M/S. Medicamen Biotech Ltd. & Anr vs Rubina Bose, Drug Inspector on 13 March, 2008

Author: Harjit Singh Bedi

Bench: Tarun Chatterjee, Harjit Singh Bedi

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           CASE NO.:
Appeal (crl.)  483 of 2008

PETITIONER:
M/s. Medicamen Biotech Ltd. & Anr

RESPONDENT:
Rubina Bose, Drug Inspector

DATE OF JUDGMENT: 13/03/2008

BENCH:
TARUN CHATTERJEE & HARJIT SINGH BEDI

JUDGMENT:
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JUDGMENT CRIMINAL APPEAL NO 483/2008 (arising out of SLP (Crl.) No. 13 of 2007 HARJIT SINGH BEDI,J.

1. Leave granted.

2. This appeal arises out of the following facts.

3. The accused appellant No.1 is a manufacturer of Enalapril Maleate tablets, a drug which is being manufactured under licence in its factory premises. The drug was released for sale only after it quality had been certified by an independent laboratory. One such batch bearing No. NT 6000 was sold on 29th September 1999 with its shelf life upto August 2002 and in addition to other organizations some of the drug from the batch was supplied to the Government Medical Stores Depot, Kolkata. The Drugs Inspector, Central Drugs Standard Control Organisation, Kolkata visited the Government Medical Stores Depot at Belvedere, Kolkata on 14th June 2000 and collected samples of the drug and after dividing the sample into four equal parts, sent one portion to the Central Drugs Laboratory, Kolkata under Clause (i) sub- section(4) of Section 23 of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the 'Act') for test/analysis. The sample portion of the drug was received in the laboratory at Kolkata on 23rd June 2000. The Drugs Inspector received the test report from the Drugs Laboratory on 6th July 2001 declaring the drug as not conforming to the prescribed standards. A show cause notice was issued to the appellants on 14th August 2001 on which the appellant once again carried out an in-house test and also obtained an analysis report from another approved laboratory. Both the reports opined that the sample satisfied the prescribed

norms. The appellant also received a show-cause notice dated 14th August 2001/17th August 2001 from the Ministry of Health and Welfare from the Government Medical Stores Depot, Kolkata informing the appellant that the drug in question had been declared sub-standard. On 28th August 2001 the appellant sent a detailed reply to the show-cause notice to the Medical Stores Department with copies to the Drugs Inspector disputing the report of the Government Analyst and requesting for a re-testing of the drug. On 31st August 2001 the appellant received a letter dated 22nd August 2001 from the Drugs Inspector once again pointing out that the sample seized was not of the prescribed standard and also called for the comments of appellant No.1 within 10 days. The appellant received yet another letter dated 7th September 2001 from the Drugs Inspector seeking certain information to which the appellant gave a reply on 13th September 2001 giving the necessary information and also disputing the test report of the Central Drugs Laboratory, Kolkata and requesting for re- analysis. On 26th September 2001 the appellant No.1 received a communication from the Drugs Inspector that the test report submitted by the Central Drugs Laboratory was conclusive evidence of the facts stated therein under section 25 of the Act and declined to consider any other report and on the contrary, a complaint was filed before the concerned Magistrate under section 27 of the Act on 2nd July 2002. The Magistrate summoned the appellant and certain others for appearance on several dates but the summons were finally served on the appellant on 9th May 2005. The proceedings initiated on account of the complaint were challenged before the Calcutta High Court and a prayer for quashing was made under Section 482 of the Criminal Procedure Code. This petition has been dismissed by the impugned order dated 19th May 2006. The learned Judge held that it would be premature to look into the matter and to take a decision on the basis of affidavits and documents filed in Court as they were not evidence strictu sensu. The Court also opined that from the facts of the case, it appeared that the allegations made in the petition did indicate the commission of an offence as they did not suffer from any "inherent absurdity so as to raise controversy in regard to its maintainability". It also held that one portion of the sample had been given to the accused and the necessary formalities had been complied with. It is in this situation the matter is before us in appeal.

4. The learned counsel for the appellants has raised several arguments in the course of the hearing. He has pointed out that section 23(4) of the Act visualized that one portion of the sample was to be sent to the Government Analyst for test or analysis, a second to be produced in court, if proceedings were to be initiated and the third to be sent to the person, if any, whose name and address have been disclosed under section 18A. It has also been submitted that as per sub-section (4) of Section 25 of the Act unless a drug had been tested in the Central Drugs Laboratory a person was entitled, within 28 days of the receipt of a copy of the report from the Government Analyst, to request the Magistrate to send for analysis the sample, which had to be filed in court, to the Director, Central Drugs Laboratory and it appeared that this exercise had not been carried out despite the objections raised by the appellants to the correctness of the report of the Government Analyst. It has further been highlighted that in any event the complaint having been filed on the 2nd July 2002, no request for re-analysis could have been effectively made as the shelf life expiry date of the drug was August 2002 and there was, thus, paucity of time. The learned counsel for the respondent has, however, pointed out that as the appellant had not made any request for sending the sample to the Central Drugs Laboratory and had not disputed the accuracy of the report of the Government Analyst and had not stated that it needed to adduce evidence to controvert the report, the appellant was

precluded from challenging the report of the Central Drugs Laboratory as provided by sub- section (4) of Section 25 of the Act. Reliance for this argument has been placed on State of Haryana vs. Brij Lal Mittal & Ors. (1998) 5 SCC 343, State of Haryana vs. Unique Farmaid (P) Ltd. & Ors. (1999) 8 SCC 190 and Amery Pharmaceuticals & Anr. Vs. State of Rajasthan (2001) 4 SCC 382.

5. As would be evident, the matter would turn on an examination of the legal provisions. Section 23 of the Act provides the procedure for taking of samples and sub-section (4) thereof, as already mentioned above, provides that the sample shall be divided into four portions and be kept/disposed of in the manner laid therein including one sample to be produced before the Magistrate. Section 25 is reproduced below:

> "Section 25. Reports of Government Analysts.- (1) The Government Analyst to whom a sample of ay 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.
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> (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.
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> (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 who 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.
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> (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.

6. 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. It is the case of the appellant that despite the fact that the appellant had repeatedly controverted the accuracy of the report of the Government Analyst the fourth sample had still not been sent to the Director for re-testing and analysis. We find that the argument raised by the learned counsel for the respondent that the appellant had never expressed a desire to controvert the report of the Drug Analyst is not correct as is clear from the letter dated 28th August 2001 addressed to the Assistant Director General, Government Medical Stores Depot in which it was stated as under:

> "On receipt of your letter, we have got the control sample of same batch analysed from an approved test house, namely Industrial Testing Laboratory, Delhi. The test house has reported our control samples to be of standard quality and conforming to IP with respect to content of Enalapril Maleate. Copy of test report No. F- 405/8- 01 dt. 25.8.2001 enclosed.
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> In the light of above facts, we do not agree with the Govt. analyst report that the sample is not of standard quality and request you to kindly get the sample retested at your end."

7. Concededly a copy of this letter was addressed to and received by the Drugs Inspector, Kolkata. The learned counsel for the appellant has also drawn our attention to the letter dated 13th September 2001 addressed to the Drugs Inspector again reiterating:

> "We have received the sealed portion of the subject sample sent by you, but we have not opened it yet. We sincerely hope that the Asstt. Director General (MS) will need our request and get the sample reanalyzed. Until we receive the result of reanalysis we will keep your subject sample intact.
>
> As per your directions, we are again enclosing herewith he manufacturing testing and distribution details of the batch in question. We request you to kindly get our sample re-analyzed at the earliest and oblige, as we do not agree with the Govt. analyst's report."

8. It is, therefore, evident that the appellant had not once but on at least two occasions and within 28 days of the receipt of the show cause notice clarified that it intended to adduce evidence to show that the test report of the Government Analyst was not correct. The judgments cited by the learned counsel for the respondent, therefore, do not apply to the facts of the case as they were given in the context where the dealer/manufacturer had not expressed its desire to challenge the veracity of the

report of the Drugs Analyst. In Brij Lal Mittal's case (supra) this Court held that a person could not claim that the fourth sample should be sent to the Central Drugs Laboratory unless the requirements of sub- section (3) of Section 25 was complied with. In that case, despite the service of the copies of the Analyst report the manufacturer had not informed the Inspector within the prescribed period that he intended to adduce evidence to controvert the report. It was held in Brij Lal Mittal's case (supra) :

> "From a bare perusal of sub-section(3) it is manifest that the report of the Government Analyst 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 or other particulars have been disclosed under Section 18-A (in this case the manufacturers) has within 28 days of the receipt 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. Sub- section (4) also makes it abundantly clear that the right to get the sample tested by the Central Government Laboratory (so as to make its report override the report of the Analyst) through the court accrues to a person accused in the case only if he had earlier notified in accordance with sub-section (3) his intention of adducing evidence in controversion of the report of the Government Analyst. To put it differently, unless requirement of sub-section (3) is complied with by the person concerned he cannot avail of his right under sub-section (4)."

9. In Unique Farmaids's case (supra) which was a case under the Insecticides Act which has provisions analogous to Section 25(4) of the Act, the court found that the accused had indeed made a request to the Inspector for sending the sample for re-testing within the prescribed time limit and as this request had not been accepted an important right given to an accused had been rendered ineffective on which the proceedings could be quashed. This is what the Court had to say:

> "It cannot be gainsaid, therefore, that the respondents in these appeals have been deprived of their valuable right to have the sample tested from the Central Insecticides Laboratory under sub-section (4) of Section 24 of the Act. Under sub-section (3) of Section 24 report signed by the Insecticides Analyst shall be evidence of the facts stated therein and shall be conclusive evidence against the accused only if the accused do not, within 28 days of the receipt of the report, notify in writing to the Insecticide Inspector or the court before which proceedings are pending that they intend to adduce evidence to controvert the report. In the present cases the Insecticides Inspector was notified that the accused intended to adduce evidence to controvert the report. By the time the matter reached the Court, the shelf life of the sample had already expired and no purpose would have been served informing the Court of such an intention. The report of the Insecticide Analyst was, therefore, not conclusive. A valuable right had been conferred on the accused to have the sample tested from the Central Insecticides Laboratory and in the circumstances of the case the accused have been deprived of that right, thus, prejudicing them in their defence.

> In these circumstances, the High Court was right in concluding that if will be an abuse of the process of the court if the prosecution is continued against the respondents, the accused persons. The High Court rightly quashed the criminal complaint. We uphold the order of the High Court and would dismiss the appeals."

10. We find that this judgment helps the case of the appellant rather than that of the respondent because in spite of two communications from the appellant that it intended to adduce evidence to controvert the facts given in the report of the Government Analyst, the fourth sample with the Magistrate had not been sent for re-analysis. The observations in Amery Pharmaceuticals's case (supra) are also to the same effect. We find that the aforesaid interpretation supports the case of the appellants inasmuch they had been deprived of the right to have the fourth sample tested from the Central Drugs Laboratory. It is also clear that the complaint had been filed on the 2nd July 2002 which is about a month short of the expiry date of the drug and as such had the accused appellant appeared before the Magistrate even on 2nd July 2002 it would have been well nigh impossible to get the sample tested before its expiry. 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.

11. The appeal is allowed accordingly and the proceedings against the appellants are quashed.