

(2013) 08 MAD CK 0056

In the Madras High Court

Case No : Criminal Original Petition No. 16931 of 2013

M/s. Embiotic Laboratories (P) Ltd., Kanthilal Jain and Harish
K. Jain

APPELLANT

Vs

Drugs Inspector

RESPONDENT

Date of Decision : 16-08-2013

Acts Referred:

Drugs and Cosmetics Act, 1940 — Section 17, 18(a)(i), 18B, 24, 25(3)

Citation : (2013) 2 LW(Cri) 475

Hon'ble Judges : R. Subbiah, J

Bench : Single Bench

Advocate : P. Ramesh Kumar, for the Appellant; C. Emalias, Assistant Public Prosecutor, for the Respondent

Final Decision : Allowed

Judgement

R. Subbiah, J.—Seeking to quash the proceedings in C.C. No. 74 of 2010 pending before the Judicial Magistrate Court, Kodumudi, the

petitioners have come up with the present petition. Petitioner are the accused in the complaint lodged by the respondent for the contravention of

section 18(a)(i) and 18-B of the Drugs and Cosmetics Act, 1940, which is punishable u/s 27(d) and 28-A of the said Act. The allegations made in

the complaint are as follows:

(a) On 27.09.2007, the Drugs Inspector, Erode, Range (I/c) went to the premises of Government Hospital, Kodumudi, Erode and drew the

samples of Enalapril Maleate tablets, I.P. 2.5 mg Batch No. ENL-146, Mfg. date 06/07; Expiry date 05/09 manufactured by M/s. Embiotic

Laboratories (P.) Limited. Thereafter, the Drugs Inspector sent the samples of the said drug for analysis to the Government Analyst (Drugs),

Chennai-6. The Government Analyst, on 26.02.2009, by his report, declared that the samples so drawn do not conform to I.P. specification for

Enalapril Maleate tablets with respect to the contents of Enalapril Maleate, as required under the Drugs and Cosmetics Act, 1940 (in short "the

Act"). Thereafter, a letter dated 20.03.2009 was sent to the Medical Officer, Government Hospital, Kodumudi, Erode in this regard and a reply

was received by the respondent stating that the product was supplied by the Tamil Nadu Medical services Corporation Limited, Perundurai, Erode

District. Thereafter, the Tamil Nadu Medical Services Corporation Limited (TNMSC), Perundurai was addressed for information and they sent a

reply on 06.04.2009 that the product was supplied by A1 with a total quantity of 3,00,000 tablets. Subsequently, on 13.04.2009, the respondent

sent a notice to A1, inter alia, to show cause as to why action should not be taken against the Company for having sold a drug which was not of

standard quality, which is in contravention of section 18(a)(i) of the Act. Along with the notice, A1 received a copy of analysis report and a portion

of what was described as a "sealed sample" on 15.04.2009. For which, the 2nd petitioner/A2, as Director of A1, sent a reply dated 16.04.2009

requesting to send a copy of the signed copy of the report as well as Protocol of Analysis for which they can offer their explanation. Since the

sample is being expired in May, 2009, the respondent did not send any report; however, the respondent sent a original copy of Form-13 and

protocol of analysis on 23.04.2009, which was received by them on 25.04.2009. On 19.05.2009, A2 sent a reply and the same was received by

the respondent on 21.05.2009.

(b) In the reply, A2 has stated that they manufactured the said drug after complying with all the specifications laid down under IP and the TNMSC

also analysed each and every batch of drugs supplied to them; they analysed the control sample of the said batch of the drug at ATOZ

Pharmaceuticals Private Limited and was found to be complying with the Assay requirements as per I.P. as per report No. F9/A/17/05 dated

19.04.2009; they tested the third portion of the sample which was sent by the respondent at Bangalore Test House and found to be complying

with the Assay requirements as per I.P. as per report No. 0257 dated 29.04.2009; they stated that the Government Analyst has deviated from IP

method which is the reason for their product to show lower assay levels and finally, they denied that they manufactured and sold a substandard

quality drug and requested to send the sample to Central Drugs Laboratory, Kolkata for second opinion.

(c) But, the petitioners did not furnish the required particulars which were called for the contravention of Section 18-B of the Act; however, the

respondent received a notice under Rule 85(2) of the said Act from the Drugs Controller of Karnataka. On a perusal of the reply sent by the

petitioners, it was found that the manufacturer had received the copy of report in Form-13 with protocol and third portion of the sample on

15.04.2009, but they had intended to differ the report of the Government Analyst by their letter dated 19.05.2009, after a lapse of 28 days. They

had adequate time to move the Court to send the sample to the Central Drugs Laboratory, Kolkata as per section 25(3) of the Act. But it is found

that they dragged time till the end of the expiry of the drug and not adduced the report within the stipulated time and they have failed to exercise

their rights under the Act. Since their reply is not satisfactory, the complaint was lodged by the respondent before the Judicial Magistrate Court,

Kodumudi.

2. It is the main submission of the learned counsel appearing for the petitioner that the samples were drawn on 27.09.2007, which were tested only

on 26.02.2009 i.e. almost 17 months after they were drawn without disclosing the condition in which they were stored. The samples relatable to

the case were drawn on 27.09.2007. The Analyst report as regard the drugs was dated 26.02.2009. The report was sent to A1, which was

received on 25.04.2009 and the complaint was filed only in February 2010. The petitioners received summons in May, 2010 from the lower court.

By the time, it was found that the shelf-life of the drug had already expired in May, 2009. Hence, the petitioners had lost their valuable right

guaranteed u/s 25(4) of the Act because they were not in a position to make a request to send another sample to the Central Drugs Laboratory,

Kolkata.

3. Learned Additional Public Prosecutor appearing on behalf of the respondent submitted that the 2nd petitioner has received the Government

Analysis report vide letter of the respondent dated 13.04.2009. As per section

25(3) of the Act, the petitioners ought to have made a request within 28 days from the date of receipt of the copy of the report, notified in writing, to the Inspector or the Court before which any proceedings in respect of the sample are pending that they intend to adduce evidence in contravention of the Government report. But, in the instant case, the request was made by the petitioners only after expiry of 28 days i.e. on 19.05.2009. Therefore, the question of sending sample to Central Drugs Laboratory, Kolkata cannot be fulfilled due to the end of the expiry of statutory period.

4. But the learned counsel for the petitioners submitted that originally what was received by the petitioners on 15.04.2009 was only xerox copy of the report and not the true copy of the report. Therefore, the petitioners sent a reply dated 16.04.2009 and received the original copy of the analysis report on 25.04.2009. Thereafter, they sent their reply within 28 days, as required u/s 25(3) of the Act on 19.05.2009 with a request to send sample to Central Drugs Laboratory, Kolkata. Further, the complaint was filed only on 09.02.2010 before the Judicial Magistrate Court, Kodumudi and the petitioners had received the summons for first appearance dated 24.10.2010 and before filing report, the shelf-life of the drug had expired. Therefore, the petitioners had lost the chance of moving Court with a request to send the sample to Central Drugs Laboratory, Kolkata. Therefore, the proceedings arisen out of complaint are liable to be quashed on this ground also.

5. This Court has considered the submissions of both sides and perused the materials available on record.

6. It is the submission of the petitioners that they had received the show cause notice dated 13.04.2009 along with the xerox copy of analysis report on 15.04.2009 and they had sent the reply on 16.04.2009 requesting to furnish original copy of the analysis report. Thereafter, the respondent had furnished the original copy of analysis report on 23.04.2009, which was received on 25.04.2009. Thereafter, the petitioners sent a reply dated 19.05.2009 with a request to send the sample to Central Drugs Laboratory, Kolkata for analysis. Therefore, according to the petitioners, they had made a request within 28 days, as required u/s 25(3) of the Act, whereas according to the respondent, the petitioners, having

received the xerox copy of the report on 15.04.2009, ought to have made a request notified in writing to the Inspector or the Court, before which

the samples are pending, to send the sample to the Central Drugs Laboratory.

7. But, in my considered opinion, the original copy of the report dated 23.04.2009 was received by the petitioners only on 25.04.2009. When the

petitioners had not received the true copy of the report dated 13.04.2009, now, no significance could be attached to the xerox copy of the report

received by them on 15.04.2009. Therefore, in my considered opinion, the petitioners had made a request within 28 days from the date of receipt

of original copy of the report, expressing their intention to adduce evidence in contravention of Government report dated 26.02.2009. Under such

circumstances, as required u/s 25(4), the petitioners ought to have sent a sample for analysis to the Central Drugs Laboratory, Kolkata. Further, as

contended by the learned counsel for the petitioners, the complaint was filed by the respondent only in the month of February 2010; by that time,

the shelf-life of the drug had expired. Therefore, the petitioners had also lost the chance of moving the Court.

8. In this regard, a reference could be placed in the judgment relied on by the petitioners reported in *Medicamen Biotech Ltd. and Another Vs.*

Rubina Bose, Drug Inspector, wherein the Hon'ble Apex Court has held that when the appellants have been deprived of a valuable right under

sections 25(3) and 25(4) of the Act, it must necessitate the quashing of the proceedings against them. The relevant paragraph is extracted

hereunder:

19. 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 u/s 25(3) and 25(4) of the Act which must necessitate the quashing of the proceedings against them. A reading of the said judgment would clearly show that filing of the complaint before expiry of shelf-life of the drug is very important and if the complaint is filed after expiry of the shelf-life of the drug, the petitioners would be losing a valuable right to make a request to the Court to send the sample for re-test. It could be understood further from the said judgment that even assuming that there is a delay in filing the complaint, there should be an explanation on the part of the respondent with regard to the said delay.

9. Another reference could be placed in the decision relied on by the petitioners reported in *State of Haryana Vs. Unique Farmaid P. Ltd. Ors.,*)

in support of their submission that they were deprived of the right to get the sample tested by Central Drugs Laboratory. The relevant paragraphs

in the said decision are extracted hereunder:

10. It has been submitted before us as well as before the High Court that the Insecticide Inspector was not competent to send the sample for re-

testing to the Central Insecticides Laboratory and that request for re-testing should have been made to the Court concerned. Then the State has

further submitted that no other defence than prescribed u/s 30 of the Act could be allowed to be raised in the prosecution filed under the Act and

further that the shelf-life of the sample was not relevant as the Act does not prescribe any expiry date. There is no substance in either of these

contentions. If the expiry date is not relevant, there was no reason why in the form prescribed for submission of the report by the Insecticide

Analyst, the date of manufacture of the article and the expiry date are mentioned. We do not find any answer to this by the State. In support of this

submission, no rule has been cited and no evidence produced showing that the expiry date of the insecticide is inconsequential. Section 30

provides for defences which may or may not be allowed in prosecution under the Act. Section 30 is as under:

30. Defences which may or may not be allowed in prosecutions under this Act. -

(1) Save as hereinafter provided in this section, it shall be no defence in a prosecution under this Act to prove merely that the accused was ignorant of the nature or quality of the insecticide in respect of which the offence was committed or of the risk involved in the manufacture, sale or use of such insecticide or of the circumstances of its manufacture or import.

(2) For the purposes of Section 17, an insecticide shall not be deemed to be misbranded only by reason of the fact that:

(a) there has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or the preparation of the insecticide as an article of commerce in a state fit for carriage or consumption, and not to increase the bulk, weight or measure of the insecticide or to conceal its inferior quality or other defect; or

(b) in the process of manufacture, preparation or conveyance some extraneous substance has unavoidably become intermixed with it.

(3) A person not being an importer or a manufacturer of an insecticide or his agent for the distribution thereof, shall not be liable for a contravention of any provision of this Act, if he proves:

(a) that he acquired the insecticide from an importer or a duly licensed manufacturer, distributor or dealer thereof;

(b) that he did not know and could not, with reasonable diligence, have ascertained that the insecticide in any way contravened any provision of this Act; and

(c) that the insecticide, while in his possession, was properly stored and remained in the same state as when he acquired it.

10. Sub-section (1) of Section 30 which appears to be relevant only prescribes in effect that ignorance would be of no defence but that does not

mean that if there are contraventions of other mandatory provisions of the Act, the accused have no remedy. Procedure for testing the sample is

prescribed and if it is contravened to the prejudice of the accused, he certainly has right to seek dismissal of the complaint. There cannot be two

opinions about that. Then in order to safeguard the right of the accused to have the sample tested from Central Insecticides Laboratory, it is

incumbent on the prosecution to file the complaint expeditiously so that the right of the accused is not lost. In the present case, by the time the

respondents were asked to appear before the Court, expiry date of the insecticide was already over and sending of sample to the Central

Insecticides Laboratory at that late stage would be of no consequence. This issue is no longer res integra. In *The State of Punjab Vs. National*

Organic Chemical Industries Ltd., this Court in somewhat similar circumstances said that the procedure laid down u/s 24 of the Act deprived the

accused to have sample tested by the Central Insecticides Laboratory and adduce evidence of the report so given in his defence. This Court

stressed the need to lodge the complaint with utmost dispatch so that the accused may opt to avail the statutory defence. The Court held that the

accused had been deprived of a valuable right statutorily available to him. On this view of the matter, the court did not allow the criminal complaint

to proceed against the accused. We have cases under the Drugs and Cosmetics Act, 1940 and the Prevention of Food Adulteration Act, 1954

involving the same question. In this connection reference be made to decisions of this Court in *State of Haryana Vs. Brij Lal Mittal and Others*,

under the Drugs and Cosmetics Act, 1940; *Municipal Corporation of Delhi Vs. Ghisa Ram*, ; *Chetumal Vs. State of Madhya Pradesh and Anr*,

and *Calcutta Municipal Corporation Vs. Pawan Kumar Saraf and Another*, all under the Prevention of Food Adulteration Act, 1954.

11. 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

Insecticide 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 Insecticides Inspector or the Court before which proceedings are pending that

they intend to adduce evidence to controvert the report. In the present cases Insecticide Inspector was notified that the accused intended to

adduce evidence to controvert the report. By the time the matter reached the court, 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

accused have been deprived of that right, thus, prejudicing them in their defence. In these circumstances, High Court was right in concluding that it

will be an abuse of the process of court if the prosecution is continued against the respondents - the accused persons. High Court rightly quashed

the criminal complaint. We uphold the order of the High Court and would dismiss the appeals. Following the principles laid down in the said

judgments, I am of the opinion that because of the delay in filing the complaint, the petitioners have been deprived of a valuable right for having the

sample tested from the Central Drugs Laboratory, Kolkata, prejudicing them in their defence. Hence, it will be an abuse of process of court if the

prosecution is continued against the petitioners. Hence, the complaint is liable to be quashed.

Accordingly, the criminal original petition is allowed and the proceedings in C.C. No. 74 of 2010 pending against the petitioners on the file of Chief

Judicial Magistrate, Kodumudi, are quashed.