
(1991) 08 MAD CK 0100

In the Madras High Court

Case No : Criminal Miscellaneous Petition No. 10225 of 1989

Concept Pharmaceuticals Pvt. Ltd.

APPELLANT

Vs

State of Tamil Nadu

RESPONDENT

Date of Decision : 19-08-1991

Acts Referred:

Drugs and Cosmetics Act, 1940 — Section 18, 18(1), 34, 34(1)

Citation : (1994) ECR 155 : (1992) 58 ELT 6

Hon'ble Judges : Arunachalam, J

Bench : Single Bench

Advocate : Mr. Arvind P. Datar, for the Appellant; Mr. B. Sriramulu, Public Prosecutor, for the Respondent

Judgement

1. The petitioners are the accused in C.C. No. 5367/89 pending on the file of the X Metropolitan Magistrate, Egmore, Madras. On a private complaint preferred by the respondent, who is the Drugs Inspector, Perambur Range, Madras, the petitioners are being prosecuted in the aforesaid case, for having contravened the provisions of Section 18(1)(i) of the Drugs and Cosmetics Act, punishable u/s 27(d) of the same Act. A perusal of the complaint discloses, that the first petitioner is the drug manufacturing firm at Bombay, while petitioners 2 and 3 are the Directors of the said firm. The fourth petitioner is the person in-charge of the conduct of the business of the first petitioner at Bombay, while the fifth petitioner is the person in charge of the Madras branch of the first petitioner, for the conduct of day-to-day business. On 18-11-1987, the then Drugs Inspector drew samples of Comoxyl dry syrup Amoxycillin, manufactured by the first petitioner, from the Medical Stores of the Southern Railway Headquarters Hospital, Aynavaram. On analysis, of the sample taken, by the Government Analyst (Drugs), Madras, it was noticed that the sample was not of standard quality, since the claim in the label, did not conform to the content of Amoxycillin, shown therein. A show cause notice was issued and a reply followed. In the reply, the petitioners are stated to have claimed, that the test adopted for analysis by the Laboratory was not the correct test, since a different analytical

method as given in USP alone, should be used. It was also pointed out by the learned Counsel, that the first petitioner had enclosed along with the reply to the show cause notice, the laboratory report obtained at its instance, which would have the effect of nullifying the offences allegedly committed. After the receipt of reply to the show cause notice, this prosecution was initiated. Process was issued to the petitioners and thereafter they had chosen to invoke the inherent powers of this Court to have the pending prosecution quashed, as not maintainable and an abuse of process of Court.

2. Mr. Arvind P. Datar, learned Counsel representing the petitioners contended, that the prescribed standard for the sample seized had not been stated in the complaint and if such prescription had not been made evident, this prosecution should not be allowed to survive. He then pointed out, that the complaint does not even make a reference to the reply made by the petitioners to the show cause notice, enclosing therein another report, which would enure in their favour. In any event, he submitted that all the petitioners are not liable to be proceeded against without a basic averment that one or other of them were in charge of and responsible for the conduct of the business of the company.

3. I have heard Mr. B. Sriramulu, learned Public Prosecutor on these contentions. He pointed out, that the sample seized contained a label which showed that the drug contained 125 mg. of Amoxycillin - the standard prescribed by British Pharmacopoeia. He would then refer to item 1 of the Second Schedule and invite the Court to hold that the standard to be complied with was, the formula or list of ingredients displayed, in the prescribed manner, on the label. If the label intended to show compliance according to the standard prescribed by British Pharmacopoeia, the petitioners cannot express any grievance, since analysis had been done under the B.P. method, to establish the contra position.

4. I have carefully considered the rival contentions of the counsel of either side. The averment in the complaint *prima facie* show, that the sample seized did not conform to the standard shown in the label, according to the report of the Analyst also indicates. Hence at this stage, subject to rebuttal evidence, it can be held, that a foundation has been laid by the prosecution, to proceed further with the trial. The defence of the petitioners, that the analysis under B.P. method was not the correct test, cannot be gone into in the exercise of inherent powers, since evidence will have to be brought on record by the defence and an opportunity furnished to the prosecution to challenge the genuineness of such evidence. Naturally, this exercise will have to be relegated for appreciation by the trial Magistrate, after evidence is brought on record, by both parties. I am unable to agree with the learned Counsel for the petitioners, that Section 18 of the Act read with Item 1 to the Second Schedule will not take in the contravention alleged, since all that is expected in the label is the list of ingredients and not the quantity thereof. To accept, this proposition would lead to disastrous results. I do not consider it necessary, that the complaint should state the prescribed standard, for a perusal of Section 18 read with Item 1 to the Second Schedule,

apparently indicates such prescription. It would have been of course better, if the prosecution had stated in the complaint, about the receipt of the reply to the show cause notice, its reaction and then the need to institute this prosecution. Not having done so will not be sufficient to throw away the prosecution.

5. Learned Counsel brought to my notice the judgment of a Division Bench of the Orissa High Court in *Gopilal Agarwal Vs. State of Orissa and Another*, , to substantiate his contention, that the provisions of the Act and the rules prescribing penalty for infringement of standard quality of the drug cannot be enforced until standard quality is prescribed. The facts therein are easily distinguishable, and as I have already stated Section 18 read with item 1 to the Second Schedule would be sufficient to negative this contention.

6. The last argument of the learned Counsel has a sufficient force. u/s 34 of the Drugs and Cosmetics Act, where an offence under the Act had been committed by a company, the persons who will be vicariously liable, would be those, who at the time when the offence was committed were in charge of and responsible for the conduct of the business of the company as well as the company itself. Before choosing to prosecute any person vicariously, prima facie the complaint must contain allegations, that such persons were in charge of and responsible for the conduct of the business of the company, at the relevant time. The absence of this basic averment would be sufficient to halt the prosecution, against those persons, who do not fall within this category contemplated by law. Only after the initial burden of "incharge of" and "responsible" is discharged by the prosecution, the proviso to Section 34(1) would come into operation, shifting the onus on the persons concerned, to prove that the offence was committed without the knowledge in spite of exercise of all due diligence to prevent commission of such an offence. The law on this question is well settled. A perusal of the complaint clearly shows, that petitioners 2 and 3 were the directors of the first petitioner and were residents of Bombay. Nowhere, it has been stated in the complaint, that petitioners 2 and 3 were in charge of and responsible for the conduct of the business of the first petitioner. The second petitioner is a lady and the wife of the third petitioner. On the sole ground that no allegations have been made against petitioners 2 and 3, which would attract the ingredients of Section 34(1) of the Act, the pending prosecution in so far as it relates to them, will have to be quashed and shall accordingly stand quashed. As far as petitioners 1, 4 and 5 are concerned, the prosecution will have to be sustained. The first petitioner is the company itself, while the fourth petitioner is not only the Chairman, but also the person in charge of the conduct of the business of the first petitioner at Bombay, where the manufacturing unit is situated. As far as the fifth petitioner is concerned, he is the person in charge of the day-to-day conduct of the business at Madras. Of course, it will be open for these petitioners to contend, before the trial Magistrate, that the offence alleged had not been established and further the proviso to Section 34(1) of the Act will attract their case. At this stage, I do not find any scope to interfere, as far as petitioners 1, 4 and 5 are concerned.

7. This petition is partly allowed by quashing the proceedings in C.C. No. 5367 of 1989, pending on the file of the X Metropolitan Magistrate, Egmore, Madras, in so far as it concerns, petitioners 2 and 3, and by allowing it to be continued, in respect of the other petitioners.