IN THE HIGH COURT OF JUDICATURE AT MADRAS

RESERVED ON : 21.04.2025

PRONOUNCED ON : 14.05.2025

CORAM

THE HON'BLE MR. JUSTICE SUNDER MOHAN

Crl.O.P.Nos.19643 & 19832 of 2022
Crl.M.P.Nos.12942, 13038, 13040 and 13041 of 2025
Crl.OP.No.19643 of 2022

Thiru. Umanga Vohra,
Managing Director of
M/s.Cipla Ltd.,
Khasra No.138, Raipur Industrial Area,
Bhagwanpur, Roorkee District,
Haridwar, Uttarkhand- 247667,
Rep. by its authorized signatory,
Mr.Suresh P.S. ... Petitioner / A2

Vs.

The State of Tamil Nadu Rep. by
C.Balaji, B.Pharma,
The Drug Inspector,
Mettupalayam Range i/c.,
O/o. The Assistant Director of Drugs Control,
Coimbatore Zone 2019,
Race Course Road, Coimbatore – 18. ... Respondent/complainant

PRAYER: Criminal Original Petition filed under Section 482 of BNSS, to call for the records in CC/STC No.784/2020 pending before the learned Judicial Magistrate, Mettupalayam pending the criminal original petition and quash the same as against the petitioner company herein.

Crl.OP.No.19832 of 2022:

M/s.Cipla Ltd.,
Khasra No.138, Raipur Industrial Area,
Bhagwanpur, Roorkee District,
Haridwar, Uttarkhand- 247667,
Rep. by its authorized signatory,
Mr.Suresh P.S. ... Petitioner / A1

Vs.

The State of Tamil Nadu Rep. by
C.Balaji, B.Pharma,
The Drug Inspector,
Mettupalayam Range i/c.,
O/o. The Assistant Director of Drugs Control,
Coimbatore Zone 2019,
Race Course Road, Coimbatore – 18. ... Respondent/complainant

PRAYER: Criminal Original Petition filed under Section 482 of BNSS, to call for the records in CC/STC No.784/2020 pending before the learned Judicial Magistrate, Mettupalayam pending the criminal original petition and quash the same as against the petitioner company herein.

For Petitioner
in both cases : Mr.P.Chidambaram, Sr. Counsel
for Mr.K.P.Anantha Krishna

For Respondent : Mr.S.Santhosh
in both cases Govt. Advocate (Crl.Side)

COMMON ORDER

These Criminal Original Petitions, have been filed by the

petitioners/A1 & A2, to call for the records in CC/STC No.784/2020 pending before the learned Judicial Magistrate, Mettupalayam and quash the same.

2. (i) The case of the prosecution is that the first accused/petitioner in Crl.OP.No.19832 of 2022 is a company having its business in Uttarkhand; that the second accused/petitioner in Crl.OP.No.19643 of 2022, is the Managing Director of the first accused company [hereinafter referred as 'Company']; that the Company is the manufacturer of a drug by name, 'OMNIGEL'; that on 28.03.2019, a sample of the said drug was drawn for analysis under Form-17 from one M/s.Sri Anushya Agencies at Coimbatore; that the same was sent for analysis on 29.03.2019 under Form-18; and that on 20.05.2019, the Drugs Inspector, Mettupalayam Range, received a report under Form-13 from the Government Analyst (Drugs), stating that the sample is 'Not of Standard Quality', for the reason that the sample does not conform to the Label claim with respect to the content of Diclofenac Diethylamine, Methyl Salicylate and Menthol;

(ii) that notices were sent to M/s.Sri Anushya Agencies and the

suppliers of the drug to the said M/s.Sri Anushya Agencies and finally to M/s.Mahaveer Medicare, Rajasthan, who stated that they obtained the drug from M/s.Cipla Limited, Dehradun, under Invoice No.1155729983 (IDST No.334/18/729983 Dt.05.05.18);

(iii) that on 23.07.2019, the respondent sent a letter to the Company, asking them to disclose the name and address of the person/persons from whom they acquired the subject drug; that the Company disclosed that the drug was received from their Loan License Vendor M/s.Pritam International Pvt. Ltd., Haridwar, Uttarakhand; that on the basis of the reply, it was concluded that the Company had manufactured "Not of Standard Quality" drug in violation of Section 18(a)(i) of the Drugs and Cosmetics Act, 1940 [hereinafter referred to as 'the Act'];

(iv) that a show cause memo dated 12.09.2019 along with Form-13 was sent to the Company, calling for an explanation for the contravention of Section 18(a)(i) of the Act; that the third portion of the sample which was collected was sent to the Company as mandated under Section 23(4)(iii) of the Act; that finally a show cause notice was sent on 16.12.2019 to the Company to offer their explanation and to produce

documents; that in reply to the notices dated 12.09.2019 and 16.12.2019, the Company had stated that they received the subject drug from their Loan License Vendor M/s.Pritam International Private Limited and did not furnish any other particulars called for by the respondent; that the second accused is the Managing Director of the Company; and thus, both the petitioners committed the aforesaid offences.

3. Mr.P.Chidambaram, learned senior counsel for the petitioners submitted

(i) that the impugned complaint is liable to be quashed, as the report of the Government Analyst that the drug was 'Not of Standard Quality', cannot be accepted, since, the testing was not done in terms of the guidelines of the department issued under Section 33(P) of the Act in the year 2008; that the drug in question neither formed part of the Indian Pharmacopoeia nor the British Pharmacopoeia; that Guideline No.9 of the said guidelines would show that the patent and proprietary formulations must be tested by the Government Analyst as provided under Rule 46 of the Drugs and Cosmetics Rules, 1945 [now called the Drugs Rules, 1945 and hereinafter referred to as 'the Rules']; that in case of non-pharmacopoeial or modified formulations, the samples should be

tested as per the procedure provided by the manufacturer, which has been duly approved by the Licensing Authority; that since the drug in question is a non-pharmacopoeial and a modified formulation, the Analyst must have tested the same as per the procedure provided by the manufacturer and any violation of the same would render the report bad; and consequently the prosecution is liable to be quashed. The learned senior counsel relied upon the judgment of the Himachal Pradesh High Court in ***Elnova Pharma Village Moginand & others v. State of Himachal Pradesh***, reported in **2022 SCC Online HP 5091,** in support of this submission.

(ii) that the guidelines referred above mandate that the investigation reports of the cases for which the prosecutions are proposed to be instituted should be placed before a Screening Committee; that the said Committee should take into consideration the criminal intent or gross negligence while recommending a prosecution; that the State of Tamil Nadu has not constituted any Screening Committee so far; and that the instant complaint, instituted without scrutiny by the Screening Committee, is liable to be quashed. The learned senior counsel relied upon the judgment of this Court in ***Lupin Limited v. State***, reported in

2023 SCC Online Mad 7527.

(iii) that the impugned complaint was filed belatedly; that the shelf-life of the drug had expired before the filing of the complaint; that it was not therefore capable of being subjected to further analysis on the orders of the Court; that therefore, the right of the petitioner under Section 25(4) of the Act, has been taken away and hence, the impugned complaint is liable to be quashed on that ground. The learned senior counsel relied upon the judgments of the Hon'ble Supreme Court in ***Laborate Pharmaceuticals India Ltd. v. State of Tamil Nadu,*** reported in **(2018) 15 SCC 93** and ***Medipol Pharmaceutical India Pvt Ltd., v Post Graduate Institute of Medical Education and Research and Another***, reported in **(2021)11 SCC 339.**

(iv) that the sanctioning authority had not applied his mind; that the reading of the Sanction Order would indicate that the sanctioning authority had not referred to the documents filed by the respondent or the reply filed by the petitioners to the show cause notice; that since the sanction order suffers from non-application of mind, the impugned complaint is liable to be quashed on that ground also. The learned

senior counsel relied upon the judgment of the Hon'ble Supreme Court in ***S.Athilakshmi v. State represented by Drug Inspector,*** reported in **(2023) 15 SCC 651** and that of this Court in **Adsila Organics Pvt. Ltd. vs. State [Crl.OP.Nos.23142 & 23148 of 2019 decided on 20.11.2023],** respectively**.**

(v) that the second accused has been prosecuted only because the website of the Company shows that he is the Managing Director; that there is not even an allegation that he was in-charge and responsible to the Company for the conduct of its business and that therefore, the impugned complaint as against the second accused is not sustainable; that the Company had specifically named the officers concerned, who were responsible for the manufacturing of the drug and hence, the respondent ought not to have mechanically prosecuted the second accused, who cannot be expected to be in-charge of manufacturing of drugs that takes place in several branches and in any case, he cannot be attributed with technical knowledge. He relied upon the judgment of the Hon'ble Supreme Court and this Court in ***Cheminova India Limited & Another v. State of Punjab & Others,*** reported in **2021 SCC OnLine 573** and ***Dr.Swati Ajay Piramal v. State of Tamil Nadu,*** reported in

2021 SCC OnLine Madras 5379, respectively.

4. *Per contra* Mr.S.Santhosh, learned Government Advocate (Crl. Side) appearing for the respondent submitted

(i) (a). that as regards the first ground, the testing was done as per Rule 46 (3) of the Rules; that though the subject drug is a patent medicine, it contains pharmacopoeial drugs for which tests or analysis are provided; that the testing was done in accordance with the Rules; that the guidelines do not have any statutory force; that in any case, the question as to whether the testing was done in accordance with the rules or guidelines is a disputed question of fact and it has to be adjudicated only in the trial; and hence submitted that the complaint is not liable to be quashed on that ground.

(b). that the respondent had sent various letters to the petitioners asking for details of the Master Formula for the subject drug and the petitioners had failed to respond to the said letters; that in a similar case this Court in ***M/s.Kwality Pharmaceuticals Pvt. Ltd. and another v. State of Tamil Nadu*** [Crl.OP.No.23190 of 2013], had refused to quash the complaint, since the accused therein had not responded to

the letters issued by the department.

(ii) that as regards the second ground, the respondent had infact obtained the opinion of the Screening Committee before launching the prosecution and produced the copy of the proceedings, which confirms that the Screening Committee was infact constituted and it was only after the Committee's opinion approving prosecution, the impugned complaint was filed.

(iii) that the third ground of delay in filing of the complaint after the expiry of the shelf-life of the drug also cannot be sustained; that the right to send the drug for re-analysis after the complaint is filed would accrue to the petitioners only if they had already exercised their right to seek reanalysis of the drug; that since the petitioners who were notified about the report of the Government Analyst in terms of Section 25(3) of the Act, did not intend to challenge the report, they had waived their right to question the correctness of the report; and that therefore, the alleged delay in filing the complaint has not caused any prejudice to the petitioners and relied upon the judgments of the Hon'ble Supreme Court in ***State of Haryana v. Brij Lal Mittal***, reported in **1998 (5) SCC 343** and ***Amery Pharmaceuticals & Another vs. State of Rajasthan,***

reported in **2001(4) SCC 382.**

(iv) that the impugned complaint cannot be quashed on the ground that there is alleged non-application of mind by the sanctioning authority, as the validity of the sanction cannot be questioned at the threshold and it can be raised only in the trial and relied upon the judgments of the Hon'ble Supreme Court in ***Dinesh Kumar v. Chairman, Airport Authority of India***, reported in **(2012) 1 SCC 532** and in **Central Bureau of Investigation v. Ashok Kumar Agarwal,** reported in (2014) 14 SCC 295; and that of the Himachal Pradesh High Court in ***Unital Formulation & Others v. Union of India Vs. others,*** reported in **2025 SCC OnLine HP 795.**

(v) that the second accused is admittedly the Managing Director of the Company; that on 12.09.2019, the respondent had issued a show cause notice calling upon the Company to furnish the required documents and also offer their explanation for the contravention under Section 18(a)(i) of the Act, and till 15.12.2019, no reply was sent; that on 16.12.2019 another show cause memo was sent; that except for stating that the first accused received the subject drug from their Loan License

Vendor M/s.Pritam International Pvt. Limited Company, the Company had not furnished any particulars as required under Section 18-B of the Act; that since the Company had not furnished any details, the second accused, who is the Managing Director, was prosecuted as the person in-charge and responsible to the Company for its affairs. In support of this submission, he relied upon the judgment of the Hon'ble Supreme Court in ***Dinesh B Patel, v. State of Gujarat***, reported in **2010 (11) SCC 125** and of this Court in ***Vikas Rambal v. State***, reported in **2022 SCC Online Mad. 4822**.

5. This Court has carefully considered the rival submissions and perused the record.

6. Though several points were raised by the petitioners in the quash petitions, the learned senior counsel for the petitioners confined his oral submissions to the grounds extracted above.

(i) (a). The first and main ground raised by the learned senior counsel is that the drug, which was found to be 'Not of Standard Quality' was a non-Pharmacopoeial drug; that it is a patent and a proprietary

medicine; that the method adopted by the analyst to conclude that it is not of standard quality is erroneous; that the authorities ought to have asked the manufacturer, viz., the Company, the procedure for testing the drug, which was duly approved by the licensing authority; and that the method adopted for testing the individual ingredients of the patent drug is in contravention of the guidelines issued by the authorities in the year 2008. For better appreciation of the said submission, the relevant guideline No.9, is extracted hereunder:

> "9. The Patent and Proprietary formulations should be tested by the Govt. analysts as provided under rule 46 of the Drugs and Cosmetics Rules. In the case of non-Pharmacopoeial or modified formulations, the samples may be tested as per procedure provided by the manufacturer, which has been duly approved by the licensing authority. In case of non receipt of such procedure on request the sample may be tested as per method of analysis available with the Government analyst."

(b) Thus, from the abovesaid guideline, it is seen that the patent / proprietary formulations should be tested by the Government Analyst as provided under Rule 46 of the Rules, and in the case of non-Pharmacopoeial or modified formulations, the samples may be tested as per the procedure provided by the manufacturer, which has been duly approved by the licensing authority.

(c) Rule 46 of the Rules reads as follows:

"46. Procedure on receipt of sample. - On receipt of a package from an Inspector containing a sample for test or analysis, the Government Analyst shall compare the seals on the packet [or on portion of sample or container] *[Inserted by G.S.R. 59(E), dated 7.2.1995 (w.e.f. 7.2.1995).]* with the specimen impression received separately and shall note the condition of the seals on the [packet or on portion of sample or container] *[Substituted by G.S.R. 59(E), dated 7.2.1995 (w.e.f. 7.2.1995).]*. After the test or analysis has been completed, he shall forthwith supply to the Inspector a report in triplicate in Form 13 of the result of the test or analysis, together with full protocols of the tests or analysis applied.

[Explanation. - It shall be deemed to be full and sufficient compliance with the requirement of the rule in respect of the supply of "protocols of the tests or analysis applied", if-

(1)for pharmacopoeial drug, where the tests or methods of analysis prescribed in the official pharmacopoeia are followed, references to the specific tests or analysis in the pharmacopoeias are given in the report;

(2)for patent or proprietary medicines for which the tests and methods prescribed in any of the official pharmacopoeias are applicable and are followed, references to the specific tests or analysis in the pharmacopoeias are given in the report;

(3)for patent or proprietary medicines containing pharmacopoeial drugs for which the official tests or analysis or methods of assays are modified and applied, a description of the

actual tests or, as the case may be, analysis or methods of assays so applied is given in the report;

(4)for patent or proprietary medicines for which no pharmacopoeial tests or methods of analysis are available or can be applied but for which tests or methods of analysis given in standard books or journals are followed, a description of such tests or methods of analysis applied together with the reference to the relevant books or journals from which the tests or methods of analysis have been adopted, is given the report;

(5)for those drugs for which methods of test are not available and have been evolved by the Government Analyst, a description of tests applied is given in the report.]

(d) It is not in dispute that the drug in question, i.e., 'OMNIGEL', is not a pharmacopoeial drug. It is a combination of a few other drugs, viz., Linseed Oil, Diclofenac Diethylamine, Methyl Salicylate & Menthol Gel.

(e) It is the contention of the learned Government Advocate that though the drug in question is a patent drug, it consists of certain Pharmacopoeial drugs and therefore, Rule 46(3) of Rules would be applicable and tests have been conducted in terms of the said rule. The question as to whether the patent drug consists of pharmacopoeial drugs, is a disputed question of fact and has to be adjudicated only in the trial.

Further, it is also seen that Sub rule 4 of Rule 46 also provides for the procedure for testing patent or proprietary medicines and that the procedure prescribed in Standard Books or Journals can be followed. The lab reports suggest that a particular method has been adopted to test the samples. For instance, one of the ingredients, viz., Diclofenac Diethylamine, was tested by 'British Pharmacopoeial (BP)' method. The other ingredients, viz., Methyl Salicylate and Menthol Gel were tested by 'Gas Chromatography' method.

(f) Further, it is seen that the respondent had called for Master Formula record of the subject drug and that it is the case of the respondent that those particulars were not furnished.

(g) In any case, this Court is of the view that the question as to whether Rule 46(3) or 46(4) of the Rules, would be applicable for testing the samples or whether the Analyst should have asked for the testing procedure from the manufacturer is a disputed question of fact and cannot be adjudicated in a quash petition. The judgment of the Himachal Pradesh High Court in ***Elnova Pharma's case*** [cited supra] would not be applicable to the facts of the case, since in that case, the method adopted by the department was erroneous, as the drug in question in the said case

had a combination of two drugs and the department had adopted a method for testing a medicine having a combination of three drugs *(refer para 30 of the said judgment).* In the instant case, no such discrepancy had been pointed out. Therefore, this Court is not inclined to accept the submission of the learned senior counsel that the proceedings are liable to be quashed on the ground, that the testing was done in accordance with the aforesaid guidelines.

(ii) (a). As regards the second ground that the prosecution was launched by the Drugs Inspector without placing it before the Screening Committee and that there is no Screening Committee in the State of Tamil Nadu, it is now brought to the notice of this Court that the complaint was in fact placed before the Screening Committee for approval and the Screening Committee had approved the prosecution of the Company.

(b) The requirement of obtaining a written opinion from the Screening Committee is also found in the guidelines issued by the department, which read as follows:

"7. The State Drug Control Departments shall constitute

screening committees comprising of at least three senior officers not below the level of Assistant Drugs Controllers or equivalent to examine the investigation reports of the cases where prosecutions are proposed to be launched. The committee may submit written opinion on the investigation reports regarding their feasibility of taking legal action. The criminal intent or gross negligence should be taken into consideration while recommending actions like prosecution etc. Care should be taken that charges framed are not based on inappropriate provisions which may be difficult to prove in the court of law in the absence of proper justification or evidence. Cases of failing in assay, brand name disputes and non-renewal of manufacturing licence in time should be examined on their merits before recommending prosecution in such cases.

8. Prosecutions by the Inspectors shall be launched on the basis of written permissions of the controlling authority and this authority in turn shall consider the recommendations of the screening committee while taking final decision in the matter."

(c). The learned counsel for the petitioner in response to the proceedings now produced by the learned Government Advocate (Crl.Side) submitted that the complaint does not specifically state that it was approved by the Screening Committee.

(d) This Court is of the view that the respondent is not obliged to refer to the opinion of the Screening Committee in the complaint. In

any case, since a Screening Committee has been constituted and it had opined that it is a fit case for prosecution, this Court is of the view that the impugned complaint cannot be quashed on that ground also. Therefore, the judgment of this Court in ***Lupin Limited's cas***e [cited supra], relied upon by the petitioner, would not be applicable to the facts of this case.

(iii) (a) The third ground raised by the learned senior counsel appearing for the petitioners is that the complaint was filed belatedly, i.e., on 08.12.2020; that the shelf-life of the drug expired in March 2020 and therefore, the Company was denied its right under Section 25(4) of the Act, to have the drug tested once again at the instance of the Court concerned.

(b) It is not in dispute that when the Government Analyst report was brought to the notice of the Company, they had not exercised their right to challenge the report under Section 25(3) of the Act.

(c) The point raised by the learned senior counsel was raised in a similar case before the Hon'ble Supreme Court in ***State of Haryana v.***

Brij Lal Mittal and others, reported in **(1998) 5 SCC 343** and the Hon'ble Supreme Court had rejected the said contention. The relevant portion of the said judgment reads as follows:

> "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 manufacturers) has within 28 days of the receipt of the report notified in *writing the Inspector or the Court before which any proceeding 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 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).
>
> 6. On a perusal of the impugned judgment we are constrained to say that the High Court did not properly consider the provisions of sub-section (3) nor did it appear to have perused the complaint and the documents annexed thereto before concluding that the respondents were deprived of their right under sub-section (4). Indeed, in quashing the impugned notification the High Court extracted Section 25 and then, without any discussion whatsoever, recorded the following peremptory finding:
>
> "It is apparent from aforesaid (Section 25) that

when the concerned report is received, one copy has to be delivered to the person from whom the same was taken. Within 28 days of the receipt of the copy, the said person can show his intention to adduce defence in contravention of the report. Sub-section (4) of Section 25 of the Drugs & Cosmetic Act, 1940 further makes the position clear. An accused can request the Court to call for the sample and send it for analysis to the Central Drugs Laboratory. By the time the petitioners were summoned, the shelf life had expired. In this process the petitioners (the respondents before us) lost their right to get the sample re-analysed from the Central Drugs Laboratory. 'The petitioners' counsel rightly alleges that a valuable right has lost and this caused prejudice to the petitioners."

7. At the risk of petition, we wish to emphasis that the right to get the sample examined by the Central Drugs Laboratory through the Court before which the prosecution is launched arises only after the person concerned notifies in writing the Inspector or the Court concerned (here the latter clause did not apply for the prosecution was set to be initiated) within twenty eight days from the receipt of the copy of the report of the Government Analyst that he intends to adduce evidence in controversion of the report. The complaint and its accompaniments (which include correspondences that took place the Inspector and the manufacturers) clearly disclose that on February 19, 1991 the Inspector served the original copies of the Analyst's report upon the Managing Director of the manufacturers along with two letters asking for their comments. They further disclose that receiving no reply from the manufacturers the Inspector again wrote a letter on March 6, 1991 directing them to reply to his letters dated February 19,

1991 and asked whether they wanted to take benefit of the provisions of Section 25(3) of the Act. Inspite thereof the manufacturers did not exercise their right (much less within 28 days from the date of the receipt of the report of the Government Analyst i.e. February 19, 1991); and, on the contrary, in their letter dated April 8, 1991 annexed to the complaint), sent in response to the letter dated March 6, 1991, asserted, that their quality control department examined and tested samples of the two drugs and found that they complied with the test of sterility. It must, therefore, be said that consequent upon their failure to notify the Inspector that they intended to adduce evidence in controversion of the report within 28 day, not only the right of the manufactures to get the sample tested by the Central Drugs Laboratory through the Court concerned stood extinguished but the report of the Government Analyst also became conclusive evidence under sub-section (3). The delay in filling the complaint till the expiry of the shelf life of the drugs could not, therefore, have been made a ground by the High Court to quash the prosecution. It will not be out of place to mention that the manufacturers' right under sub-section (3) expired four months before the expiry of the shelf life of the drugs. In view of the above discussion, the reasoning of the High Court for quashing the prosecution against the three respondents cannot at all be sustained."

[emphasis supplied]

(d) In view of the aforesaid findings, this Court is of the view that the delay in the complaint has not caused any prejudice to the petitioners, since the Company had not exercised their right in accordance with Section 25(3) of the Act.

(e) In ***Laborate Pharmaceuticals India Ltd. v. State of Tamil Nadu,*** reported in **(2018) 15 SCC 93**, the accused therein had indicated his desire to have the sample sent to the Central Laboratory for reanalysis which was refused by the authorities, since the request was made after 28 days and therefore, the Hon'ble Supreme Court found that the right of the accused to have the drug sent for reanalysis had been violated.

(f) Similarly, in ***Medipol Pharmaceutical India Pvt Ltd., v Post Graduate Institute of Medical Education and Research and Another***, reported in **(2021)11 SCC 339,** the facts are different. In that case, the initial testing by the Government Analyst was itself delayed for a considerable period, resulting in the sample being drawn towards the end of its shelf-life and therefore, the Hon'ble Supreme Court held that the right to have the sample tested again, was violated *[refer para 13 of the said judgment]*.

(g) The facts in this case are identical with the facts of the case dealt with by the Hon'ble Supreme Court in ***Brij Lal Mittal's case [cited supra]*** extracted above. Therefore, this Court is not inclined to accept the submission of the learned senior counsel that because the complaint was filed belatedly, the right to have the drug tested once again has been violated.

(iv) (a) The fourth ground raised by the learned senior counsel for the petitioners, is that the sanctioning authority had not applied his mind while sanctioning the prosecution of the accused. The Act does not provide for obtaining sanction for prosecuting the accused for all the offences committed under the Act. Sanction as per Section 33 M of the Act, is required only if an accused is prosecuted under Chapter IV A of the Act, which deals with Ayurvedic, Siddha and Unani Drugs. In this case, the accused are not prosecuted for the offences under Chapter IV A of the Act. This view was taken by this Court in ***M/s.Y.V.S. & Co., & another vs. The State, rep. by the Drugs Inspector*** *[Crl.OP.No.6127 of 2020 dated 14.06.2022]* and the Himachal Pradesh High Court in ***Unital Formulation's case*** [cited supra].

(b) Be that as it may. It is well settled that there is a distinction between the absence of sanction and the invalidity of sanction on account of non-application of mind and that the former question can be adjudicated at the threshold, but the latter can be raised only during the trial.

(c) The point raised by the learned senior counsel is that there is a total non-application of the mind by the sanctioning authority. This issue is directly covered by the judgment of the Hon'ble Supreme Court in **Central Bureau of Investigation v. Ashok Kumar Agarwal,** reported in (2014) 14 SCC 295. The relevant observation in the said judgment reads as follows:

> "58. The most relevant issue involved herein is as at what stage the validity of sanction order can be raised. The issue is no more res-integra. In Dinesh Kumar v. Chairman Airport Authority of India & Anr., AIR 2012 SC 858, this Court dealt with an issue and placing reliance upon the judgment in Parkash Singh Badal & Anr. v. State of Punjab & Ors., AIR 2007 SC 1274, came to the conclusion as under:
>
> "13. In our view, having regard to the facts of the present case, now since cognizance has already been

> taken against the appellant by the trial Judge, the High Court cannot be said to have erred in leaving the question of validity of sanction open for consideration by the trial court and giving liberty to the appellant to raise the issue concerning validity of sanction order in the course of trial. Such course is in accord with the decision of this Court in Parkash Singh Badal…"
>
> 59. Undoubtedly, the stage of examining the validity of sanction is during the trial and we do not propose to say that the validity should be examined during the stage of inquiry or at pretrial stage."

(d) Therefore, this Court is of the view that the validity of the sanction, even assuming that it is necessary, can be examined only during the trial and not at the threshold and therefore, this Court is not inclined to quash the complaint on that ground also.

(v) (a) The last ground raised by the learned senior counsel for the petitioners is that the second accused is not liable to be prosecuted, as there is nothing to suggest that the second accused was in-charge of the affairs of the Company; that the Company while obtaining license, had named persons who are in-charge of manufacturing the drug; that those are the persons who had the knowledge of the composition of the drug; that they were not prosecuted and the second accused ought not to have

been prosecuted.

(b) It is the further case of the second accused that he is a Non-Resident Indian having his temporary residence in Mumbai; that he was not involved in the manufacture of one of the many drugs manufactured by the company and cannot be made liable for any alleged defect in the quality of the said drug.

(c) As stated earlier, the second accused is prosecuted since it was mentioned in the website that he is the Managing Director. Apart from that, there are no other allegations against the second accused.

(d) It is contended by the respondent that the Company did not furnish the particulars as required under Section 18(B) of the Act and therefore, they were not in a position to identify the officers, who had knowledge about the manufacturing process of the drug.

(e) It is not in dispute that the loan license was issued to the Company as per Rule 70-A in Form-25-A. In the license under the said Form issued on 17.01.2014 and valid upto 16.01.2019, the names of the competent technical staff have been mentioned, who are in-charge of the manufacturing of the drug in question.

(f) The Hon'ble Supreme Court in ***Cheminova India Limited and another v. State of Punjab and others***, reported in **2021 SCC OnLine SC 573**, had dealt with an identical situation while dealing with the prosecution of the Managing Director of a company. The relevant portion of the said judgment reads as follows:

> "15. In the instant case, the Company has passed a resolution, fixing responsibility of one of the Managers namely Mr. Madhukar R. Gite by way of a resolution and the same was furnished to the respondents by the 2nd Appellant in shape of an undertaking on 22.01.2013. When furnishing of such undertaking fixing the responsibility of the quality control of the products is not in dispute, there is no reason or justification for prosecuting the 2nd Appellant – Managing Director, on the vague and spacious plea that he was the Managing Director of the Company at the relevant time. A reading of Section 33 of the Act also makes it clear that only responsible person of the Company, as well as the Company alone shall be deemed to be guilty of the offence and shall be liable to be proceeded against.
>
> 16. Though, the Managing Director is overall incharge of the affairs of the company, whether such officer is to be prosecuted or not, depends on the facts and circumstances of each case and the relevant provisions of law. Having regard to specific provision under Section 33 of the Act, and the undertaking filed in the present case, respondent cannot prosecute the 2nd Appellant herein. Thus, we find force in the contention of Mr. Sidharth Luthra, learned Senior Counsel, that allowing the prosecution against 2nd Appellant – Managing Director is nothing but, abuse of the process of law. At the same time, we do not find any ground

at this stage to quash the proceedings against the 1st Appellant – Company." *[emphasis supplied]*

(g) Further, this Court in ***Dr.Swati Ajay Piramal v. State of Tamil Nadu,*** reported in **2021 SCC OnLine Madras 5379**, held as follows:

> "24. A reading of the instant complaint also reveals that the complainant had stated the facts but had never stated at any point of time that the petitioner herein was directly in charge of the company and was responsible to the company for the conduct of its business. There is also no allegation that the petitioner herein was responsible to the company for its day-to-day management. There is also no averment regarding the manner in which the petitioner was responsible for the conduct of the business of the company. Further unimpeachable evidence has not been brought on record leading to a conclusion that the petitioner was responsible for the conduct of the company at the relevant time."

(h) In the instant case also, as stated earlier, apart from stating that the second accused is the Managing Director, there is no averment in the complaint that he was in-charge and responsible to the Company for the conduct of its business. In the facts of this case and considering the nature of the offences, that cannot be presumed since, as stated earlier, the names of the competent technical staff in-charge of manufacture and analysis of the drug, are mentioned in the license itself.

(i) In the judgment of the Hon'ble Supreme Court relied upon by the learned Government Advocate (Crl.Side) in ***Dinesh B. Patel's cas***e [cited supra], there were specific allegations that the Directors were privy to the manufacturing of the medicine by the concerned company and they were involved in the manufacturing process *(refer to para 8 and 9 of the said judgment)*.

(j) The judgment of this Court in ***Vikas Rambal's cas***e [cited supra] is contrary to the judgment of the Hon'ble Supreme Court in ***Cheminova's case*** [cited supra]. Therefore, this Court is of the view that the impugned complaint as against the second accused is liable to be quashed. It is needless to say that if any evidence is adduced during the course of the trial regarding the involvement of any officers of the Company, it is open to the Court concerned to summon such persons as accused in terms of Section 358 of BNSS (Section 319 of Cr.P.C.).

7. In the result, quash petition filed by the Company in Crl.OP.No.19832 of 2022 is dismissed and the quash petition filed by the second accused in Crl.OP.NO.19643 of 2022, is allowed, for the aforesaid reasons. Consequently, the connected Criminal Miscellaneous

Petitions are closed.

14.05.2025

Index: Yes/No
Speaking / Non-Speaking Order
Neutral Citation : Yes/No
ars

SUNDER MOHAN, J.
ars

To

1. The Drug Inspector,
Mettupalayam Range i/c.,
O/o. The Assistant Director of Drugs Control,
Coimbatore Zone 2019,
Race Course Road, Coimbatore – 18.

2.The Public Prosecutor,
High Court of Madras.

Pre-delivery common order in
Crl.O.P.Nos.19643 & 19832 of 2022

14.05.2025