A GLAXO SMITHKLINE PHARMACEUTICALS LTD. & ANR

v.

STATE OF MADHYA PRADESH

(Criminal Appeal No. 1489 of 2011)

JULY 28, 2011

B

[P. SATHASIVAM AND DR. B.S. CHAUHAN, JJ.]

The Drugs and Cosmetics Act, 1940:

C *s. 25(3) and 35 – Drug manufactured by company found not of 'standard quality' – Intention to controvert report of analyst not expressed within the period of limitation – Delay in filing the complaint – Effect of – HELD: The report of analyst is conclusive – In the instant case, the manufacturers* D *did not express their intention to adduce evidence to controvert the report of the analyst within the period of limitation – In the circumstances, the delay in filing the complaint becomes immaterial – On earlier occasions also the company was informed that the medicine in question was not of standard quality, but it did not make its intention clear* E *to adduce any evidence to controvert Government Analyst's report – There is no ground to interfere with the well reasoned judgment of High Court declining to quash the criminal proceedings – Delay/Laches.*

F **The Drug Inspector, on 9.12.1996, took from a shop, a sample of Betnesol tablets manufactured by the appellant-company. The sample was sent for chemical analysis to the laboratory i.e. Government Analyst, Madhya Pradesh (Bhopal) on 10.12.1996. The** G **Government Analyst by certificate dated 27.8.1997 declared that the sample was not of "standard quality" as defined under the Drugs and Cosmetics Act, 1940 (the Act). A show cause notice was issued to the appellant-company on 29.9.1997. The reply was submitted on**

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3.11.1997, stating that the sample of the medicine in question ought to have been examined/analysed under Indian Pharmacopoeia ('I.P.') 1996 and it had wrongly been analysed under I.P. 1985. On 3.7.2001, the department filed a complaint against the appellant-company as well as its Managing Director and other Officers for commission of offence punishable u/s 35 of the Act. The Chief Judicial Magistrate issued summons to all the accused. The appellants filed an application u/s 25(3) of the Act before the trial court with a prayer that sample of Betnesol tablets be sent for chemical analysis to the Director, Central Drugs Laboratory for being tested as per I.P.1996. The application stood rejected. The appellants approached the High Court for quashing the proceedings. The prayer was declined by the High Court.

Dismissing the appeal filed by the manufacturers, the Court

HELD: 1.1 It is a settled legal proposition that the report of the analyst is conclusive. It means that no reasons are needed in support of conclusion given in the report, nor is it required that the report should contain the mode or particulars of the analysis. [para 7] [612-C-D]

Dhian Singh v. Municipal Board, Saharanpur & Anr., 1970 (1) SCR 736 = AIR 1970 SC 318 – relied on.

1.2 However, 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 u/s 25(3) of the Act. In the instant case, as 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

A 1998, i.e., only after 4 months of submission of the reply by the appellants, and they did not fulfill 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 B stage. So far as the application of I.P. 1985 or I.P. 1996 is concerned, such an issue can be agitated at the time of trial. [paras 7 and 8] [612-E-F; 613-B-D]

State of Haryana v. Brij Lal Mittal & Ors. 1998 (3) SCR 104 = (1998) 5 SCC 343 - relied on.
C

Medicamen Biotech Limited & Anr. v. Rubina Bose, Drug Inspector 2008 (4) SCR 936 = (2008) 7 SCC 196 - distinguished

D 1.3 It is pertinent to mention that the appellants had earlier also been informed by the Drug Inspector of various cities on many occasions that the medicine in question, i.e., Betnesol Tablet, was not of standard quality and the authorities had been making an attempt to initiate E 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, it did not make its intention clear to adduce any evidence to F controvert the Government Analyst's report. [para 11] [614-D-F; 615-B]

1.4 The appellants and other co-accused did not give any option to adduce evidence in contravention of the G analyst's report within statutory limitation period. Even if there was inordinate delay in launching the criminal prosecution or filing the complaint, it is of no consequence. There is no ground to interfere with the well reasoned judgment of the High Court. [para 12] [615-H D]

Case Law Reference: A

1970 (1) SCR 736	**relied on**	**para 7**
2008 (4) SCR 936	**distinguished**	**para 9**
1998 (3) SCR 104	**relied on**	**para 10** B

CRIMINAL APPELLATE JURISDICTION : Criminal Appeal No. 1489 of 2011.

From the Judgment & Order dated 14.09.2010 of the High Court of Madhya Pradesh at Jabalpur in Criminal Misc. Case C No. 6315 of 2008.

R. Ramachandran , U.A. Rana, M. Majumbar, Gagrat & Co. for the Appellants.

Vibha Datta Makhija for the Respondent. D

The Judgment of the Court was delivered by

DR. B.S. CHAUHAN, J. 1. Leave granted.

2. This appeal has been preferred against the judgment E and order dated 14.9.2010 passed by the High Court of Madhya Pradesh at Jabalpur in Misc. Criminal Case No. 6315 of 2008 which rejected the application of the appellants for quashing the complaint under the provisions of The Drugs and Cosmetics Act, 1940 (hereinafter called `the Act 1940'). F

3. Facts and circumstances giving rise to this appeal are that:

A. The Drug Inspector under the Act 1940 had taken a sample of Betnesol tablets (Batch No. NC 160 Mfg. October G 1996, expiry March 1998), manufactured by the appellant-company from the shop of one Mahesh Agarwal at Chattarpur on 9.12.1996. The statutory authority sent the medicine for chemical analysis to the laboratory i.e. Government Analyst, Madhya Pradesh (Bhopal) on 10.12.1996. H

A B. The said Government Analyst vide certificate dated 27.8.1997 declared that the sample was not of "standard quality" as defined under the Act 1940. The sample led to "analytical difficulties" for the purpose of determining compliance with the official standards as stated under uniformity B of content.

C. In view thereof, a show cause notice was issued to the appellant-company by the statutory authority on 29.9.1997 as to why proceedings should not be initiated against the appellants and others. The appellant submitted its reply on C 3.11.1997, submitting that sample of the aforesaid medicine ought to have been examined/analysed under Indian Pharmacopoeia (hereinafter called 'I.P.') 1996 and it had wrongly been analysed under I.P. 1985. Subsequent thereto, the department filed a complaint against the appellants on D 3.7.2001 impleading the company as well as its Managing Director and Officers under the provisions of the Act 1940. A prayer was made that the appellants and other accused be punished under Section 35 of the Act 1940 and information of the said punishment be published in the newspapers at the cost E of the accused.

D. The Chief Judicial Magistrate, Chattarpur, took cognizance and issued summons to all accused persons including the appellants. The appellants filed an application F under Section 25(3) of the Act 1940 before the Chief Judicial Magistrate, Chattarpur, with a prayer that sample of Betnesol tablets be sent for chemical analysis to the Director, Central Drugs Laboratory for being tested as per I.P.1996 on 1.10.2007. The said application stood rejected vide order G dated 5.5.2008. The appellants approached the High Court by filing Misc. Criminal Case No. 6315 of 2008 for quashing the proceedings in Criminal Case No. 982 of 2001 (State of Madhya Pradesh v. M/s Aggarwal Medical Stores and Ors.). The said application stood rejected by the impugned judgment and order dated 14.9.2010. Hence, this appeal. H

4. Shri R. Ramachandran, learned senior counsel appearing for the appellants, submitted that the Drugs Inspector issued show cause notice dated 29.9.1997 which was duly replied by the appellants on 3.11.1997. Therefore, there was no occasion for the respondent- authorities to file a complaint, that is too after the expiry of more than 3 years and 9 months of the expiry date of the medicine itself. The appellants could not avail their remedy under Section 25(3) of the Act 1940 which can be exercised within 28 days from the date of service of show cause notice. The chemical analyst's report was not clear at all. The certificate declared that the medicine "was not of the standard quality". The analyst had analytical difficulties in determining the compliance with the official standards as stated "Under uniformity of Contents". The purpose of exercising his right under Section 25(3) of Act 1940 is to ask the statutory authority to send the medicine to some other laboratory for chemical analysis in case the report was not acceptable to the accused. In the instant case, it was the technical problem as the fault had been found in view of analytical defects, and thus, there was no violation of substantive character. There could be no justification for the State to file the complaint at such a belated stage. Thus, the High Court erred in rejecting the application for quashing the complaint.

5. On the other hand, Ms. Vibha Datta Makhija, learned counsel appearing for the respondent-State, has vehemently opposed the appeal contending that the applicants are the manufacturer of drugs and under Section 18(a)(i) of the Act 1940, they could not manufacture drugs of sub-standard quality. They could have expressed their option to adduce evidence in contravention of the analytical report within the period of limitation i.e. 28 days which they did not do. Unless the accused has given option that it would adduce evidence in contravention of the analytical report, it cannot ask the court to send the medicine for chemical analysis to the Central Government Laboratory. As no such option had been made by the appellants, they are not entitled to challenge the report. More

A so, the onus of proof was on the appellants to tell as on what date the company had received the show cause notice dated 29.9.1997. The appellants have not disclosed the date of receipt of the show cause notice till date. The issue of launching criminal prosecution at a much belated stage has not been B raised before the High Court in the gravity in which it is being agitated before this Court. Appeal lacks merit and thus, is liable to be dismissed.

6. We have heard the learned counsel for the parties and C perused the records.

7. The issue involving herein is no more res integra matter. The issues have been examined time and again. It is a settled legal proposition that report of the analyst is conclusive. It means that no reasons are needed in support of conclusion D given in the report, nor it is required that the report should contain the mode or particulars of the analysis. (See: *Dhian Singh v. Municipal Board, Saharanpur & Anr.*, AIR 1970 SC 318.)

E However, 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 Act 1940. 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 F 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 G 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 H 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 the I.P. 1985, it could have been done under I.P. 1996 because the I.P.1996 had come into force prior to the date of taking the sample on 9.12.1996.

8. 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 fulfill 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 I.P. 1985 or I.P. 1996 is concerned, such an issue can be agitated at the time of trial.

9. The judgment in *Medicamen Biotech Limited & Anr. v. Rubina Bose, Drug Inspector,* (2008) 7 SCC 196, was heavily relied on by Shri R. Ramachandran, learned senior counsel appearing for the appellants. Nevertheless, the facts of the said case are quite distinguishable. In that case, the complaint had been filed about a month short of expiry date, and the accused therein had expressed their option to lead evidence in contravention of the analyst's report within limitation time but were not able to do so as shortly thereafter the medicine expired.

10. We agree with Ms. Makhija that the case is squarely covered by the judgment of this Court in *State of Haryana v. Brij Lal Mittal & Ors.,* (1998) 5 SCC 343 wherein this Court has held as under:

> "....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

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 B cannot avail of his right under sub-section (4)."

In the said case, like the present case, the manufacturer did not notify the Inspector within the prescribed period that he intended to adduce evidence in contravention of the report. Also, akin to the case at hand, the manufacturer's right under C section (3) of Section 25 expired few months before expiry of shelf life. Holding for the directors of the manufacturing company on different grounds, the court opined that the right to get drugs tested by Central Drugs Laboratory does not arise unless requirement of sub-section (3) is complied with.

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11. 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 E 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 F 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 G initiate action for manufacturing Betnesol Tablets B.No. NA 660, Mfd. Dec. 92, Exp. May 94, NB 290, Mfd. Nov. 94, Exp. Apr. 96, NB 538, Mfd. May 95, Exp. Dec. 96 and NB 656, Mfd. Sep. 95, Exp. Feb. 97, which were earlier declared as not of standard quality by Government Analyst, H Bhopal for facing analytical difficulties during the

determination of uniformity of content by the IP 1985 method."

(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."

12. 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 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 well reasoned judgment of the High Court. The appeal lacks merit and is, accordingly, dismissed.

R.P. Appeal dismissed.