(2018) 10 BOM CK 0191

In the Bombay High Court

Case No : Criminal Writ Petition No.54 Of 2018

AFD Laboratories Pvt. Ltd. — APPELLANT

Vs

Union of India — RESPONDENT

Date of Decision : 29-10-2018

Acts Referred:

Drugs and Cosmetics Act, 1940 — Section 9B, 13, 18, 18A, 18B, 18(c), 18(i)(a), 18(b), 23, 27(d), 28, 32, 32(1)
Drugs and Cosmetics Rules, 1945 — Rule 85
Code of Criminal Procedure, 1973 — Section 200, 482

Citation : (2018) 10 BOM CK 0191

Hon'ble Judges : Nutan D. Sardessai, J

Bench : Single Bench

Advocate : Shivan Desai, Susan Linhares

Final Decision : Allowed

Judgement

1. TheÂ petitionersÂ haveÂ assailedÂ theÂ orderÂ dated 21. 07.2017 passed by the learned JMFC, Vasco, pursuant to which the learned JMFC

ordered the issuance of process against the petitioners on the complaint lodged by the respondent under Section 18(i)(a) read with Section 32 of The

Drugs and Cosmetics Act, 1940, (Act, for short hereinafter) by invoking the jurisdiction of this Court under Section 482 of the Cr.P.C.

2. It was the case of the petitioners that although allegations were made against them, the material on record did not even disclose, prima facie, any

case under Sections 18(i)(a) and 27(d) of the the Act. The complaint did not contain any material allegation against the petitioners and that the

summons had been issued arbitrarily and in a most perfunctory manner. The respondent had not even followed the procedure established by law in

reaching the conclusion to investigate the issue regarding the drug manufactured

by the company and, therefore, non following of the procedure

rendered both i.e. the complaint as well as the summons issued therein without warrant or authority of law and the same were liable to be quashed.

The petitioners have been involved in the process of manufacturing the subject drug Diltiazem Tablets IP (Cardem-30) i.e. the subject drug for

brevity's sake from the year 2006-2007 under a loan license obtained by the petitioner no.1 and conforming to the specifications for the subject drug as

per the Indian Pharmacopoeia Standards i.e. IP 2007 with only method as Modified Release. However, as per the Indian Pharmacopoeia Standards

2010, the subject drug was given to dissolution methods i.e. Method A (Modified Release) and Method B (Conventional Release) and were continued

for IP 2014 as well. The petitioners from the inception and commencing the manufacturing of the said drug used to conform the drug to the Method of

Modified Release as per IP 2007 i.e. Method A of Modified Release. The respondent however lodged a complaint against the petitioners herein

arraying them as the accused without appreciating the facts and circumstances and the law applicable thereon on the premise that the subject drug

was not conforming to the IP Standards prescribed.

3. The case of the respondents was that the sample of the subject drug manufactured by the petitioner no.1 was drawn from the Hospital Pharmacy

of Goa Medical College for test and analysis under Section 23 of the said Act to the Government Analyst, Central Drugs Testing Laboratory Chennai.

The Government Analyst of the said Laboratory found samples of the subject drug non complaint with the IP standards with respect to the tests for

dissolution. The respondent informed the pharmacist at the hospital pharmacy of the subject drug not being of standard quality and requested the

pharmacist to stop the sale and recall the stock and the investigation revealed that the petitioners were manufacturing the subject drug.

4. The petitioners vide their letter dated 16.06.2015 challenged the report drawn by the analyst and submitted that the drug was manufactured by them

pursuant to the loan licenses and that right from the inception the test procedure for the subject drug was as per IP 2007 monographs which

prescribed only one method being the Modified Release Method. The petitioners had informed the respondents that in another batch relating to the

same drug a similar problem had arisen and the subject drug was declared not of

standard quality on account of the failure in dissolution test by the

Food and Drugs Laboratory, Vadodara and had requested the Drugs Controller, Karnataka for getting the same re-analysed as per Test A method.

The sample drug was tested by the Government facility Karnataka and they had declared the subject drug to be of standard quality with regard to

dissolution by Method A and in turn forwarded a copy of the test report issued in the prescribed form. The petitioners by their letter dated 16.06.2015

requested the respondents that they would challenge the said report drawn by the Government Analyst and requested them to refer the samples to

CDL Kolkatta by the dissolution A Method and by letter dated 31.08.2015 addressed to the Director, CDL, Kolkatta, the petitioner no.1 also requested

them to analyse the sample of drug as per dissolution A Method.

5. The respondent however alleged that CDL Kolkatta issued a report in Form 2 and declared the sample not of standard quality. However, according

to the petitioners, CDL Kolkatta followed Method B to arrive at its conclusion which itself was erroneous and the report was completely inconclusive.

The respondent in the complaint alleged various purported non-compliances as per their report dated 25. 07.2016 whereof has not been provided to the

petitioners. Nonetheless, on verifying the records it was found that the said report recommended a show cause notice to be issued under Rule 85 of

the Drugs and Cosmetic Rules. The learned JMFC thus passed the order dated 21.07.2017 issuing process against them and therefore they were

constrained to invoke the jurisdiction of this Court under Section 482 of the Cr.P.C. to quash the impugned summons and the complaint.

6. The petitioners in their status as the Directors of the petitioners-Companies in Criminal Writ Petition No.54/2018, invoked the jurisdiction of this

Court again under Section 482 of Cr.P.C. for quashing the process issued against them pursuant to the order dated 21.07.2017 on the basis of the

complaint lodged by the respondent under Section 18(a)(i) read with Section 27(d) of the said Act read with Section 200 of the Cr.P.C. It was their

case that the impugned order had been passed by the learned JMFC in pursuance to the complaint lodged by the respondents under Section 18(a)(i)

read with Section 32(1) of the said Act read with Section 200 Cr.P.C. The allegations made against them read with the material on record did not

disclose even a prima facie case under the said sections or Section 18(b) thereof

and yet process had been issued against them. Rest of their case

was verbatim that pleaded in WPCR No.54/2018 while praying for the quashing of the process and the complaint filed against them.

7. Heard Shri Shivan Desai, learned Advocate appearing for the petitioners who submitted at the outset that the order of issuance of process was

without recording any reasons and on that premise alone the process was liable to be quashed and set aside. It was his contention next that the case

of the respondent was that the quality of the drug in question did not meet the IP Standard 2010. The sample of the subject drug was drawn on

30.05.2014 while the petitioners were appointed as the Directors of the Companies on 28.05.2015 and 14. 09.2015 respectively. Therefore, both of

them were not in charge of and responsible for the affairs of the companies in question on the date of the alleged commission of the offence when the

sample of the subject drug was drawn by the complainant. It was next his submission that another inspection was held on 25.07.2016 which was an

independent offence and there could be no amalgamation of the two incidents which were independent of each other. The order of issuance of

process was therefore vitiated. There was also no material to show what was the role played by the petitioners when the first offence took place and

on that premise alone the process had to be quashed and set aside.

8. Shri Desai, learned Senior Advocate next adverted to Section 18(b) read with 85 of the Rules and submitted that there was a power in the

respondent to issue a show cause notice and in the absence of the issuance of such a notice, the prosecution could not lie against them. He placed

reliance in Domnic Mendes vs. The Goa State Pollution Control Board [WPCR No.68/2018], Rajendra Rajoriya vs Jagat Narain Thapak & anr.

[CRIA No.312/2018], State of Haryana vs. Brij Lal Mittal & Ors. [(1998) 5 SCC 343]and in A.V.Mody & Ors. vs. S. R. Salunke & Ors.

[Manu/MH/1492/1999]. It was once again his contention that even a perusal of the joint inspection report revealed that Method A was applicable and

not Method B and there was a complete failure by the respondent to show how Method B applied to the case of the petitioners. It was a fit case to

invoke the jurisdiction of this Court and quash the process and the complaint filed against them.

9. Ms. Susan Linhares, learned Special Public Prosecutor on behalf of the

respondent submitted that the subject drug was tested which was found to

be spurious and of sub-standard quality. The petitioners failed to name the persons responsible for the affairs of the Company despite queries. There

was a clear opinion given by the laboratory that the subject drug was not of a standard quality. The first offence was regarding the manufacture of

spurious drugs by the petitioners who were the Directors of the Company. In any event, the learned JMFC had applied its mind before issuing process

against them. She adverted to the affidavit in reply and submitted that an alternate remedy was available to the petitioners and no remedy was

available by invoking the writ jurisdiction of this Court.

10. Shri Shivan Desai, learned Advocate for the petitioners in reply submitted that there was no allegation against the petitioners that they had not

disclosed the information. In any event and assuming that there was no disclosure, it contemplated penalty in terms of Section 28 of the Act. The reply

as filed by the respondents could not be looked into which was well beyond the scope of the complaint. The record of the Registrar of the Companies

was adequate to show that the petitioners were not responsible for the affairs of the company at the relevant time and therefore on all these counts,

the process had to be quashed and set aside.

11. i would consider their submissions, the relevant provisions of the Act and the Rules framed thereunder, the judgments relied upon and in view

thereof, decide the petitions appropriately.

12. The Act has been enacted to regulate the import of manufacture for distribution of sale of drugs and cosmetics. What constitutes a spurious drug

is contained in Section 9B of the Act. Section 13 deals with the offence under the Act. Section 18 is concerned with the prohibition of manufacture

and sale of certain drugs and cosmetics and reads that no person shall himself or by any other person on his behalf '(a) manufacture for sale or for

distribution, or sell, or stock or exhibit or offer for sale or distribute, (i) any drug which is not of a standard quality or is misbranded, adulterated or

spurious.

13. Section 27 deals with the penalty for manufacture, sale, etc., of drugs in contravention of this Chapter and sub-clause (d) provides that whoever

himself or by any other person on his behalf manufactures for sale or distribution, or sells, or stocks or exhibits or offers for sale or distributes any drug

other than a drug referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this Chapter or any rule made

thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and with fine

which shall not be less than twenty thousand rupees. Provided that the Court may for any adequate and special reasons to be recorded in the judgment

impose a sentence of imprisonment for a term of less than one year. Section 18A deals with the disclosure of the name of the manufacture and

provides that 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. Section 18B requires maintenance

of records and furnishing of information and provides that every person holding a licence under clause (c) of Section 18 shall keep and maintain such

records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any

function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.

14. Section 28A of the Act deals with the penalty for non-disclosure of the name of the manufacture and provides that whoever contravenes the

provisions of Section 18A shall be punishable with imprisonment for a term which may extend to one year, or with fine which shall not be less than

twenty thousand rupees or with both. In other words looking to the scheme of the Act, the learned JMFC had to act appropriately while dealing with

the complaint lodged by the respondent.

Besides, in terms of Section 18B of the Act, the complainant was required to issue a notice to the petitioners in terms of Rule 85 to show cause which

it failed to do. In other words, the respondent without following the predicates of the Act, proceeded to file the complaint against the petitioners even

without giving a show cause notice to the petitioners why an order should not be passed to cancel the license or suspend it for such period as he thinks

fit in respect of the drug to which it relates as the case may be.

15. First and foremost, there is force in the contention of Shri Desai, learned Counsel appearing for the petitioners that the learned JMFC totally fell in

error while issuing the process inasmuch as there was no application of mind and

order made by the learned JMFC to issue summons to the

accused/petitioners was without recording even in a cryptic manner its reasons for issuing such a process against the petitioners. On that count itself,

the order of the learned JMFC is vitiated. Secondly and once again and as rightly submitted by Shri Desai, the learned Advocate for the petitioners,

they were appointed as the Directors of the two Companies on 28. 05.2015 and 14.09.2015 unlike the samples being drawn on 30.05.2014. In other

words, both of them were not in charge of and responsible for the affairs of the company at the time of the commission of the alleged offence and,

therefore, they could not be prosecuted by the respondents. On that count too, the order of issuance of process nor the complaint can be sustained

against them. Last but not the least, the joint investigation report drawn of the two Companies indicates in no uncertain terms that the manufacturers

followed Method A for dissolution testing as specified in respect of the subject drug unlike the Method B adopted by the laboratory at Kolkatta to hold

that the product was not of standard quality. The respondents had otherwise not shown how Method B for Conventional Release was applicable to the

case of the petitioners. The complaint too was silent in that regard. Moreover, the petitioners had clearly conveyed to the respondents that the subject

drug manufactured by them on loan license was by following the dissolution test procedure as per IP 2007 monograph namely for Modified Release

Method.

16. It is claimed in the reply that the petitioners have alleged several disputed questions of fact which is not at all the position. The plea on behalf of

the respondent that an efficacious alternate remedy is available to the petitioners too has not been shown and quite on the contrary the reply filed by

the respondent in material aspects travels beyond the scope of the complaint.

17. In Domnic Mendes (supra), a learned Single Judge of this Court (C.V. Bhadang,J), relied in Anil Kumar & Ors. vs. M. K. Aiyappa & anr. [(2013)

10 SCC 705] and Rajendra Rajoriya vs. Jagat Narain Thapak & Ors. [AIR 2018 SC 1229] where it was held that at the stage of issuance of process

and taking cognizance the Magistrate is expected to apply its mind and record reasons although such reasons may not be elaborate. It was found in

the facts of the case that the impugned order was totally unreasoned and therefore the accused no.3 could not be vicariously made liable under the

provisions of the Act in question. The learned Single Judge also considered Vijay & Ors. vs. State of Maharashtra & Ors. [AIR 2017 SC 397]which

held that availability of an alternate remedy was not an absolute bar and would not limit the availability of the inherent powers under Section 482 of the

Cr.P.C. The question whether such a petition could be entertained, essentially would depend upon the facts and circumstances of each case.

18. In Rajendra Rajoriya (supra), the Hon'ble Apex Court while dealing with the aspect as to the legality of the order of the learned Magistrate taking

cognizance of the matter observed that the standard required by the Magistrate while taking cognizance is well settled by this Court in a catena of

judgments. It referred to Subramanian Swamy vs. Manmohan Singh & anr. [(2012) 3 SCC 64,) where it explained the meaning of the word

'cognizance' holding that â??...In legal parlance cognizance is taking judicial notice by the court of law, possessing jurisdiction, on a cause or matter

presented before it so as to decide whether there is any basis for initiating proceedings and determination of the cause or matter judicially.â? We may

note that the Magistrate while taking cognizance has to satisfy himself about the satisfactory grounds to proceed with the complaint and at this stage

the consideration should not be whether there is sufficient ground for conviction. It may not be out of context to note that at the stage of taking

cognizance, the Magistrate is also not required to record elaborate reasons but the order should reflect independent application of mind by the

Magistrate to the material placed before him.

19. In Brij Lal Mittal (supra), the Hon'ble Apex Court held where the offences were committed by companies that simply because a person is a

Director of the company he vicariously does not necessarily mean that he fulfils the requirements so as to make him liable. Conversely, without being

a director a person can be in charge of and responsible to the company for the conduct of its business.

20. In A. V. Mody (supra), the learned Single Judge of this Court while dealing with the petition for quashing of the complaint filed by the respondent

before the learned JMFC Khed and the process being issued therein under the provisions of the Act held at paragraph 5 as below :

â??In the instant case what is averred in para 2 of the complaint is that accused Nos. 1 to 4 are the Directors of the accused No. 8 Company. It is

further averred in para 20 that as per the provisions of Section 34 of the Act accused Nos. 1 to 11 were responsible for manufacture, for sale, for

distribution and for sale of the drug in question which was not of standard quality and hence committed offence under Section 18(a)(i) of the Act. The

said averments in the complaint, in my view, do not make out the prima facie case against the petitioners accused who were the Directors of the

company and, therefore, the petitioners are not liable for being prosecuted under Section 34 for the alleged offence committed by the company.â??

21. Moreover, as rightly submitted by Shri Desai, learned Advocate appearing for the petitioners, the complaint also no where indicates as to how

Method B applied to the case of the petitioners. Therefore, considering the law on the point, the complaint as it stands and the plea taken by the

petitioners, the complaint must fail and as the process issued without the application of mind too would not lie.

22. In view thereof, i pass the following :

ORDER

The petitions are allowed and the orders issuing process and the complaint are quashed and set aside.

