of the company and, therefore, the prosecution against him is unwarranted and prays for the quashing of the proceeding".

9. *Per contra*, learned counsel for the non-applicant by filing reply denied all the contentions and submitted that after the chain established and as disclosed under Section 18A of the said Act, one copy of test report with one sealed portion of the sample was sent to the Distributor and Marketer. By letter dated 2.11.2017, a copy of the letter was addressed to the manufacturer. A joint investigation has been carried out wherein firm provided memorandum and articles of Curetech Formulations Private Limited shows name of the applicant as one of Directors of the same company.

The notice under Section 25(3) was duly sent to the manufacturer with test report in Form No.31 to provide explanation within 28 days, however no response was received. The manufacturer never informed the Drugs Inspector that they wanted to challenge the findings of the test report issued in Form No.13 by the Government Analyst not intended to send remaining one sealed portion of the sample.

10. On analysis, the sample was not found complying with the manufacturers specifications. The sample was tested and reported after 9 months before the date of expiry. Thus, sample was tested well before the date of expiry. After complying all requirements, the complaint was filed and considering involvement of the applicant, process was issued against the applicant.

11. Learned Senior Counsel for the applicant has taken me through various provisions of the said Act namely Sections 23 and 25 and Rule 45 of the Rules of 1945. To point out the right of the applicant to lead evidence against analytical report and further time line fixed for providing such analytical report to show non-compliance of the said provisions, he submitted that such non-compliance vitiates the proceedings. He also submitted that the sample was not analyzed within 60 days. The applicant was deprived from challenging the finding of the analyst as complaint was filed after 3 years i.e. beyond limitation after the expiry of shelf life of the said drugs. Moreover, in view of Section 34 of the said Act, it deals with aspect of offences by companies. M/s.HBN Herbals is a unit of Curetech Formulations Private Limited and it is not made as a necessary party to the complaint. There is nothing on record to show

that the applicant was Director of said HBN Herbals. But, she was Director of Curetech Formulations Private Limited. Similarly, there is no material on record to show that the applicant incharge and responsible for day to day activities of the said company and, therefore, she is responsible for the day to day activities of the said company. For all above these grounds, the proceeding initiated against the applicant deserves to be quashed and set aside.

12. In support of his contentions, learned Senior Counsel for the applicant placed reliance on following decisions:

1. P.R.Naik and anr vs. State of Maharashtra, reported in 2024 SCC OnLine Bom 3856;

2. Medicamen Biotech Limited and anr vs. Rubina Bose, Drug Inspector, reported in (2008)7 SCC 196;

3. Prabhu Chawla vs. State of Rajasthan and anr, reported in (2016)16 SCC 30,

4. Criminal Application (APL) No.1623/2022 (Mahadeo s/o Shankar Jadhav and ors vs. The State of Maharashtra) decided by this on 19.3.2025,

5. Lalankumar Singh and ors vs. State of Maharashtra, reported in 2022 SCC OnLine SC 1383,

6. Cognizance for Extension of Limitation, reported in (2022) 3 SCC 117,

7. Himanshu vs. B.Shivamurthy and anr, reported in (2019)3 SCC 797,

8. Laborate Pharmaceuticals India Limited and ors vs. State of Tamil Nadu, reported in (2018)15 SCC 93, and

9. GHCL Employees Stock Option Trust vs. India Infoline Limited, reported in (2013)4 SCC 505.

13. In the matter in hand, it is evident that there is no averment or statement in the complaint that the applicant working as Director of the company was

responsible or incharge of the conduct of the business of the company in respect of which the offence in question alleged to have been committed so as to determine the vicarious liability for the offence committed by the company. Moreover, there is no satisfaction recorded by learned Magistrate about *prima facie* case against the applicant and role played by him in the capacity of the Director. On the contrary, the joint investigation report shows details of M/s.IBN Herbals and also shows that one Mr.Sumit Singla is the proprietor of the firm. It further reveals that during course of the investigation, the documents are verified relevant to the manufacturing and quality control of the impugned batch. Thus, the documents on record shows that Mr.Sumit Singla is the Proprietor of M/s.IBN Herbals. Thus, this document shows that the applicant is not Director of said IBN Herbals, but he is the Director of

Curetech Formulations Private Limited which is not made an accused to the present complaint.

14. Learned Senior Counsel vehemently submitted that in absence of impleading the company as a party of which the applicant is Director, no responsibility can be casted on the present applicant. He invited my attention towards Section 34 of the said Act which deals with offences by companies. The said Section is reproduced for reference:

> **"34. Offences by companies. — (1)** Where an offence under this Act has been committed by a company, every person who at the time the 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:Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the

company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation.—For the purposes of this section-

(a) “company” means a body corporate, and includes a firm or other association of individuals; and

(b) “director” in relation to a firm means a partner in the firm.

15. In the present case, except the statement that the applicant was Director of the M/s.IBN Herbals, there is no other statement that he was at the relevant time incharge and responsible to the firm for the conduct of its business.

16. While considering *pari materia* provisions under Section 141 of the Negotiable Instruments Act, the Hon'ble Apex Court by referring Three Judge Bench Judgment, in the case of **Aneeta Hada vs. M/s.Godfather Travels and Tours Pvt.Ltd., reported in (2012)5 SCC 661** observed that applying the doctrine of strict construction, we are of the considered opinion that commission of offence by the company is an express condition precedent to attract the vicarious liability of others. Thus, the words "as well as the company" appearing in the Section make it absolutely unmistakably clear that when the company can be prosecuted, then only the persons mentioned in the other categories could be vicariously liable for the offence subject to the averments in the petition and proof thereof. One cannot be oblivious of the fact that

the company is a juristic person and it has its own respectability.

It is further held that in view of our aforesaid analysis, we arrive at the irresistible conclusion that for maintaining the prosecution under Section 141 of the Act, arraigning of a company as an accused is imperative. The other categories of offenders can only be brought in the dragnet on the touchstone of vicarious liability as the same has been stipulated in the provision itself.

17. Thus, liability depends on the role one plays in the affairs of a company and not on designation or status. If being a director or manager or secretary was enough to cast criminal liability, the section would have said so. If being director/manger, secretary are not liable by their designations. They are liable if they are

by holding responsibility in day to day affair of the company and only persons who can be said to be connected with the commission of a crime who are incharge of the said company.

18. Perusal of Section 34 of the said Act, shows that every person connected with the company will not fall within the ambit of the provision. It is only those persons who were in charge of and responsible for the conduct of business of the company at the time of commission of an offence, who will be liable for criminal action. It follows from this that if a director of a company who was not in charge of and was not responsible for the conduct of the business of the company at the relevant time, will not be liable under the provision. The liability arises from being in charge of and responsible for the conduct of business of the

company at the relevant time when the offence was committed and not on the basis of merely holding a designation or office in a company. Conversely, a person not holding any office or designation in a company may be liable if he satisfies the main requirement of being in charge of and responsible for the conduct of business of a company at the relevant time.

19. In the light of the above legal provisions, there is no dispute that M/s.IBN Herbals which is a unit of Curetech Formulations Private Limited is not made an accused of which the applicant was Director. The documents on record no where show that the applicant was Director of M/s.IBN Herbals which is a unit of Curetech Formulations Private Limited.

20. Thus, in absence of the satisfaction recorded by the Magistrate about *prima facie* against the applicant

and role played by him in capacity of the Director which is *sine qua non* for initiating criminal action against him. Therefore, I have no hesitation to hold that learned Magistrate has committed error in issuing the process against the applicant.

21. Before adverting to merits of the case, it is necessary to refer relevant provisions of the said Act.

22. Section 16 of the said Act deals with the standards of quality for drugs and cosmetics. The said Section is reproduced for reference:

> **"16. Standards of quality.—**
>
> (1) For the purposes of this Chapter, the expression "standard quality" means—

(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.

(2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly.

23. Section 18 of the said Act prohibits the manufacture, sale, or distribution of certain drugs and

cosmetics. Whereas, Section 18(a) deals with disclosure of the name of the manufacturer. Said Section 18 is reproduced for reference:

> **"18. Prohibition of manufacture and sale of certain drugs and cosmetics.—**
>
> From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—
>
> (a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute—
>
> (i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;

(ii) any cosmetic which is not of a standard quality, or is misbranded, adulterated or spurious;

(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities, thereof;

(iv) any drug which by means of any statement design or device accompanying it or by any other means, purports or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed;

(v)any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder."

24. Section 25 of the said Act deals with Reports of Government Analysts, which is reproduced as under:

"25. Reports of Government Analysts. —

(1) The Government Analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken and another copy to the person, if any, whose name, address

and other particulars have been disclosed under section 18A, and shall retain the third copy for use in any prosecution in respect of the sample.

(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.

(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 sample of the drug or cosmetic produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

(5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct.

25. Rule 45 of the Drugs and Cosmetics Rules is reproduced as under:

"45. Duties of Government Analysts.—(1) The Government Analyst shall cause to be analyzed or tested such samples or drugs 1[and cosmetics] 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.

(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."

26. As far as present matter is concerned, Section 18(a)(i) of the said Act is relevant which says that no person shall himself or by any other person on his behalf manufacture for sale or for distribution, or sell, 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.

27. Section 18(a) mandates ever person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.

28. Section 20 of the said Act, empowers the State Government or the Central Government to appoint the Government Analyst in respect of such drugs areas in the State and in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification issued for such appointment.

29. Section 22 of the said Act deals with powers of inspector. Section 24 says that every person for the time being in charge of any premises whereon any drug or cosmetic is being manufactured or is kept for sale or distribution shall, on being required by any Inspector so to do, be legally bound to disclose to the Inspector the place where the drug or cosmetic is being manufactured or is kept, as the case may be. Section 25(1) relates to report of Government Analyst. Section 25(2) mandates Inspector on receipt thereof shall deliver one copy of the

report to the person from whom the sample was taken and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A, and shall retain the third copy for use in any prosecution in respect of the sample. Section 25(3) provides that any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under section 18A has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in contravention of the report. Section 25(4) lays down that 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 incontroversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused: cause the sample of the drug or cosmetic produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

30. Similarly, Rule 45 is relevant which lays down that Government Analyst shall cause to be analyzed or tested such samples of drugs and cosmetics 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.

31. In the light of the above said referred provisions, the facts of the present matter are to be appreciated and, therefore, the dates are relevant:

1. on 23.9.2016 drug sample Enteric Coated Rabeprazole and Domperidone (sustained released) Capsules has been drawn by Dr.Kamal Halder for testing

and analysis under the provisions of Section 23 of the said Act;

2. The sampled drug was manufactured in May 2016 and its expiry date was April 2018;

3. the sample was forwarded to the Central Drug Testing Laboratory on 26.9.2016 which was received by the said centre on 29.9.2016; and

4. on 17.7.2017, the Government Analyst, the Central Drugs Testing Laboratory prepared its analytical report in Form No.13 and forwarded to the Drug Inspector i.e. approximately after 9 months.

32. To see whether there is compliance or not, again reference is to be made to some of provisions.

33. Section 23(4) of the said Act states that 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.

34. Sub-sections 3 and 4 of Section 25 of the said Act confers an accused valuable right of challenging findings of the analysis report prepared by the

government analyst or getting the same sampled drug analyzed. It expressly provides for right to challenge the said report by adducing evidence before the Magistrate, only when the proceeding in respect of sample drug has already been instituted.

35. Admittedly, sample drug in April 2018 and impugned complaint was filed on 21.10.2020. Thus, by that time the shelf life of the said drug had expired and therefore it was unfit for re-analyzing. In view of the delayed registration the complaint, the applicant lost his valuable right conferred under sub-sections 3 and 4 of Section 25 of the said Act. This aspect is sufficient to vitiate the prosecution against the accused.

36. In the case of **Medicamen Biotech Limited and anr** *supra* the Hon'ble Apex Court held 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 had been filed. Likewise, we observe that the requests for retesting of the drug had been made by the appellant in August/September 2001 as would be clear from the facts already given above and there is absolutely no reason as to why the complaint could not have been filed earlier and the fourth sample sent for retesting well within time.

It is further held that unless requirement of sub-section (3) is complied with by the person concerned he cannot avail of his right under sub-section (4). 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 18-a (in this case the manufacturers) 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 incontroversion 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 incontroversion 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).

37. One part of the sample drug was forwarded the Government Analyst on 26.9.2016 which was received in the lab on 29.9.2016. The government analyst analyzed the sample drug and prepared report on 17.7.2017 nearly 10 months after receipt of the sample in violation of Rule 45. Thus, when the compliance under Rule 45 if taken into consideration, the date of the receipt of the sample and date of report are considered, it is evident that beyond the stipulated period of 60 days.

38. In the present case, the report was submitted approximately after 9 months.

39. The co-ordinate bench of this court, while dealing with importance of time frame given under the

said Act and Rules thereof, observed that fastest course of action as it relates to drugs which are consumed by the consumer and public at large. It relates to the life of the consumer who consumed these drugs across the counter as they are prescription drugs. Therefore any action taken by the Drugs Inspector in accordance with the provisions of the said Act and more specifically the provisions delineated hereinabove have to be in strict compliance of the said Act and timelines have to be scrupulously followed for taking and initiating any action.

40. In present case, it took about 9 months to furnish report against timeline of 60 days fixed for such report.

41. Thus, considering the date of expiry of the drug in April 2018, it can be said that the analytical report is

prejudicial to the rights of the accused. It is so because 28 days time frame is provided under Section 25(3) of the said Act from the date of receipt of the reply of the report to notice to adduce evidence in contravention of the report.

42. The chronology of the events shows that on receipt of the analytical report, a letter was issued to M/s.Sidhivinayak Medical Agencies on 26.7.2017 and, thereafter, M/s.Sidhivinayak Medical Agencies issued letter to the complainant disclosing that said drug was purchased from a supplier namely Triokaa Pharmaceuticals Limited. Thereafter, a communication was issued on 9.12.2017 to Triokaa Pharmaceuticals Limited and said Triokaa Pharmaceuticals Limited disclosed that the drug was purchased from M/s.IBN Herbals.

43. It is to be noted that under Section 18 of the said Act, the memorandum was issued to the Government Analyst wherein the name of M/s.IBN Herbals was mentioned. However, no communication was issued to M/s.IBN Herbals on the date of collection of sample drug.

44. It is indeed common knowledge and a regulatory requirement that drug labels include essential information. This includes the manufacturer's name, generic name, active ingredients, storage conditions, expiry date, and distributor information. Despite this, it is the contention of the complainant that first time by way of communication from Triokaa Pharmaceuticals Limited on 9.11.2017 i.e. approximate after 1 year they received information as to the name of the manufacturer and the complainant got knowledge of the name of the

manufacturer. Thus, the above said thing that about more than 12 months to find out name of manufacturer cannot be ignored and discarded while considering the timeline framed under the said Act and Rules thereof and also the right of the applicant to lead evidence in such matters incontroversion of the Government Analyst Report.

45. The further action on the part of the complainant shows that he issued communication to the drugs controller general on 7.3.2015 and the drug controller granted sanction on 25.9.2018 and copies of the communication as well as the order of granting sanction received is of dated 25.9.2018 and the complaint was filed on 8.10.2020 i.e. approximately after one and half year.

46. In the entire complaint, there is no averment made to the effect that copy of the Government Analysis Report was supplied to the applicant or to the company. The supply of such report is significant to notify the intention to lead evidence incontroversion of the report.

47. Thus, in this case, the applicant is deprived from exercising his right to adduce the evidence against analytical report within a period of 28 days as stipulated under Section 25(3) of the said Act. There is no compliance of Rue 45.

48. As observed earlier, there is no averment in the complaint that the applicant was Director and was incharge and looking after day to day affairs of the said company.

49. The Hon'ble Apex Court in the case of **Lalankumar Singh and ors** *supra* observed that 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. merely because a person is a director of a company, it is not necessary that he is aware about the day to day functioning of the company. There is no universal rule that a director of a company is in charge of its everyday affairs. It was, therefore, necessary, to aver as to how the director of the

company was in charge of day to day affairs of the company or responsible to the affairs of the company.

50. Thus, the delay in giving report by the Government Analyst denying right to the applicant to lead evidence incontroversion of the report is prejudicial to the applicant in absence of the averments as to the fact that the applicant is responsible for the day to day affairs of the company. These facts are ignored by the trial court while issuing the process and, therefore, it would be abuse of process of court if the prosecution is allowed to continue against the applicant.

51. The words used in Section 204 of the CrPC "sufficient grounds for proceeding" are to be taken into consideration which are the most important. If a *prima facie* case has been made out, the Magistrate ought to have issued process. At the same time, summoning a

person is a serious act and, therefore, a person ought not to be dragged in the court merely because a complaint has been filed and, therefore, an opinion is to be formed only after due application of mind that there is sufficient basis for proceeding against the said accused and formation of such an opinion is to be stated in the order itself, as observed by the Hon'ble Apex Court in **Lalankumar Singh and ors** *supra.*

52. In the light of the above discussion and circumstances, it will be abuse of process of court if the prosecution is allowed to be continued against the applicant. It is apparent on the face of the record that the Magistrate has not applied his own mind to satisfy himself whether *prima facie* case has been made out. In this view of the matter, I proceed to pass following order:

51

ORDER

(1) The Criminal Application is **allowed**.

(2) Complaint Case No.2450/2020 against the present applicant pending before learned Chief Judicial Magistrate at Nagpur is quashed and set aside

(3) The order of issuance of process dated 21.10.2020 is also quashed and set aside.

Rule is made absolute in the above said terms.

(**URMILA JOSHI-PHALKE, J.**)

!! BrWankhede !!