IN THE HIGH COURT OF JAMMU & KASHMIR AND LADAKH
AT SRINAGAR

Reserved on: 12.10.2022
Pronounced on: 01.11.2022

CRMC No.169/2016

M/S SWISS GARNIER LIFE SCIENCES
AND OTHERS ... PETITIONER(S)

Through: - Mr. Prince Hamza, Advocate, vice Mr. M. Y. Bhat, Sr. Advocate.

Vs.

UNION OF INDIA …RESPONDENT(S)

Through: - Ms. Masooda Jan, Advocate.

CORAM: HON'BLE MR. JUSTICE SANJAY DHAR, JUDGE

JUDGMENT

1) The petitioners have challenged the complaint filed by respondent Drugs Inspector against them and the co-accused before the Court of Chief Judicial Magistrate, Srinagar, alleging commission of offences under Section 18(a)(i) read with Section 27(d) of the Drugs and Cosmetics Act, 1940.

2) It appears that on 26.04.2013, sample of a drug, namely, Zargo-50 (Losartan Potassium Tab IP) Batch No.BPSG12198, manufacturing date 10/2012, expiry date 9/2014, manufactured by petitioner No.1, was lifted from the premises of co-accused EFF AAY Traders Pharmaceutical Distributors House No.131, Nursingh Garh,

Srinagar, by the respondent Drugs Inspector. One portion of the sealed sample of the drug was sent to the Government Analyst i.e., Regional Drugs Testing Laboratory, Sector 39-C, Chandigarh, and vide report dated 26.06.2013, it was reported that the drug in question is of standard quality.

3) Vide order dated 10.09.2013, passed by a Division Bench of this Court in PILNo.6/2013 titled Dr. Nisar ul Hassan and another vs. State of J&K and Ors., general directions were issued that the samples collected by Drug Inspectors be sent to more than one laboratories for testing so as to dispel any impression of error or any other extraneous consideration. Accordingly, the respondent Drugs Inspector sent sample of the drug in question to Central Drugs Laboratory, Kolkata, for re-analysis through the court of Judicial Magistrate, 1st Class, Jammu. As per the test report issued by Central Drugs Laboratory, Kolkata, on 28.02.2014, the sample in question was found to be of not a standard quality. Accordingly, the prosecution was launched against the petitioners who happen to be the manufacturers of the drug in question and the co-accused by filing a complaint before the Court of Chief Judicial Magistrate, Jammu, which later on came to be presented before the Court of Chief Judicial Magistrate, Srinagar.

4) The petitioners have challenged the impugned complaint and the order passed by the learned Chief Judicial Magistrate, Srinagar, whereby process has been issued against them, on the grounds that the

manufacturer has a statutory right to controvert the report of the Government Analyst by adducing evidence but in this case said right of the petitioners has been violated. It has been contended that the respondent Drugs Inspector has not issued any notice to the petitioners under Section 23 and 25 of the Drugs and Cosmetics Act nor a portion of the sample was sent to the petitioners. It has been contended that the impugned complaint has been filed by the respondent Drugs Inspector at a time when there was no time left for the date of expiry of the drug in question and, as such, the petitioners had no opportunity of applying to the Court with a request for re-analysis of the sample. According to the petitioners, on this ground alone the prosecution is liable to be quashed in terms of the law settled by the Supreme Court on the issue. It has been contended that under the garb of the orders of the High Court, the statutory protection given to a manufacturer cannot be taken away. It is also contended that even otherwise the variation in the content of the drug in question is not of a significant nature as would make the drug spurious and, as such, it was not open to the respondent Drugs Inspector to launch prosecution against the petitioners.

5) I have heard learned counsel for the parties and perused the material on record including the trial court record.

6) There can be no dispute to the fact that that manufacturer of a drug has a statutory right to adduce evidence in controversion of the

report of the Government Analyst and he has to exercise this right within 28 days of receipt of copy of the report. Once this intension is notified by the manufacturer, the sample of the drug produced before the Magistrate has to be sent for testing or analysis to the Central Drugs Laboratory. There is no dispute to the legal position that if violation of this right has taken place because of the circumstances attributable to the prosecution, the prosecution against the accused manufacturer is liable to be quashed.

7) If we have a look at the facts of the instant case, as per the report of the Government Analyst, Chandigarh, the sample of the drug manufactured by the petitioners was found to be of standard quality. Thus, there was no occasion for the respondent Drugs Inspector to issue a notice to the petitioners in terms of sub-section (2) of Section 25 of the Drugs and Cosmetics Act which provides for furnishing of a copy of the report to the manufacturer or the person from whom the sample was taken. Since the sample was found to be of standard quality, as such, there was no occasion for the petitioners to notify their intension of adducing evidence in controversion of the report.

8) In the instant case after receipt of the report of the Government Analyst, Chandigarh, the sample was sent for re-analysis to Central Drugs Laboratory, Kolkata, under the directions of the High Court. The question that arises for consideration is as to whether in such circumstances, when the sample has been tested by the Central Drugs

Laboratory, a manufacturer or any other person has a right to seek a direction for re-analysis of the sample. In this regard it is necessary to have a look at the relevant provisions of the Drugs and Cosmetics Act, 1940. Sub-section (4) of Section 25 of the said Act provides for re-analysis of the sample after receipt of the Government Analyst's report. It reads as under:

> *(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 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.*

9) From a perusal of the aforesaid provision, it is clear that once a manufacturer or the person from whom the sample was taken notifies his intention of adducing evidence in controversion of the report of Government Analyst, the sample of the drug has to be sent for test or analysis to the Central Drugs Laboratory and once such report is received, the same becomes conclusive evidence of the facts stated therein. But the difficulty arises in a case where the sample has already been analyzed by the Central Drugs Laboratory. The provision begins with the expression "unless the sample has already been tested or analyzed in the Central Drugs Laboratory" meaning thereby that if

the sample has already been tested or analyzed in the Central Drugs Laboratory, the same cannot be sent for re-analysis again to the same laboratory or to any other laboratory. It is to be noted that in the instant case, the sample has been sent to Central Drugs Laboratory, Kolkata, pursuant to the directions of the High Court.

10) The question whether there is any bar to sending of sample of drugs directly to the Central Drugs Laboratory came up for consideration before the Supreme Court in the case of **Ram Shankar Misra vs. State of U.P,** (1980) 1 SCC255. The Court after interpreting the provisions contained in Section 25 (4) of the Act observed as under:

> *"4. The mode prescribed under Section 25(4) is one method of sending it to the Director of the Central Drugs Laboratory. The other method is by the Drugs Inspector sending it direct as contemplated under the first part of Section 25(1). It is significant that Sub-section (4) of Section 25 starts with the words "unless the sample has already been tested or analysed in the Central Drugs Laboratory." These words clearly indicate that apart from the mode prescribed in Section 25(4), the sample can be sent for analysis to the Central Drugs Laboratory."*

11) From the aforesaid ratio laid down by the Supreme Court, it is clear that there is no prohibition in the Act or the Rules barring the inspector from sending the sample directly to the Central Drugs Laboratory and, as such, the contention of the petitioners that by sending the sample to the Central Drugs Laboratory, Kolkata, in terms

of the Court directions is not in accordance with law, does not hold any merit.

12) Another question which falls for determination is as to whether the right of a person from whom the sample has been collected or of the manufacturer of the drug to adduce evidence in controversion of the report of Central Drugs Laboratory would get defeated and violated once the sample is sent directly for analysis to the said laboratory. This contention was raised before the Supreme Court in **Ram Shankar Misra's** case (supra). The Court repelled the said contention by observing as under:

> *"….The submission is that by sending the sample straight to the Director, Central Drugs Laboratory, Calcutta, the appellant was deprived of his right under Section 25(4) of requesting the Court to send the sample for analysis by the Central Drugs Laboratory. We do not see any substance in this contention. Section 25(1) deals with the reports of Government Analyst. Section 25(1) provides that the Government Analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form. The sub-section contemplates two modes of sending samples one by sending the drug for test or under Sub-section (4) of Section 23. There is no restriction as to how a sample of the drug or cosmetic has to be submitted by the Drugs Inspector. Section 25(4) contemplates sending of the sample through the Court. It provides that 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 Government Analyst's report 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 laboratory."*

13) In **Amery Pharmaceuticals and Another vs. State of Rajasthan,** (2001) 4 SCC 382, a contention was raised before the Supreme Court that non supply of one portion of the sample to the manufacturer, who was joined as an accused in the complaint, has resulted in depriving him of a valuable right to test the correctness of the report of the Government Analyst. It was submitted that the consequence of such non-supply was that the conclusiveness attached by law regarding the findings mentioned by the Government Analyst was lost and the report of the Government Analyst would not be binding on the manufacturer. It was argued that the conclusiveness of the report of the Government Analyst would nail the manufacturer with the findings in the report as he would otherwise be disabled from controverting the said findings because he had no right to challenge such findings due to the absence of a portion of the sample with him.

14) The Supreme Court dealt with the aforesaid contentions by observing as under:

> *"24. The extent of the implication of the words "such evidence shall be conclusive" as employed in Section 25(3) of the Act has to be understood now. Section 4 of the Evidence Act says that when one fact is declared by the said Act to be conclusive proof of another "the court shall, on proof of one fact, regard the other as proved, and shall not allow evidence to be given for the purpose of disproving it." The expression "conclusive evidence" employed in Section 25(3) of the Act cannot have a different implication as the legislative intention cannot be different. Such an import as for the word "conclusive" in the interpretation of statutory provisions has now come to stay. If so, what would*

happen if the manufacturer is disabled from challenging the facts contained in the document which would visit him with drastic consequences when he is arraigned in a trial. Any legal provision which snarls an indicted person without affording any remedy to him to disprove an item of evidence which could nail him down cannot be approved as consistent with the philosophy enshrined in Article 21 of the Constitution. The first effort which courts should embark upon in such a situation is to use the power of interpretation to dilute it to make the provision amenable to Article 21.

25. In our view the court should lean to an interpretation as would avert the consequences of depriving an accused of any remedy against such evidence. He must have the right to disprove or controvert the facts stated in such a document at least at the first tier. It is possible to interpret the provisions in such a way as to make a remedy available to him. When so interpreted the position is thus: The conclusiveness meant in section 25(3) of the Act need be read in juxtaposition with the persons referred to in the sub-section. In other words, if any of the persons who receives a copy of the report of the Government Analyst fails to notify his intention to adduce evidence in controversion of the facts stated in the report within a period of 28 days of the receipt of the report, then such report of the Government Analyst could become conclusive evidence regarding the facts stated therein as against such persons. But as for an accused, like the manufacturer in the present case, who is not entitled to be supplied with a copy of the report of the Government Analyst, he must have the liberty to challenge the correctness of the facts stated in the report by resorting to any other modes by which such facts can be disproved. He can also avail himself of the remedy indicated in sub-section (4) of Section 25 of the Act by requesting the court to send the other portion of the sample remaining in the court to be tested at the Central Drugs Laboratory. Of course, no court is under a compulsion to cause the said sample to be so tested if the request is made after a long delay. It is for that purpose that a discretion has been conferred on the court to decide whether such sample should be sent to the Central Drugs Laboratory on the

> *strength of such request. However, once the sample is tested at the Central Drugs Laboratory and a report as envisaged in Section 25(4) of the Act is produced in court the conclusiveness mentioned in that sub-section would become incontrovertible."*

15) The Supreme Court further went on to observe as under:

> *"When the provision can be interpreted in such a way as to avert absurd consequences in the manner indicated above it is not congenial to the interest of criminal justice to acquit the manufacturers of forbidden medicines or drugs on a technical ground that there is a lacuna in the legislation by not supplying copy of the report of the Government Analyst to the manufacturer in certain situations. To adopt the course of acquitting such offending manufacturers only on the legislative lacuna (if at all it is lacuna) would be hazardous to public health and the lives of the patients to whom drugs are prescribed by medical practitioners would be in jeopardy. Hence, when the legislative provision is capable of being interpreted as we did now, the courts need not feel helpless in administering criminal justice in accordance with the objects sought to be achieved by the statute.*

16) From the foregoing analysis of law on the subject, it is clear that while a manufacturer has a valuable right of getting the sample re-tested/re-analyzed by the Central Drugs Laboratory so as to adduce evidence in controversion of the report of the Government Analyst but once the sample has been tested by the Central Drugs Laboratory, there is no occasion for sending the sample again for testing to the same laboratory. It has been further laid down by the Supreme Court in the aforequoted judgment, that the conclusiveness meant in Section 25(3) of the Act has reference to the person referred to in the said sub-section, meaning thereby that the facts stated in the report of the Government Analyst would become conclusive only against the person who despite having been provided a copy of the report, has

failed to notify his intention to adduce evidence regarding facts stated therein within a period of 28 days. This conclusiveness of the facts stated in the report would not come into play in a case where the manufacturer or any other person has either not been provided the copy of the report or where such manufacturer or person had no occasion to notify his intention to adduce evidence in controversion of the report. In view of the above, the question whether in a particular case, conclusiveness is to be attached to the report of the Central Drugs Laboratory and whether valuable right of a manufacturer to adduce evidence in controversion of the report would get violated in a particular case depends upon the facts and circumstances peculiar to that case.

17) In case, like the present one, the manufacturers/petitioners were not provided the copy of the report of the CDL, Kolkata, or if at all the same was provided, the petitioners/manufacturers could not ask for reanalysis of the sample as the same had already been tested by Central Drugs Laboratory. Therefore, the report would not be conclusive against the petitioners. The petitioners would be at liberty to adduce evidence in controversion of the said report before the trial court. In these circumstances no prejudice has been caused to the petitioners even if the complaint has been filed when the shelf life of the drug in question was due to expire or because in the circumstances explained hereinbefore, they could not seek reanalysis of the sample

of the drug in question. The report of the CDL, Kolkata, as already stated, in the facts and circumstances of the case is not conclusive against the petitioners and they have a right to controvert the same by leading evidence before the trial court. However, the fact that the petitioners herein are disabled from seeking reanalysis of the sample, in the facts and circumstances of the instant case, does not offer a ground to question the proceedings against them.

18) Apart from the above, the principle that right to adduce evidence against the report of the Government Analyst is violated can be applied to cases where conduct of the prosecution has resulted in denial of opportunity to the manufacturer to exercise this right. Different considerations would arise if the right gets frustrated for the reasons for which the prosecution is not responsible.

19) In the instant case, the sample was sent to Central Drugs Laboratory under the directions of the High Court. The first report of the Government Analyst was in favour of the petitioners, as such, there was no occasion for the respondents to invite the petitioners to adduce evidence in controversion of the said report. Once the report of the Central Drugs Laboratory was received, there was no provision for the re-analysis of the sample and, as such, the respondent Drugs Inspector had no obligation to give opportunity to the petitioners to adduce evidence in controversion of the said report. So, it is not a case where the prosecution is to be blamed for not providing an

opportunity to the petitioners to seek reanalysis of the sample. The contention of the petitioners that their aforesaid right has been violated due to the reasons attributable to the prosecution. is without any merit.

20) It has been contended by the petitioners that even as per the report of the CDL, Kolkata, variation in the content of the drug in question is not of such significance as would entail criminal prosecution of the petitioners. In this regard, it is to be noted that the question whether the variation in the content of the drug was of significant nature or otherwise is a matter of trial and the same can be determined only after examining the expert who has analyzed the sample of the drug. This Court cannot act as an expert to determine this question in these proceedings.

21) For the foregoing reasons, I do not find any merit in this petition. The same is, accordingly, dismissed.

22) The trial court record along with copy of this judgment be sent to the trial court.

(SANJAY DHAR)
JUDGE

Srinagar,
01.11.2022
"Bhat Altaf, PS"

Whether the order is speaking: ***Yes/No***
Whether the order is reportable: ***Yes/No***