BEFORE THE MADURAI BENCH OF MADRAS HIGH COURT

DATED: 18.03.2024

CORAM

THE HON'BLE MR.JUSTICE **SATHI KUMAR SUKUMARA KURUP**

CRL.O.P (MD) No.191 of 2024
and
Crl.M.P.(MD)Nos.141 and 142 of 2024

1.M/s.Alkem Laboratories Limited,
represented by its Managing Director,
Sandeep Singh, Mumbai

2.Sandeep Singh ...Petitioners

vs

State represented by
the Drug Inspector,
Bodinayakkanur Range,
Madurai. ...Respondent

PRAYER: Criminal Original Petition filed under Section 482 of Cr.P.C, praying, to call for the records pertaining to S.T.C.No.2205 of 2023 on the file of the Judicial Magistrate Court, Uthamapalayam, Theni District and to quash the same so far as these Petitioners are concerned in the interest of justice.

For Petitioners : Mr.K.Karthick
Senior Counsel
for Mr.C.Muthusaravanan

For Respondent : Mr.T.Senthil Kumar
Additional Public Prosecutor

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**O R D E R**

This Criminal Original Petition had been filed seeking to quash the complaint in S.T.C.No.2205 of 2023 on the file of the Judicial Magistrate Court, Uthamapalayam, Theni District, against the Petitioners herein.

2. The learned Senior Counsel Thiru.V.Karthick for Mr.C.Muthusaravanan for the Petitioners submitted his arguments. It is the contention of the learned Senior Counsel for the Petitioners that the Petitioners are arrayed as Accused Nos.4 and 5 in the complaint in S.T.C.No.2205 of 2023 on the file of the learned Judicial Magistrate, Uthamapalayam, Theni District. The complaint was filed by the Drugs Inspector, Bodinayakanur Range, Office of the Assistant Director of Drugs Control, Madurai North Zone. As per the complaint, the samples of Omee-Caine Gel (Oxetacaine, Aluminium Hydroxide & Magnesium Hydroxide Gel), 200 ml, Batch No.OME21011SR, Mfg. Date 09/2021, Exp. Date: 08/2023. Made in India by: Skymap Pharmaceuticals Pvt. Ltd., B-3, Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road, Roorkee – 247 667.

Marketed by: ALKEM LABORATORIES LTD., ALKEM HOUSE, Senapati Bapat Marg, Lower Parel, Mumbai – 400 013, was drawn as sample for analysis at the premises of M/s.Nila Medical & Generals, 45E, Ward No.31, Sukkangalpatti Street, New Municipal Street, Cumbum – 625 516 on 03.08.2022 under Form 17 by Tmt.Sathyapriya L.S., Drugs Inspector, Bodinayakanur Range and the same was sent for analysis to the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai – 600 006 under Form 18 for analysis.

3. Nila Medicals from which the Drugs seized by the Drugs Inspector was sent to Government Analyst (Drugs), Drugs Testing Laboratory, Chennai. The report of the Drug Testing Laboratory, Chennai stated that the Drugs does not conform to label claim with respect to the content of Oxetacaine (4.787 mg. (47.87%)) which is in contravention of Section 18(a) (i) of the Drugs and Cosmetics Act, 1940. The analytical report in Form-13 (along with Protocol of Estimation of Oxecatacaine by HPLC Method) was furnished as per Section 25(2) of the said Act and a show-cause memo was issued to Proprietor-cum-endorsed Pharmacist of M/s.Nila Medical & Generals, 45E, Ward No.31, Sukkangalpatti Street, New Municipal Street,

Cumbum, directing them to disclose the name, address and other particulars from whom they acquired the subject drug as per Section 18-A of the said Act. The Proprietor of M/s.Nila Medical & Generals, Cumbum gave a reply dated 18.10.2022 in which he had stated that there is no stock of subject drugs. He had purchased the subject drugs from M/s.Amba Agencies, No. 212-A, First Floor, Naicker New Street, Madurai – 625 001 under invoice. Therefore, a photo copy of the analytical report in Form 13 (along with Protocol of Estimation of Oxetacaine by HPLC Method) along with show cause memo dated 19.10.2022 was sent by Registered Post with Acknowledgment Due to M/s.Amba Agencies, No.212-A, First Floor, Naicker New Street, Madurai – 625 001 directing them to disclose the name, address and other particulars from whom they acquired the subject drug as per Section 18-A of the said Act. A reply dated 28.10.2022 was received on 31.10.2022 from M/s.Amba Agencies, Madurai – 625 001 in which they had disclosed the purchase and other particulars and stated that they had acquired the subject drug from M/s.Ramesh Pharma, 88/22, Rasappa Chetty Street, 1st Floor, Park Town, Chennai – 600 003. Hence, a photo copy of analytical report in From 13 (along with Protocol of Estimation of Oxetacaine by HPLC Method) along with the show cause

memo dated 31.10.2022 was sent by Registered Post with Acknowledgment Due to M/s.Ramesh Pharma, 88/22, Rasappa Chetty Street, 1st Floor, Park Town, Chennai – 600 003 directing them to disclose the name, address and other particulars from whom they acquired the subject drug as per Section 18-A of the Drugs and Cosmetics Act, 1940. A reply dated 08.11.2022 was received on 11.11.2022 from M/s.Ramesh Pharma, Chennai – 600 003 in which they had disclosed the purchase and other particulars and stated that they had acquired the subject drug from M/s.Praveen Pharma, 88/22, Rasappa Chetty Street, 1st Floor, Park Town, Chennai – 600 003 under invoice. Hence, a photo copy of analytical report in Form 13 (along with Protocol of Estimation of Oxetacaine by HPLC Method) along with the show cause memo dated 11.11.2022 was sent by Registered Post with acknowledgment due to M/s.Praveen Pharma, 88/22, Rasappa Chetty Street, 1st Floor, Park Town, Chennai – 600003 and directing them to disclose the name, address and other particulars from whom they acquired the subject drug as per Section 18-A of the Drugs and Cosmetics Act, 1940. A reply dated 18.11.2022 was received on 21.11.2022 from M/s.Praveen Pharma, Chennai – 600 003 in which they had disclosed the purchase and other particulars and stated that they had acquired the subject drug from

M/s.Shubh Pharma Distributor, 53, Baker Thiruvengada Mudali Street, 1st Floor, Choolai, Chennai – 600 112 under invoice. Hence, a photo copy of analytical report in Form 13 (along with Protocol of Estimation of Oxetacaine by HPLC Method) along with the show cause memo dated 25.11.2022 was sent by Registered Post with Acknowledgment Due to M/s.Shubh Pharma Distributor, 53, Baker Thiruvengada Mudali Street, 1st Street, Choolai, Chennai – 600 112 and directing them to disclose the name, address and other particulars from whom they acquired the subject drug as per Section 18-A of the Drugs and Cosmetics Act, 1940. A reply dated 01.12.2022 was received on 05.12.2022 from M/s.Shubh Pharma Distributor, Chennai – 600 112 in which they had disclosed the purchase and other particulars and stated that they had acquired the subject drug from M/s.Alkem Laboratories Limited, Khazana Associates, 38, Madhavaram Redhills Road, 1st Floor, Vadaperumbakkam, Madhavaram, Chennai – 600 060 under invoice. Hence, a photo copy of analytical report in Form 13 (along with Protocol of Estimation of Oxetacaine by HPLC Method) along with the show cause memo dated 09.12.2022 was sent by Registered Post with Acknowledgment Due to M/s.Alkem Laboratories Limited, Khazana Associates, 38, Madhavaram Redhills Road, 1st Floor, Vadaperumbakkam,

Madhavaram, Chennai – 600 060 and directing them to disclose the name, address and other particulars from whom they acquired the subject drugs as per Section 18-A of the Drugs and Cosmetics Act, 1940. A reply dated 13.12.2022 was received on 19.12.2022 from M/s.Alkem Laboratories Limited, Khazana Associates, 38, Madhavaram Redhills Road, 1st Floor, Vadaperumbakkam, Madhavaram, Chennai – 600 060 in which they had disclosed the purchase and other particulars and stated they had acquired the subject drug from M/s.Alkem Laboratories Limited, Derabassi Warehouse, Village Sundra, NR Parabolic Drugs PO: Mubarikpur Tehsil Derabassi Mohali, Mohali (Punjab) – 140 201 under invoice. Hence, a photo copy of analytical report in Form 13 (along with Protocol of Estimation of Oxetacaine by HPLC Method) along with the show cause memo dated 22.12.2022 was sent by Registered Post with Acknowledgment Due to M/s.Alkem Laboratories Limited., Derabassi Warehouse, Village Sundra, NR Parabolic Drugs PO: Mubarikpur Tehsil Derabassi Mohali, Mohali (Punjab) – 140201 and required them to disclose the name, address and particulars from whom they acquired the subject drug as per Section 18-A of the Drugs and Cosmetics Act, 1940. A reply dated 29.12.2022 and 11.01.2023 was received on 09.01.2023 and 18.01.2023 from M/s.Alkem

Laboratories Limited, Mohali (Punjab) – 140201 in which they had purchased the subject drug from the manufacturer of the subject drug M/s.Skymap Pharmaceuticals Pvt., Ltd., B3, Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road, Roorkee – 247 667, Uttarkhand, India under invoice. A copy of analytical report in Form 13 (along with Protocol of Estimation of Oxetacaine by HPLC Method) along with show cause memo dated 13.01.2023 and third portion of the sample were sent by Registered Post with Acknowledgment Due to the manufacturer M/s.Skymap Pharmaceuticals Pvt., Ltd., B3, Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road, Roorkee – 247 667 Uttarkhand, India for having manufactured for sale and sold the subject "Not of Standard Quality" drug in contravention of Section 18(a)(i) of the Drugs and Cosmetics Act, 1940 and Rules, 1945. The firm was also instructed to furnish information and particulars connected to the subject drug, as per Section 18-B of the said Act. A reminder dated 14.02.2023 and a letter dated 03.03.2023 was also issued. A reply dated 15.02.2023, 03.03.2023 and 31.03.2023 was received on 21.02.2023, 13.03.2023 and 10.04.2023 respectively from M/s.Skymap Pharmaceuticals Pvt. Ltd., Roorkee - 247 667 Uttarakhand, India in which they had stated that they are having a valid Drug Manufacturing License in

Form 25 bearing No.97/UA/2007 dated 01.04.2015 and retained upto 30.03.2025 and having endorsement in the name of Oxetacaine, Aluminium Hydroxide and Magnesium Hydroxide Gel dated 01.04.2015.

4. On perusal of the documents received, it was observed that Thiru.Vinod Kumar Gupta is the Director responsible for day-to-day activities of M/s.Skymap Pharmaceuticals Pvt., Ltd., B3, Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road, Roorkee - 247 667 Uttarakhand, India and Thiru.Akshya Kumar Chauhan, Person responsible for day-to-day activities of M/s.Skymap Pharmaceuticals Pvt., Ltd., B-3, Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road, Roorkee – 247 667.

5. In the meantime, a photo copy of analytical report in Form-13 (along with Protocol of Estimation of Oxetacaine by HPLC Method) along with show cause memo dated 18.01.2023 were sent by Registered Post with Acknowledgment Due to the marketer M/s.ALKEM LABORATORIES LTD., ALKEM HOUSE, Senapati Bapat Marg, Lower Parel, Mumbai – 400 013 for having marketed the subject Not of Standard Quality drug in contravention of Section 18(a)(i) r/w. Rule 84-E of the Drugs and Cosmetics

Act, 1940 and Drugs Rules 1945. The firm was instructed to furnish information and other particulars connected to the subject drug, as per Section 18-B of the said Act and also required them to produce the Certified Copy of Agreement with the manufacturer, M/s.Skymap Pharmaceuticals Pvt., Ltd., B-3, Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road, Roorkee – 247 667 for marketing the subject drug as per Section 18(c) r/w. Rule 84-D of the said Act. A reply dated 27.01.2023 was received on 07.02.2023 from M/s.Alkem Laboratories Ltd., Mumbai – 400013 in which they have submitted Drug License retention particulars of Form 20B and 21B valid upto 04.05.2025, Memorandum & Articles of Association, a certified copy of agreement between M/s.Alkem Laboratories Ltd., Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai – 400013 and M/s.Skymap Pharmaceuticals Pvt., Ltd., B-3, Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road, Roorkee – 247 667 and Recall Letter of the subject drug. Their reply is not satisfactory.

6. A report dated 13.04.2023 was submitted to the Director of Drugs Control, Tamil Nadu, Chennai – 600 006 through proper channel to prosecute M/s.Skymap Pharmaceuticals Pvt., Ltd., B-3, Dev Bhoomi

Industrial Estate, Puhana Iqbalpur Road, Roorkee, Distt. Haridwar, Uttarakhand – 247667 represented by its Director responsible for day-to-day activities Thiru.Vinod Kumar Gupta and Thiru.Aksya Kumar Chauhan.

7. It is the contention of the learned Senior Counsel for the Petitioners that the complaint by the Respondent does not disclose any incriminating conduct of the Petitioners herein who were arrayed as Accused Nos.4 and 5. It is the contention of the learned Senior Counsel for the Petitioners that M/s.Alkem Laboratories Ltd., Alkem House, Devashish, Senapati Bapat Marg, Lower Parel, Mumbai – 400013 represented by its Managing Director Thiru.Sandeep Singh and Thiru.Sandeep Singh, Managing Director of M/s.Alkem Laboratories Ltd., Alkem House, Devashish, Senapati Bapat Marg, Lower Parel, Mumbai – 400013 for the contravention of Section 18(a)(i) r/w. Rule 84-E of the Drugs and Cosmetics Act, 1940 and Drugs Rules 1945 for having marketed a “Not of Standard Quality” drug Omee-Caine Gel (Oxetacaine, Aluminium Hydroxide & Magnesium Hydroxide Gel). 200Ml, Batch No.:OME21011SR, Mfg. Date: 09/2021, Exp. Date: 08/2023. Made in India by: Skymap Pharmaceuticals Pvt. Ltd., B-3, Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road,

Roorkee – 247667. Marketed by: ALKEM LABORATORIES LTD., ALKEM HOUSE, Senapati Bapat Marg, Lower Parel, Mumbai – 400 013, which is punishable under Section 27 (d) of the said Act. No specific overt act was mentioned in the complaint by the Drugs Inspector, Uthamapalayam against the Accused 4 and 5. Accused 4 and 5 are only the Distributors of the medicine – Oxetacaine. They are in no way connected with the manufacture of the drugs. They cannot be held liable for manufacturing a drug "Not of Standard Quality".

8. The learned Senior Counsel for the Petitioners also invited the attention of this Court to the agreement between M/s.Alkem Laboratories Ltd., a company registered under the Indian Companies Act, 1956 and having its registered office at Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai – 400 013 and M/s.Skymap Pharmaceuticals Pvt. Ltd., a company incorporated under the Indian Companies Act, 1956 and having its registered office at: 302, Narmada Block-5, Pocket D-6, Vasant Kunj, New Delhi – 110070 and factory at: Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road, Roorkee, Dist. Haridwar (Uttarkhand) India (hereinafter referred to as "the Manufacturer" in which Clause 6 (c) it is stated that The

Manufacturer shall be solely and exclusively liable for payment of all taxes and levies payable by the Manufacturer including Goods and Services Tax on or in connection with the manufacture and sale of the said products by the Manufacturer to the Company under and in accordance with this Agreement and the Company shall in no event be liable or responsible therefor. In the event, any claim, penalty or liability is levied on or incurred by the Company in this behalf at any time, the Manufacturer shall indemnify and keep indemnified the Company from and against all such claims.

9. As per the report of the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai, the sample of Omnee-Caine Gel is in violation of Section 18(a)(i) of Drugs and Cosmetics Act, 1940. Also, the learned Counsel for the Petitioners submitted that the learned Judicial Magistrate, Uthamapalayam, had not followed Sections 200 and 202 of Cr.P.C., as amended and had not considered to take cognizance of the offence. Also, the learned Judicial Magistrate, Uthamapalayam, had not considered the provisions of Section 18(a)(i) of Drugs and Cosmetics Act, 1940.

10. By no stretch of imagination, the Stockist or the Distributor can

be arraigned as Accused for selling Not of Standard Quality drugs. Professional informations regarding manufacturing is available only to the manufacturer. The Petitioners herein are not manufacturers. They are only dealing with the supply of the drugs to various stockists.

11. The learned Senior Counsel for the Petitioners relied on the decision of the Hon'ble Supreme Court in ***2022 Live Law (SC) 833*** [***Lalankumar Singh and others vs State of Maharashtra]*** wherein it is held as follows:

> *"28. The order of issuance of process is not an empty formality. The Magistrate is required to apply his mind as to whether sufficient ground for proceeding exists in the case or not. The formation of such an opinion is required to be stated in the order itself. The order is liable to be set aside if no reasons are given therein while coming to the conclusion that there is a prima facie case against the accused. No doubt, that the order need not contain detailed reasons. A reference in this respect could be made to the judgment of this Court in the case of Sunil Bharti Mittal vs. Central Bureau of Investigation9, which reads thus:*
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> *"51. On the other hand, Section 204 of the Code deals with the issue of process, if in the opinion of the Magistrate taking cognizance of an offence, there is sufficient ground for proceeding. This section relates to commencement of a criminal proceeding. If the Magistrate taking cognizance of a case (it may be the Magistrate receiving the complaint or to whom it has been transferred under Section 192), upon a consideration of the materials before him (i.e. the complaint, examination of the complainant and his witnesses, if present, or report of inquiry, if any), thinks that there is a prima facie case for*

*proceeding in respect of an offence, he shall issue process against the accused.*

*52. A wide discretion has been given as to grant or refusal of process and it must be judicially exercised. A person ought not to be dragged into court merely because a complaint has been filed. If a prima facie case has been made out, the Magistrate ought to issue process and it cannot be refused merely because he thinks that it is unlikely to result in a conviction.*

*53. However, the words "sufficient ground for proceeding" appearing in Section 204 are of immense importance.*

*It is these words which amply suggest that 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. The order is liable to be set aside if no reason is given therein while coming to the conclusion that there is prima facie case against the accused, though the order need not contain detailed reasons.* A fortiori, the order would be bad in law if the reason given turns out to be ex facie incorrect."

12. The learned Senior Counsel for the Petitioners relied on yet another decision of this Court in ***2009 SCC OnLine Mad 1644 [P.Sukumar vs. State represented by Senior Drugs Inspector, Salem Zone, Salem],*** wherein it is held as under:

***"****18. It is well-settled by a catena of decisions of the Hon'ble Apex Court that if the allegations contained in the complaint taken in its entirety to be true and no offence made out, then the complaint is liable to be quashed. The said principle of law is squarely applicable to the case on hand as in this case also even if the allegations contained in the complaint taken in its entirety to be true, no offence made out much less the contravention alleged in the complaint. Therefore, allowing the proceedings to continue against*

*the petitioner pursuant to the complaint preferred by the respondent herein is nothing but a clear case of abuse of process of Court and as such the proceedings pending against the petitioner is liable to be quashed and accordingly, the proceeding pending in C.C.No.577 of 2005 on the file of the learned Judicial Magistrate, Krishnagiri, is hereby quashed in so far as the petitioner/A6 is concerned."*

13. The learned Senior Counsel for the Petitioners relied on yet another decision of this Court in ***Sharmila vs the State*** in ***Crl.O.P.(MD)No. 18629 of 2022***, dated 30.06.2023, in which, it is held as follows:-

*"10.In the light of the above reported decision, the Petitioners cannot be proceeded against by invoking Section 18 of the Drugs and Cosmetics Act, 1940, since the involvement of the offence are not attracted against the Petitioners who is the retailer who had purchased the medicine from distributor of the manufacturer. The manufacturer being M/s.Revive Formulations India Private Limited and the distributor is M/s.Gutford Pharmaceuticals, the Petitioners is neither a manufacturer nor distributor. Therefore, she cannot be held liable for having stocked for sale and sold a "Not of standard quality" which is beyond her due diligence."*

14. Therefore, he seeks to quash the criminal complaint filed by the Drugs Inspector against the Accused 4 and 5/Petitioners herein.

15. The learned Additional Public Prosecutor vehemently objected to the same stating that the Drug manufacturer are taking technical pleas.

Technical pleas may not be considered by this Court exercising the jurisdiction under Section 482 of Cr.P.C. What had been stated by the learned Counsel for the Petitioners shall be put to test only in trial. What will be the defence of the accused need not be considered by this Court to strike out the case against the Accused under Section 482 of Cr.P.C., This Petition may be dismissed as having no merits.

16. In support of his contention, the learned Additional Public Prosecutor relied on the following rulings of the Hon'ble Supreme Court:

(1) In ***Dinesh B. Patel and others vs. State of Gujarat and another [(2010) 11 SCC 125]*** it has been observed as under:-

> ***"10.*** *Under the peculiar circumstances of this case and realising the seriousness of the allegations, we would not take a technical view based on pleadings in the complaint. Mr Raichura contended that as per the settled law by this Court in complaints under Section 138 of the Negotiable Instruments Act, 1881 against a company and its directors also specific averment about the active role of directors in running the company has to be made, failing which the directors cannot be proceeded against. The same logic should apply even in the present case. We cannot agree. Firstly, the language of Section 34(2) of the Act substantially differs from the language of Section 141 of the Negotiable Instruments Act. Secondly, here we are dealing with an offence which has a direct impact on public health. We, therefore, would choose not to interfere with the order of the High Court. It will be open for the Directors to show to the trial court that they had nothing to do with the manufacturing process and, therefore, they should not be held liable under Section 34(2) of the Act."*

***(2)*** In ***Sunil Todi and others vs State of Gujarat and another (2021 SSC OnLine SC 1174)*** it has been observed as under:

> ***"44.*** *In this backdrop, it becomes necessary now to advert to an order dated 16-4-2021 of a Constitution Bench in Expeditious Trial of Cases under Section 138 of NI Act, 1881, In re [Expeditious Trial of Cases under Section 138 of NI Act, 1881, In re, (2021) 16 SCC 116] . The Constitution Bench notes "the gargantuan pendency of complaints filed under Section 138" and the fact that the "situation has not improved as courts continue to struggle with the humongous pendency". The Court noted that there were seven major issues which arose from the responses filed by the State Governments and the Union Territories including in relation to the applicability of Section 202CrPC. Section 143 of the NI Act provides that Sections 262 to 265CrPC (forming a part of Chapter XXI dealing with summary trials) shall apply to all trials for offences punishable under Section 138 of the NI Act. On the scope of the inquiry under Section 202CrPC in cases under Section 138 of the NI Act, there was a divergence of view between the High Courts. Some High Courts had held that it was mandatory for the Magistrate to conduct an inquiry under Section 202CrPC before issuing process in complaints filed under Section 138, while there were contrary views in the other High Courts. In that context, the Court observed : (SCC p. 125, paras 10-11)*
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> > *"10. Section 202 of the Code confers jurisdiction on the Magistrate to conduct an inquiry for the purpose of deciding whether sufficient grounds justifying the issue of process are made out. The amendment to Section 202 of the Code with effect from 23-6-2006, vide Act 25 of 2005, made it mandatory for the Magistrate to conduct an inquiry before issue of process, in a case where the accused resides beyond the area of jurisdiction of the court. (See : Vijay Dhanuka v. Najima Mamtaj [Vijay Dhanuka v. Najima Mamtaj, (2014) 14 SCC 638 : (2015) 1 SCC (Cri) 479] , Abhijit Pawar v. Hemant Madhukar Nimbalkar [Abhijit Pawar v. Hemant Madhukar Nimbalkar, (2017) 3 SCC 528 : (2017) 2 SCC (Cri) 192] and Birla Corpn. Ltd. v. Adventz Investments & Holdings Ltd. [Birla Corpn. Ltd. v. Adventz Investments & Holdings Ltd., (2019) 16 SCC 610 : (2020) 2 SCC (Civ) 713 : (2020) 2 SCC (Cri) 828] ). There has been a divergence of opinion amongst the High Courts relating to the applicability of Section 202 in respect of complaints filed under Section 138 of the Act. Certain cases under Section 138*

*have been decided by the High Courts upholding the view that it is mandatory for the Magistrate to conduct an inquiry, as provided in Section 202 of the Code, before issuance of process in complaints filed under Section 138. Contrary views have been expressed in some other cases. It has been held that merely because the accused is residing outside the jurisdiction of the court, it is not necessary for the Magistrate to postpone the issuance of process in each and every case. Further, it has also been held that not conducting inquiry under Section 202 of the Code would not vitiate the issuance of process, if requisite satisfaction can be obtained from materials available on record.*

*11. The learned Amici Curiae referred to a judgment of this Court in K.S. Joseph v. Philips Carbon Black Ltd. [K.S. Joseph v. Philips Carbon Black Ltd., (2016) 11 SCC 105 : (2016) 4 SCC (Civ) 616 : (2017) 1 SCC (Cri) 270] where there was a discussion about the requirement of inquiry under Section 202 of the Code in relation to complaints filed under Section 138 but the question of law was left open. In view of the judgments of this Court in Vijay Dhanuka [Vijay Dhanuka v. Najima Mamtaj, (2014) 14 SCC 638 : (2015) 1 SCC (Cri) 479] , Abhijit Pawar [Abhijit Pawar v. Hemant Madhukar Nimbalkar, (2017) 3 SCC 528 : (2017) 2 SCC (Cri) 192] and Birla Corpn. Ltd. [Birla Corpn. Ltd. v. Adventz Investments & Holdings Ltd., (2019) 16 SCC 610 : (2020) 2 SCC (Civ) 713 : (2020) 2 SCC (Cri) 828] , the inquiry to be held by the Magistrate before issuance of summons to the accused residing outside the jurisdiction of the court cannot be dispensed with. The learned Amici Curiae recommended that the Magistrate should come to a conclusion after holding an inquiry that there are sufficient grounds to proceed against the accused. We are in agreement with the learned Amici."*

***53.** In the present case, it is evident that the principal grounds of challenge which have been set up on behalf of the appellants are all matters of defence at the trial. The Magistrate having exercised his discretion, it was not open to the High Court to substitute its discretion. The High Court has in a carefully considered judgment, analysed the submissions of the appellants and for justifiable reasons has come to the conclusion that they are lacking in substance."*

## Point for consideration:

***Whether the complaint filed by the Respondent in S.T.C.No.2205 of 2023 pending on the file of learned Judicial Magistrate, Uthamapalayam, is to be quashed?***

17. On perusal of the complaint, it is found that nowhere in the complaint the specific overt act regarding the process of manufacture on the fourth and fifth Respondents is not at all stated which is mentioned against the fourth Respondent who is M/s.Alkem Laboratories Ltd., which is a Company incorporated under Indian Companies Act, 1956 and also having entered into a contract for distribution of the medicines. The confidential information regarding preparation of medicine will not be shared by the manufacturer with the Distributor. The Distributor is interested only in commercial activities of distributing the product (medicine) to various medical stores throughout India, the drug manufactured by the manufacturer M/s.Skymap Pharmaceuticals Pvt., Ltd.. The learned Additional Public Prosecutor placed reliance on the Agenda No.6 of the Minutes of the 79th Meeting of of Drugs Technical Advisory Board held on 16th May, 2018 at Director General of Health Services, Nariman Bhavan, New Delhi in which reads as under:

"AGENDA No.6

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 FOR INCLUDING THE PROVISIONS FOR RESPONSIBILITY TO THE PERSONS WHO ARE DINLY THARKETING THE DRUGS WITHOUT HAVING ANY MANUFACTURING FACILITY USING LICENCED FACILITIES MANUFACTURERS

The DTAB deliberated the matter and agreed for the proposal to make the provisions under the Drugs and Cosmetics Rules in addition to the existing provisions for fixing the responsibility to persons who are marketing the drugs without having any manufacturing facility using licenced facilities of manufacturers. The Board however, clarified that the pensons involved in any distribution channel should not be affected. The marketing firm should be treated as an agent of the manufacturer and no plea under Section 19 of the D&C Act, 1940 should be applicable to it."

Based on which the learned Additional Public Prosecutor vehemently objected to quash the private complaint in S.T.C.No.2205 of 2023 filed by the Drugs Inspector, Uthamapalayam before the learned Judicial Magistrate, Uthamapalayam. Further, the learned Additional Public Prosecutor relied on the reported decision of the Hon'ble Supreme Court in ***(2010) 11 SCC 125 [Dinesh B. Patel and others vs. State of Gujarat and another].*** It was a case where the Directors of the Company which manufactures drugs for human consumption approached the Hon'ble High Court of Gujarat under

Section 482 of Cr.P.C. to quash the proceedings before the learned Judicial Magistrate as they were Directors of the Company and not liable for prosecution as they were not responsible for the day-to-day proceedings of the Company. In that case, the Drugs seized from the Medical Stores were found defective because of the growth of fungus. In the complaint, it was specifically pleaded the active involvement of the individual Directors of the Company in the day-to-day affairs of the Company which manufacture the drugs. Therefore, the petition filed by the Directors of the Company that they were not liable for the day-to-day affairs of the Company were not accepted by the Hon'ble High Court of Gujarat and the petition under Section 482 of Cr.P.C. was dismissed. Against which, they preferred Appeal before the Hon'ble Supreme Court wherein the Hon'ble Supreme Court has held that there was clear allegation that the Directors were privy to the manufacturing of medicine by the Company and the averments in the complaint were not bald statement. The offence involved has direct impact on public health. Hence, it is serious. The High Court rightly took the view that the Directors were responsible for the affairs of the Company. Therefore, the drug manufactured by the Company is found to be defective and all the Directors could be prosecuted. The High Court correctly

proceeded on the basis of the specific language of Section 34(2) to hold that the complaint filed against the Directors could not be disposed of under Section 482 of Cr.P.C. as it requires appreciation of facts on the basis of the evidence to be let in before the trial Court, interference by the High Court order not warranted.

18. Here, as per the averments in the complaint, M/s.Alkem Laboratories Ltd., is only a Distributor. Nowhere in the complaint the role played by the Distributor in the process of manufacturing of substandard medicine was stated. Therefore, it is nothing but an abuse of process of Court by the Drugs Inspector, Uthamapalayam.

19. In yet another decision of the Hon'ble Supreme Court in ***2021 SSC OnLine SC 1174 [Sunil Todi and others vs State of Gujarat and another]*** cited by the learned Additional Public Prosecutor, the fact is with regard to Section 138 of Negotiable Instruments Act, 1881, in which also the complaint stated that individually all the Directors of the Company, who had issued cheque and which cheque was bounced, are responsible, wherein in paragraph 54 of the judgment, the Hon'ble Judges of the Hon'ble Supreme

Court held that what was raised in the case are triable issue to be agitated before the trial Court. The defence of the Accused as to the valuable defence of the Accused cannot be considered to quash the complaint. The ratio of that decision was relied by the Hon'ble Judges of the Hon'ble Supreme Court in ***2022 SCC OnLine 1383 [Lalankumar Singh and others vs. State of Maharashtra]*** wherein the Appellants were the Directors of M/s.Cachet Pharmaceuticals Private Ltd., which was granted permission to manufacture 'Hemfer Syrup' which falls under Schedule C & C (1) to the Drugs and Cosmetics Rules, 1945 where the samples seized from M/s.Priya Agencies at Beed and subjected to analysis by the Drugs Control Laboratory, Mumbai, was found that the samples was not of Standard Quality as the content of “Cyanocobalamin” was less than the permissible limit. The Appeal before the Hon'ble Supreme Court by the Directors of the Company that they are not liable for the day-to-day affairs of the Company was considered by the Hon'ble Supreme Court. In that case, the learned Judicial Magistrate had issued summons after satisfying himself that the *prima facie* case made out in the complaint against the Directors of the Company. Therefore, the attempt of the Directors of the Company to quash the complaint was rejected. Here, the Petitioners are not the manufacturers

of Oxetacaine. The decisions cited by the learned Additional Public Prosecutor also will not help the case of the Prosecution to dismiss the petition under Section 482 of Cr.P.C.

20. The learned Additional Public Prosecutor also had filed detailed counter stating that after issuance of the memo to each of the agency which had distributed the drugs to Nila Medicals & Generals from M/s.Alkem Laboratories to M/s.Shubh Pharma Distributor and M/s.Praveen Pharma, Chennai, from whom Nila Medicals & Generals had sent the drug sample to the National Chemical Laboratory at Kolkata and obtained test result wherein also it was found out that the medicine “Oxetacaine” was of substandard quality. For the counter filed by the learned Additional Public Prosecutor, the Petitioners herein had filed reply statement stating that the sample sent to the National Chemical Laboratory at Culcatta was after taking cognizance of the offence by the learned Judicial Magistrate, Uthamapalayam and issuing summons to the Accused. Therefore, it has no bearing on the Accused. It cannot be considered by the Court since it was sent only after filing of the complaint. The complaint was filed based on the test report obtained from the Drugs Laboratory at Chennai. Based on which

sanction to prosecute was obtained by the Drugs Inspector, Uthamapalayam. After filing of such complaint before summon was issued to the Accused, the attempt of the Drugs Inspector seeking second opinion by forwarding the seized drug samples to the National Drugs Laboratory at Culcatta cannot be accepted. Also, the manufacturer on receipt of memo by the Drugs Inspector had disputed the finding of the Drugs Laboratory at Chennai that the drugs is substandard. Only after appearance of the Accused, the Accused is given his right to refer the second opinion from a different laboratory.

21. The reliance placed by the learned Senior Counsel for the Petitioners in the reported decision in ***2022 Live Law (SC) 833*** [***Lalankumar Singh and others vs State of Maharashtra]*** and the decision of this Court in ***Sharmila vs the State*** in ***Crl.O.P.(MD)No.18629 of 2022***, the submission of the learned Additional Public Prosecutor that the Distributor has the liability, cannot be accepted by this Court until otherwise the Drugs and Cosmetics Act is amended by fixing liability on the Distributor, also for defect label, till such time, the Distributor cannot be held liable.

22. In the light of the reported decision cited by the learned Senior Counsel for the Petitioners in ***2009 SCC OnLine Mad 1644 [P.Sukumar vs. State represented by Senior Drugs Inspector, Salem Zone, Salem],*** this Court had quashed the charges against the Petitioners in the case of ***M.Sujatha vs. State of Tamil Nadu represented by Drugs Inspector*** reported in ***2020 SCC OnLine Mad 4666*** and also in the case of ***Sharmila vs. State represented by the Drugs Inspector, Thirumangalam-II Range, Madurai in Crl.O.P.(MD)No.18620 of 2022 dated 30.06.2023***. The facts of the above said cases squarely applies to the facts of this case. Therefore, the Petitioners cannot be held liable for manufacturing of a substandard quality. They are only Distributor. As per the contract between the Petitioners and M/s.Skymap Pharmaceuticals Pvt., technical details are not shared with the Distributor. Therefore, the vehement objection to quash the complaint against Accused Nos.4 and 5 by the learned Additional Public Prosecutor cannot be accepted. Hence, it is rejected.

23. In the light of the facts stated by the learned Counsel for the Petitioners, the Petitioners herein are arraigned as A-4 and A-5 in S.T.C.No.

2205 of 2023 on the file of the learned Judicial Magistrate Court, Uthamapalayam. Their role is distribution of medicines manufactured by the Respondents 1 to 3. Therefore, whether the product was standard product or not of standard product cannot be understood by the Petitioners herein as the information is not shared by the manufacturer. The agreement between the Manufacturer and the Distributor is available only with the Manufacturer and not with the Distributor. Therefore, without any specific pleading regarding violations of Drugs and Cosmetics Act, cognizance taken by the learned Judicial Magistrate, Uthamapalayam, is erroneous. The complaint is bereft of details regarding the violation of the Drugs and Cosmetics and Act and Rules. Under those circumstances, mere mentioning of the names of the Respondents 4 and 5 is not sufficient materials to attract prosecution under Drugs and Cosmetics Act and Rules.

24. In the light of the above discussion, the point for consideration is answered in favour of the Petitioners and against the Respondent. The complaint filed by the Respondent in S.T.C.No.2205 of 2023 pending on the file of learned Judicial Magistrate, Uthamapalayam, is to be quashed.

In the result, the ***Criminal Original Petition*** is allowed and the proceedings in S.T.C.No.2205 of 2023 pending on the file of the learned Judicial Magistrate, Uthamapalayam, is quashed, in so far as the Petitioners are concerned. Consequently, connected Miscellaneous Petitions are closed.

Internet :Yes/No
Index :Yes/No
NCC :Yes/No
cmr/srm

18.03.2024

To

1.The Judicial Magistrate,
Uthamapalayam.

2.The Drug Inspector,
Bodinayakkanur Range,
Madurai.

**SATHI KUMAR SUKUMARA KURUP, J.**

cmr/srm

CRL.O.P(MD)No.191 of 2024

18.03.2024