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

% ***Pronounced on: 07th May, 2025***

\+ **W.P.(CRL.)2605/2021**

1. SANOFI INDIA LIMITED
Registered office at:
Sanofi House, CTS No.117-B
L&T Business Park,
Saki Vihar Road,
Powai, Mumbai,
Maharashtra-400072.

2. SHAILESH KRIPALU AYYANGAR
S/o Sh. Kripallu Garudachar Ayyangar
R/o Villa 9, Adarsh Palm Retreat,
Ballandur
Balgalore-560103.

....Petitioners

Through: Mr. Tanveer Ahmed, Senior Advocate with Ms. Ariona Ahluwalia, Advocate.

versus

UNION OF INDIA
Through Drugs Inspector
Smt. Suniti Choudhary
Central Drugs Standard Control Organization
(C.D.S.C.O) North Zone,
Kamla Nehru Nagar,
Ghziabad.

..... Respondent

Through:

CORAM:
HON'BLE MS. JUSTICE NEENA BANSAL KRISHNA

J U D G M E N T

NEENA BANSAL KRISHNA, J.

1. Petition under Articles 226 and 227 Constitution of India has been filed for quashing of the Summoning Orders dated 22.07.2019, 10.02.2021 and 05.10.2021 and Criminal Complaint No.9215/2019 filed under S. Section 18(a)(i) read with Section 16 punishable under Section 27(d) *Drugs and Cosmetics Act, 1940* ('the Act' *hereinafter*).

2. ***Briefly stated***, Petitioner No.1-Sanofi India Limited is the manufacturer of Drugs duly licensed by State Drugs Controller, Licensing Authority cum Controlling Authority, Gujarat. In June, 2015 Petitioner No.1 manufactured the Drug '*Combiflam'* (Ibuprofen and Paracetamol Tablets) *vide* Batch No.A150683. It was supplied to Vedant Medicare Agencies on 20.07.2015, who in turn supplied it to Government Medical Stores Depot, New Delhi on 27.07.2015.

3. On 04.05.2016, a sample of the Drug from the aforesaid Batch Number was taken by Smt. Shraddha Srivastava, the then Drugs Inspector, Central Drug Standards Control Organization (CDSCO), North Zone, Ghaziabad from CGHS Wellness Centre, Laxmi Nagar, Delhi ('***Drug Inspector***' hereinafter), in the presence of Chief Medical Officer for *Test and analysis*.

4. The sample of the Drug was sent on 05.05.2016 to Government Analyst, Regional Drugs Testing Lab, Chandigarh ('***Government Analyst***' hereinafter) for testing. The Report dated 09.06.2016 of the Government Analyst was received with the statement that the Drug was "*Not of Standard Quality*". Pertinently, the Government Analyst had tested the

pharmaceutical Drug sample as per the old method analysis, prevalent at that time in the Indian Pharmacopeia i.e. IP-2014, which got subsequently changed in the year 2018, on the representation of the Petitioner No.1.

5. Pursuant to the Test Report dated 09.06.2016, Show Cause Notice dated 17.06.2016 under Sections 18A and 18B of the Drugs and Cosmetics Act, 1940 (hereinafter "***the Act***") was sent to Chief Medical Officer, CGHS, New Delhi directing him to stop usage/distribution and to disclose the name and address of the Firm from whom the Drug was obtained. The Notices were thereafter issued to Vedant Medicare Agencies, New Delhi and thereafter, Show Cause Notice dated 06.08.2016 was sent to the Petitioner No.1 by Food and Drugs Control Administration, Gujarat ('**FDCA**' *hereinafter*), being the manufacturer of the Drug, to which response was given on 24.08.2016.

6. In the Reply to the Show Cause Notice dated 06.08.2016, Petitioner No.1 also asserted that the old Manufacturing and Packaging processes were executed as per the instructions. There was no deviation observed in the Manufacturing and Packaging. The Analytical Test Report for the Batch found it to be of standard quality with respect to all the test parameters including Disintegration Test at the time of release.

7. Another Show Cause Notice dated 27.09.2016 was again issued by Drug Inspector, CDSCO under Section 18A and 18B of the Act to Petitioner No.1 directing him to stop usage/distribution of the subject Drug. A similar Reply as given to FDCA, was given to the Show Cause Notice by Petitioner No.1 on 05.10.2016 informing the Drug Inspector that the sale has been stopped and the entire Batch has been recalled. It also specifically

mentioned that there was no deviation observed during manufacturing and packaging of the Batch. The probable root cause of failure is *the Disintegration test result from improper storage conditions at market and formulation aspects.* Petitioner No.1 assured that it would implement corrective and preventive measures to avoid such issues in the future.

8. Thereafter, again a Show Cause Notice dated 13.10.2016 was issued by the Drug Inspector to Petitioner No.1 vide which the Drugs Inspector sent the Test Report along with a sample portion to Petitioner No. 1 and directed him to submit certified copies of certain documents required under Section 18A, 18B and 22(1)(cca) of the Act. The relevant documents and certified copies were duly submitted on 28.10.2016 with its Reply wherein the earlier stand was reiterated by Petitioner No.1.

9. On 12.12.2016 Deputy Drugs Controller, CDSCO, Ghaziabad requested Deputy Drugs Controller (1), CDSCO, Ahmedabad to carry out joint investigation at the manufacturing premises of Petitioner No.1. On 22.03.2017 FDCA, Gujarat issued a License Suspension Order against Petitioner No.1 suspending its License for 3 days from 24.04.2017 to 26.04.2017 under Rule 85(2) *Drugs and Cosmetics Rules, 1945*. On 25.02.2019, Drugs Controller General (I) granted permission for initiating further legal action which was received by Deputy Drugs Controller, CDSCO, North Zone on 12.03.2019.

10. The present *Complaint No.9215/2019 under Section 18(a)(i) read with Section 16 punishable under Section 27(d) of the Act was accordingly filed on 20.05.2019 before the Trial Court.*

11. The ld. Counsel for Petitioners has submitted that the Summoning Order dated 22.07.2019, 10.02.2021 and 05.10.2021 have been passed mechanically and does not disclose any application of mind. Therefore, the cognizance taken against the Petitioner is bad in law. Reliance has been placed on *Pepsi Foods Ltd. and Another vs. Special Judicial Magistrate and Others* AIR 1998 SC 128.

12. The Petitioners have sought the quashing of Complaint and the summoning Order on the ground that the Batch of the Drug expired in May, 2018, thereby defeating the *valuable right of second test* which allows and provides an opportunity to an accused to get the seized sample tested again under the supervision of the Higher Authority, to avoid continuation of any criminal proceedings.

13. The Supreme Court in *Municipal Corporation of Delhi vs. Ghisa Ram* (1967) 2 SCR 116 while dealing with Section 13 of the *Prevention of Food Adulteration Act, 1954* had observed that the right of getting the second test done, is a valuable right as the Certificate of the Director supersedes the Report of the Public Analyst and is treated as conclusive evidence of its contents. Once the right has been given, he should be able to have the sample kept in his charge, analyzed by a greater expert whose certificate is to be accepted by the Court as conclusive evidence. In a case where there is denial of this right on account of the deliberate conduct of the prosecution, it seriously prejudices the right of the accused and it would not be proper to uphold his conviction on the basis of the Report of the Public Analyst.

14. Similar observations have been made by the Apex Court in *State of Haryana vs. Unique Farmaid (P) Ltd*. (1999) 8 SCC 190.

15. It is contended that the Petitioners had a valuable right of retesting under Section 24 and 25 of the Drugs and Cosmetics Act. However, because the sample got expired before the filing of the Complaint, the Petitioners were deprived of their valuable right. In *Laborate Pharmaceuticals India Limited & Others vs. State of Tamil Nadu*, (2018) 15 SCC 9 the Apex Court categorically held that if the Complaint is filed after the expiry of the Drug in question, then it would vitiate the entire criminal proceedings.

16. The quashing of the Complaint and the Summoning Order is also sought on the ground that *no specific role has been attributed to Petitioner No.2 except that he was the Managing Director of the Company.* Reliance has been placed on *Maksud Saiyed vs. State of Gujarat and Others* (2008) 5 SCC 668, wherein it was observed that while deciding the vicarious liability of the Directors for the charges leveled against the Company, it is obligatory on the part of the Complainant to make requisite allegations which would attract the provisions constituting vicarious liability. Merely a repetition without specific allegations, would not lead to any inference that they had anything to do with the alleged offence.

17. Similar observations have been made in the case of *Shiv Kumar Jatia vs. State of NCT of Delhi*, (2019) 17 SCC 193, wherein the Appellant claimed himself to be a Managing Director and the only non-independent and Executive Director of the Company. The Supreme Court relied upon *Sunil Bharti Mittal vs. CBI*, wherein it was observed that when an individual who is claimed to have perpetrated the offence on behalf of a Company and has been made an accused along with the Company, there should be

sufficient evidence of his active role coupled with criminal intent. Merely being the Managing Director is not sufficient to impose vicarious liability in the absence of specific allegations involved. Similarly, reliance has been placed on *Rajesh Kumar & Ors. vs. State* 2017 SCC OnLine J&K 381.

18. It is further submitted that IP (2014) recommended Disintegration Test by use of *single Apparatus* for all sizes of tablets and capsules. However, since this practice was not in line with the global standards, Petitioner No.1 wrote a letter dated 03.06.2016 to Indian Pharmacopeia Commission requesting for inclusion of Apparatus B for Disintegration Test in India Pharmacopeia. This recommendation was eventually accepted and was incorporated in 2018.

19. Reliance has been placed on *Ratan Lal vs. State of Punjab* (1964) 7 SCR 676 and *T. Barai vs. Henry A.H. Hoe & Another* (1983) 1 SCC 177, wherein the Apex Court observed that where any amendment or change seeks to mollify the rigors of the existing law, then the accused who is being prosecuted under the previous law has to be given the benefit of amended law.

20. Similar observations have been made in *B.L, Kohli & Another vs. Delhi Administration* (1986) 30 DLT 336 and *Shyam Lal vs. State* AIR 1968 Allahabad 392.

21. It is submitted that the Batch of the Drug failed in Disintegration Test not because of the Drug being sub-standard, but because the method of analysis used was an old method which is not according to the global standards. The quality and efficacy of the Batch in question, was never compromised and did not change.

22. It is also contended that the Criminal Complaint is not maintainable *for want of territorial jurisdiction* as the Complaint had been filed by Drugs Inspector, CDSCO, Kamla Nehru Nagar, Ghaziabad while the Drug was picked up from CGHS Wellness Centre, Laxmi Nagar, East Delhi.

23. Further, it is submitted that this Complaint has been filed belatedly and is liable to be quashed. In *Sanofi India Limited & Anr. Vs. Union of India and Another*, in W.P.(Crl.) 645/2021, decided on 30.11.2021, wherein the sample had been taken from an earlier batch and similar Complaint was filed against the Petitioner which was challenged and was quashed on the ground of delay in filing the Complaint. The quashing of the Complaint has been thus sought on the ground of being belated and beyond the period of limitation.

24. In the end, it is submitted that Writ Petition (Crl.) No.2615/2021 had been filed by Mr. Aditya Narayan, co-accused in the present Complaint, in this Court for quashing of the summoning Order and the present Criminal Complaint No. 9215 of 2019 which was quashed vide Order dated 22.02.2023 on the ground that he was an independent Director who was appointed subsequent to the manufacturing of the drug and therefore, he could not be held vicariously responsible for the conduct of the Company.

25. It is, therefore, submitted that the Summoning Order be set aside and the present Petition be quashed.

26. The Respondents were duly served, but they did not put an appearance.

27. **Submissions heard and record perused**.

28. At the outset, it needs to be clarified that Aditya Narayan, who got summoned by the learned MM *vide* order dated 20.07.2019 filed Writ Petition (Crl.) No. 2615/2021 challenging his Summoning Order in the present Complaint No. 9215/2019 before this Court. The Writ Petition was allowed by the Coordinate Bench of this Court on 22.02.2023 and the Summoning Order dated 22.07.2019 and all consequential proceedings arising therefrom were quashed. Though, in the first instance, it may see that the entire Complaint was quashed but the said Order has to be read in the context of the relief claimed in the Writ Petition, which was confined by the Petitioner for quashing of the Summoning Order and the Complaint qua him. Therefore, it is evident that the Order dated 22.02.2023 quashed the Complaint qua Aditya Narayan and not against the other accused persons. The same has been clarified by co-ordinate bench of this Court in its Order dated 16.07.2024 in W.P. (Crl.) 2615/2021.

29. The ***first ground*** for challenging the Summoning is that the *filing of the Complaint after the expiry of the drug* in question vitiated the entire proceedings insomuch as the valuable right of the Petitioners to seek re-testing of the sample in terms of Section 25 of the Act got defeated. Sub-sections 3, 4 and 5 of Section 25 of the Act are relevant, which are reproduced as under:-

> *(3)Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under section 18A has, within twenty-eight*

days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(4)Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused: cause the sample of the drug or cosmetic produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

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

30. The first aspect which emerges is that the Report of the Government Analyst shall be evidence of the facts stated therein and shall be conclusive unless such person from whom the sample has been taken, has within 28 days of receipt of the copy of the Report, notified in writing to the Inspector or the Court before which the proceedings are pending, that he intends to adduce evidence in controversion of the Report.

31. The record herein shows that a *Show Cause Notice* dated 27.09.2016 was sent to the Petitioner Company wherein it was stated that the samples

have been found substandard by the Government Analyst, who had given the Report dated 09.06.2016 that the samples did not confirm to claim as per patent and propriety in respect of *Disintegration test*.

32. This *Show Cause Notice* was duly responded by the Petitioner Company *vide* reply dated 05.10.2016 wherein it was submitted that they have already stopped the sale of the Combiflam batch No. 8150683 and the mandatory recall of the said batch was initiated on 12.07.2016. Further assurance was given that appropriate correct and preventive action shall be initiated at site to prevent such out of specification result in further. In addition, it requested for inclusion of Apparatus B in addition to Apparatus A in the Disintegration Test as prescribed by Indian Pharmacopeia.

33. In the said Reply, the Report of the Government Analyst was not challenged by the Petitioner No.1 – Company; rather they abided by the Show Cause Notice and recalled the *Combiflam* supplied *vide* impugned batch number.

34. Further, the Report of Government Analyst was sent to the Petitioner No. 1 on 13.10.2016 to which Reply reiterating the contents of previous Reply was sent on 28.10.2016 by Petitioner No.1- Company. Not only this, they never questioned the genuineness of the analysis of the sample by the Regional Drug Testing Laboratory, Chandigarh nor did they seek any opportunity to adduce any evidence to challenge the Report of the Government Analyst or to seek a re-testing from the Government Laboratory.

35. The Petitioners itself had not sought any re-testing or any further evidence in response to the Show Cause Notice served on 27.09.2016. The

Petitioners herein cannot now claim that its valuable right under Section 25(3) and 25(4) of the Act has been defeated, as has been alleged by them. This ground to seek quashing of the Complaint is, *therefore, not tennable.*

36. The ***second ground*** which has been raised by the Petitioners is that the request of the Petitioners sent *vide* Reply dated 05.10.2016 to include Apparatus B while conducting the Disintegration Test has been eventually accepted and has been included in Indian Pharmacopeia in 2018. The Complaint has been filed in 2019. The Petitioner has placed reliance on *Ratan Lal vs. State of Punjab* (supra); *T. Barai* (supra) *B.L. Kohli* (supra) to assert that the benefit of subsequent modification of the test must be extended to him.

37. However, once the samples have been tested in accordance with the prescribed Disintegration test as has been admitted by the Petitioners, any subsequent change in the methodology of testing cannot enure to the benefit of the Petitioners at the time of filing of Complaint or summoning unless there is evidence led in this respect. Therefore, the summoning Order itself is not amenable to this challenge on account of any subsequent modifications in conducting the test, which can be ascertained only after the evidence has been led by the parties. Herein, the Petitioners are seeking quashing of the Complaint and taking of cognizance on the same.

38. ***Third objection*** taken on behalf of the Petitioners was that the samples had been collected by Drug Inspector, Central Drug Standard Control Organization, North Zone, Ghaziabad, which implies that the Complaint should have been instituted in Ghaziabad while the entire

proceeding has been conducted in Delhi, ***which is beyond the territorial jurisdiction.***

39. No more fallacious contention could have been raised by the Petitioners as the samples have been taken by the Drug Inspector for the North Zone, which may have been defined as Ghaziabad, but there is nothing to show that the North zone did not include Delhi or that she had no jurisdiction to collect the samples from Delhi. Admittedly, the samples have been collected from CGHS, Laxmi Nagar, New Delhi and the Complaint has also been filed in Delhi. Therefore, the jurisdiction of Delhi Court has been rightly invoked and the contention on behalf of the Petitioners is clearly not tenable on the face of it.

40. **Fourth contention** raised on behalf of the Petitioner No. 2 Sh. Shailesh Kripalu Ayyangar is that though he was the Managing Director, but was not responsible for the day-to-day affairs of the Company and is entitled to be discharged. Though in the case of *Maksud Saiyed* (supra) and *Shiv Kumar Jatia* (supra) it has been held that specific allegations must be made against the Director in the Complaint, however, Petitioner No. 2-Sh. Shailesh Kripalu Ayyangar is admittedly the Managing Director. Aside from claiming that he was not involved in day-to-day affairs of the Company, he has failed to explain who, if not he, was responsible for the acts of the Company. Baldly asserting that though he was a Managing Director, but was not responsible for the affairs of the Company would not be sufficient at this stage to discharge the Petitioner No. 2.

41. At no point of time, in any of the Responses or the Reply to Show Cause Notice or any independent letter was it ever averred by the Petitioner

No. 2 that he was not involved in the day-to-day affairs of the Company. Such averment to challenge the Summoning Order, cannot be accepted.

42. Pertinently, pursuant to Board Resolution dated 23 February 2021, the Authorised Representative has been nominated and the Power of Attorney issued in the name of individuals but significantly, no Minutes of Board Resolutions have been annexed nor is there any document filed to show that the Petitioner No. 2 as Managing Director was not involved in the day to day affairs of the Company.

43. The ***last aspect*** which requires consideration is whether the Complaint had been filed within the **period of limitation.** Admittedly, samples of drug *Combiflam* were lifted on 04.05.2016. This drug on testing was found to be sub-standard. Consequently, after following the entire procedure, the Complaint before the District Court, Rohini was filed under Section 18(1)(a) read with Section 16 punishable under Section 27D of the Act on 20.05.2019.

44. Section 27D of the Act prescribes the punishment as under:-

> *"(d) any drug, other than a drug referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this Chapter or any rule made thereunder,* ***shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years [and with fine which shall not be less than twenty thousand rupees]:***
>
> *Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than one year.]"*

45. The minimum punishment, therefore, which can be imposed upon the Petitioners, was one-year upto a maximum of two years. Section 468 Cr.P.C. states that where the maximum punishment that can be imposed is up to two years, *the limitation for taking cognizance is three years under Section 468(2)(c) Cr.P.C.* as has also been observed by the Coordinate Bench of this Court in the case of *Sanofi India Limited (Supra)*.

46. In the present case, as has been noted earlier, the samples were taken on 04.05.2016, while the Complaint has been filed on 20.05.2019. This bar of limitation could have been extended under Section 473 Cr.P.C. provided an Application was filed to this effect. Evidently, no such Application has been filed and, therefore, no cognizance could have been taken, it being barred by Limitation.

47. Though none of the grounds which have been agitated to seek discharge of the Petitioners is made out, but the Complaint *has been filed beyond the period of limitation* and is therefore, quashed and the Petitioners herein are hereby discharged.

48. Petition is allowed.

49. The Petition is disposed of accordingly, along with pending Application(s).

(NEENA BANSAL KRISHNA)
JUDGE

MAY 07, 2025
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