

Reserved On: 06.05.2025

Delivered On: 27.05.2025

Court No. - 73

Case :- APPLICATION U/S 528 BNSS No. - 4060 of 2025

Applicant :- Sharad Gupta And 2 Others

Opposite Party :- State of U.P. and Another

Counsel for Applicant :- Anand Kumar Singh

Counsel for Opposite Party :- G.A.

Hon'ble Vikas Budhwar,J.

1. Heard Sri Sanjeev Agarwal along with Sri Anand Kumar Singh, learned counsel for the applicants and Sri S.K. Singh, learned AGA for the State.

2. This Court on 05.04.2025 had entertained the present application requiring learned AGA to file his response by 30.04.2025 and rejoinder affidavit by 05.05.2025. A counter affidavit has been filed by learned AGA dated 05.05.2025 on behalf of opposite party no.2 sworn by Assistant Commissioner Drugs, Jhansi, U.P. which is taken on record. A statement has been made by learned counsel for the applicants, Sanjeev Agarwal and Anand Kumar Singh, learned counsels that they do not propose to file any rejoinder affidavit to the counter affidavit filed today and the application be decided on the basis of documents available on record. With the consent of the parties, the application be being decided at the fresh stage.

3. The case of the applicants is that M/s Omni Lab Pvt. Ltd has been granted the license to manufactured the drugs and allied items under Drugs and Cosmetics Act 1940 in the year 1991 and the licence is being renewed from time to time. According to learned counsel for the applicants an inspection was conducted in the premises of Dubey Medical Store, Devi Road, Mainpuri on 19.11.2013 in the presence of one Raj Kamal Dubey wherein samples of 7 drugs were taken. The samples so drawn were sent for laboratory test before the Government Analyst U.P. Lucknow on 19.11.2013 which was received in the laboratory on 23.11.2013. The batch number of the sample was LLT-91 manufacturing date August 2012 and expiry date July, 2015. By virtue of the test report

of the Government Analyst U.P. Lucknow dated 20.06.2024, it was found that the content of Cetirizine Dihydrochloride is 11.563 mg in each tablet of average weight which exceeds the declared amount of 10 mg. Thus the sample is not of standard quality in respect of content of Cetirizine Dihydrochloride. It is also misbranded in respect of labeling. It is also alleged that the report of the Govt. Analyst U.P., Lucknow was sent to the Dubey Medical Store and the information was sought about the seller of the said drugs to M/s Dubey Store and it was informed to the authorities that the same was procured from Sri J.K. distributors, Ghaziabad. A notice was sent to J.K. Distributors Ghaziabad who in turn apprised that the said drug was purchased from the firm M/s Omni Pvt. Ltd, Ghaziabad. As per the complaint on 30.07.2024 a notice was issued by the drug authorities to the M/s Om Lab Pvt Ltd. apprising them that the drugs in question was did not confirm to the minimum standards and certain direction was also issued. The applicants tendered their reply on 06.09.2024 mentioning therein that they had also got the sample tested from an approved lab- M/s Indian Analytical Lab, Delhi in which the standard of I.P. was found to be 9.864 mg and a request was made to not to take action since the applicants would be careful in future. Thereafter, on 12.04.2016 the complaint stood lodged against the applicants along with the other three accused before the court of District and Sessions Judge, court no.9 Agra being case SST NO. 45 of 2016 U/s 18 read with section 27 of the Drugs and Cosmetics Act 1940.

4. The court of the Special Judge, Drugs Act, Agra proceeded to summon the applicants on 12.04.2016 under Section 18 read with section 27 of the Drugs and Cosmetics Act, 1940.

5. The applicants have thus filed the present application U/s 528 BNSS for quashing the entire proceeding of complaint case SST No. 45 of 2016 (State of U.P. vs. Sharad Gupta & Ors) U/s 18 punishable under Section 27 of Drugs & Cosmetics Act, 1940, P.S. Mainpuri passed by learned Additional Sessions Judge, court n.14 Special Judge Drugs Act, Agra.

6. Learned counsel for the applicant submitted that the complaint lodged by the opposite party no. 2 on 12.04.2016 cannot be sustained even for a single moment. Elaborating the said submission, it is submitted that as per the complainant's case the sample was drawn from the M/s Dubey Medical Stores on 19.11.2013, it was sent for testing before the Government Analyst U.P. Lucknow on 19.11.2013 received on 23.11.2013 and the manufacturing date of the said sample was August 2012 and the expiry date is July, 2015 and as per the test report dated 20.06.2014 of the Government Analyst U.P., Lucknow the same was not confirming to the standard and on 30.07.2014 a notice was issued to the applicants by the drug authorities along with samples and the report and the applicants on 06.09.2014 tendered their reply disputing the report of the Government Analyst while annexing the copy of the report of an approved by Indian Analytical Laboratory but the complaint stood lodged on 12.04.2016 even subsequent to the expiry of the subject drug in the month of July, 2015. Thus, the opportunity of the applicant to get the retesting done from the Central Drug Lab as per section (4) of section 25 of the Act stood extinguished. Submission is that it was a legal vested right of the applicant to have moved to the court in case the complaint had been lodged within the time with a request for the sample be again tested by the Central Drug Lab. Contention is that the said legal right has been taken away that to on the lethargy and the delay attributable to the drug administration. Learned counsel further submits that it is apparent from the complaint that it was on account of internal routine communication between the drug authorities which became the basis of lodging of the complaint post expiry of the drug in question. The argument is that reasons in lodging the complaint after enormous delay is inconceivable and not liable to be accepted particularly when this much has been recited in the complaint that communications were made between the authorities of the drug administration for inputs on 31.12.2014, 28.01.2015, 22.04.2015 and 22.07.2015. Reliance has been placed upon the judgment

of the Hon'ble Apex Court in the case of *Medicamen Biotech and another vs. Rubina Bose, Drug Inspector (2008) 7 SCC 196* so as to content that the right under section 25 (4) is a substantive right which cannot be defeated on account of lethargy in filing the complaint, taking away the vested right to get the samples retested from the Central Laboratory.

7. It is next contended that the summoning order dated 12.04.2016 is cryptic, non reasoned and does not even recite the case of the complainant as on mere asking the applicants have been summoned without due application of mind. Additionally, it has been argued that though the summoning order is stated to have been issued on 12.04.2016 but the summoning order at no point of time served upon the applicants. However, without there being any satisfaction recorded in the order sheet that the service upon the applicant was sufficient, non-bailable-warrants and proceedings U/s 82 of Cr.P.C. have been initiated. It is thus prayed that the summoning order as well as the entire proceedings be quashed.

8. Countering the submissions of the learned counsel for the applicant, learned AGA has submitted that the present application has been filed after an inordinate delay of eight years as the applicant had been summoned on 12.04.2016 and non-bailable warrants have been issued on 07.06.2017 followed by the proceedings under section 82 on 19.11.2019 and in absence of any explanation, set forth for consideration by the applicants, this Court may not interfere at this stage and scuttle the proceedings. It is also contended that there had been no request made by the applicant under section 25 sub section (4) of the Drugs and Cosmetics Act for getting the samples re-tested from Central Laboratory.

9. I have heard the counsels for the parties and perused the record carefully.

10. Apparently, an inspection was conducted in the premises of M/s Dubey Medical Store on 19.11.2013 wherein the samples of seven drugs

were drawn. The manufacturing date of the subject drugs was August 2012 and the expiry date is July, 2015. The samples so drawn on 19.11.2013 which was received in the Government Analyst Lab, U.P. Lucknow on 23.11.2013. Thereafter, as per the record on 30.07.2014 a notice came to be issued to the applicant which is quoted herein under:

"M/s

दिनांक- 30.07.2014

Omn Laboratories (P) Ltd.

E-25-07, Kavi Nagar, Ind Area Ghaziabad-201002

विषय- अधोमानक औषधि *Cetwin Tablets, B. No.LLT-91, MFG 08/2012, EXP. 07/2015* के सम्बन्ध में।

उपरोक्त विषयक अवगत कराना है कि दिनांक 19.11.2013 को अधोहस्ताक्षरी द्वारा मै० दुबे मैडिकल स्टोर, देवी रोड जिला मैनपुरी से *Cetwin Tablets, B.No.LLT-91, MFG 08/2012, EXP 07/2015* का नमूना संग्रह कर विश्लेषण हेतु प्रयोगशाला लखनऊ भेजा गया था जिसकी विश्लेषण रिपोर्ट संख्या डी/4329-13 दिनांक 20.06.2014 में उपरोक्त औषधि को अधोमानक औषधि घोषित किया है। अतः औषधि एवं प्रशासन सामग्री अधिनियम 1940 की धारा 25(2) के अनुपालन में प्रपत्र 13 जाँच रिपोर्ट की मूलप्रति यहाँ संलग्न है। उक्त औषधि आबैकी मामी द्वारा निर्मित है। आपको इस पत्र के साथ भेजे गये नमूने का एक भाग भेजा जा रहा है। इस सम्बन्ध में आप उपरोक्त औषधि से सम्बन्धित निम्नलिखित अभिलेख अधोहस्ताक्षरी को पाँच दिन के अन्दर उपलब्ध कराना सुनिश्चित करें-

- *Batch Production Record including packing.*
- *COA of Packing Material of the particular batch.*
- *Packing Material receipt & its use in different batch nos of same products.*
- *Despatch details of the particular batch*
- *COA of Finished Product of the particular batch.*

औषधि एवं प्रशासन अधिनियम 1940 एवं नियमावली 1945 की धारा 18 बी के अन्तर्गत आपसे यह अपेक्षा की जाती है। पत्र प्राप्त होते ही आपा उक्त औषधि का विक्रय/अपूर्ति तत्काल बन्द कर दें साथ यह बतायें कि उक्त औषधि आप द्वारा किस-किस फर्मों/संस्थानों को आपूर्ति की गयी है एवं कितनी मात्रा में की गई है, का पूर्ण विवरण दें एवं सभी फर्मों/संस्थानों को आपूर्ति की हुई औषधि की मात्रा का दाखला नगाना सुनिश्चित करें, जिसके लिये आपको पाँच दिवसों का समय नियत किया जाता है।

यदि आप निर्धारित समयावधि में उपरोक्त निर्देशों का पालन नहीं करते हैं तो की गई कार्यवाही के लिये सम्पूर्ण जिम्मेदारी आपकी होगी और यह मान लिया जायेगा कि इस सम्बन्ध में आपको

कुछ नहीं कहना है और आपके विरुद्ध निथम- 1945 (औषधि एवं प्रसार भमगरी) के तहत एक पक्षीय सुसंगत कार्यवाही अमल में लाई जायेगी।

विश्लेषण रिपोर्ट संख्या डी/4329-13 दिनांक: 20.06.2014 की प्रति एवं नमूना संग्रह का एक भाग।"

11. The applicant had replied to the said notice on 06.09.2014 which reads as under:

**"E-26, Sector-17, Kavi Nagar Industrial Area,
GHAZIABAD-201002 (U.P.)**

Dated: 06.09.2014

***The Inspector of Drugs,
Office of the Drug Inspector,
Food Safety and Drugs Administration,
Mainpuri (U.P)***

Sub: Regarding Cetwin Tablets BNo.LLT-91, D/M 08/2012, E/D 07/2015, declared as substandard

D/Sir,

Received your letter No. 5/2014-15-53 dated 30.09.14 regarding the above said drug along with report of Govt. Analyst and a portion of sealed sample. In this regard, it is to submit as under-

(1) As shown in the report that the drug is misbranded with respect of labeling. It is to inform that the name of drug is mentioned in claim / formulae of drug, however due to oversight the name could not be written along with the trade name. We have corrected the above mistake and are enclosing here with new corrected label for your kind perusal.

(2) As per Govt. analyst report, the content of Cetrizine Di HCl IP are above the prescribed limits, it is to say that as per our test report No. AF 22612, the content of Cetrizine Di HCl are 9.932 mg which are in the prescribed limits of IP. After receiving your letter, we had also sent our control sample to outside approved lab, M/S Indian Analytical Laboratories, Delhi for testing the contents of the said drug. The test result (Assay) is in compliance with respect to standards of IP which is 9.864 mg / tablet. As we are not adding any overages, the content of the said drug cannot be more than 10 mg/tablet.

Please also find enclosed here with Batch Production Record, COA of the Raw Material, dispatch details of the said batch and COA of the finished product for your kind perusal.

We hope you will find above in order, how ever we shall be more careful in future. We request you to have a sympathetic consideration and not to take any action in this regard.

Thanking you,"

12. Thereafter on 12.04.2016 the complaint was lodged by the opposite party no.2 under section 18 read with section 27 of the Drugs and Cosmetics Act, 1940 and the applicant was summoned on 12.04.2016. The summoning order dated 12.04.2016 is being herein quoted herein under:

"आज औषधि निरीक्षक मैनपुरी द्वारा अभियुक्तगण शरद गुप्ता आदि के विरुद्ध परिवाद पत्र दाखिल किया। मैने परिवाद पत्र के साथ संलग्न सभी प्रपत्रों का अवलोकन किया। आधार पर्याप्त है। संज्ञान लिया गया। पेश होकर आदेश हुआ कि दर्ज रजिस्टर हो। अभियुक्तगणों के विरुद्ध समन दिनांकित 30.04.2016 के लिए जारी हो।"

13. The sheet anchor of argument of learned counsel for the applicants that once they had disputed the contents of the report of the Government Analyst and had also filed a report which was in their favour then a decision ought to have been taken either to lodge the complaint forthwith so as to given an opportunity to exercise the right for getting the retained samples tested in a Government Laboratory. Since the complaint was filed on 12.04.2016 after the expiry of the drugs on July, 2015 thus, their valuable right has been taken away as per the subsequent 4 of Section 25 of the Drugs and Cosmetics Act, 1940.

14. Section 25 of the Drugs and Cosmetics Act, reads as under:

25- Report of Government Analyst

"(1) The Government Analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A, and shall retain the third copy for use in any prosecution in respect of the sample.

(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."

15. Indeed, a perusal of the summoning order dated 12.04.2016 would go to show that the same is non speaking, unreasoned and it does not even advert to the case of the complainant. The same apparently has been passed by total non-application of mind. Though at the stage of summoning, the Courts are not required to conduct a mini trial, but what is relevant is that there has to be at least recording of sufficiency or satisfaction that the case is triable. Naturally, there are issues relatable to delay in lodging of the complaint post-expiry of drug and also the effect and impact of the applicability of Section 25(4) of Drugs & Cosmetics Act.

16. The Hon'ble Apex Court in the case of ***JM Laboratories vs. State of Andhra Pradesh: 2025 INSC 127***, has observed as under:-

"9. In the present case also, no reasons even for the namesake have been assigned by the learned Magistrate. The summoning order is totally a non-speaking one. We therefore find that in light of the view taken by us in criminal appeal arising out of SLP (Crl.) No. 2345 of 2024 titled "INOX Air Products Limited Now Known as INOX Air Products Private Limited and Another v. The State of Andhra Pradesh", and the legal position as has been laid down by this Court in a catena of judgments including in the cases of Pepsi Foods Ltd. and another Vs. Special Judicial Magistrate and others, Sunil Bharti Mittal Vs. Central Central Bureau of Investigation, Mehmood U Rehman Vs. Khazir Mohammad Tunda and others and Krishna Lal Chawla and others Vs. State of Uttar Pradesh and another, the present appeal deserves to be allowed."

17. Though the summoning order had been issued on 12.04.2016 and non-bailable warrants had also been issued followed by the proceedings under Section 82 of Cr.P.C., however, this Court is not delving into the said issue, since the summoning order itself has not been passed as per the mandate of the law in *M/s J.M Laboratories (Supra)*, thus, this Court has no option but to interfere with the summoning order.

18. Accordingly, the summoning order dated 12.04.2016 passed in complaint S.S.T. No. 45 of 2016, under Sections 18/27 of Drugs and Cosmetics Act, 1940 by Addl. Sessions Judge, court no. 14, Special Judge (Drugs Act), Agra is set aside.

19. Matter stands remitted back to the court below to pass a fresh order strictly in accordance with law.

20. With the said observations, the present application is disposed of.

21. Let learned AGA to communicate the order passed today for due compliance.

Order Date :-27.05.2025

C. MANI

(Vikas Budhwar,J.)