

HIGH COURT OF TRIPURA

A_G_A_R_T_A_L_A_

Crl. Rev. P. No.49 of 2024

Maman Chand Jain and Another

.....Petitioners

_V_E_R_S_U_S_

The State of Tripura & Another

.....Respondents

For Petitioner(s) : Mr. P. Roy Barman, Sr. Advocate.
Mr. K. Chakraborty, Advocate.
Mr. K. Nath, Advocate.
For Respondent(s) : Mr. S. Ghosh, Addl. P.P.
Whether fit for reporting : YES

HON'BLE MR. JUSTICE T. AMARNATH GOUD

_F_I_N_A_L_O_R_D_E_R_

22.07.2024

Heard Mr. P. Roy Barmna, learned senior counsel assisted by Mr. K. Chakraborty, learned counsel appearing for the petitioners also heard Mr. S. Ghosh, learned Addl. P.P. appearing for the respondents.

[2] The present petition has been filed under Section-397 & 401 of the Code of Criminal Procedure, 1973 challenging the legality, correctness and propriety of the impugned order dated 26.04.2024 passed by the learned Special Judge, West Tripura, Agartala, in case No. Special (DC) 01 of 2013 whereby, prayer of the petitioners to discharge them was rejected.

[3] The facts in brief are that on 20.11.2013, the Inspecting Officer (Drugs) filed the connected Complaint, marked as Special (DC) 01 of 2013, before the learned Special Judge (District & Sessions Judge), West Tripura, Agartala, under Sections 36-AD & 36-AC of the Drugs and Cosmetics Act, 1940, read with Section-200 of the Code of Criminal Procedure, 1973, and sought for taking cognizance against the petitioners herein, under the aforesaid provisions. Vide an order dated 01.08.2022, passed by the Hon'ble High Court of Himachal Pradesh, passed in Criminal Misc. Petition (Main) No. 433 of 2019, the manufacturing License of the petitioners was held to be valid.

[4] Thereafter, vide an order dated 24.04.2023, passed by the Hon'ble Supreme Court of India in SLP (Crl.) No.9303/2023, the said order dated 01.08.2022 was affirmed. On 18.03.2024, the petitioners prayed for discharge in

connection with Special (DC) No. 01 of 2013, before the learned Special Judge, West Tripura, *inter alia* on the ground of initiation of the connected proceeding in non-conformity with Sections-23 & 25 of the Drugs and Cosmetics Act, 1940. The learned Special Judge, West Tripura thereafter passed the impugned order dated 26.04.2024, thereby rejecting the prayer of the petitioners for discharge.

[5] Hence, the present petition has been filed by the petitioners before this Court for redress.

[6] Mr. P. Roy Barman, learned senior counsel assisted by Mr. K. Chakraborty, learned counsel appearing for the petitioner has submitted that while passing the impugned order dated 26.04.2024, the learned Special Judge, West Tripura, Agartala has committed manifest error of law in failing to appreciate that the issue regarding non-possession of a valid manufacturing licence by the petitioners has already been settled concurrently, conclusively and authoritatively in their favour by the Hon'ble High Court of Himachal Pradesh and subsequently by the Hon'ble Supreme Court holding that they had valid manufacturing licence. The purported complaint cannot be sustained being baseless and hence the same is liable to be quashed and set aside.

[7] The allegations made against the petitioners are untenable inasmuch as the petitioners' firm had duly supplied the drugs, after the same were tested by a Government approved and appointed analyst at the State Drug Testing Laboratory. Upon a second testing carried out at the Regional Drug Testing Laboratory made in the absence of the petitioners behind their back a second report was prepared holding that the concerned drugs supplied by the petitioners firm were found to be spurious and not of standard quality.

[8] It has been further contended that the sample was taken by the Inspecting Officer (Drugs) from the Pharmacist-in-Charge, Central Medical Store, Director of Health Services, Govt. of Tripura but no sample thereof was provided to the petitioners which was mandatory as per the provisions of Section 23(4)(iii) of the Drugs and Cosmetics Act, 1940. Furthermore, the report prepared by the government analyst was never supplied to the petitioners. Thus, their valuable vested rights, under the Drugs and Cosmetic Act, 1940 were violated by the respondents herein. Therefore, it is clearly a case, where the petitioners were deprived of the opportunity of exercising their right to have the samples examined

by independent laboratory. As such, the complaint is vitiated by this circumstances of denial of the valuable rights to the petitioners, guaranteed by the Drugs and Cosmetic Act, 1940.

[9] The shelf life of the samples has already expired now, as such, it would be impossible to get the samples re-tested before any other laboratory. Resultantly, the petitioners have lost their valuable right to controvert the report of the government analyst which cannot be conclusive in view of non-conforming with the procedures as stipulated under Section-25 of the Drugs and Cosmetics Act, 1940. M/s Vardhaman Pharma is a reputed distributor and wholesale supplier of home use medical devices, surgical items, medical consumables, healthcare products and medicines. The firm has been in business for more than 15 years and has a diverse supplier base ranging from high end branded devices to an affordable solution without compromising on quality. The firm provides supplies and services to government and semi government hospitals, corporate hospitals and medical store. Thus, it is submitted that the connected complaint is nothing but to malign the reputation and good will of the petitioners, who are suffering a cascading effect of such complaint being filed against them in other States as well.

[10] The law laid down by the Hon'ble Supreme Court in number of cases that the accused is required to be granted the right of getting the drug re-tested from another laboratory to controvert the report of government analyst and this retesting is to be done during shelf life of the drugs in question. In similar cases, the Apex Court has quashed the criminal proceedings in the said cases, in which the shelf life of the sample drugs had expired, where the fresh testing of the samples could not be done. Thus, the connected complaint is liable to be quashed and set aside.

[11] Nowhere in the entire complaint it discloses that the report of government analyst was sent and received by the manufacturer or anyone else. It is a matter of record that no report of the government analyst was ever received by the petitioners at any state. At this juncture, reference may be made to Section-23 of the Drugs and Cosmetics Act, 1940, prescribing for the procedure for collection of samples, which reads as under:

“(1) Where an Inspector takes any sample of a drug or cosmetic under this Chapter, he shall tender the fair price thereof and may require a written acknowledgement therefor.

(2) Where the price tendered under sub-section (1) is refused or where the Inspector seizes the stock of any drug or cosmetic under clause (c) of section 22, he shall tender a receipt therefore in the prescribed form.

(3) Where an Inspector takes a sample of a drug or cosmetic for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked:

Provided that where the sample is taken from premises whereon the drug or cosmetic is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that where the drug or cosmetic is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug or cosmetic be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:-

(i) One portion or container he shall forthwith send to the Government Analyst for test or analysis;

(ii) The second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug or cosmetic; and

(iii) The third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.”

[12] Furthermore, Section-25 of the Drugs and Cosmetics Act, 1940 statutorily mandates that a copy of the government analyst report shall be provided to the manufacture, which reads as under:

“(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.”

[13] Therefore, it is the case of the petitioners is that having a valid licence under Drugs and Cosmetics Act, 1940 and conducting the business strictly in accordance with law and to his surprise a case has been registered on 20.11.2013 by the inspecting officer under the said Act and thereafter, the sample has been drawn and therefore the case was under trial. The learned Court below by order dated 26.04.2024 dismissed the application made by the petitioners seeking to discharge them since the allegation of having no licence is already decided by the Hon'ble High Court of Himachal Pradesh and the same has attained finality vide an order dated 24.04.2023, passed by the Hon'ble Supreme Court of India.

[14] It is also their case on the factual issue regarding drawing of samples, the learned counsel has insisted upon the manner in which the officers have registered the case by drawing the samples under Sections-23 & 25 of the Drugs and Cosmetics Act. Sufficient samples were not drawn as per the Act and more so, opportunity of getting the samples tested was not provided and also the reports were not furnished to the petitioners.

[15] Finally, it is pointed out that there was no necessary for cross-examination on the framing of charge and relied on (i) Criminal Appeal No.483 of 2008 decided on 13.03.2008 titled as Medicamen Biotech Ltd. and Others v. Rubina Bose (ii) Criminal Appeal No.364 of 2017, titled as Laborate Pharmaceuticals India Ltd. and Others v. State of Tamil Nadu and (iii) Municipal Corporation of Delhi v. Ghisa Ram reported in (1967) 2 SCR 116.

[16] In *Municipal Corporation of Delhi v. Ghisa Ram* reported in (1967) 2 SCR 116, the testing of samples was dealt with by Section-13 of the Prevention of Food Adulteration Act, 1954 the Hon'ble Apex Court observed thus:

“There can be no doubt that sub-s. (2) of S. 13 of the Act confers a right on the accused vendor to have the sample given to him examined by the Director of the Central Food Laboratory and to obtain a certificate from him on the basis of the analysis of that sample. It is when the accused exercises this right that a certificate has to be given by the Director of the Central Food Laboratory and that certificate then supersedes the report given by the Public Analyst. If, in any case, the accused does not choose to exercise this right, the case against him can be decided on the basis of the report of the Public Analyst.

..... In the present case, we find *that the decomposition of the sample, which the respondent desired should be analyzed by the Director of the Central Food Laboratory, took -place because of the long delay that had occurred in sending the sample to the Director.

..... It appears to us that when a valuable right is conferred by S. 13 (2) of the Act on the vendor to have the sample given to him analyzed by the Director of the Central Food Laboratory, it is to be expected that the prosecution will proceed in such a manner that that right will not be denied to him. The right is a valuable one, because the certificate of the Director supersedes the report of the Public Analyst and is treated as conclusive evidence of its contents. Obviously, the right has been given to the vendor in order that, for his, satisfaction and proper defence, he should be able to have the sample kept in his charge analyzed by a greater expert whose certificate is to be accepted by Court as conclusive evidence In a case where there is denial of this right on account of the deliberate conduct of the prosecution, we think that the vendor, in his trial, is so seriously prejudiced that it would not be proper to uphold his conviction on the basis of the report of the Public Analyst, even though that report continues to be evidence in the case of the facts contained therein.

[17] In *Medicamen Biotech Ltd. v. Rubina Bose, Drug Inspector* reported in (2008) 7 SCC 196, the Hon'ble Apex Court observed thus:

“13.....A reading of the aforesaid provisions would reveal that they lay certain obligations as well as provide safeguards for a person from whom a drug has been seized for analysis or testing as Section 25(3) specifies that unless such a person controverts the correctness of the report submitted by the Government Analyst within 28 days in writing that he intends to adduce evidence to controvert the report of the Analyst, it would be deemed to be conclusive evidence of the quality of the drug whereas sub-section (4) of Section 25 obliges the Magistrate on the request of the complainant or the accused or on in his own motion to send the fourth sample which has been disputed for fresh testing to the Director of the Central Drugs Laboratory.

.....19. In the affidavit filed to the petition by Dr. D. Rao, Deputy Drugs Controller, and in arguments before us, it has been repeatedly stressed that the delay in sending of the sample to the Central Drugs Laboratory had occurred as the appellant had avoided service of summons on it till 9th May 2005. This is begging the question. We find that there is no explanation as to why the

complaint itself had been filed about a month before the expiry of the shelf life of the drug and concededly the filing of the complaint had nothing to do with the appearance of the accused in response to the notices which were to be issued by the Court after the complaint had been filed. Likewise, we observe that the requests for retesting of the drug had been made by the appellant in August/September 2001 as would be clear from the facts already given above and there is absolutely no reason as to why the complaint could not have been filed earlier and the fourth sample sent for retesting well within time. We are, therefore, of the opinion that the facts of the case suggest that the appellants have been deprived of a valuable right under Section 25(3) and 25(4) of the Act which must necessitate the quashing of the proceedings against them.

[18] Similarly in the case of *Laborate Pharmaceuticals India Ltd. v. State of Tamil Nadu*, reported in (2018) 15 SCC 93, the Hon'ble Apex Court held as under:

“7. The cognizance of the offence(s) alleged in the present case was taken on 4th March, 2015 though it appears that the complaint itself was filed on 28th November, 2012. According to the appellant the cough syrup had lost shelf life in the month of November, 2012 itself. Even otherwise, it is reasonably certain that on the date when cognizance was taken, the shelf life of the drug in question had expired. The Magistrate, therefore, could not have sent the sample for reanalysis by the Central Laboratory.

8. 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.”

[19] Per contra, Mr. S. Ghosh, learned Addl. P.P. appearing for the respondents has submitted before this Court that the petitioners have not approached before this Court with clean hands and on the same facts the petitioners had approached this Court on earlier round of litigations and they could not succeed and even in this revision petition there are several disputed questions of fact. The learned Court below has not committed any error and needs no interference and prayed to dismiss the same and direct the petitioners to face the trial.

[20] Admittedly, It is seen from the record that the case has been registered on two points i.e. on the point of having no valid licence; and it is seen

from the evidence of the officers before the trial Court that the documents regarding certain certificates of licence are fake. Insofar as drawing of the samples is concerned, number of opportunities were given to the petitioners by sending the same on different occasions to the address given by way of registered post but, the same could not be received as the addressee was not found and in view of the same it cannot be said that the Inspecting Officers have not given opportunity to the petitioners for collecting the relevant documents and also samples as contemplated under the Act. For the purpose of reference, relevant portions of the above discussed issues [Annexure-7] may be reproduced hereunder:

“That, 08(eight) samples of Drugs manufactured & supplied by said Vardhman Pharma, to Govt. of Tripura were drawn under provisions of the Drugs & Cosmetics Act, 1940, & Rules made there under from Central Medical Store, Agartala on 22/04/2013 (Copies of Form-17 are at Annexure-2). The said samples of Drugs were sent in Forms 18 to the Regional Drugs Testing Laboratory, Govt. of India, Guwahati for test or analysis under provisions of the Drugs & Cosmetics Act, 1940 & Rules there under (Copies of Form-18 at Annexure-3).

That, Govt. Analyst, Regional Drugs Testing Laboratory, Guwahati, sent the test reports in Form-13 of the said 08(eight) samples of Drugs declaring six samples as "Not of Standard Quality" and two samples declared as "Not of Standard Quality & Spurious Drugs". (Copies of Form-13 at Annexure-4).

That, on receipt of the said test reports, the respective Pharmacist in- charge, Central Medical Store, Govt. of Tripura, Agartala (from where the samples were drawn) were informed under Drugs & Cosmetics Act, 1940 & Rules there under to disclose the name & address of the manufacturer and supplier of the aforesaid samples of drugs to Central Medical Store, Govt. of Tripura Agartala vide letter dated 31/07/2013, 02/08/2013, 05/09/2013 & 08/10/2013 of Inspecting Officer Drugs, Agartala. (Copies of letters at Annexure-5).

That, the Pharmacist in charge, Central Medical Store, Govt. of Tripura, Agartala, informed the undersigned vide their letter, dated 02/08/2013, 03/08/2013, 06/08/2013, 09/09/2013 & 15/10/2013 that the said samples of Drugs were supplied by said Vardhman Pharma vide challan/ invoice No. 1289 dt.-10/11/2012, 1290 dt.-10/11/2012, 1304 dt.-02/12/2012, 1395 dt. 20/12/2012, 1394 dt. 20/12/2012, 1304 dt. 02/12/12, 1305 dt. 02/12/12 & 1392 dt. 20/12/2012 (Copies of letters at Annexure-6 & challan at Annexure 7).

That, as per provision of Drugs & Cosmetics Act, 1940 & Rules there under, a part of each of the Six samples of the aforesaid Drugs were sent to said Vardhman Pharma at its administrative address based at Haryana with a letter informing to explain reasons as to why necessary action should not be taken against the said firm for violation of the provisions of Drugs & Cosmetics Act, 1940, & Rules there under, by Registered Parcel vide letter No.F.DCA/IOD (11-7)/2013/Sub-1/ 2304-05, 2306-07, 2308- 09,2310-11 dated-16/08/2013 of the undersigned. But the said Registered Parcel was returned to the undersigned by postal Department with a remark "Left with Lock" in the first instance. Then the said parcel was again sent to the manufacturing address of the firm based at Himachal Pradesh vide letter dated 13/09/2013 of the undersigned. This was also again returned by postal Department with the remark "closed". (Copies of letters at Annexure-8). One part each of

remaining two samples were also sent to the said Vardhman Pharma, based it's address in H.P. vide registered parcel letter dated 13/09/2013 & 30/10/2013. Out of which the parcel dated 13/09/2013 was returned by postal Dept. without any remark & the fate of the other parcel sent on 30/10/2013 is yet to be known.

Dy. Drugs Controller, Govt. of Tripura sent to me copies of two letters vide No. HFW-H(Drugs) 248/04-4075, dated 22/10/2013 of Drug Licensing Authority, Himachal Pradesh, wherein the Constitution of the firm was known & letter No. NHN/Drugs/13/212 dated 07/10/2013 of Drugs Inspector of Himachal Pradesh from where it is known that, Manufacturing Drug Licence of the said Vardhman Pharma was not renewed after 2009, i.e., validity of the said Manufacturing Licence was up to 2009 (09/12/2009). (Copies of letters at Annexure-9).

That, the said Vardhman Pharma at the time of submission of tender to the Director of Health Services, Govt. of Tripura, during the year 2012-13 submitted a document purported to be issued by Drug Control Department, Himachal Pradesh, showing that, the Manufacturing Drug Licence of the said Vardhman Pharma was valid up to 2014, which is fabricated & false as per official letter dated 07/10/2013 of Drugs Inspector of Himachal Pradesh. (Copies at Annexure-10). The said accused persons of Vardhman Pharma manufactured drugs for sale or sell or distribution, without any valid drug licence, violating Sec-18(c) of the said act thus punishable under section 27(b)(ii) of the said act."

[21] However, if the petitioners feel that there is gross violation of certain procedural irregularities and the petitioners is having valid licence; it is open for them to place all relevant documents in support of their case during the trial. The judgments as cited above are not relevant to the facts and circumstances of the case as the present case on hand is at premature stage. This Court cannot appreciate the evidentiary value of the documents.

[22] In view of the above, the present petition stands dismissed. As a sequel, miscellaneous application pending, if any, shall stand closed.

T. AMARNATH GOUD, J

A. Ghosh

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