Reportable/un-reportable

IN THE HIGH COURT OF HIMACHAL PRADESH, SHIMLA

ON THE 30th DAY OF SEPTEMBER 2022

BEFORE

HON'BLE MR. JUSTICE SATYEN VAIDYA

CRIMINAL REVISION NO. 336 OF 2022

Between:-

M/S HETERO LABS LIMITED (UNIT II), VILLAGE KALYANPUR, CHAKKAN ROAD, TEHSIL BADDI, DISTRICT SOLAN, H.P. THROUGH AUTHORIZED SIGNATORY MADHUSUDHANA REDDY GUNTAKA S/O SH. VEERA REDDY GUNTAKA R/O HOUSE NO. 262, PHASE-III, HOUSING BOARD, BADDI, DISTRICT SOLAN, H.P.

....PETITIONER

(SH. N.S. CHANDEL, SR. ADVOCATE WITH SH. VINOD KUMAAR GUPTA, ADVOCATE)

AND

UNION OF INDIA, THROUGH DRUGS INSPECTOR, CENTRL DRUGS STANDARD CONTROL ORGANISATION, (C.D.S.C.O.) SUB ZONE, CONTAINER CORPORATION OF INDIA BUILDING, VILLAGE SHEETALPUR, BADDI, DISTT. SOLAN, H.P.

....RESPONDENT

(SH. BALRAM SHARMA, ASGI).

Reserved on: 23.9.2022

Date of decision: 30.9.2022

This petition coming on for order this day, the Court passed the following:

O R D E R

By way of instant petition, petitioner has prayed for setting aside the order dated 15.6.2022, passed by learned Additional Chief Judicial Magistrate, Nalagarh, District Solan, H.P. in Complaint No. 239/4 of 2022, whereby the prayer of the petitioner to send the seized second sample, lying in the custody of the Court, for its analysis to Central Drugs Laboratory, Kolkata has been rejected.

2. Brief facts necessary for adjudication of petition are as under: -

2.1 Petitioner is one of the accused in complaint case No. 239/4 of 2022, pending adjudication before learned Additional Chief Judicial Magistrate, Nalagarh, District Solan, H.P.

2.2 The complaint has been filed by Union of India through Drug Inspector under Section 18 (a)(i) and (vi) read with Section 16 (i)(a), punishable under Section 27 (d) of The Drugs and Cosmetics Act, 1940 (for short, 'the Act').

2.3 It is alleged in the complaint as under:

(i) That on 15.3.2021, the Drug Inspector had drawn the drug samples of Azilsartan Medoxomil tables 80mg (Abel-80), manufactured by petitioner

at its manufacturing Unit at Baddi, District Solan, H.P. under Section 23 of the Act from the premises of M/s Lupin Limited, Zirakpur, Punjab. The spot reports were prepared at the time of sampling.

(ii) The sample was sent to Government Analyst, Regional Drugs Testing Laboratory, Chandigarh for its test and analysis on 15.3.2021.

(iii) The Government Analyst vide report dated 3.6.2021 declared the sample as not of standard quality.

(iv) One copy of Test Report dated 3.6.2021 was made available to the petitioner along with notice under Section 18 (b), 22(1)(cca) and 25 (3) of the Act on 17.6.2021. In addition, one sealed portion of sample was also handed over to the petitioner on the same day i.e. 17.6.2021.

(v) The petitioner got the controlled sample tested and found the same as per prescribed standard.

(vi) Petitioner communicated with Drug Inspector vide its letter dated 13.7.2021 and disclosed the result of test got conducted by it on controlled

sample. Petitioner, however, opted not to challenge the FDA results.

2.4 During the pendency of the complaint, petitioner filed an application before learned Additional Chief Judicial Magistrate, Nalagarh under Section 25 (4) of the Act, making a prayer to send the second sample, lying in the custody of the Court for analysis to Central Drugs Laboratory, Kolkata.

2.5 The prayer for sending the second sample was made on following grounds:

(i) That a bare perusal of complaint did not disclose even a prima-facie case against the petitioner, therefore, framing of charge against the petitioner and consequent trial would be an exercise in futility and as such, petitioner was entitled for sending the seized sample by the Drugs Inspector for analysis by Central Drugs Laboratory, Kolkata.

(ii) Petitioner further had placed reliance on the analysis of the Control Sample, CDSCO (Portion of Withdrawn Sample) and Hub Sample (received from Lupin Hub) and as per analytical research all the samples were found complying with the specifications.

(iii) It was further submitted that in view of satisfactory product development report, R&D stability data along with stability data of marked batch, coupled with analytical results of above noted samples, the dissolution result report in Form-13 by Government Analyst might be due to moisture absorption/improper integration of peak or analytical error/calculation error/instrumental error etc.

2.6 Learned Additional Chief Judicial Magistrate, Nalagarh rejected the prayer of the petitioner on the ground that the petitioner vide its letter dated 13.7.2021, addressed to Drugs Inspector had clearly mentioned that the petitioner did not intend to challenge the FDA results and had initiated the batch recall as per FDA instructions.

2.7 Thus, the learned trial Court inferred that the petitioner had forfeited the claim to challenge the Government Analyst Report.

2.8 It was further held that the petitioner could have challenged the report of Government Analyst within 28 days from its receipt and on such basis, the application filed by the

petitioner on 13.4.2022 before the learned trial Court was held to be highly belated.

3. Petitioner has assailed the impugned order dated 15.6.2022 on the grounds that it had not given up its right to challenge the Government Analyst Report. As per petitioner, its communication dated 13.7.2021 to the Drugs Inspector was in fact a notification under Section 25 (3) of the Act and, therefore, the petitioner was well within its right to invoke the remedy under Section 25 (4) of the Act, by making a prayer, before learned trial Court to send the seized sample for testing by Central Drugs Laboratory, Kolkata. Petitioner further contends that it had never admitted the report of Government Analyst to be correct, as the communication dated 13.7.2021, if read as a whole, would clearly spell out the intent of the petitioner. As a matter of fact, the petitioner had clearly communicated the factum of tests got conducted by it of Control Sample, CDSCO Sample and Hub Sample. As per contention of petitioner, merely because the petitioner had communicated its wish not to challenge the FDA results at that stage cannot be construed to be an act of giving up of its right under Section 25 (3) and (4) of the Act.

4. Per contra, respondent has contested the plea of petitioner. It has been contended by way of reply filed on behalf of the respondent that once the petitioner had given up its right to challenge the FDA results and had initiated the batch recall on the instructions of FDA, petitioner had forfeited its right to challenge the Government Analyst Report subsequently. As per respondent, the communication dated 13.7.2021 of the petitioner, did not convey the requisite notification under Section 25 (3) of the Act.

5. I have heard Mr. N. S. Chandel, learned Senior Advocate for the petitioner and Mr. Balram Sharma, learned Assistant Solicitor General of India for the respondent and have also gone through the record carefully.

6. The factual aspect of the matter is more or less admitted by the parties. The sample was drawn on 15.3.2021 from Lupin Limited. Petitioner was the manufacturer of the drugs, for which the sample was drawn. The sample was sent to the Government Analyst on 15.3.2021. The report of the Government Analyst was received by the Drugs Inspector on 3.6.2021. A Copy of such report was supplied to the petitioner on 17.6.2021.

7. It is also not in dispute that petitioner had sent a communication dated 13.7.2021 to the Drugs Inspector. The question for adjudication is whether the communication dated 13.7.2021, sent by petitioner to Drugs Inspector was a notification under Section 25 (3) of the Act?

8. Section 25 of Drugs and Cosmetics Act reads as under:-

> ***"25 Reports of Government Analysts***. —
>
> *(1) The Government Analyst to whom a sample of any drug 116 [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 117 [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 118 [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 116 [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."

Thus, the report of Government Analyst becomes conclusive evidence of the facts stated therein, unless the person, from whom the sample was taken or the person whose particulars were disclosed under Section 18-A of the Act,

within 28 days of the receipt of a copy of the report notifies in writing the Inspector or the Court before which any proceeding in respect of the sample is pending that he intends to adduce evidence in controversion of the report.

9. Reverting to the facts of the present case, according to the petitioner the contents of its communication dated 13.7.2021 amounted to notifying its intent to adduce evidence in controversion of the report. Respondent controverted such assertion on the ground that the petitioner had unequivocally given up its right to challenge the FDA reports and consequently had forfeited its right to avail remedy under Section 25 (4) of the Act.

10. To appreciate the rival contentions, it is apt to notice the relevant extracts from the communication dated 13.7.2021 as under: -

> *"After receipt of communication from Central Drugs Standard Control Organization (Baddi), we have performed the genuineness study of the complaint sample received form CDSCO Baddi and control sample & concluded that product is genuine &manufactured at hetero Labs Ltd. Unit II, Baddi. Batch records analytical documents & other batch related documents has been received and found satisfactory. All in process & analytical results of said batch found well within predetermined*

specifications. In addition to above, we have analyzed the control sample, complaint sample (sample received from GDSCO, Baddi) of same product/batch Azilasartan Medoxomil Tablets 80mg (Lupin Abel 80/Batch No. QZ210101). As per analytical results, all samples i.e. control sample & complaint sample (CDSCO sample) are complying with specification (reported as below). Analytical results of control sample and CDSCO sample enclosed in ***Annexure B****:*

Batch No.: QZ210101 Results dissolution (By HPLC) Limit: NLT 75% (D) of the labeled amount of Azilsartan Medoxomil should dissolved in 45 minutes		
-	Control sample	Complaint sample (CDSCO sample
Tablet1	96.0%	95.9%
Tablet 2	99.0%	95.4%
Tablet 3	95.7%	94.8%
Tablet 4	98.5%	101.7%
Tablet 5	96.4%	96.0%
Tablet 6	99.8%	95.0%
Average:	97.6%	96.5%

Based on documents review, analytical results of control sample & complaint sample (CDSCO sample) we confirm that there is no quality issue in the said batch associated with dissolution results of the batch."

> "*Considering the above explanation and dissolution results of control sample & complaint sample (CDSCO sample) mentioned above, we confirm that there is no quality issue in the said batch. Further in this regard, we do not want to challenge the FDA results and initiated the batch recall as per FDA instruction.*"

10. It is revealed from the communication dated 13.7.2021 that the petitioner had got Control Sample, CDSCO (Portion of Withdrawn Sample) and Hub Sample (received from Lupin Hub) tested and as per reports received on such tests, those samples were found to be within the prescribed standard. This fact undoubtedly was communicated to the Drugs Inspector. It is on the basis this part of the communication that the petitioner submits to have notified its intent to adduce evidence to controvert the report of Government Analyst.

11. Another aspect of the matter is revealed from the contents of aforesaid communication, whereby petitioner had stated that it did not want to challenge the FDA results and had initiated the batch recall on the instructions of FDA. Simultaneously, petitioner had written that based on the action taken and dissolution results of control sample and CDSCO sample, the product was in compliance of product specification

and as per petitioner, the failure encountered might be due to moisture/ analytical/instrumental error.

12. What is provided by Section 25 (3) is only the notification of intent to adduce evidence to controvert the report of Government Analyst. Such notification is to be made within 28 days on the receipt of Government Analyst's report. Once such option is exercised by either the person from whom sample was taken or the person whose particulars were disclosed under Section 18A of the Act, he becomes entitled to exercise right under sub-section (4) of Section 25 of the Act. Section 25(4) of the Act provides that if the sample had already not been tested or analyzed in Central Drugs Laboratory and the person has notified his intention under sub-Section (3) of Section 25 of the Act, the Court is empowered either on its own motion or in its discretion on the request of either complaint or the accused to cause the sample of the drug produced before the Magistrate under sub-Section (4) of Section 23 to be sent for test or analysis to Central Drugs Laboratory.

13. A comprehensive reading of communication dated 13.7.2021 cannot be construed as an act of petitioner to give up its right under Section 25 (4) of the Act. The communication was within 28 days of the receipt of sample by

the petitioner. Petitioner had got the controlled and CDSCO samples tested with sufficient promptitude and had found them to be as per prescribed standards and thus was in possession of some evidence to controvert the report of Government Analyst. In the considered view of this Court, communication dated 13.7.2021 was sufficient compliance of sub-Section (3) of Section 25 of the Act at the end of the petitioner. Petitioner had never communicated that in case of prosecution being launched against it, the same would not be contested or the petitioner would confess the charges framed against him. The decision of the petitioner not to challenge FDA results and to recall the batch on the instructions of FDA cannot be taken to be an admission of guilt on his part, for the reasons that in the same breath, the petitioner had reiterated its belief on the sample got tested by the petitioner and its apprehension about the results of analysis conducted by the Government Analyst being due to moisture/ analytical/ instrumental error.

14. The right under Section 25 (4) of the Act is valuable and indefeasible right, which cannot be easily taken away. In criminal prosecution, the right to defend oneself is an absolute and unbridled right. Reference can be made to ***Laborate***

Pharmaceuticals India Limited vs. ***State of Tamil Nadu*** reported in***2018 (15) SCC 93***, wherein Hon'ble Supreme Court has observed as under:-

> *"All the aforesaid facts would go to show that the valuable right of the appellant to have the sample analysed in the Central Laboratory has been denied by a series of defaults committed by the prosecution; firstly, in not sending to the appellant-manufacturer part of the sample as required under Section 23(4) (iii) of the Act; and secondly, on the part of the Court in taking cognizance of the complaint on 4th March, 2015 though the same was filed on 28th November, 2012. The delay on both counts is not attributable to the appellants and, therefore, the consequences thereof cannot work adversely to the interest of the appellants. As the valuable right of the accused for re-analysis vested under the Act appears to have been violated and having regard to the possible shelf life of the drug we are of the view that as on date the prosecution, if allowed to continue, would be a lame prosecution*".

15. Learned Assistant Solicitor General of India, on the other hand, has placed strong reliance on the judgments passed by Hon'ble Supreme Court in ***State of Haryana vs. Brij Lal Mittal &others*** reported in ***1998 (5) SCC 347*** and ***Glaxosmithkline pharmaceuticals limited & another vs.***

State of Madhya Pradesh reported in ***2011 (13) SCC 75*** to lay stress on its contention that the right, if any, existing in favour of petitioner had been waived off by it.

16. The reliance on above referred judgments may not help the cause of respondent for the reasons that those were passed in the specific fact situations prevailing in those cases. The marked distinction being that in both the above referred cases, admittedly the opportunity as provided in sub-Section (3) of Section 25 of the Act was not availed within 28 days from the receipt of report of Government Analyst, whereas in the facts of the case in hand the communication dated 13.7.2021 was issued within 28 days of the receipt of report.

17. In view of above discussion, the impugned order dated 15.6.2022, passed by learned Additional Chief Judicial Magistrate, Nalagarh, District Solan, H.P. in Complaint No. 239/4 of 2022, cannot be sustained. The learned Additional Chief Judicial Magistrate has clearly erred in not appreciating in right perspective the severable relation between sub-Section (3) and sub-Section (4) of Section 25 of the Act.

18. Resultantly, the petition is allowed. The impugned order dated 15.6.2022 is set side. Application of the petitioner under Section 25 (4) of the Act filed before learned trial Court is

ordered to be allowed. The seized sample, lying in custody of learned trial Court is ordered to be sent to Central Drugs Laboratory Kolkata at the cost of petitioner forthwith, so as to obtain the report from such laboratory before the date of expiry of the sample.

19. Petition is accordingly disposed of. Pending applications, if any, also stand disposed of.

(Satyen Vaidya)
Judge

30th September, 2022.
(kck)