Biochem Pharmaceutical and ors. Vs. State

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Court : Delhi

Decided On : May-30-2005

Reported in : 121(2005)DLT207; 2005(82)DRJ653

Judge : Manju Goel, J.

Acts : Drugs and Cosmetics Act, 1940 - Sections 18, 18A, 22, 23, 23(4), 25 and 27; Insecticides Act, 1968; Constitution of India - Article 227; Code of Criminal Procedure (CrPC) - Sections 482

Appeal No. : Criminal M. (M). No. 3712/2001

Appellant : Biochem Pharmaceutical and ors.

Respondent : State

Advocate for Def. : Richa Kapoor, Adv.

Advocate for Pet/Ap. : S.S. Gandhi, Sr. Adv. and; Poonam Singh, Adv

Judgement :

Manju Goel, J.

1. Petitioner No. 1 is a partnership firm. Petitioners 2 to 4 are partners of petitioner No. 1 and petitioner No. 5 is an employee of petitioner No. 1. Petitioner No. 1 is accused No. 1 in complaint case No. 01/04 of 1998 for offence Section 18(a)(i)

punishable under Section 27(d) of The Drugs and Cosmetics Act, 1940 (in short the `Act'). The petitioners are in the business of manufacturing drugs.

2. On 25.2.1997, a sample of drug known as Ampilox Dry Syrup, Batch No. AS-74896, with manufacturing date December, 1996 and expiry date May, 1998 was collected by the Drug Inspector from premises of M/s. Galaxy Medicos, A-2, DDA Market, Mata Sundri Road, New Delhi, in the presence of the proprietor of the firm. Intimation in form 17 about the collection of the samples and one sealed sample of the drug was handed over to the proprietor. On 25.2.97 one sealed sample portion of the drug was forwarded to the Government Analyst, Delhi. On analysis the sample of the drug was found to be not of standard quality. On 13.11.1997, a certificate of test of analysis on Form 13 in triplicate was received in the office of Drug Inspectors, who is the complainant. On 13.11.1997, the complainant forwarded the copy of the test report to M/s. Galaxy Medicos and sought disclosure of the name, address and other particulars of the person from whom the drug had been acquired by the firm. M/s. Galaxy Medicos disclosed that it had purchased the drug from M/s. Hindustan Pharmaceuticals, Ansari Road, Darya Ganj, New Delhi against an invoice dated 6.2.1997. The manufacturer of the drug, who are the petitioners before this court was asked to stop further sale of the drug and to recall the supplies already made. The manufacturing firm in its reply dated 18.12.1997 (within 28 days of receipt of the copy of the report) stated that it did not accept the Government Analyst's report and intended to adduce evidence in controversion of the test report as provided for under Section 25 of the Act and requested that sealed sample portion of the drug be sent to them. On 16.1.1998, the third sealed sample of the drug along with copy of the test report in original was forwarded to M/s. Hindustan Pharmaceticals, New Delhi who in turn confirmed to have purchased the drug from the petitioner and to have sold the drug to M/s. Galaxy Medicos. The complainant vide its letter dated 22.1.1998 informed manufacturing firm that as per the requirement of Section 23(4) of the Act, the third sample portion of the drug had been sent to the person whose name was disclosed by M/s. Galaxy Medicos. The complainant allege that the manufacturing firm/petitioner was advised to submit the copies of evidence which they wanted to adduce in controversion of the Government Analyst's report. The complaint was lodged with the allegation that the petitioner failed to adduce any

evidence in this regard. Accordingly the complaint was filed on 1.4.1998 under the provisions of Section 18a(i) of the Act.

3. The Magistrate summoned the petitioners who moved an application for withdrawing the orders of summoning which was dismissed by the Magistrate. This order was challenged in a revision petition which was also dismissed by the court of Additional Sessions Judge on 20.8.2001. This has led to the filing of the present petition praying for setting aside the order dated 20.8.2001 and for dismissal of the complaint.

4. Before coming to the grounds on which the prayer is made, it is necessary to recall a few provisions of the Act. The procedure of collection of sample has been provided under Section 23. The portions of Section 23 relevant for the present purpose are sub-Sections (1),(2),(3) & (4), which are extracted below:

'23. Procedure of Inspectors.- (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 thereforee.

(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 thereforee 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 willfully 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. It is to be noted that the sample has to be divided in four portions unless the sample is taken from the premises of the manufacturer. One of the four portions of the sample has to be restored to the store from which the sample is collected. One portion has to be sent to the Government Analyst. One portion goes to the court and the fourth goes to the person whose name, address and other particulars have been disclosed under Section 18A of the Act. Section 18A requires disclosure of the name of the manufacturer, etc. which is as under:

'18A. Disclosure of the name of the manufacturer, etc.- Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.'

6. It is to be noticed that under Section 18A the retailer from whom the sample is collected is required to disclose to the Inspector the name, address and other particulars of the person from whom he has acquired the drug or the cosmetic. In case the drug is acquired not directly from the manufacturer but through a wholesaler, the retailer may disclose only the name of the wholesaler or distributor. In other words, it is not necessary that the retailer discloses the name

of the manufacturer. In case the name of the manufacturer is not given under Section 18A and only the name of the distributor is disclosed then the Drug Inspector will supply a portion of the collected sample to the distributor. Thus, the manufacturer of the drug has not to be supplied with a portion of the sample collected.

7. Section 25 prescribes as to how to deal with the report of the Government Analyst and the provisions of Section 25 which is extracted below:

'25. Reports of Government Analysts.- (1) The Government Analyst to whom a sample of any drug of 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 on 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.'

8. Thus, the Inspector is required to deliver one copy of the report to the person whose name has been disclosed in compliance with the query under Section 18A and one copy to the person from whom the sample is collected. The third copy is retained by the Drug Inspector for use in prosecution in respect of the sample. The report of the Analyst shall be the evidence of facts stated therein unless the retailer or the person whose name is disclosed under Section 18A notifies within 28 days of receipt of the copy of the report in writing to the Inspector or to the Court that he intends to adduce evidence in controversion of the report. Once such intention is notified the sample produced before the Magistrate under sub-Section (4) of Section 23 will be sent to the Central Drugs Laboratory. The report of the Central Drugs Laboratory, under the authority of the Director, was to be the conclusive proof of facts stated therein.

9. Now to revert to the facts under the present case, the petitioners who are the manufactures were not favored with a portion of the sample collected from M/s. Galaxy Medicos. When the test report was received by the complainant, the complainant vide his letter dated 13.11.1997 forwarded the copy of the test report in original to M/s. Galaxy Medicos and asked for the name and address of the person from whom the drug had been acquired by the firm. M/s. Galaxy Medicos replied vide letter dated 21.11.1997 that they had purchased the drug from M/s. Hindustan Pharmaceuticals, Ansari Road, Darya Ganj, New Delhi. The complainant does not disclose in the complaint whether a copy of the test report was sent to M/s. Hindustan Pharmaceuticals. It is, nonetheless, alleged that the manufacturing firm, namely, the petitioners in their reply dated 18.12.1997 submitted that they were unable to accept the Government Analyst's report and intended to adduce evidence in controversion of the test report under Section 25

of the Act and requested to send the sealed portion of the sample to them as required under Section 23 of the Act. On 16.1.1998, i.e., after the reply dated 18.12.1997 was received from the manufacturing firm, the complainant sent the third sealed sample portion of the drug along with copy of the test report to M/s. Hindustan Pharmaceuticals. Copy of the letter dated 22.1.1998 has not been placed on the record. Further it is alleged in the complaint that by the letter dated 22.1.1998, the complainant informed the manufacturer that one portion of the drug had been sent to M/s. Hindustan Pharmaceuticals and that the petitioner was advised to submit the copies of evidence which they wanted to adduce in controversion of the Government Analyst's report. The petitioners then wrote the letter dated 29.1.1998, which is as under:

' BIOCHEM PHARMACEUTICAL INDUSTRIES

AIDNU Bldg. 1st Dhobi Talao, P.O.Box 2217, Mumbai-400002.

Date: 29.1.1988

Our Ref: BF/GNC/0198/023

To:

Mr. S.K.Agrawal

Asst. Drug Controller

Govt. of National Capital Territory of Delhi

Drugs Control Department

15, Sham Nath Marg

Delhi - 54'

Sub:Ampilox Dry Syrup Batch No. AS-74896 and the Government Analyst Report No. CIPL/6014/255 dated 27.10.1997.Dear Sir,

With reference to your letter No. 19(510)/96-97/GADC/726 dated 22.1.1998 in respect of the subject refer above in this connection in reply to para II of your letter. We desire to adduce evidence as per the provisions of Section 25 of Drugs & Cosmetic Act, 1940 (Xerox copy of Section 25 of the Act is enclosed). This evidence is to be adduced as per section 25-4 by sending the sample to the Central Drugs Lab for analysis by following the procedure stipulated under the said section. The report of the director of the Central Drug Lab being the conclusive evidence nature the same can supercede the report of Govt. Analyst. We have already exercise the right by communicating you within 28 days of the receipt of the report.

Regarding the portion of the sample as the portion of the sample cannot be send to us, we cannot determine whether the sample drawn is authentic or substitute in the name of company.

We are sure that this will clarify the matter.

Thanking you, we remain.

Yours faithfully,

For BIOCHEM PHARMACEUTICAL INDUSTRIES

FACtorY MANAGER'

10. The complainant says that the manufacturing firm by its reply dated 29.1.1998 reiterated their intention to adduce evidence as per the provisions of Section 25 of the Act but failed to adduce evidence in controversion of the test report. The complainant does not disclose in the complaint as to what was done in response to the prayer of the petitioners for sending the sample to the Central Drugs Laboratory. It appears that the complainant did not pay any heed to the request. Nonetheless, the complaint was filed on 1.4.1998.

11. Now the drug collected had been manufactured in December, 1996 and was to expire in May, 1998. When the complaint was filed on 1.4.1998, the drug had still not expired. Summons was ordered to be issued on 1.4.1998. The petitioners did

not appear on 20.4.1998 but obtained exemption from personal appearance. On the subsequent date, i.e., on 3.8.1998, the petitioners appeared and copies of the complaint were given to the petitioners. On 3.8.1998, when the petitioners received the copies, the drug had already expired and by then it was too late for the petitioners to pray to the court for sending the sample to the Central Drugs Laboratory.

12. The petitioners say that when the writ of summons were served, the copies of the complaint were not provided to the petitioners and that the copies of the complaint were given to the petitioners for the first time on 3.8.1998. thereforee, it can be presumed that it was only on that date that the petitioners came to know that the report of the Central Drugs Laboratory had not been obtained by the complainant and the request made by the petitioner in its letter dated 18.12.1997 and 29.1.1998 had not been taken care of. It is also clear that the complainant did not respond to the letter dated 29.1.1998 and did not inform the petitioners that he did not intend to send the sample to the Central Drugs Laboratory.

13. The ground on which the complaint is asked to be dismissed is that the petitioners had been deprived of their valuable right of controverting the report of the Government Analyst and, thereforee, could not be prosecuted for the offence. This contention of the petitioners has been over-ruled by the Additional Sessions Judge (in short `ASJ'). The ASJ has observed, inter alia, that the petitioners did not ask for the copies on the first date on which date they actually asked for exemption from personal appearance. It was only on the second date, i.e., 3.8.1998, that the copies were given. The ASJ has also doubted that the petitioners may already have received the copy of the complaint along with writ of summons. This observation of the learned ASJ cannot, however, be accepted because had it been so the report of the service would have categorically shown that writ of summons was actually accompanied by a copy of the complaint. In fact, the order-sheet of 3.8.1998 shows that the complainant offered the copy and the same was received by the petitioners. The order-sheet does not show that the complainant at all raised any dispute on this issue. The complainant did not claim on that day that the copy of the complaint had already been supplied and, thereforee, was not required to be supplied again. The order-sheets suggest that

the complainant for the first time served the copy of the complaint on the petitioners on 3.8.1998.

14. The learned ASJ has observed that the petitioners attempted to wriggle out from the situation by not appearing on the first date. At the same time, it can be said that the complainant also did not make any effort for providing the copy of the complaint to the petitioners on any date prior to 3.8.1998. With these facts in view, an analysis of the law on the subject can be made.

15. It may be stated now that the judgments on Insecticides Act as well as those on the Drugs and Cosmetics Act will be relevant for the analysis. The Insecticides Act, 1968 has very similar provisions. Both Insecticides Act and the Drugs and Cosmetics Act require the sample to be divided in portions and one portion to be handed over to the person from whom the sample is taken. The Drugs and Cosmetic Act requires a portion of the sample to be provided to the person whose name is disclosed by the person from whom the sample is taken. The Drugs and Cosmetics Act requires a portion of the sample to be provided also to the person whose name is disclosed by the person from whom the sample is taken. The manufacturer as such is not entitled to a portion of the sample under any of the two Acts. None of the two Acts requires a copy of the report to be handed over to the manufacturer unless it was the manufacturer of the drug under the Drugs and Cosmetics Act whose name was disclosed under Section 18A. Both the Acts require the report to be controverter within a statutory time without which the report of the Government Analyst/Insecticides Analyst would be final. On the basis of these statutory provisions, the right of the manufacturer has to be determined.

16. Four judgments of the Supreme Court have been cited on the law in question. The first of the four judgments cited is of State of Haryana v. Brij Lal Mittal and Ors. reported as : 1998 CriLJ3287 . In this case the manufacturer of the drug did not controvert the report within the required period of 28 days after receipt of the report of the Government Analyst and by way of defense he submitted that the complaint had been filed after a long delay by which time the shelf-life of the drug had expired and, thereforee, there could be no fresh analysis of the drug by the Central Drugs Laboratory. The contention of the accused manufacturer in that

case was rejected and the court said, 'It must, thereforee, be said that consequent upon their failure to notify the Inspector that they intended to adduce evidence in controversion of the report within 28 days, not only the right of the manufacturers to get the sample tested by the Central Drugs Laboratory through the court concerned stood extinguished but the report of the Government Analyst also become conclusive evidence under sub-section (3). The delay in filing the complaint till the expiry of the shelf-life of the drugs could not, thereforee, have been made a ground by the High Court to quash the prosecution.'

17. The second judgment on this aspect is that of State of Haryana v. Unique Farmaid (P) Ltd. and Ors. reported as : 2000 CriLJ2962 . In this case firm `U' was not entitled to sample, being the manufacturer. When it received the report of the Senior Analyst, Quality Control (Insecticides), it sent a reply denying the allegations and informed its intention to adduce evidence in support of its contentions and requested for getting the sample tested by the Central Insecticides Laboratory at `U's cost. Without adverting to the said request of `U', the Insecticides Inspector filed a criminal complaint against several parties including `U'. `U' and its sales officers approached the High Court under Section 482 Cr.P.C. & Article 227 of the Constitution. They contended that on the one hand their request for testing the sample was ignored by the Inspector and on the other hand by the time they were asked to appear in court to stand trial, the shelf-life of the insecticides, of which sample was taken, already expired. The High Court held that they were thus deprived of the valuable right of their defense. The Supreme Court upheld the High Court's decision to quash the criminal complaint.

18. The third case of the Supreme Court in this field is that of Amery Pharmaceuticals and Anr. v. State of Rajasthan reported as : 2001 CriLJ1686 . In this case the manufacturer, though served with a copy of the report of the Government Analyst, did not notify its intention to challenge the report. During prosecution and defense it was submitted that non-supply of one portion of the sample to the manufacturer who was joined as an accused in the complaint had resulted in depriving him of a valuable right to test correctness of the report of the Government Analyst. This contention was rejected by the trial court as well as by the High Court. Referring to the procedure laid down in the Drugs and Cosmetics

Act, the Supreme Court observed that the obligation of the Inspector was to give one portion of the sample to the person whose name etc. had been disclosed as the person from whom the vendor acquired the drug and that the requirement of the legal provisions stood complied with when the Inspector gave a portion of the sample to such person apart from sending one portion to the court and one portion to the Government Analyst. The manufacturer was not entitled to a portion of the sample. The Supreme Court held that non-supply of sample did not prejudice the manufacturer. Further the Supreme Court said the manufacturer was required to notify the trial court or the Inspector his intention to adduce evidence in controversion of the report but if such person failed to give any such notice within the statutory period of 28 days, the finding in the report would operate as conclusive evidence against the person who failed to give such notice.

19. The last judgment in this series is in the case of Gupta Chemicals Pvt. Ltd. and Ors. v. State of Rajasthan and Anr. reported as 2002 (4) Crimes 33 (SC). In this case the manufacture on receiving the copy of the report of the State Insecticides Laboratory and within the statutory time notified his intention to lead evidence against the report. The Insecticides Inspector did not take any action on such intimation and did not send the sample for testing by the Central Insecticides Laboratory. By the time the complaint was filed the shelf-life of the insecticides in question had expired. The High Court declined to quash the criminal proceedings in exercise of powers under Section 482 Cr.P.C. The Supreme Court held:

'12. From our perusal of the aforequoted provisions it is manifest that ordinarily in the absence of any material to the contrary, the report of the insecticides analyst will be accepted as final and conclusive of the material contained therewith. This is however, subject to the right of the accused to have the sample examined by the central insecticides laboratory provided he communicates his intentions for the purpose within 28 days of the receipt of the copy of the report. It needs no emphasis that this right vested under the statutes valuable for the defense, particularly in a case where the allegations are that the material does not conform to the prescribed standard. As noted earlier in the present case the appellants had intimated the insecticides inspector their intention to have the sample tested in the central insecticides laboratory within the prescribed period of 28 days of receipt of

the copy of the state analyst report, yet no step was taken by the inspector either to send the sample to the central insecticides laboratory or to file the complaint in the court with promptitude in which case the appellants would have moved the magistrate for appropriate order for the purpose. The resultant position is that due to sheer inacation on the part of the inspector, it has not been possible for the appellants to have the sample examined by the central insecticides laboratory and in the meantime, the shelf-life of the sample of insecticides seized had expired and for that reason no further step could be taken for its examination. In the circumstances, we are of the view that continuing this criminal prosecution against the appellant will be a futile exercise and abuse of the process of court. The High Court was not right in dismissing the petition filing (sic) under section 482 of Cr.P.C.'

20. Now to revert to the facts of the case in hand, one can see that the petitioners did not default in notifying their intention to controvert the report of the Government Analyst. Despite such notification of intention by the petitioner-manufacturer the drug inspector did not take any step for getting the sample tested by the Central Drug Laboratory. Further the drug inspector/ complainant did not inform the petitioner that he did not intend to send the sample for testing in the Central Drugs Laboratory. Thus, the petitioner was entirely kept in the dark about the action or inaction on his demand for testing the sample in the Central Drugs Laboratory. When the complaint was made to the court the drug still had its shelf-shelf. As explained earlier, by the time the copy of the complaint was served on the petitioner the shelf-life was over. The complainant did not even inform the court that he had not taken any action on the letter of the petitioner asking for the sample being tested by the Central Drugs Laboratory. Had the Inspector done so, the court could possibly have sent the portion of the sample available with it to the Central Drugs Laboratory. The summons thereafter was issued to the petitioners but without the copy of the complaint. The petitioner was actually served for a date when the shelf-life was still alive. However, the petitioners being in the dark about the action taken on their request was not required by law to make another request to the court. When the intention was already notified and the petitioner had already availed of the legal remedy available to it, it was the duty of the prosecution to take all steps to fortify its case by sending the sample to the Central Drugs Laboratory.

The law does not require that the petitioner to repeat its request again when he appears before the court in response to the summons. Further, as mentioned earlier, by the time the petitioner actually received copy of the complaint, that is, when he was duly served with the summons shelf-life of the drug was over.

21. Neither in the case of Amery Pharmaceuticals (Supra) nor in the case of State of Haryana v. Brij Lal Mittal (Supra), the manufacturer had taken care to controvert the report by notifying its intention to lead evidence against the report of the Government Analyst. In none of the two cases the manufacturer availed of his right to get the sample tested by the Central Drugs Laboratory. In the other two cases, namely, State of Haryana v. Unique Farmaid (Supra) & M/s. Gupta Chemicals (Supra) the manufacturer had notified his intention of leading evidence in controversion of the report. In both the cases there was default on the part of the complainant and in both the cases the Supreme Court held that the complaint was required to quashed.

22. In view of above analysis of the facts and law, I find that the petitioners in this case falls in the same bricked as the one in which the manufacturer in the case of State of Haryana v. Unique Farmaid (Supra) & M/s. Gupta Chemicals (Supra) were placed. There is no reason why the petitioners should not get the same treatment as the manufacturer in those two cases. The petitioners are entitled to a similar relief. I hold that in the given situation, the petitioners were deprived of their valuable right of defending themselves and that continuing the criminal prosecution against them will be an abuse of the process of the court. The petition is allowed and the complaint is quashed.

23. Before parting with the case I must express my concern about the conduct of the complainant/Drug Inspector, on account of whose failure to take appropriate steps by getting the sample tested again in the Central Laboratory, the prosecution has failed. In case the manufacturer is innocent, the proceedings have resulted only in his harassment. On the other hand, if the drug was actually sub-standard the omission of the Inspector has resulted in the manufacturer escaping the clutches of the law and in encouraging manufacturing of sub-standard medicines which is dangerous to public health. The Drug Control Department, Govt. of NCT

of Delhi is advised to take care to set its own house in order to ensure that such omissions on the part of the Drug Inspectors do not take place in future. Copy of the judgment be sent to the Head of the concerned department.