**HIGH COURT OF JAMMU AND KASHMIR AND LADAKH AT JAMMU**

Reserved on 04.12.2021
Pronounced on 31.01.2022

CRMC No. 185/2013 (O&M)

Symbiosis Pharmaceuticals Pvt. Ltd. …..Appellant(s)/Petitioner(s)

Through: Mr. Sachin Gupta, Advocate

**vs**

State of J&K and another ….. Respondent(s)

Through: Mr. H. A. Siddiqui, Sr. AAG

**Coram: HON'BLE MR. JUSTICE RAJNESH OSWAL, JUDGE**

**ORDER**

1. The present petition has been filed by the petitioner-company for quashing the proceedings of the complaint titled "Drugs Inspector Jammu zone-VI vs. M/s. R. G Enterprises and others" pending before the court of learned Chief judicial Magistrate Jammu (hereinafter to be referred to as the trial court) on the following grounds:

   (a) That there is no reference to the actual role played by the petitioner and the Directors in the commission of alleged offence, which is the subject matter of the instant case and in the absence of any such specific role attributed to the petitioner, no proceedings can be initiated against the petitioner.

   (b) That the proceedings initiated by the respondent No.1 against the petitioner are illegal and without any justification on the ground that the same is contrary to the guidelines issued by the

Central Drugs Standard Control Organization, New Delhi India (Statutory Authority Under Act). The nature of the defect in the present case falls under category "B" "Minor Defects" and as per the guidelines so issued by CDSCO, only administrative measures by way of suspension of license could have been resorted to by the respondent No. 1 against the petitioner-company rather than initiating the criminal proceedings against the petitioner. The Drugs Licensing Authority, Drugs Control Administration, Solan, Himachal Pradesh suspended the license of the petitioner-company for a period of around two months to manufacture the drug in question and hence the continuation of the criminal proceedings against the petitioner is illegal and without jurisdiction.

(c) That the learned trial court without application of mind took cognizance against the petitioner when the substantial right of the petitioner for getting the drug in question retested/reanalysed by the Central Drug Laboratory Kolkatta as envisaged in section 25 (3) and section 25 (4) of Drugs and Cosmetics Act, 1940 was denied to the petitioner by the deliberate conduct of the respondent No.1 and also by failure on its part to supply one sealed sample portion of drug in question to the petitioner as required under section 23 (4) (ii) and further respondent No.1 filed the complaint without adhering to the letter/reply addressed to the respondent No.1 by the petitioner in

which the test report in question was disputed and reanalysis was demanded.

(d) That the learned trial court without application of the mind, took cognizance against the petitioner in light of the fact that the present complaint was filed very shortly before the expiry of shelf life of the drug in question and by that time the petitioner received summons, the drug in question had already expired. The petitioner, as such, has lost its valuable right of getting the drug in question reanalyzed/retested from the Central Laboratory Kolkatta.

(e) That the failure of the respondent No.1 to promptly send the sample for test by the Central Drug Laboratory in view of the objections raised by the petitioner with regard to the report of the Government Analyst as per I.P. method and not as per B.P method and also in view of the fact that the report of the government analyst is contrary to the report submitted by the in-house laboratory of the petitioner, has caused prejudice and denial of opportunity to the petitioner to avail the vital right provided under section 25 (4) of the Drugs and Cosmetics Act 1940.

2. The respondent No. 1 has filed the response, in which it has been stated that the petitioner has raised the disputed question of facts in the present petition, which are required to be appreciated only at the stage of trial and besides narrating the factual aspects of the case, the respondent No. 1 has specifically stated that the petitioner failed to

reply to the notice dated 18.11.2011 and did not notify its intention to controvert the report of the Government Analyst.

**Facts of the case:**

3. On 26.09.2011, the respondent No. 1 went for a routine inspection in his jurisdictional area and during inspection visited the premises/shop of respondent No. 2 situated at Roop Nagar Jammu. The respondent No.1 inspected the premises and prepared inspection note and respondent No. 2, who was the competent person and proprietor was found present inside the shop and while inspecting the aforesaid shop, the respondent No. 1 disclosed his identity to the respondent No. 2 and expressed his intention to lift the samples of drugs for test/analysis from Government Analyst as mentioned in the form No. 17 i.e. Napris-500 (Batch No: ST-8321, Mfg, Date -08/10, Exp. Date -07/12, Manufactured by M/S Symbiosis Pharmaceuticals Ltd., Suket Road, Kala Amb Sirmour, Himachal Pardesh), Cosclox Capsules and Itchicos cream.

4. That after completing the necessary technical requirements, the respondent No. 1 sent one sample in question i.e. Napris-500 manufactured by the petitioner company, to the Government Analyst i.e. CFDL Jammu. The respondent No. 1 received the certificate of test no. CFDL/LS/tests/NC/468/Sep-11 dated 21.10.2011 from the Government Analyst i.e. CFDL Jammu under section 25 (1) of Drugs and Cosmetics Act 1940, vide communication dated 31.10.2011 and No. CFDL/511-12 and the sample of the drug in question i.e. Napris-500 (Batch No: ST-8321) was declared to be not of standard quality

as defined in Drugs and Cosmetics Act 1940 and the report further stated that the sample failed in assay of Naproxen.

5. That the respondent No. 1 sought from the respondent No. 2 the requisite information and the respondent No. 2 also submitted an invoice dated 02.03.2011 issued by the petitioner and it clearly showed that the drug has been manufactured and sold by the petitioner.

6. That the respondent No. 1 by letter dated 18.11.2011 sent through registered post informed the petitioner about the report of the Government Analyst with regard to the drug in question. The copy of the test report of the Government Analyst and sample portion of the drug in question was also enclosed with the said letter. The petitioner company failed to reply the communication sent by the respondent No. 1 within a period of 28 days as stipulated in section 25 (3) of the Act and the petitioner also did not provide the sale record, stock record, manufacturing record of the drug in question within the said period to the respondent No. 1.

7. That after receiving a sanction for prosecution of the petitioner and other accused, the complaint was filed by the respondent No. 1 against the accused for commission of offences under section 18 (a) (i) read with section 27 (D) of the Drugs and Cosmetics act 1940. That the learned trial court vide order dated 29.12.2011 issued the process against the petitioner and the other accused for commission of offence under section 27 (d) read with section 18 (a) (i) of the Drugs and Cosmetics Act 1940.

**Arguments**:

8. Though the present petition has been filed on numerous grounds, however, Mr. Sachin Gupta, learned counsel for the petitioner restricted his arguments only on two issues and did not press the other issues raised in the petition. He vehemently argued that the vital right of the petitioner for getting the drug retested/reanalyzed has been violated by the respondent No.1 particularly when the petitioner had sent the reply to the letter dated 18.11.2011 and further that the drug was required to be tested by the standards prescribed by the British Pharmacopoeia (B.P) 2010 but the government analyst analyzed the drug in question as per the standards prescribed by Indian Pharmacopoeia (I.P) addendum I-III edition 1985. Mr. Gupta placed much reliance upon the letter dated 20.12.2011 claimed to have been sent by the petitioner to the respondent No. 1 through Courier.

9. Mr. H. S. Siddiqui, learned AAG has vehemently argued that the letter dated 20.12.2011 was never received by the respondent No. 1 as the same has been allegedly sent through courier service and the receipt of the courier does not reflect that the same was sent to the respondent No. 1 as the address has not been correctly mentioned upon the said receipt. He further argued that the said letter has been annexed to mislead this Court and the same cannot be accepted as a mode of service and even no presumption of service can be drawn to such mode of communication. He further submitted that the drug in question is included in the Indian pharmacopoeia and has to be tested

as per I. P. Protocol and though the petitioner has on its label mentioned British pharmacopoeia but this does not cast any obligation on the drug analyst to apply British pharmacopoeia. He also urged that under entry 5 of the 2nd schedule, the drug included in the Indian pharmacopoeia is required to be tested by applying standards of identity, purity and strength specified for drugs in the edition of such Indian pharmacopoeia for the time being in force and such other standards as may be prescribed are to be followed. Mr. Siddiqui further submitted that the petitioner has not denied that the drug in question is not included in the Indian pharmacopoeia and that the testing protocol whether Indian pharmacopoeia or British pharmacopoeia cannot make any material difference on the standard of identity, purity and strength of a drug. He also submitted the written submissions.

10. Heard and perused the record.

**DISCUSSION:**

11. The first contention raised by the learned counsel for the petitioner is that the petitioner-company has been deprived of its valuable right for getting the sample of the drug in question retested/reanalyzed from the Central Drug Laboratory Kolkata. The perusal of the report of the government analyst dated 31.10.2011 reveals that the drug in question has been found to be not of standard quality. Further, the petitioner has admitted the receipt of communication dated 18.11.2011 of the respondent No. 1 on 25.11.2011 in para 5 (d) of the petition, whereby, the test report along with the sample was sent

to the petitioner. The petitioner had a right to dispute the correctness of the report of the government analyst within the statutory period of 28 days from the date of the receipt of the report as per the mandate of section 25 (3) of the Act. The letter dated 20.12.2011 relied upon by the petitioner was allegedly sent through courier and in the courier receipt dated 20.12.2011 relied upon by the petitioner neither the designation nor the address of the respondent No.1 is correct, as such, no reliance can be placed upon the said letter at this stage particularly, when the receipt of the said letter has been denied by the respondent No. 1. Whether the letter dated 20.12.2011 was sent to the respondent No. 1 at his correct address or not and further whether the same was received by the respondent No. 1 or not becomes a disputed question of fact and the same cannot be adjudicated by this Court while exercising jurisdiction under section 561-A (now 482) Cr.P.C and the petitioner will be well within its right to prove the fact of receipt of the letter dated 20.12.2011 by the respondent No.1 during the course of trial. The complaint was filed on 29.12.2011 before the learned trial court and the same cannot be said to have been filed just before the expiry of the shelf life of the drug in question particularly when the sample was lifted on 26.09.2011. Thus this contention is rejected.

12. The second contention raised by the petitioner is with regard to the testing protocol applied for conducting the analysis of the drug in question. As per the petitioner the drug in question was required to be tested by the government analyst, CFDL Jammu as per the

procedure prescribed under British pharmacopoeia 2010 (B. P.) and not as per Indian Pharmacopoeia. The petitioner has not denied that the drug in question i.e Naproxen is included in the Indian pharmacopoeia and has to be tested as per I.P protocol. Though Mr. Siddiqui in his written submissions has placed on record the material that provides that the testing protocols mentioned in the Indian pharmacopoeia and British pharmacopoeia are similar and has also placed reliance upon the article that provides that the comparative study reveals that Indian pharmacopoeia is on par with United States, British pharmacopoeia but without commenting upon the same, it requires to be noted that as per the mandate of section 25 (3) of the act, any document purporting to be a report signed by a Government Analyst shall be evidence of 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 18-A, has within 28 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 contravention of the report. As this Court has already rejected the prayer of the petitioner for considering the reply dated 20.12.2011 as exercise of the right by the petitioner demonstrating its intention to adduce evidence in contravention of the report in terms of section 25(3) of the Act, at this stage for the purpose of quashing of the criminal proceedings, therefore, as per the mandate of section 25 (3) of the Act, the report

of the government analyst CFDL Jammu is conclusive in nature and the petitioner can raise the said plea during the course of the trial. More so, serial No. 5 of the 2nd schedule of the Act provides the standards to be complied with for the drugs included in the Indian pharmacopoeia and as already noticed above the petitioner has not denied that the drug in question is not included in the Indian pharmacopoeia, as such, the 2nd contention of the petitioner too deserves to be rejected, leaving the petitioner free to raise the said issue before the trial court during the course of trial.

13. Both the contentions raised by the petitioner-company are squarely covered by the judgement of the Apex Court in **Glaxosmithkline Pharmaceuticals Ltd. v. State of M.P.,** reported in **(2011) 13 SCC 72,** where the Hon'ble Apex court has observed and held as under:

> "8. However, the law permits the drug manufacturer to controvert the report expressing his intention to adduce evidence to controvert the report within the prescribed limitation of 28 days as provided under Section 25(3) of the 1940 Act. In the instant case, the report dated 27-8-1997 was received by the statutory authorities who sent the show-cause notice to the appellants on 29-9-1997 and the appellants replied to that notice on 3-11-1997. The case of the statutory authorities is that option/willingness to adduce evidence to controvert the analyst's report was not filed within the period of 28 days i.e. limitation prescribed for it. The appellants are the persons who knew the date on which the show-cause notice was received. For the reasons best known to them, they have not disclosed the said date. It is a Company which must be having Receipt and Issue Department and should have an office which may inform on what date it has received the notice, and thus, should have made the willingness to controvert the report. In fact, such application had only been made on the technique adopted for analysis. It has

been the case that instead of testing the medicine under IP 1985, it could have been done under IP 1996 because IP 1996 had come into force prior to the date of taking the sample on 9-12-1996.

9. In view of the fact that the appellants did not express an intention to adduce evidence to controvert the analyst report within the statutory limitation period of 28 days, further delay in filing the complaint becomes immaterial. Even otherwise, expiry date of the medicine was March 1998 i.e. only after 4 months of submission of the reply by the appellants, and they did not fulfill their burden of expressing intention to adduce evidence in contravention of the report. Therefore, they cannot raise the grievance that the complaint had been lodged at a much belated stage. So far as the application of IP 1985 or IP 1996 is concerned, such an issue can be agitated at the time of trial."

14. In view of what has been said and discussed above, there is no merit in the petition and as such, the same is dismissed, leaving the petitioner free to raise the above issues before the trial court during the course of trial.

15. Disposed of.

**(Rajnesh Oswal)**
**Judge**

**JAMMU**
31.01.2022
Rakesh

Whether the order is speaking: Yes
Whether the order is reportable: Yes