

# HIGH COURT OF JUDICATURE FOR RAJASTHAN AT JODHPUR

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S.B. Criminal Misc(Pet.) No. 6621/2023

1. Ganesh Narayan Nayak S/o Narayan Vaikunth Nayak, Aged About 68 Years, R/o- 3 Ashwamegh Part V, Satellite, Ahmedabad, Gujarat

Nitin Kumar Dalsukhray Parekh S/o Dalsukhray Dharshibhai Parekh, Aged About 62 Years, R/o- 73, Asopalav Bunglow, Thaltej, Ahmedabad, Gujarat

----Petitioners

#### Versus

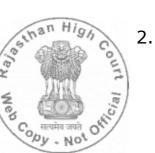
- 1. State Of Rajasthan, Through Pp
- 2. Drugs Control Officer, Rajasamand, Office Of Civil Surgeon Rajasamand, Rajasthan.

----Respondents

### Connected With

S.B. Criminal Misc(Pet.) No. 6626/2023

- M/s Biochem Pharmaceuticals Industries Ltd., (Now Amalgamated With M/s Zydus Healthcare Limited), 301, P.n. Kothari Industrial Estate, L.b.s. Marg, Bhandup (West), Mumbai Through Authorised Signatory Mr. Sachin Sangare, Aged 47 Years, E-10, Rishikesh Chsl, Evershine Nagar, Malad West, Mumbai
- Mayank Jaswantlal Shah S/o Jaswantlal Shah, Aged About 58 Years, R/o- Sudharma 801, Plot-1, Cts 310A, The Hotkesh Chsl, J.v.p.d. Scheme, Juhu Corner, 5Th Road, Ville Parle North, Mumbai-400056, Director Of M/s Biochem Pharmaceuticals Industries Limited (Now Amalgamated With M/s Zydus Healthcare Limited), 301, P.n. Kothari Industrial Estate, L.b.s. Marg Bhandup (West), Mumbai.
- 3. Shreyansh Jaswantlal Shah S/o Jaswantlal Shah, Aged About 57 Years, R/o- 318, Avanti Apartment, Flank Road, Soin, Mumbai-400022, Director Of M/s Biochem Pharmaceuticals Industries Limited (Noqw Amalgamated With M/s Zydus Healthcare Limited), 301, P.n. Kothari Industrial Estate, L.b.s. Marg, Bhandup (West), Mumbai.
- 4. Shruti Mayank Shah W/o Mayank Shah, Aged About 57





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Years, R/o- Sudharma 801, Plot-1, Cts 310A, The Hotkesh Chsl, J.v.p.d. Scheme, Juhu Corner, 5Th Road, Ville Parle North, Mumbai-400056, Director Of M/s Biochem Pharmaceuticals Industries Limited (Now Amalgamated With M/s Zydus Healthcare Limited), 301, P.n. Kothari Industrial Estate, L.b.s. Marg Bhandup (West), Mumbai.

- Rajinder Kanhiyalal Singhvi S/o Kanhiyalal Singhvi, Aged
  About 57 Years, R/o- Sunita Niwas, 78, Swami
  Vivekanand Road, Santa Cruz (West) Mumbai-400054,
  Director Of M/s Biochem Pharmaceuticals Industries
  Limited (Now Amalgamated With M/s Zyduis Healthcare
  Limited), 301, P.n. Kothari Industrial Estate, L.b.s. Marg,
  Bhandup (West), Mumbai.
- 6. Suresh Gautamchand Kothari S/o Gautamchand Kothari, Aged About 54 Years, R/o- 301, Shri Mukti Dham Chs Limited, Station Road, Opposite Saraswat Bank, Kalwa (North), Thane, Mumbai-400605 Director Of M/s Biochem Pharmaceuticals Industries Limited (Now Amalgamated With M/s Zyduis Healthcare Limited), 301, P.n. Kothari Industrial Estate, L.b.s. Marg, Bhandup (West), Mumbai.
- 7. Umesh Lad Competent Person Of M/s Biochem Pharmaceuticals Industries Limited, (Now Amalgamated With M/s Zyduis Healthcare Limited), 301, P.n. Kothari Industrial Estate, L.b.s. Marg, Bhandup (West), Mumbai.
- 8. Raj Kumar Devram Patil S/o Devram Patil, Aged About 52 Years, Competent Person Of M/s Biochem Pharmaceuticals Industries Limited (Now Amalgamated With M/s Zyduis Healthcare Limited), 301, P.n. Kothari Industrial Estate, L.b.s. Marg, Bhandup (West), Mumbai.
- M/s Mks Pharma Ltd, Plot No. 114, Huda Industrila Estate, Sector 59, Faridabad, Haryana Now At 1135 Basement And Ground Floor, Opposite Transport Nagar, Sector 58, Ballabhgarg, District Faridabad Thorugh Its Authorized Signatory Mr. Sanjay Gupta, Director.
- Sanjay Gupta S/o Shri K.I. Gupta, Aged About 61 Years, R/o- D-947, Chawla Colony, Ballabhgarh, District Faridabad, Haryana, Director Of M/s Mks Pharma Ltd 1135 Basement And Ground Floor, Opposite Transport Nagar, Sector 58, Ballabhgarh, District Faridabad.

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- Manish Gupta S/o Shri K.L. Gupta, Aged About 58 Years, R/o- D-947, Chawla Colony, Ballabhgarh, District Faridabad, Haryana, Director Of M/s Mks Pharma Ltd 1135 Basement And Ground Floor, Opposite Transport Nagar, Sector 58, Ballabhgarh, District Faridabad.
- 12. Kishori Lal Gupta S/o Late Shri Gulab Chand Gupta, Aged About 57 Years, R/o- D-947, Chawla Colony, Ballabhgarh, District Faridabad, Haryana, Director Of M/s Mks Pharma Ltd 1135 Basement And Ground Floor, Opposite Transport Nagar, Sector 58, Ballabhgarh, District Faridabad.
- 13. Aridaman Kumar Jain S/o Shri Shikhar, Aged About 56 Years, R/o- Railway Road, Barot, Baghpat, Up, Director Of M/s Mks Pharma Ltd 1135 Basement And Ground Floor, Opposite Transport Nagar, Sector 58, Ballabhgarh, District Faridabad.
- 14. Sapna Gupta W/o Shri Manish Gupta, Aged About 58 Years, R/o- D-947, Chawla Colony, Ballabhgarh, District Faridabad, Haryana, Competent Person Of M/s Mks Pharma Ltd 1135 Basement And Ground Floor, Opposite Transport Nagar, Sector 58, Ballabhgarh, District Faridabad.

----Petitioners

### Versus

- 1. State Of Rajasthan, Through Pp
- 2. Drugs Control Officer, Rajasamand, Office Of Civil Surgeon Rajasamand, Rajasthan.

----Respondents

### S.B. Criminal Misc(Pet.) No. 108/2024

- M/s Skymap Pharmaceuticals, B-3, Dev Bhoomi Industrial Estate, Pohana, Iqbalpur Road, Roorkee District Haridwar 247667 (Uttarakhand) Through Its Authorised Represetative Arbind Kumar Sharma , Aged 43 Yeaes, House No. 573, West Amber Talab, Roorkee, Haridwar
- Sanjay Gupta S/o Shri K.I Gupta, Aged About 49 Years, D-987 Chawla Colony Ballabhgarh District Faridabad Haryana Director Of M/s Skymap Pharmaceuticals, B-3, Dev Bhoomi Industrial Estate, Pohana, Iqbalpur Road,





Roorkee District Haridwar 247667 (Uttarakhand)

- 3. Kishori Lal Gupta S/o Late Shri Gulab Chand Gupta, Aged About 71 Years, D-987 Chawla Colony Ballabhgarh District Faridabad Haryana Director Of M/s Skymap Pharmaceuticals, B-3, Dev Bhoomi Industrial Estate, Pohana, Iqbalpur Road, Roorkee District Haridwar 247667 (Uttarakhand)
  - Arbind Kumar Sharma S/o Harinath Sharma, Aged About
    43 Years, Son Of Shri Harihar Nath Sharma House No 573
    West Amber Talab, Roorkee Haridwar, Manufacuring
    Chemist Of M/s Skymap Pharmaceuticals, B-3, Dev
    Bhoomi Industrial Estate, Pohana, Iqbalpur Road, Roorkee
    District Haridwar 247667 (Uttarakhand)
- 5. Naresh Kumar Bahaduriya S/o Shri Chander Mohan Singh, Aged About 43 Years, R/o House No. 19 Chao Mandi, Roorkee Haridwar, Manufacuring Chemist Of M/s Skymap Pharmaceuticals, B-3, Dev Bhoomi Industrial Estate, Pohana, Iqbalpur Road, Roorkee District Haridwar 247667 (Uttarakhand)
- 6. Shri Sanjiv Kuamr Saini S/o Surinder Kumar Saini, Aged About 46 Years, R/o House No. 476/3, Nishant Chao Mandi Roorkee Haridwar, Analytical Chemist Of M/s Skymap Pharmaceuticals, B-3, Dev Bhoomi Industrial Estate, Pohana, Iqbalpur Road, Roorkee District Haridwar 247667 (Uttarakhand)
- Rahul S/o Shri Chitranjan Singh, Aged About 46 Years, House No. 767, Chao Mandi Roorkee Haridwar, Analytical Chemist Of M/s Skymap Pharmaceuticals, B-3, Dev Bhoomi Industrial Estate, Pohana, Iqbalpur Road, Roorkee District Haridwar 247667 (Uttarakhand)

----Petitioners

#### Versus

- 1. State Of Rajasthan, Through Pp
- 2. Drugs Control Officer, Rajsamand , Office Of Civil Surgeon Rajasamand, Rajasthan

----Respondents

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For Petitioner(s) : Mr. Akshay Jain Mr. Vineet Jain, Sr.Adv. With Mr. Pankaj Kumar Gupta Mr. Sanjay Kumar Jain For Respondent(s) : Mr. N.S. Chandawat, Dy.G.A.

## HON'BLE MR. JUSTICE FARJAND ALI

### <u>Order</u>

### <u>Reportable</u> 21/03/2025

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- 1. These criminal miscellaneous petitions under Section 482 read with Section 483 of the Code of Criminal Procedure, 1973 (Cr.P.C.), have been filed by the respective petitioners seeking quashing of Complaint No. 158/2017 dated 06.02.2017, titled State of Rajasthan through Drug Control Officer vs. M/s Life Line Fluid and Drug Store, Rajsamand and Others, along with all subsequent proceedings arising therefrom, pending before the learned Chief Judicial Magistrate, Rajsamand, Rajasthan, on the ground that the same is illegal and amounts to an abuse of the process of law.
- Given the similar nature of allegations, legal issues, and prayers involved in all the petitions, they are being decided together through this consolidated order.
- 3. The origin of the dispute dates back to an inspection conducted on 30.11.2012 by the Drugs Control Officer (respondent No. 2) at the premises of M/s Life Line Fluid and Drug Store, Rajsamand. During the said inspection, a sample



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of the drug "Tab. Glimp-2" (Batch No. BD-11374), manufactured by M/s Skymap Pharmaceuticals, was collected for analysis. The Government Analyst, Jaipur, vide report dated 15.01.2013, declared the sample as not of standard quality due to non-conformity with the dissolution test.

- 4. The distribution chain of the subject drug was traced back through intermediary distributors, eventually leading to M/s Biochem Pharmaceuticals Industries Limited (now amalgamated with M/s Zydus Healthcare Limited), which marketed the product, and M/s MKS Pharma Limited, a wholesale license holder. Despite this tracing, the Drugs Control Officer did not follow the statutory requirement of sending the sample to the manufacturer for reanalysis under Section 25(3) of the Drugs and Cosmetics Act, 1940 (hereinafter "the 1940 Act").
- 5. The prosecution proceeded to file Complaint No. 158/2017 on 09.01.2017 before the learned Chief Judicial Magistrate, Rajsamand, under Sections 18(a)(i), 18(a)(vi) read with Sections 16(i)(a) and 17A, punishable under Section 27(b)(i) of the 1940 Act. Cognizance was taken vide order dated 06.02.2017.
- 6. The petitioners before this Court include the following: CRLMP No. 6621/2023: M/s Biochem Pharmaceuticals





Industries Limited - Additional Directors (Non-Executive), and others.

CRLMP No. 6626/2023: M/s Biochem Pharmaceuticals Industries Limited, its Directors, competent persons, M/s MKS Pharma Limited, and its Directors. CRLMP No. 108/2024: M/s Skymap Pharmaceuticals, its partners, manufacturing chemists, and analytical chemists.

- 7. This Court has heard the learned counsels present for the parties, meticulously perused the records and given its thoughtful consideration to the facts of the case, the legal provisions involved, and the judgments cited. The fundamental issue at hand pertains to the legality of the complaint and the subsequent proceedings, keeping in view the statutory provisions under the Drugs and Cosmetics Act, 1940, and the Code of Criminal Procedure, 1973.
- 8. A comprehensive review of the complaint and the attendant circumstances reveals a glaring procedural lapse, which vitiates the very foundation of the prosecution. The principle of vicarious liability, as embodied under Section 34 of the Drugs and Cosmetics Act, 1940, fastens liability only upon those individuals who were in charge of and responsible for the conduct of the business at the time of the alleged offence. In the present case, the petitioners, who were appointed as Additional Directors (Non-Executive) much after the relevant period, cannot be saddled with criminal liability





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merely by virtue of their designation. The Hon'ble Supreme Court, in *Gunmala Sales (P) Ltd. v. Anu Mehta, (2015) 1 SCC 103,* has enunciated the principle that unimpeachable documents, such as Form-32 and board resolutions, can be relied upon for quashing criminal proceedings under Section 482 Cr.P.C. The present case falls squarely within the ambit of this settled legal proposition, as the documents on record unequivocally establish that the petitioners had no nexus with the affairs of the company at the time of the alleged offence.

- 9. Further, the Hon'ble Supreme Court in Sunil Bharti Mittal v. CBI, (2015) 4 SCC 609, held that non-executive directors cannot be held vicariously liable in the absence of specific allegations regarding their role in the offence. The same principle was reiterated in Sunita Palita v. Panchami Stone Quarry, (2022) 10 SCC 152. In the instant matter, the complaint merely mentions the petitioners as directors of the company but does not establish their involvement in the alleged offence. The absence of any substantive allegation or material indicating their active participation renders the prosecution unsustainable in law.
- Additionally, the limitation aspect cannot be ignored. The alleged offence was detected on 15.01.2013, yet the complaint was filed only on 09.01.2017, beyond the threeyear statutory limitation prescribed under Section 468 Cr.P.C.





for offences punishable under Section 27(d) of the 1940 Act. The Hon'ble Supreme Court, in *Cheminova (India) Ltd. v. State of Punjab, (2021) 8 SCC 818*, while dealing with the Insecticides Act (a statute pari materia to the Drugs and Cosmetics Act, 1940), held that prosecution beyond the limitation period is barred. The present case falls squarely within this legal framework, rendering the continuation of the proceedings against the petitioners legally untenable.

- 11. Another critical aspect pertains to the failure of the Drugs Control Officer to comply with the statutory requirement under Section 25(3) of the 1940 Act, which mandates sending a portion of the sample to the manufacturer for reanalysis in case of a disputed report. The Hon'ble Supreme Court in *Medicamen Biotech Ltd. v. Rubina Bose, (2008) 7 SCC 196,* categorically held that non-compliance with this statutory mandate vitiates the entire prosecution. In the present case, despite procedural irregularities and non-adherence to mandatory requirements, the complaint was filed and cognizance was taken, which is a serious lapse on the part of the prosecution.
- 12. Moreover, the statutory protection under Section 19(3) of the 1940 Act, which absolves persons other than the manufacturer from liability if the drug was purchased from a duly licensed entity and stored in the same condition, has been disregarded. The Hon'ble Supreme Court in *Kisan Beej*





**Bhandar v. Chief Agricultural Officer, 1990 Supp SCC 111,** while interpreting a pari materia provision under the Insecticides Act, reiterated this protection for wholesalers and retailers. The petitioners, being mere marketers and distributors, fall within the purview of this statutory safeguard. Thus, their prosecution is not only unwarranted but also a clear abuse of the process of law.

- 13. Furthermore, it is evident from the record that the learned Magistrate failed to conduct a mandatory inquiry under Section 202 Cr.P.C. before issuing process, despite the petitioners residing outside the court's jurisdiction. The Hon'ble Supreme Court in *National Bank of Oman v. Barakara Abdul Aziz, (2013) 2 SCC 488, and Abhijit Pawar v. Hemant Madhukar Nimbalkar, (2017) 3 SCC 528,* has emphasized that an inquiry under Section 202 Cr.P.C. is imperative in such cases. The failure of the learned Magistrate to adhere to this mandatory requirement renders the summoning order legally unsustainable.
- 14. Additionally, the Government Analyst's report itself indicates that the drug in question failed the dissolution test but had an active ingredient within the standard limits. The Guidelines issued by the Central Government under Section 33-P of the 1940 Act classify such defects as minor, which do not warrant prosecution under Section 27(b)(i). The Hon'ble Supreme Court in *Laborate Pharmaceuticals India Ltd.*





**v. State of Tamil Nadu, (2018) 15 SCC 93,** has held that where minor defects are noted, initiation of prosecution is impermissible.

- 15. In the present case, the drug's active pharmaceutical ingredient (API) was found to be within the prescribed standards, and the only deviation was in the dissolution rate. A delayed dissolution does not render the drug spurious or useless; it merely implies a slower release of the active content, which still remains effective. The therapeutic efficacy of the drug is not entirely negated by such a delay. Dissolution rates can be influenced by several factors, including the quality of excipients, manufacturing processes, temperature control, and climatic conditions during production and storage. The presence of the correct active ingredient in the specified quantity is the primary factor in determining a drug's standard quality. If the core content of the drug remains intact and effective, classifying it as substandard, spurious, or useless would be legally and scientifically untenable.
  - 16. The mechanical approach of the prosecution in filing the complaint, without considering the nature of the defect and its actual impact on drug efficacy, further substantiates the contention that the proceedings are an abuse of the process of law.





- 17. The complaint was filed much after the expiry of the shelf life of the drug, thereby frustrating the valuable right of the petitioners under Sections 25(3) and 25(4) of the 1940 Act to seek retesting. The Hon'ble Supreme Court in *State of Haryana v. Brij Lal Mittal, (1998) 5 SCC 343,* and *State of Haryana v. Unique Farmaid (P) Ltd., (1999) 8 SCC 190*, has consistently held that when the right to retesting is denied due to the expiry of the drug, the prosecution is rendered null and void. The present case is no exception, as the petitioners have been deprived of their statutory right due to an unjustifiable delay in filing the complaint.
- 18. In light of the aforesaid discussion, this Court finds that the entire prosecution is vitiated by multiple legal infirmities, including non-compliance with mandatory procedural safeguards, lack of vicarious liability, expiry of limitation, and statutory protection available to distributors and marketers. The continuation of the proceedings would, therefore, amount to a gross abuse of the process of law.

19. Accordingly, the present petitions are allowed.

20. Furthermore, it is imperative to clarify that the quashing of proceedings is not limited to the petitioners before this Court but shall also extend to all those who are similarly placed but have not approached this Court. It would be an exercise in futility to require such individuals to



separately seek the same relief when the legal infirmities affecting the complaint are identical in their case as well. Judicial propriety demands that similarly situated persons should not be subjected to unnecessary litigation and procedural rigmarole when the very foundation of the prosecution is untenable.

- 21. The prosecution cannot be permitted to proceed selectively against some individuals while awaiting others to approach the Court for relief. Such an approach would lead to unnecessary harassment and prolonged legal proceedings, compelling individuals to endure procedural hardships despite the evident illegality in the complaint. The Court cannot allow a scenario where individuals, facing the same legal infirmity, are left with no choice but to initiate fresh litigation, engage legal counsel, and await case listings merely to obtain an order identical to the present one. Justice must be dispensed in a manner that prevents such avoidable hardship and ensures uniform application of legal principles.
- 22. The essence of justice lies in ensuring that individuals are not subjected to unwarranted litigation, compelling them to engage in avoidable legal battles. The legal system exists to dispense justice, not to create a situation where litigants are burdened with repeated procedural hurdles. Accordingly, all proceedings arising from Complaint No. 158/2017,





pending before the learned Chief Judicial Magistrate, Rajsamand, stand quashed in their entirety, leaving no scope for further continuation against any individual.



- 23. In view of the above, the learned Trial Court shall treat the proceedings as quashed and formally close the case. No further steps shall be taken in pursuance of the quashed complaint. The file shall be consigned to the record.
- 24. The stay petitions and all pending applications, if any, stand disposed of accordingly.

### (FARJAND ALI),J

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