

1.M/S.Time Pharmaceuticals, Vs. State Represented By

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Court : Chennai

Decided On : Sep-03-2015

Judge : The Honourable Ms.Justice R.Mala

Appellant : 1.M/S.Time Pharmaceuticals,

Respondent : State Represented By

Judgement :

BEFORE THE MADURAI BENCH OF MADRAS HIGH COURT DATED:

03. 09.2015 CORAM THE HONOURABLE MS.JUSTICE R.MALA Criminal Original Petition(MD) No.21860 of 2014 and M.P.(MD)Nos.1 and 2 of 2014 1.M/s.Time Pharmaceuticals, R.No.151/1, Sri Nathan Nagar, Villianour, Pondicherry-605 110, Represented by its Partner, Tmt.M.Sathammai. 2.M.Sathammai 3.S.Laiqa Parveen 4.S.Karunambigai 5.N.Saravanan 6.M/s.Kronie Health Care (P) Ltd., Represented by V.Meenakshi Sundaram 7.V.Meenakshi Sundaram : Petitioners Vs. State represented by The Drug Inspector, Theni Range, Madurai Zone, O/o.the Assistant Director of Drugs Control, No.5, Ramaiah Street, Shenoy Nagar, Madurai-625 020. : Respondent Prayer: Criminal Original Petition is filed under Section 482 of Cr.P.C., praying to call for the records of the case in S.T.C.No.4944 of 2010, on the file of learned Judicial Magistrate, Uthamapalayam, and quash the said case in S.T.C.No.4944 of 2010, by setting aside the order dated 09.04.2014 passed in CrI.M.P.No.5575 of 2012 therein. !For Petitioners :Mr.M.Saravanan ^For Respondent :Mr.K.Anbarasan, Government

Advocate(Crl. Side) :

ORDER

This Criminal Original Petition is directed against the order dated 09.04.2014 passed in Crl.M.P.No.5575 of 2012, whereby and whereunder, the learned Judicial Magistrate, Uthamapalayam, dismissed the application filed by the petitioners to discharge them from the prosecution.

2. Heard both sides.

3. The learned counsel for the petitioners would submit that the respondent, as a complainant, filed a complaint for contravention under Section 18(a)(i) of Drugs and Cosmetics Act, 1940, which is punishable under Section 27(d) of the said Act. He would further submit that the first petitioner is the Pharmaceutical Firm. The petitioners 2 to 5 are the partners. The petitioner No.6 is the purchaser of medicine and the petitioner No.7 is the Managing Director of petitioner No.6.

4. Adding further, he would submit that on 23.01.2007, one Panneerselvam, the then Drugs Inspector of Theni Range had drawn for analysis the drug samples of Gropex-Dx Cough Formula 100 ml, Batch No.GIL-602, and it has been manufactured in June, 2006 and the expiry date is May, 2009. The sample was sent for analysis to the Government Analyst (Drugs), Chennai and the report has been received on 29.12.2008, in which, it was declared that the sample does not conform to label claim with respect to the content of Phenylephrine Hydrochloride and the sample deemed to be "Not of Standard Quality", as it is found to contain only 0.53 mg (21.2%) phenylephrine hydrochloride instead of the label claim of 2.5 mg. On receipt of the report, a show cause memo was issued to the concerned parties and called for explanation for the contravention of Section 18(a)(i) of Drugs and Cosmetics Act, 1940, and to disclose the details of the person from whom the said drug was purchased and lastly, a memo dated 23.03.2009 was issued to the first petitioner herein to offer their explanation for having manufactured and sold the not of standard quality cough syrup formula 100 ml bearing its Batch No.GIL-602 and to furnish other required particulars, for which, the first petitioner sent a reply on 31.03.2009 stating that they have manufactured only 998 bottles of the

said batch (GIL-602) and out of which, 3 were kept as control sample and 995 bottles were supplied to the M/s.Great Indian Remedies and M/s.Kronie Health Care (P) Ltd. The complaint has been filed only on 13.05.2010 after the expiry of the expiry date of the medicine in the sample. Thus, the right of the first petitioner to send the sample to Central Drugs Laboratory is curtailed under Section 25(4) of the Act. Hence, the learned counsel prayed for discharging the petitioners from the prosecution.

5. To substantiate his argument, he relied upon the decisions reported in *Medicamen Biotech Ltd. v. Drug Inspector* [2008(7) SCC196 and *M/s. Unicure (India) Pvt. Ltd., & another vs. State rep. by M.N.Sridhar, Drug Inspector* [2010(2) Drugs Cases (DC) 297.

6. Resisting the same, the learned Government Advocate (Criminal side) would submit that after taking sample, it was sent for analysis to the Government Analyst (Drugs), Chennai and the report has been received on 29.12.2008 and memo has been issued on 23.03.2009 to the first petitioner, but the date of expiry of cough syrup is May 2009 and as such, they are having a period of two months to send the sample for Central Drugs Laboratory for analysis. Therefore, the right to send the sample for Government Analyst has not been deprived, as alleged by the petitioners.

7. In support of his contention, he relied upon a decision of Karnataka High Court, Circuit Bench at Dharwad in Criminal Petition No.8006 of 2010 [*M/s.Agron Remedies PVT Ltd., and another vs. State by Drug Inspector*]. and a decision of the Supreme Court in Criminal Appeal No.1489 of 2011 [*Glaxosmithkline Pharmaceuticals Ltd., v. State of Madhya Pradesh*]. and prayed for dismissal of this petition.

8. I have considered the rival submissions made on both sides and perused the typed-set of papers.

9. A perusal of the complaint would go to show that the Drug Inspector filed a complaint for contravention under Section 18(a)(i) of Drugs and Cosmetics Act, 1940, which is punishable under Section 27(d) of the said Act, stating that one

Panneerselvam, the then Drugs Inspector of Theni Range, made surprise inspection on 23.01.2007 and took sample of Gropex-Dx Cough Formula 100 ml, Batch No.GIL-602, and it has been manufactured in June, 2006 and the expiry date is May, 2009. The sample was sent for analysis to the Government Analyst (Drugs), Chennai and the report has been received on 29.12.2008, in which, it was declared that the sample does not conform to label claim with respect to the content of Phenylephrine Hydrochloride and the sample deemed to be "Not of Standard Quality", as it is found to contain only 0.53 mg (21.2%) phenylephrine hydrochloride instead of the label claim of 2.5 mg.

10. It is an admitted fact that the cough syrup has been manufactured in June, 2006 and the date of expiry is May, 2009. It is also true that the memo has been issued on 23.03.2009, i.e., well within the period of expiry of medicine. Immediately, thereafter, the first petitioner sent a reply on 31.03.2009, stating that they also sent the control samples of Gropex-Dex available with them, to the Analytical Testing Lab-M/s.Dr.Ceeal Analytical Labs and it was found that all the ingredients in the drug found to be well within the standards required, but, whereas, the complaint has been filed not immediately, but it was filed only on 13.05.2010, i.e., after the expiry of one year. The report has also been enclosed at Page No.4 of the additional typed-set of papers, wherein it was stated that the sample is of standard quality.

11. At this juncture, it is appropriate to incorporate Section 25 of the Drugs and Cosmetics Act, 1940, which reads thus:

"5. 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 18-A, 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 18-A 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."

12. The Supreme Court in *Medicamen Biotech Ltd. v. Drug Inspector* [2008 (7) SCC196, observed thus: "8. On 26.9.2001 Appellant 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 Magistrate concerned under Section 25 of the Act on 2.7.2002. The Magistrate summoned the appellant and certain others for appearance on several dates but the summons were finally served on the appellant on 9.5.2005. 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 19.5.2006. 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 *stricto sensu*. 10. 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 visualised 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 18-A.

11. 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.

12. It has further been highlighted that in any event the complaint having been filed on 2.7.2002, no request for reanalysis 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 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 v. Brij Lal Mittal*, *State of Haryana v. Unique Farmaid (P) Ltd.* and *Amery Pharmaceuticals vs. State of*

Rajasthan.

13. As would be evidence, 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....."

A reading of the aforesaid provisions would reveal that they lay certain obligations as well as provided 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 his own motion to send the fourth sample which has been disputed for fresh testing to the Director of the Central Drugs Laboratory."

13. In the said case, the Apex Court, after considering the decision in State of Haryana v. Brij Lal Mittal [1998(5) SCC343, held that the appellants therein have been deprived of a valuable right under Sections 25(3) and 25(4) of the Act, which must necessitate the quashing of the proceedings against them.

14. On going through the judgment cited supra, I am of the view that the above citation is squarely applicable to the facts of the present case.

15. It is also to be noted that the said judgment has been followed by this Court in M/s. Unicure (India) Pvt. Ltd., & another vs. State rep. by M.N.Sridhar, Drug Inspector [2010(2) Drugs Cases (DC) 297. In paragraph No.10 of the judgment, this Court held thus:

"0. A cumulative reading of the aforesaid provisions coupled with the decision of the Honourable Apex Court in Medicamen Biotech Limited and another v. Rubina

Bose, Drug Inspector reported in 2008(1) Drug Cases (DC) 163 : (2008) 7 Supreme Court Cases 196, would unambiguously and unequivocally make the point pellucidly and palpably clear that well before the expiry of the shelf-life of the drug concerned, the complaint should be filed, then only the accused also could get the drug concerned retested by the Central Drugs Laboratory concerned. But, in this case, that test was conducted only by the Tamil Nadu Drugs Testing Laboratory and not by the Central Drugs Laboratory."

16. In the decision relied upon by the learned Government Advocate (Criminal side) in Criminal Appeal No.1489 of 2011 [Glaxosmithkline Pharmaceuticals Ltd., v. State of Madhya Pradesh]., the Supreme Court observed thus:

"1. It is pertinent to mention herein that present appellants had earlier also been informed by the Drug Inspector of various cities on many occasions that the aforesaid medicine was 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 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 B.No.NA660 Mfd. Dec.92, Exp. May 94, NB290 Mfd. Nov.94 Exp. Apr.96, NB538 Mfd. May 95, Exp. Dec 96 and NB656 Mfd.Sep.95, Exp. Feb 97, which were earlier declared as not of standard quality by Government Analyst, Bhopal for facing analytical difficulties during the determination of uniformity of content by the IP1985method."

(Emphasis added) 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 matter as closed."

17. A perusal of the said judgment would go to show that the accused therein did not give any option to adduce evidence in contravention of the analyst's report within statutory limitation period and on that basis only, the judgment in *Medicamen Biotech Ltd. v. Drug Inspector* [2008(7) SCC196] has been distinguished. Therefore, the above judgment relied on by the learned Government Advocate (Criminal side) is not applicable to the case on hand.

18. Likewise, the case in Karnataka High Court, Circuit Bench at Dharwad in Criminal Petition No.8006 of 2010 [M/s.Agron Remedies PVT Ltd., and another vs. State by Drug Inspector], is entirely different from the facts of the present case, because after receipt of notice, the petitioners therein have not made any objection under Sub-Section (3) of Section 25, but whereas, in the case on hand, as soon as the accused received the analyst report, they sent a reply, which was also enclosed in the additional typed-set of papers, and the complaint has been filed after one year. As such, the said decision is not applicable to the case on hand.

19. In view of the foregoing reasons and the judgment in *Medicamen Biotech Ltd. v. Drug Inspector* [2008(7) SCC196], I am of the view that the impugned order dated 09.04.2014 passed in CrI.M.P.No.5575 of 2012, on the file of learned Judicial Magistrate, Uthamapalayam, is liable to be set aside and accordingly, it is, hereby, set aside and consequently, S.T.C.No.4944 of 2010 is also quashed. The petitioners are discharged from the charges levelled against them.

20. The Criminal Original Petition is allowed as indicated above. Consequently, the connected miscellaneous petitions are closed. To 1.The Judicial Magistrate, Uthamapalayam. 2.The Drug Inspector, Theni Range, Madurai Zone, O/o.the Assistant Director of Drugs Control, No.5, Ramaiah Street, Shenoy Nagar, Madurai-625 020. 3.The Additional Public Prosecutor, Madurai Bench of Madras High Court, Madurai. .