IN THE HIGH COURT OF JHARKHAND AT RANCHI
Cr.M.P. No. 1870 of 2011

M/s Aventies Pharma Limited through its C & F Agent and Authorized Signatory Mr. Ajit Kumar Agrawal son of Sri C.P. Agrawal resident of Rameshwaram, Bariyatu Road, P.S. Bariyatu, District- Ranchi having its registered office at 54/1 Sir Mathura Das basanji Road, Chakla, Andheerej (East), P.O. and P.S. Andheri, Mumbai …… Petitioner

Versus

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1.The State of Jharkhand
2. State Drug Inspector, Jharkhand, Namkoom, P.O. and P.S. Namkoom, District-Ranchi
3. State Drug Controller and Licensing Authority, Jharkhand, P.O. and P.S. Namkoom, District-Ranchi

…… Opposite Parties

CORAM: HON'BLE MR. JUSTICE SANJAY KUMAR DWIVEDI

For the Petitioner : Mr. Indrajit Sinha, Advocate (Through V.C.)
Mr. Akshat Hansaria, Advocate(Through V.C.)
Mrs. Jyoti Nayan, Advocate
For the State : Mr. Shailesh Kumar Sinha, A.P.P.

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C.A.V. on 28/02/2024 **Pronounced on: 05/03/2024**

Heard Mr. Indrajit Sinha and Mr. Akshat Hansaria (through Video Conferencing) and Mrs. Jyoti Nayan, learned counsels for the petitioners, and Mr. Shailesh Kumar Sinha, learned counsel for the State.

2. The present petition has been filed for quashing of entire criminal proceeding including order taking cognizance dated 15.10.2008 passed in Complaint Case No. C/III-188/2008 wherein cognizance has been taken under section 27(d) of the Drug and Cosmetics Act, 1940, pending in the Court of learned Chief Judicial Magistrate, Ranchi.

3. The Complaint Case has been filed alleging therein that the Drugs Inspector, Ranchi under Letter No. 3/6 dated 8th March, 2008 forwarded copies of the Test Reports Nos. NW/6430, 6433 and 6436 of the Government Analyst working in the Central Drug Laboratory, Kolkata by which samples of Ofloxacin Infusion of Batch No. 237007, 236015 and 236019 manufactured by the petitioner-company were alleged to have been found not of standard quality

4. Mr. Indrajit Sinha, learned counsel for the petitioner through Video Conferencing submitted that the petitioner has its regional offices at Delhi, Mumbai, Chennai, Kolkata, Hyderabad and Lucknow. The petitioner had necessary wholesale licenses dated 28th August, 2001 in Form-20B and 21B for sale of Drugs by way of wholesale in the State of Jharkhand. He further submitted that that the petitioner-company is manufacturing 130 products under its various licenses, one of which is Tarivid, I.V, 100 ml. According to him, it is an anti infective infusioin administered intravenously and contained Ofloxacin as an active ingredient. He further submitted that the said product is packed in glass bottles or vials of 100 ml containing 200 mg of Ofloxacin with Aluminium seal and dark green flip-off seals packed in pre-printed carton provided with plastic hanger and package insert. He further submitted that the petitioner-company is manufacturing Tarivid I.V.100 ml since 1998 initially at the petitioner's own then existing plant at Mulund, Mumbai and thereafter the same was shifted to its external manufacturing site at M/s. Wintac Ltd. Bangalore under a loan license arrangement under the said Act and Rules. According to him there is not a single instance of failure of the said product in the past and the petitioner has not received any quality complaint from the market or from any doctor or hospital. In this background he submitted that the Drugs Inspector, lodged the complaint case which is without following the due procedure of Drugs and Cosmetics Act, 1940. He submitted that by letter dated 14.03.2008 the petitioner informed the said Drugs Inspector that control samples of three batches were tested by the petitioner in its laboratory and were found to be of standard quality with the contents of Ofloxacin within the permissible limits and in view of that the petitioner has controverted the findings of the Government Analyst recorded in the report of the Government. By way of referring Annexure-3 he submitted that by letter dated 01.04.2008 the Drug Inspector, Ranchi informed the petitioner that he had taken only one

vial of each batch for the purpose of test and analysis and in view of that counterpart was not available with the Drug Inspector and in view of that he submitted that Section 23 of the Drugs & Cosmetics Act, 1940 was not followed. He further elaborated his argument by way of submitting that the Drug Inspector has not tendered the fair price or any price of the sample, thus violated the provision of Section 23(1) of the said Act and he has not tendered any receipt in the prescribed forma and thus violated the provision of 23(2) of the said Act. Further he has not divided the sample into four parts or sealed or marked the same and not allowed the persons from whom the vial is alleged to have been taken to put his seal or mark and thus violated Section 23(3) of the Act. He further submitted that the petitioner has been deprived of valuable right under section 25 (4) of the Act as in absence of supply of sample the petitioner has not been able to challenge the same. He submitted that if the said procedure of sections 23 and 25 are not followed the valuable right of the petitioner was not allowed to be exercised and in view of that no fair trial can take place and to buttress this argument, he relied in the case of ***"T. Nagappa V. Y.R. Muralidhar" reported in (2008) 5 SCC 633***. He referred to para 8 of the said judgment which is quoted hereinbelow:-

> *"8. An accused has a right to fair trial. He has a right to defend himself as a part of his human as also fundamental right as enshrined under Article 21 f of the Constitution of India. The right to defend oneself and for that purpose to adduce evidence is recognised by Parliament in terms of sub-section (2) of Section 243 of the Code of Criminal Procedure, which reads as under:*
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> *"243. Evidence for defence. (1)*
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> *(2) If the accused, after he has entered upon his defence, applies to the Magistrate to issue any process for compelling the attendance of any witness g for the purpose of examination or cross-examination, or the production of any document or other thing, the Magistrate shall issue such process unless he considers that such application should be refused on the ground that it is made for the purpose of vexation or delay or for defeating the ends of justice and such ground shall be recorded by him in writing:*
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> *Provided that, when the accused has cross-examined or had the h opportunity of cross-examining any witness before entering on his defence, the attendance of such witness, shall not be compelled under this section unless the Magistrate is satisfied that it is necessary for the ends of justice."*

5. Relying on the aforesaid judgment, Mr. Sinha, learned counsel for the petitioner submitted that for non compliance of the aforesaid sections, the valuable right of defence of the petitioner is jeopardized and in view of that fair trial is not possible. On these grounds, he submitted that the entire criminal proceeding may kindly be quashed.

6. On the other hand, Mr. Shailesh Kumar Sinha, learned counsel for the State submitted that proclamation without any related evidence for not receiving any quality complainant from the market or any doctor or hospital does not prove the innocence of the petitioner as it is clear that a sub-standard drugs is manufactured, distributed and sold by the petitioner's firm. He further submitted that the control sample have been always kept under the full control of the accused person at manufacturing units hence generating report from the control sample it its own laboratory is not relevant in this case because it is clear fact that the Drugs Tarivid I.V 100 ml B. No. 237007, Tarivid I.V 100 ml B. No. 236015 and Tarivid I.V 100 ml B. No. 236019 was declared not of standard quality by Central Drugs Laboratory, Kolkata which is designated appellate laboratory under the Drugs and Cosmetics Act, 1940. He further elaborated his argument by way of submitting that the information was received from the Director, Rajendra Institutes of Medical Sciences, Bariatu, Ranchi regarding the reaction of the drug observed in a patient who was treated with Travid I.V (Ofloxacin Infusion), B. No. 237007 manufactured by the petitioner's company. He further submitted that Drug Inspector consisting of Mr. Arun Kumar, Arun Kumar, Former Drugs Inspector, Ranchi and Mr. Sujit Kumar former Drugs Inspector, inspected the firm M/s Rohit Medical Hall, Bariatu Chowk, Ranchi and M/s Maa Kali Medical Hall, Bariatu Chowk, Ranchi on 03.08.2007 under section 22 and section 23 of the Drugs and Cosmetics Act, 1940 During the inspection, Drugs Inspector took the sample of Travid I.V (Ofloxacin Infusioin), B. No. 237007 in the prescribed form 17 and divided into

four parts in compliance of the provision of Section 23 of Drugs and Cosmetics Act, 1940 from Mr. Sunil Prasad, Proprietor of Maa Kali Medical Hall, Bariatu Ranchi, one sealed portion of the sample had been handed over to Mr. Sunil Prasad the person from whom the drug samples had been taken and remaining three sealed portions, one sealed drug sample sent to the Government analyst for test and analysis and second portion sealed drug sample had handed over to Mr. Sushil Kumar Dorolia, Proprietor of M/s Dorolia Distributor, Ranchi in compliance with section 23 (4) (iii) of the Drugs and Cosmetics Act, 1940 and third and last portion of sample had remain kept in compliance with Section 23 (4) (ii) of the Drugs and Cosmetics Act, 1940. In these back grounds he submitted that this compliance of procedure under section 23 of the Drugs and Cosmetics Act, 1940, was followed. He further submitted that the sufficient quantity divided into four parts as required under Drugs and Cosmetics Act, 1940 were not sufficient and all the collected samples were sent to the Government Analyst, Central Drugs Laboratory, Kolkata.

7. Further the medicine was taken from the shop which was sufficient quantity which was divided into four parts and in view of that Section 23 of the Drugs and Cosmetics Act, 1940 was complied with. He submitted that serious allegation of reaction of the said drug was there by none other than a Government institution namely, Director of Rajendra Institute of Medical Sciences, (RIMS), Ranchi. He further submitted that once the seal of bottle is broken to divide into four portions the product will fail to retain its sterility and ultimately the quality. He further submitted that the petitioner never adduced evidence in contravention of Government Analyst Report before the stipulated time limits i.e 28 days in front of a Drugs inspector or the designated court before the expiry of Drugs Samples as the photocopy of the letter dated 28.05.2008 issued by the M/s Sanofi Aventis (petitioner's firm) does not contain

any statement regarding adducing evidence in contravention of the test report issued by the appellate authority. Hence, the provision of section 25(3) and Section 25(4) are not attracted in this case. He further submitted that these are disputed question of fact which can be settled in the trial only. He further submitted that the petitioner has already filed his discharge petition dated 25.02.2019 which is pending. On these grounds, he submitted that case is fit to be rejected.

8. Admittedly, the dispute is there with regard to the sample of Ofloxacin Infusion of Batch No. 237007, 236015 and 236019. The said samples were collected pursuant to the complaint made by the Director, Rajendra Institute of Medical Science (RIMS), Ranchi which was examined by the Government Analyst, Kolkata and report is annexed with the complaint petition by the Drug Inspector. What has been noted in the argument of the learned counsel for the State that why the initial sample was not divided into four parts is the matter which can be appreciated in the trial however, it was divided into four parts after collecting from the concerned Shopkeeper namely, M/s Rohit Medical Hall, Bariatu Chowk, Ranchi and M/s Maa Kali Medical Hall, Bariatu Chowk, Ranchi and if such disputed question of fact is there as to whether standard was followed by the government analyst while conducting analysis of drugs can be agitated during trial and all these aspects have been considered by the Hon'ble Supreme Court in the case of ***"Glaxosmithkline Pharmaceuticals Limited and Another Vs. State of Madhya Pradesh"*** reported in ***(2011) 13 SCC 72*** wherein para 8, 9, 12 to 14 the Hon'ble Supreme Court has 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 fulfil 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.

12. It is pertinent to mention herein that the present appellants had earlier also been informed by the Drug Inspectors of various cities on many occasions that the aforesaid medicine i.e. Betnesol tablet, was not of standard quality and the authorities had been making an attempt to initiate proceedings against them as is evident from the pleadings taken by the appellants themselves and the letter dated 1-7-1996 (Annexure P-9) wherein the appellant Company wrote a letter to the Controller, Food and Drug Administration, Madhya Pradesh. The relevant part thereof reads as under:

> *"During the past one month we have received requests from the Drug Inspectors of Dhar, Rewa, Seoni and Ambikapur all under your kind control, to provide memorandum of articles of association, constitution, etc. of our Company to initiate action for manufacturing Betnesol tablets Batch No. NA 660, Mfd. December 1992, Expiry May 1994; NB 290, Mfd. November 1994, Expiry April 1996; NB 538, Mfd. May 1995, Expiry December 1996 and NB 656, Mfd. September 1995, Expiry February 1997, which were earlier declared as not of standard quality by the Government Analyst, Bhopal for facing analytical difficulties during g the determination of uniformity of content by IP 1985 method."*
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> *(emphasis added)*

13. In that letter also the appellant Company does not make its intention clear to adduce any evidence to controvert the government analyst's report, rather made the following request:

"Under these circumstances, we respectfully reiterate that our product Betnesol tablets referred above are of standard quality and request you to kindly treat all the matters as closed"

14. As explained hereinabove, the appellants and other co-accused did not give any option to adduce evidence in contravention of the analyst's report within the statutory limitation period. Even if there was inordinate delay in launching the criminal prosecution or filing the complaint, it is thereby of no consequence. We do not find any ground to interfere with the b well-reasoned judgment of the High Court. The appeal lacks merit and is, accordingly, dismissed."

9. As discussed hereinabove, it appears that the petitioner has not given any evidence to adduce any evidence in contravention of Analyst report and if such disputed questions of facts are there in the light of judgment of the Hon'ble Supreme Court in the case of ***Glaxosmithkline Pharmaceuticals Limited (supra)*** that can be only agitated before the trial court. Further, the petitioner can avail remedy indicated under sub-section 4 of Section 25 of the

Act by requesting the Court to send the other portion of sample remaining in the court to be tested at the Central Drugs Laboratory. However, no Court is under compulsion to cause the said sample so tested if the request is made after a long delay. However, the discretion is conferred to the Court to decide whether the such sample should be sent to the Central Analyst Report from the report on the strength of such request.

10. For the correct appreciation Section 23 and 25 of the Drugs and Cosmetic Act, 1940 are quoted herein below:-

> "***23. Procedure of Inspectors.—***
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> *(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 therefor 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.*
> *(5)Where an Inspector takes any action under clause (c) of section 22,—*
> *(a)he shall use all despatch in ascertaining whether or not the drug or cosmetic contravenes any of the provisions of section 18 and, if it is ascertained that the drug or cosmetic does not so contravene forthwith revoke the order passed under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized;*
> *(b)if he seizes the stock of the drug or cosmetic, he shall as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof;*
> *(c)without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug or cosmetic, he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.*
> *(6)Where an Inspector seizes any record, register, document or any other*

material object under clause (cc) of sub-section (1) of section 22, he shall, as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof.

25. Reports of Government Analysts. —

(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."

11. Admittedly, reaction has been occurred to the patient because of the use of the said medicine. The medicine was also not in adequate quantity before the patient that is why at that time samples were not been divided into four parts as such compliance of Section 23(4) was not done that time, but lateron at the time of inquiry Drug Inspector collected the samples from the concerned medical shops and made the compliance of Sectio 23 of the Drugs and Cosmetic Act.

12. The judgment relied by the learned counsel for the petitioner in the case of ***T. Nagappa (supra)*** in that case, Section 20 of the Negotiable Instrument Act was subject matter which was rejected by the trial court as well as High Court and that was set aside by the Hon'ble Supreme Court.

13. In view of above facts, reasons and analysis the Court finds that

there is disputed questions of fact which can be only decided in the trial. Accordingly, this petition is dismissed. Pending I.A, if any, stands disposed of.

14. However, it is made clear that what are discussed hereinabove is with regard to parameters of Section 482 of Cr.P.C. and if the trial will proceed that will be decided in accordance without prejudice to this order. Pending I.A., if any, stands disposed of.

(Sanjay Kumar Dwivedi, J.)

Jharkhand High Court, Ranchi
Dated 5th of March, 2024
Satyarthi/A.F.R.