* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

Reserved on: 12th August, 2025

% ***Pronounced on: 23rd September, 2025***

\+ **CRL.M.C. 2085/2021, CRL.M.A. 14031/2021 & CRL.M.A. 28366/2023**

1. **REVACURE LIFESCIENCES LLP**
Regd. Office at: A-63, Sarita Vihar,
Delhi-110075
Through its authorized representative
Ravi Saxena S/o Dr. Ramesh Chand Saxena
R/o A-63, Sarita Vihar,
New Delhi-l10075 **.....Petitioner No.1**

2. **RAVI SAXENA,**
S/o Dr. Ramesh Chand Saxena
R/o A-63, Sarita Vihar,
New Delhi-I 10075 .....**Petitioner No.2**

3. **RAJEEV SAXENA,**
S/o Dr. Ramesh Chand Saxena
R/o 8/16 South Civil Lines,
near IG Police Bungalow,
Jabalpur Madhya Pradesh- 482003 .....**Petitioner No.3**

4. **NEETI BHARDWAJ,**
D/o late Sh. C.S. Dixit
R/o PC4/305, Pavillion Court Tower 4,
Jaypee Wish Town, Sector 128,
Noida (UP)- 201304
Delhi- 110075 **.....Petitioner No.4**

5. **SAURABH SINGH,**
S/o Shri. Surender Singh
R/o R 206, Tower R, Supertech Ecociti,
Sector 137, NoidaU.P.201301 **.....Petitioner No.5**

6. MANOJ DUTTA,
S/o Late Sh. Narendra Nath Gupta
R/o H. No. 789/A-1, II Floor,
Gali No.7, Govindpuri Kalkaji,
New Delhi- 110011 **.....Petitioner No.6**

Through: Mr. Aditya Singh Deshwal and Mr. Daksh Sharma, Advocates

versus

1. STATE GOVT OF NCT DELHI **.....Respondent No.1**

2. M/S BHARDWAJ INDIA PRIVATE LIMITED
Regd. Office: A-112, First Floor,
DDA Sheds, OKHLA Phase- II
New Delhi- 110020 **.....Respondent No.2**

3. BHUPENDRA MOHAN BHARDWAJ
R/o A-112, First Floor,
DDA Sheds, Okhla Phase- II
New Delhi-110020 **.....Respondent No.3**

4. LAXMEE BHARDWAJ
R/o A-112, First Floor,
DDA Sheds, Okhla Phase- II
New Delhi- 110020 **.....Respondent No.4**

Through: Mr. Utkarsh, APP for the State with SI Sonu Kumar PS. OIA.
Mr. Biswajit Swain and Mr. Akhil Ganga, Advocates for Respondent No. 2 to 4 I.E.

CORAM:
HON'BLE MS. JUSTICE NEENA BANSAL KRISHNA

O R D E R

% 12.08.2025

1. Petition under Section 482 Criminal Procedure Code, 973 has been filed for quashing of Order dated 02.02.2019 whereby learned MM, Delhi allowed Application under Section 156(3) Cr.P.C. resulting in registration of ***FIR No. 0053/2019 under Sections 274/275 IPC and Section 13 Drugs and Cosmetics Act, 1940*** (*hereinafter referred to as the "D&C Act"*), dated 14.02.2019 at P.S. Okhla Industrial Area.

2. ***Briefly stated,*** a Criminal Complaint was filed by Respondent No.2/*M/s Bhardwaj India Private Limited* Delhi against Petitioner No. 1/*Revacure Lifesciences LLP* and its Partners and employees, before the Court of Ld. MM, for deliberately supplying them *defective medicines i.e. Docetaxel 20 mg* as it had broken glasses and visible foreign particles in the vials, which was noticed after the delivery of the product. Despite this being brought to the notice of the Complainant, the Respondent No.1 failed to take any corrective measures. The Complainant, therefore, sought registration of FIR against the Petitioners for their illegal acts of "*manufacturing of product, medicines and injections which may cause serious harm to the patient.*"

3. *The learned MM under Section 156(3) Cr.P.C*. directed registration of FIR against Petitioner No. 1 and its partner and employees, vide Order dated 02.02.2019, which resulted in registration of *FIR No. 0053/2019.*

4. The Petitioner No. 1 has ***challenged this Order*** directing the registration of FIR on the ***ground*** that the Complainant has ***concealed material facts.*** It is explained that Petitioner No. 1/*Revacure* owns its manufacturing facility at Jabalpur, Madhya Pradesh. Respondent No. 2-

Company is in the business of Pharmaceuticals and Drugs. Since the Complainant was not having any facility to manufacture drugs in India, it entered into a ***Loan License Agreement*** dated 20.12.2012 and 18.03.2013 with Petitioner No. 1 under which the manufacturing was to be done by Petitioner No. 1 while the product was to be sold by Respondent No. 2 (*P to P business*). For this purpose, Respondent No. 2 Company got a separate *License No. 28-A/19/2018* from the Licensing Authority, Food and Drugs Administration, Madhya Pradesh for manufacture of drugs on *Loan License basis* at the Manufacturing unit of Petitioner No. 1, in terms of Rule 76A of D & C Act.

5. During the process of applying for the License, Respondent No. 2 gave an Undertaking that *the product quality, product strength and product purity* shall be completely its responsibility. Likewise, Licensee was also required to take permission from Petitioner No. 1 for manufacture of pharmaceutical products in its premises.

6. It is explained that essentially, the relationship between Petitioner No. 1 and the Respondent No. 2 was that of a *landlord and tenant*, insomuch as the Petitioner No. 1 was receiving the rent in lieu of giving its manufacturing facility, staff, equipment and testing facility to Respondent No. 2 for a given period till 14.02.2023 ***(as per the duration of license given to Respondent No. 2 in Form 28A).*** The payment terms between the parties was that 50% was to be paid in advance, while the remaining 50% was payable before the dispatch of final product manufactured in the premises of Petitioner No. 1.

7. The Petitioners have asserted that *Respondent No. 3/Bhupendra Mohan Bhardwaj*, in due course, realised that he did not have the requisite market to sell the manufactured products. On 09.06.2018, Respondent No. 2/Company sought delivery of the final product without payment of the balance 50%. Petitioner No. 1 however, demanded the balance payment in terms of the Agreement through an e-mail dated 09.06.2018 written by Saurabh Singh, Technical Head of Petitioner No. 1 to the Technical Head of Respondent No. 2.

8. On 27.06.2018 in its own legitimate interest, Petitioner No. 1 gave a final ultimatum to Respondent No. 2 to take delivery of the manufactured Product by paying the remaining 50% payment. Immediately upon receiving the email, Mr. Mohan Bhardwaj, Respondent No. 3 wrote an email dated 27.06.2018 threatening the Petitioners with false implication.

9. After unpleasant communication between the parties, Respondent No. 2 agreed to take the delivery of the Product after making payment of 50% balance amount. It was also agreed that the employees of Respondent No. 2, shall visit the premises of Petitioner No. 1in order to ensure the quality of the Product before its dispatch. Accordingly, two of its employees went to the manufacturing Unit of Petitioner No. 1, where they stayed for 03 days to ensure the dispatch of the Product after verification and inspection.

10. The Petitioners have claimed that with an ill intention, Respondent No.3/Mr. Mohan Bhardwaj himself contaminated the products and started making false allegations of the defective products having been supplied to him. The partners of Petitioner No. 1 were surprised as the Product had been dispatched to Mr. Mohan Bhardwaj only after the Product had been gotten

tested by himself from an outside laboratory of his choice and the verification of the Product by its two employees, before dispatch.

11. Petitioner No. 2 with *bona fide* intentions, sent Mr. Manoj Dutt, Petitioner No. 6, one of its employees of sister concern *cGMP Pharma 'n' Plans Pvt. Ltd.* to address the grievances. However, he was illegally detained, harassed and manhandled by Mr. Mohan Bhardwaj at his office, on 07.08.2018. He was made to write a confession under coercion, taking the liability of the defective Product on Petitioner No. 1. Mr. Manoj Dutt gave Criminal Complaints dated 08.08.2019 and 09.08.2019 about the cruelty inflicted on him by Mr. Mohan Bhardwaj. Not only this, Respondent No. 3 in order to bulldoze the business of the Petitioner No.1, made false Complaints before every possible Authority.

12. Consequently, the factory of the Petitioner No. 1 was raided by a Joint Inspection Team of Central Drugs Standard Control Organization (CDSCO), a National Regulatory Authority along with Drug Inspector of FDA, M.P. Jabalpur, on 20.08.2018 and a Joint Inspection dated 20.08.2018, was conducted, *but it absolved the Petitioner No. 1 from all the charges*.

13. Further, the *Report dated 07.12.2018 of the Government Analyst, Karnataka under Section 25(1) D&C Act,* affirmed that the Product met the critical quality parameters as per IP, *including assay and sterility* ***except presence of particles***. The *assay* defines the purity of active pharmaceutical ingredient, which is the key raw material used in the manufacture of the product. *Sterility* means that the product was found free of any microorganisms and also reflects that the product was manufactured under highly sanitized environment. *Therefore, ipso facto, the Report reflected that*

the Product had been intentionally tampered with by Mr. Mohan Bhardwaj after its delivery to him.

14. However, the plan of Respondent No. 2 to defame the name of Petitioner No. 1 did not stop. It sent the samples of the Product which was contaminated by Respondent No. 3, to the Drug Control Department Bengaluru, Karnataka and tried to create the picture that the Product was manufactured by Petitioner No. 1 for sale by Respondent No. 2. The Drug Inspector issued Notices under section 18A and 18B D & C Act to Petitioner No. 1 which was duly replied on 04.02.2019 and 08.06.2019.

15. ***It is thus, submitted*** that Respondent No. 2 has concealed *material facts* cleverly in his Complaint that the Product was manufactured on ***Loan License basis*** at the premises of Petitioner No. 1. The Product was of Respondent No. 2, manufactured under the license of M/s Bhardwaj India Private Limited, only by taking the facilities and staff of Petitioner on loan, in terms of *Loan License Facility Arrangement* and also various *Undertakings* that were given by Respondent No. 2 under the said License. The petitioner was in no way responsible for the Quality of the Product which was the sole responsibility of the Respondent No.2. No liability under Section 13 of D&C Act can be fastened on Petitioner No. 1 as no act can be attributed to Petitioner No. 1

16. The learned MM has relied upon the Report of Karnataka, FDA but ignored the fact that no action was taken in Karnataka by the Drug Inspector, despite being equipped with the powers to launch criminal prosecution against Petitioner No. 1.

17. It is submitted that the *impugned Order is liable to be set aside* as the

Product had been contaminated by Respondent No. 3 at his own place after the dispatch, only to defame Petitioner No. 1.

18. The ***second ground*** of challenge is that as per ***Section 32 of D&C Act,*** it is only the Drug Inspector who has the special powers to initiate a criminal prosecution for violation of the provisions of the Act. The Police official is not competent to register an FIR for the offences under D&C Act or to investigate them, which is in the absolute jurisdiction of the Drugs Inspector. The FIR is therefore, liable to be quashed.

19. The ***third ground of challenge*** is that offences under *Section 274 IPC for Adulteration of Drugs* and *Section 275 IPC for Sale of Adulterated Drugs*, ***are both non-cognizable and no FIR*** could have been registered for these offences. Petitioner No. 1, in response to the Notice under Section 91 and 41A Cr.P.C, has given detailed Reply explaining each and every aspect. It is further asserted that ***Section 190 Cr.P.C.*** provides that no cognizance can be taken unless a *prima facie* cognizable offence is made out. *In the present case, no offence is disclosed in the Complaint*.

20. The ***fourth ground*** is that the Complaint is a ***sheer abuse of process of law*** as the Respondents intend to extort money from Petitioner No. 1 since Respondent No. 2 was unable to sell their products in the market. Moreover, it an endeavour to settle a *commercial dispute*. This is evident as Respondent No. 2 had sent a *Legal Notice dated 09.07.2021* to Petitioner No. 1, to refer their dispute to Arbitration without mentioning the Loan License Manufacturing Arrangement. *It is claimed that dispute is purely commercial in nature, which should have been decided by way of*

Arbitration or civil adjudication.

21. Reliance is placed on the case of *R.K. Vijayasarathy vs. Sudha Seetharaman* (2019) 16 SCC 739, wherein it was held that where on bare reading of the Complaint, it is evident that the matter is essentially of a civil nature which has been given a clothe of criminal exercise and the ingredients do not make out a criminal offence, it amounts to abuse of the process of the Court and is liable to be quashed under Section 482 Cr.P.C.

22. *In the end,* it is asserted that the impugned Order does not consider any of the aforesaid factors and does not mention the aspects which require Police investigations while directing registration of FIR and is therefore, it is ***a non-speaking Order which is liable to be set aside.***

23. Reliance is placed on *Anil Kumar and Ors. vs. N.K. Ayyappa and Ors.* (2013) 10 SCC 705, wherein it was observed that the Order under Section 156(3) Cr.P.C. *must state the reasons for directing investigation*. No reasons have been given in the impugned Order directing the registration of the FIR.

24. *It is thus, submitted that the present Order dated 02.02.2019 directing the registration of FIR and the consequent FIR No. 0053/2019, be quashed.*

25. ***Status Report has been filed on behalf of the State*** wherein the averments made in the Complaint, are reproduced. It is further explained that in compliance of the Notices under *Section 91 Cr.P.C.*, Petitioner No. 1 has produced the relevant documents, which were seized by the Investigating Officer. Reply dated 20.07.2019 was filed on behalf of the Petitioner requesting to close the investigations of the case. On 16.09.2012, the Complainant Company had produced the drugs allegedly supplied by the Petitioner *Revacure*, which was seized and preserved in the store of the

Complainant Company.

26. As per the Letter dated 18.03.2019, a *joint inspection* was carried out by Drugs Inspector, Government of M.P. on 20.08.2018 at the premises of Petitioner No.1 at Jabalpur, M.P. where the drugs were being manufactured. The Inspection Report of Assistant Drug Controller, Indore, M.P., revealed that Petitioner had manufactured Docetaxel 20 mg/1 ml injection IP, as per the *Master Formula Record*, as per pharmacopeial standards and the Firm performed validation of the said drug and carried out stability studies of those Batches. The Firm does not manufacture any commercial batch of Bortezomib 2.5 mg injection and Carboplatin injection of any strength.

27. It was also intimidated on 27.10.2018 that Drugs Inspector, Bangalore had drawn three Drugs samples for Test/Analysis under Form 17 & 17A from the same Batch of drugs from New BEL Road, Bangalore maintained by the Complainant Company, and all three samples had been declared as ***Not of Standard Quality*** by Government Analyst, Karnataka *vide* Report dated 07.12.2018. *Hence, Section 13 of the D & C Act was replaced by Sections 9A/27 of the D & C Act.*

28. During further course of investigation, the Drugs Inspector, Drug Control Department, Government of NCT of Delhi, vide Letter dated 10.01.2020 intimated Drugs Inspector, Bangalore, Karnataka Drug Control Department, being the concerned Investigating Officer in the case under the Drugs and Cosmetics Act, 1940 and Rules thereunder, wherein the proceedings had been initiated in the present case.

29. During further investigations in this FIR, in response to the Notice

under Section 41A Cr.P.C., Mr. Ravi Saxena, Mr. Rajeev Saxena and Ms. Neeti Bhardwaj, Partners of Petitioner No.1 *M/s Revacure Life Sciences LLP*, had joined the investigations and had submitted their written Reply stating therein that the complainant Company has filed the FIR by misleading and presenting the case as that of adulteration of drug, whereas the actual issue is a commercial dispute and a vengeance/revengeful act to deliberately contaminate the drug.

30. ***Respondent No.2****/M/s Bhardwaj India Private Limited* ***in its Reply*** has taken a *preliminary objection* that Petitioners with mala fide intention have not disclosed the correct facts and circumstances and filed instant Petition with half-baked facts and circumstances. Therefore, the Petition is liable to be dismissed on this sole ground of having approached the Court with *unclean hands*, by not deliberately filing the Agreements/Documents executed between the parties, which are against the interest of the Petitioners.

31. Learned MM in his detailed Order, has not only considered the sub-standard quality of drugs supplied by the Petitioners to Respondent No.2 Company as per the Agreements and Test Reports, but had also categorically observed that the Petitioners after taking the entire money from the Respondent No.2 and its Directors in advance, had supplied sub-standard medicines which is also admitted by the Petitioners, as per the e-mail communication.

32. It is further asserted that the Petitioners have filed incomplete Form 28A without enclosing the name of Approved/Competent Technical Staff, as mentioned in Clause 3 of Form 28A. It has not even been whispered that in

Form 27 issued by the Madhya Pradesh Drug Authority, categorically mentions that the expert Technical Staff responsible for the Manufacturing and Testing, shall be of Petitioner Company.

33. The Petitioners in order to escape its wrong deeds, has not filed the *Technical Agreement* Dated 05.12.2017, which outlines the responsibilities and activities relating to the manufacture, testing and release of the aforesaid products; the *Supply Agreement* Dated 31.03.2018, which comprises of terms and conditions relating to the supply, distribution and payment of the products and the *General Agreement* dated 09.07.2018.

34. It is reiterated that as per the *Technical Agreement* dated 05.12.2017, Petitioners had to provide the documents to Respondent No. 2 Company in regard to the supply, analysis & approval of ingredients & PM, Product Quality and control, Administrative & Prescribing Information, Product Quality API amongst other documents. These documents were necessary to show that the *Petitioners were solely responsible for manufacturing the drugs and for further sale/supply of medicines in the market.* Manufacturing of drugs was governed by the Schedule M, of D&C Rules titled "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products".

35. ***Clause 8*** provides for *Manufacturing, Operations and Controls* and more specifically, *sub-clause 8.1* categorically states that all manufacturing shall be carried out under the supervision of the Technical Staff of the Licensing Authority. Likewise, *Clauses 10.3, 10.4, 10.9* of the aforesaid Rules and Regulation stipulate that the raw materials used in the manufacturing of Drugs shall be purchased, examined and released for the

manufacturing by the *Quality Control Department exclusively*. It is evident from *Form 27 and 28A*, the Agreements executed between the parties and the email exchanges that the Technical Staff and Quality Assurance/Control members were of Petitioner No.1 Company and nowhere was Respondent No.2 involved at all. Petitioner under the garb of Loan Licence Agreement is trying to evade its responsibility.

36. Further averments as made in the Complaint, have been reiterated. It is further submitted that as per *Test Reports/Analysis* of Drug Control Department, Karnataka, it is clear that the drugs manufactured and supplied by Petitioner No.1 were *not of standard quality* and these facts have been duly appreciated by the learned MM.

37. *It is submitted that there is not merit in the present Petition, which is liable to be dismissed.*

38. ***Petitioners in their Rejoinder*** have essentially reiterated the same grounds as stated in the Petition.

39. Reliance has been placed on *Union of India vs. Ashok Kumare Sharma,* in Crl. Appl. 200/2020 decided on 28.08.2020, *Ramdev Food Products Private Limited vs. State of Gujarat,* MANU/SC/0286/2015, and *Commissioner of Central Exercise Goa vs. Cosme Farma Laboratories Limited,* (2015) 11 SCC 605.

Submissions heard and record perused.

Registration of FIR in respect of any offence under the Drugs and Cosmetics Act, 1940:

40. *First aspect* for consideration is whether offences under Section 13 or 27 of the D & C Act are amenable to registration of FIR and investigations

by the Police and could the registration of FIR be directed under these Sections by the learned MM in the Application under Section 156(3) Cr.P.C.

41. In this regard, it would be pertinent to refer to Section 32 of Drugs and Cosmetics Act reads as under:

> ***"32. Cognizance of offences —***
> *(1) No prosecution under this Chapter shall be instituted except by—*
> ***(a) an Inspector; or***
> ***(b) any gazetted officer of the Central Government or a State Government authorised in writing*** *in this behalf by the Central Government or a State Government by a general or special order made in this behalf by that Government;*
> *(c)* ***or the person aggrieved;***
> *(d)* ***or a recognised consumer association*** *whether such person is a member of that association or not.*
> *(2) Save as otherwise provided in this Act, no court inferior to that of a Court of Session shall try an offence punishable under this Chapter.*
> *(3) Nothing contained in this Chapter shall be deemed to prevent any person* ***from being prosecuted under any other law*** *for any act or omission which constitutes an offence against this Chapter."*

42. In the recent judgement of *Ashok Kumar Sharma (supra)*, after discussing all the provisions of Drugs and Cosmetics Act and the relevant provisions of Cr.P.C, it has been held as under:

> *"170.1. In regard to cognizable offences under Chapter IV of the Act, in view of Section 32 of the Act and also the scheme of Cr.P.C,* ***the police officer cannot prosecute offenders in regard to such offences****. Only the persons mentioned in Section 32 are entitled to do the same.*
> *.....*
> *170.3. Having regard to the scheme of Cr.P.C and also the mandate of Section 32 of the Act and on a conspectus of powers which are available with the Drugs Inspector under*

> *the Act and also his duties,* ***a police officer cannot register an FIR under Section 154 Cr.P.C, in regard to cognizable offences under Chapter IV of the Act*** *and he cannot investigate such offences under the provisions of Cr.P.C."*

43. Therefore, in the light of law as explicitly explained in *Ashok Kumar* (*supra*), the present FIR could not have been registered for any offences under the D & C Act by the police, which is in the exclusive domain of Drugs Inspector. Moreover, it is noted in the Status Report that Drugs Inspector, Karnataka has already initiated investigations in the allegations of adulterated/spurious drugs, under D&C Act.

44. *Therefore, the FIR for the offences under the D & C Act is hereby quashed with liberty to the Drugs Inspector to proceed as per the provisions of the D & C Act.*

FIR in Respect of IPC Offences:

45. Another relevant aspect is that while the FIR in respect of the offences under D&C Act may be quashed, what would be the fate of the offences under IPC which have also been invoked in the same transaction, which lies within the competence of the Police to investigate these offences, under Cr.P.C.

46. The guiding light comes from S. 32(3) D&C Act which explicitly provides that "*Nothing contained in this Chapter shall be deemed to prevent any person* ***from being prosecuted under any other law*** *for any act or omission which constitutes an offence against this Chapter..,"* thereby implying that **the FIR for IPC offences shall sustain itself and investigations therein shall be continued by the Police**.

Registration Of FIR for Non-Cognizable Offences:

47. Having held that the investigations for IPC offences can be continued by the police, another *jurisdictional question* has arisen, which is: *whether any direction could be given under Section 156(3) Cr.P.C. for registration of FIR under Sections 274/275 IPC which are non-cognizable offence, when such directions can be issued only under Section 155 Cr.P.C.*

48. S.155 Cr.P.C reads as under:

> *"**Section 155 - Information as to non-cognizable cases and investigation of such cases.***
>
> *(1) When information is given to an officer in charge of a police station of the commission within the limits of such station of a non-cognizable offence, he shall enter or cause to be entered the substance of the information in a book to be kept by such officer in such form as the State Government may prescribe in this behalf, and refer the informant to the Magistrate.*
> *(2) **No police officer shall investigate a non-cognizable case without the order of a Magistrate having power to try such case or commit the case for trial.***
> *(3) Any police officer receiving such order may exercise the same powers in respect of the investigation (except the power to arrest without warrant) as an officer in charge of a police station may exercise in a cognizable case.*
> *(4) Where a case relates to two or more offences of which at least one is cognizable, the case shall be deemed to be a cognizable case, notwithstanding that the other offences are non-cognizable."*

49. According to S.155 Cr.P.C. in the cases of non-cognizable offences, the Police officer to whom the Complaint has been made shall cause the substance of information to be entered in the information book and refer the *informant* to the Magistrate. Furthermore, *no police officer shall investigate a non-cognizable case without the order of a Magistrate. However, once*

such directions are given, the Police officer shall have same powers of investigation as for cognizable offence.

50. In the present case, the Complaint had been made to the Magistrate under Section 200 Cr.P.C. along with Application under Section 156(3) Cr.P.C. In effect, it is the Informant/ Complainant, who has placed the Complaint before the Magistrate, who had directed the registration of the FIR. Therefore, even though the direction was given in an Application under S.156 (3) Cr.P.C. but in effect the directions are under S.155 Cr.P.C. and registration of FIR cannot be challenged on this ground.

51. In this regard, reference be made to **Section 460 Cr.P.C.** which deals with irregularities which do not vitiate proceedings. Clause (b) of Section 460 Cr.P.C. reads as under:

> *"**Section 460 – Irregularities which do not vitiate proceedings***
> *If any Magistrate not empowered by law to do any of the following things, namely:*
> 1. *.....*
> 2. ***to order under section 155, the police to investigate an offence;***
> 3. *....*
>
> ***erroneously in good faith** does that thing, his proceedings shall not be set aside merely on the ground of his not being so empowered."*

52. Section 460 Cr.P.C. therefore, clearly provides that where erroneously but in good faith, directions are given by the Magistrate under Section 155 Cr.P.C. to investigate into an offence, it shall not be set aside merely on the ground of being not so empowered.

53. Therefore, in the light of **Section 460 Cr.P.C.**, *whether it was Section*

155 Cr.P.C. or Section 156 Cr.P.C., the FIR was registered pursuant to directions of learned MM, which at best can be termed an irregularity, and cannot be a ground to quash the FIR.

Whether the Offences Under S.274 & S.275 are made out in the Facts of this case:

54. Having held that the FIR is not liable to be quashed on technical grounds, the question which still arises is whether there is any case made out under these two Sections.

55. *Section 275 IPC* deals with the *sale of adulterated drugs*. It reads as under:

> *"**S. 275 Sale of adulterated drugs***
> *Whoever, knowing any drug or medical preparation to have been adulterated in such a manner as to lessen its efficacy, to change its operation, or to render it noxious,* ***sells the same, or offers or exposes it for sale,*** *or* ***issues it from any*** *dispensary for medicinal purposes as unadulterated,* ***or causes it to be used for medicinal purposes*** *by any person not knowing of the adulteration, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to one thousand rupees, or with both."*

56. In the present case, the complaint was about manufacturing *of drugs and not of sale*. There is not an iota of word that these adulterated drugs were ever sold in any market.

57. *Therefore, offence under Section 275 IPC is not disclosed from the averments made in the Complaint and the same is liable to be quashed.*

58. Other offence for which the FIR has been registered is Section ***274 IPC***, which reads as under:

> *"**S.274: Adulteration of Drugs** –*
> *Whoever adulterates any drug or medical preparation in such a manner as to lessen the efficacy or change the operation of such drug or medical preparation, or to make it noxious, intending that it shall be sold or used for, or knowing it to be likely that it will be sold or used for, any medicinal purpose, as it had not undergone such adulteration, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to one thousand rupees, or with both."*

59. According to this S.274 IPC, the person who adulterates the Drug which is intended to be sold in the market is liable to be punished with imprisonment and/or fine. To appreciate whether offence under S. 274 IPC is made out, it is essential to consider the relationship between the parties herein in regard to *manufacture of the Drugs*.

60. It is not in dispute that Petitioner No.1 and Respondent No.2 entered into a ***Loan-License Agreement***. The relationship of the Parties has been explained by the Petitioner aptly as essentially in the layman's word, as a relationship of landlord and tenant, whereby the Petitioner No.1 loaned its factory to Respondent No.2 for manufacture of their drugs and medicines for which it was not responsible in any manner.

61. To appreciate this contention, the relevant Sections and Rules may be considered. ***Rule 69A*** provides for Application for the grant or renewal of loan licensees for the manufacture or sale or distribution of drugs other than those specified in Schedule C1 and 11, which has been made in Form 24A to the Licensing Authority.

62. Rule 75A Drugs & Cosmetics Rules, 1945 provide for *Loan Licenses*

as under:

> *"**75A. Loan licences.**–*
> ...
> ***Explanation** – For the purpose of this rule **a loan licence means a licence which a licensing authority may issue to an applicant who intends to avail the manufacturing facilities owned by a licensee in Form 28.***
> ....
> *(2) The licensing authority, shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture and facilities for testing to undertake the manufacture on behalf of the applicant for a loan licence.*
> ..."

63. ***Explanation 2 to Rule 75A*** lays down that the Licensing Authority shall, before the grant of a loan license, satisfy itself that the *Manufacturing Unit* has adequate equipment staff capacity for manufacture and facilities for testing to undertake the manufacture on behalf of the Applicant for loan licensee.

64. The import of Loan Licence was explained in the case of *Indica Laboratories Pvt. Ltd. vs. Union Of India*, 1991 (32) ECC 15 by the Gujarat High Court. In the said case, a question arose whether where the factory is owned by the Petitioner, the manufacture of PP Medicines by those persons who do not have their own facilities to manufacture the same, shall be termed as the manufacturer. It was observed that the term '***manufacture'*** is defined under ***Section 3(f)*** to mean in relation to any drug or cosmetic, any purpose or part of the process for making or altering, ornamenting, finishing, packing, labelling, break up or otherwise treating or adopting any drug or cosmetic with the view of a sale and distribution. Reference was made to

Loan License under Drugs and Cosmetics Act, 1940, to observe that those persons who hire such shift or shifts, are known as the ***loan licensees***, who are permitted to get their PP Medicines manufactured at the shift hired at factories owned by persons like the Petitioners who are the owner of the factory premises. Such practice is permitted and contemplated under Rule 69A and 74B of the Drugs and Cosmetics Act, 1940. The ***loan licensees were held to be Manufacturer*** who were manufacturing the proprietary medicines in the factory of the Petitioners.

65. In the case of ***Indica Laboratories Pvt. Ltd (supra),*** it was thus concluded that from the aforesaid Drugs and Cosmetics Act and the Rules, system of ***Loan Licensing is accepted by the Legislature*** in the field of manufacture of Drugs and Cosmetics and PP medicines. These manufacturers do not have their own facility to manufacture these goods but get loan licensees entitling them to utilize infrastructure belonging to somebody also where at, they can manufacture their goods. While interpreting the term '***manufacturer'*** in terms of Excise Act, as defined under Section 2(f), it was held that the loan licensees, who are manufacturing their PP medicines in the factory premises of another, would also qualify in the definition of manufacturer.

66. *Thus, it becomes clear that a* ***loan licensee being a manufacturer*** *will certainly have to be held to be in sole authority over the quality of the drugs manufactured under its supervision.*

67. Another aspect to which reference may be made is the observations of Joint Inspection carried out on 20.08.2018, by the Drugs Inspector, CDSCO Sub Zone, Indore along with Drugs Inspector of FDA, M.P. Jabalpur, in the

presence of the representatives of the Petitioner, and the sample was taken by the Drugs Inspector. In the *Joint Inspection Report* dated 20.08.2018 while the control sample taken from the Factory of the Petitioner was found to be of Standard Quality, it was noted thus:

> *"....In view of above observations, area inspected, people interviewed the joint investigation team is of opinion that* ***the firm by and large complies with the provisions of schedule M-GMP of the Drugs and Cosmetics Rules, 1945****.*
>
> *The Joint investigation team reviewed the Batch Manufacturing records of Docetaxel20 mg/1ml inj. LP. 80 mg/4ml inj. LP. and 120 mg/6 ml inj. LP., Batch No. AJ18001V-P01, AK18001V-P01, AL18001V-POI respectively along' with test and analysis report of material used to manufacture the said' products has found* **satisfactory as per the requirement of Schedule M-GMP.**
>
> *The* ***firm*** *has manufactured Docetaxel 20mg/1ml Inj. IP as per master formula record and tested as per pharmacopeial standards. The firm has performed process validation of said product and carried out stability studies of those batches. The firm does not manufacture any commercial batch of Bortezomib 2.5 mg inj. and Carboplatin inj. of any strength.*
>
> *Therefore, the joint investigation team is of the opinion that M/s Bhardwaj India Pvt. Ltd. C-145, Okhla Industrial Area, Phase- I, New delhi110020 and 92AGS Layout 4th cross, New BEL Road, Bangalore- 560054* ***is loan licensee and bearing license no. 28-A/19/2018 in Form-28A valid upto 14.02.2023*** *may also be investigated to take appropriate action as per Drugs and Cosmetics Act, 1940 and Rules 1945 in the said matter*."

68. This further confirms that Respondent No.2 being a Loan Licencee, was the manufacturer and responsible for the quality and the standard of

medicines produced in the factory premises of the Petitioner at Indore.

69. In this background, ***the facts may be considered***. The parties admittedly entered into *Loan Licence dated 15.02.2018* in terms of Explanation to Rule 75A(1), and the *undertaking* in Form 27A had been given by Respondent No.2, which reads as under:

Date: 27/12/2017 Annexure-F

FORM OF UNDERTAKING FOR A LOAN LICENCE TO ACCOMPANY APPLICATION IN FORM 27-A FOR MANUFACTURING LICENCE

I Mohan Bhardwaj, Managing Director of M/s Bhardwaj India Private Limited. Registered Office: C-849,DDA SFS Flats,Sheikh Sarai –I, New Delhi-110017. Corporate Head Office: C-145, Okhla Phase 1, New Delhi – 110020. Corporate Office – Technical: 92,AGS Layout, 4th Cross, New BEL Road, Bengaluru- 560054. , will be entirely responsible for the quality, purity and strength of the products which are manufactured on our behalf at **M/s REVACURE LIFESCIENCES LLP, Plot No.58 to 67,Sector B-1, Umariya-Dungaria, Tehsil-Shahpura, District-Jabalpur (M.P.) India – 482003** and I/we also undertake to depute our representative to the manufacturing premises at the time, our products are manufactured and whenever required by the licencing Authority.

I/we further undertake to deposit or surrender the manufacturing licence in case the licence of **M/s REVACURE LIFESCIENCES LLP, Plot No.58 to 67,Sector B-1, Umariya-Dungaria, Tehsil-Shahpura, District-Jabalpur (M.P.) India – 482003.** whose premises, Staff, equipments and testing facilities will taken on loan by me/us is ever suspended or cancelled as the case may be.

For **Bhardwaj India Private Limited**

Bhardwaj India Pvt. L
Regd.Off:C-849,Sheikh Sarai Ph
New Delhi-110017
Corp Off Technical:92,AGS
4th Cross,New BEL
Bangalore

Mohan Bhardwaj
Managing Director

70. It is evident from the aforesaid Undertaking that it is the Respondent No. 2 and not the Petitioners, who *were in no way responsible for the quality, purity and strength of the products* which were manufactured on behalf of Complainant in the manufacturing unit of the petitioners.

71. Further, in terms of the Loan Licence Agreement, after the drugs were manufactured at the factory of Petitioner No.1, the dispatch of consignment

was to be made only after the payment of balance 50% was made. Petitioners demanded money before dispatching the final Lot. As per the Complaint itself, after some negotiations, it was agreed that two employees of Respondent No.2 shall visit the premises of Petitioner No.1 for ensuring the quality of the product before dispatch. In this regard, reference be made to *the Visiting Passes* dated 17.07.2018, 18.07.2018 and 19.07.2018, issued to the employees of the Respondent No. 2, to confirm that the employees of the Respondent No. 2, had visited the factory.

72. Thereafter, Respondent No.2 itself got the Product tested from a Laboratory of his own choice, before the product was dispatched. The Final Dispatch Report dated 19.07.2018 has also been annexed to confirm that the various medicines as stated therein, were duly dispatched.

73. Pertinently, no such adulteration was noted till the products got dispatched from factory of Petitioner No.1 at Jabalpur, M.P. and were noticed only after the same were delivered at premises of Respondent No.2.

74. Thereafter, it was only on 06.08.2018, a Complaint was forwarded by the Respondent No. 2 about the presence of particles in the Products, to the Petitioners, who responded *vide* e-mail dated 10.08.2018 and stated that Mr. Manoj Dutta, its representative had been immediately sent to visit the Okhla Office, on receipt of the Complaint dated 06.08.2018, to take necessary steps to address the Complaint with regard to Schedule M. It was further stated that the Complaint made by the Respondent No. 2 had been taken seriously and a Complaint has already been lodged with the QA Department as per the SOP and Schedule M.

75. Mr. Manoj Dutta visited the premises of the Respondent No. 2 and checked the Products and noted *that there were glass particles in many of the vials as delivered to the Respondent No. 2*, as is established from his Letter dated 07.08.2018.

76. A request was sent for investigations of the defective samples found at the factory of Respondent No. 2. It was also indicated that the Respondent No. 2 was a ***loan licensee*** under the Drugs and Cosmetic Act, 1940 and it was his responsibility to maintain the quality and safety of the pharmaceutical products.

77. On receiving the Complaint from Respondent No. 2, Joint Inspection was conducted on 20.08.2018, by the Drugs Inspector, CDSCO Sub Zone, Indore along with Drugs Inspector of FDA, M.P. Jabalpur, *in the presence of the representatives of the Petitioner*. The entire factory premises were inspected and records/Registers were checked the sample was taken by the Drugs Inspector. The *Joint Inspection Report* dated 20.08.2018 has arrived at the following finding in regards to the quality of the control sample taken from the facility of the Petitioner, and the final Opinion was as under:

> "*....The joint investigation team visually inspected and verified the control samples of Docetaxel 20 mg/1 ml inj. IP, 80mg/4 ml inj. I.P. and 120 mg/6 ml inj. I.P. batch No. AJ18001V-P01, AK18001V-P01, AL18001V-P01 respectively* ***and not found any black particles, white particles, glass pieces and fibres in said product****".*

78. From this Report, it is evident that the drug was found to be in conformity with the prescribed standards and there were no suspended particles/adulteration noticed in the control samples taken from the premises of the Petitioner.

79. In these circumstances, whatever the particles that may have been found in the Product, they were definitely not present till the Product got dispatched from the factory of Petitioners.

80. The subsequent Inspection was done in Karnataka, and the sample was lifted from the premises of the Respondent No. 2 on 27.10.2018 by the Drugs Inspector, who had inspected the product. After analysis, he had given a Report dated 06.12.2018 wherein also it was stated that the Test was ok in respect of *extractable volume* and *sterility* showing that the drug manufacturing was according to the given standards. However, this Report also found the presence of particles and thus reported that the sample did not pass the test for particulate matter. The sample was consequently declared as ***not of standard quality***, as it did not confirm to the test for *particulate matter*.

81. This again reflects that the Product was of Standard quality till it got dispatched from the Factory of the Petitioner, but the Particulates came in during the transit or thereafter, for which the Petitioner cannot be held responsible.

82. In this context, it is also significant to mention that parties had taken their dispute to the arbitration where a *nil* Arbitration Award dated 11.09.2023 has been given. In the Award it has been specifically concluded as under:

> *"...Thus, in light of the aforesaid provisions we can safely reach a conclusion that* ***once the possession of the product has been transferred, the Respondent was no longer in control of the drugs. Once the Respondent is no longer in possession of the product, there is a likelihood and substance in the submission of the Respondent that the***

Claimant itself has tampered the product.... *"*

83. To put it concisely, adulteration has *prima facie* been noticed only at the premises of Respondent No.2 and not at the time of dispatch from the Manufacturing Unit of the Petitioner No.1. Also, the Product never got sold in the market. Further, the proceeding for prosecution under D&S Act has already been initiated by the Drugs Inspector, Karnataka, as per the Status Report.

84. Even from the averments made in the Compliant, there is nothing to suggest that petitioners can be attributed responsibility for the presence of suspended particles as noticed in the products at the premises of Respondent No.2, which were not present at the time of dispatch from factory of Petitioner No.1.

85. ***There is prima facie no offence under Section 274 IPC made out against the Petitioners even if all the averments made in the Complaint are admitted.***

Whether Quashing Of FIR is Merited under S.482 Cr.P.C.:

86. ***The next aspect*** which arises is whether quashing of FIR is merited in the given circumstances, in exercise of powers under S.482 Cr.P.C. It may be noted is that the FIR was registered on 14.02.2019 under Sections 274/275 IPC which are punishable for **maximum sentence of six months and/or fine**. As per Section 468 Cr.P.C, limitation for taking cognizance on the Chargesheet for the said offences is one year.

87. Even though Section 473 Cr.P.C. enables the Court to take cognizance of the offence even after expiry of the period of limitation, but in the present case, investigations have not been concluded despite registration

of FIR in the year 2019 for no explicable reason. Further, it emerges that there is not even a prima facie case to justify registration of FIR under the IPC offences. In such circumstances, continuation of investigations in this FIR is not ***expedient or in the interest of justice to continue with such proceedings after lapse of about six years of the alleged commission of offence.*** *The FIR is liable to be quashed under S.482 Cr.P.C.*

Conclusion:

88. From the aforesaid discussion, it is concluded that the Police does not have any jurisdiction to register an FIR in respect of the offences under D & C Act which can be undertaken only by the competent officer under S.32 D & C Act. Therefore, the registration of FIR under the provisions of D & C Act is without jurisdiction and FIR in respect of offences under D & C Act is quashed.

89. *Secondly,* the FIR under Section 274 and 275 IPC IPC though maintainable, but in the present case the offences under have not been prima facie made out, as discussed above. Also, the FIR was registered in the year 2019, but till date even the investigations have not been completed. The limitation as per Section 468 IPC for concluding the investigations and the Chargesheet to be filed in the Court for the purpose of taking cognizance is one year. *It is not expedient or in the interest of justice* to let the investigations be continued in such a case which is hopelessly barred by limitation. It is in fact, *an abuse of the process of law* which merits a quashing.

Relief:

90. *The Petition is allowed and the FIR No.053/2019 under Sections*

274/275 IPC and Section 13 of the D & C Act registered at PS Okhla Industrial Area is hereby, quashed.

91. It is clarified that observations made herein are only for the purpose of aforesaid FIR and are not an expression on the merits for any other proceedings under the D & C Act or any other enactment that may have been initiated or undertaken.

92. Petition along with pending Application(s), if any, is disposed of.

(NEENA BANSAL KRISHNA)
JUDGE

SEPTEMBER 23, 2025
N/R