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Crl.O.P No.2547 of 2022

IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 02.08.2023

CORAM

THE HONOURABLE MR. JUSTICE N. ANAND VENKATESH

Crl.O.P No.2547 of 2022

and

Crl.M.P.No.1167 of 2022

1. Crescent Therapeutics Limited
(Presently known as Sanctus Global Formulations Ltd.)
Through its Directors
Factory at Khasra No.587/588, Village Kunjhal,
Beside Jharmajri,
Baddi, Solan District, Tehsil, Nalagarh,
Himachal Pradesh – 173 205.
2. Vijay Kumar Joshi
Director, Crescent Therapeutics Limited
(Presently known as Sanctus Global Formulations Ltd.)
Through its Directors
Factory at Khasra No.587/588, Village Kunjhal,
Beside Jharmajri,
Baddi, Solan District, Tehsil, Nalagarh,
Himachal Pradesh – 173 205.
3. Vinod Kumar Joshi
Director, Crescent Therapeutics Limited
(Presently known as Sanctus Global Formulations Ltd.)
Through its Directors
Factory at Khasra No.587/588, Village Kunjhal,
Beside Jharmajri,
Baddi, Solan District, Tehsil, Nalagarh,
Himachal Pradesh – 173 205.



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4.Sahil Joshi

Director, Crescent Therapeutics Limited
(Presently known as Sanctus Global Formulations Ltd.)
Through its Directors
Factory at Khasra No.587/588, Village Kunjhal,
Beside Jharmajri,
Baddi, Solan District, Tehsil, Nalagarh,
Himachal Pradesh – 173 205.

... Petitioners

vs.

Union of India,
represented by
Drugs Inspector,
Office of the Deputy Drugs Controller (India),
Central Drugs Standard Control Organization,
2nd Floor, Shastri Bawan, Annexe,
26, Haddows Road,
South Zone, Chennai – 600 006.

... Respondent

PRAYER: Criminal Original Petition filed under Section 482 of the Code of Criminal Procedure, to call for the records of the proceedings in C.C.No.343 of 2021 on the file of the XV Metropolitan Magistrate's Court, George Town, Chennai and to quash the same as illegal.

For Petitioners : Mr.Sarath Chandran
for Ms.Aditi Ashok

For Respondent : Mr.M.Karthikeyan



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ORDER

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This petition has been filed challenging the proceedings pending in C.C.No.343 of 2021, on the file of the XV Metropolitan Magistrate Court, George Town, Chennai.

2. The respondent has filed a complaint before the Court below against the accused persons (A1 to A4) for contravention of Section 18(a)(i) r/w Section 16 and Section 18-B of the Drugs and Cosmetics At, 1940 (hereinafter referred to as 'the Act') punishable under Sections 27(d) and 28-A of the Act.

3. The sum and substance of the complaint given by the respondent is that the company is manufacturing drugs of substandard quality and hence, the company and its directors have contravened the provisions of the Act and consequently they are punishable for the said contravention.

4. Heard the learned counsel for the petitioners and the learned Standing counsel appearing on behalf of respondent.



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5. Even though the quash petition has been filed by all the four accused persons, the learned counsel for the petitioners submitted that he is confining his arguments only insofar as the petitioners 2 to 4 (A2 to A4).

6. It was submitted that the complaint filed by the respondent completely lacks any specific allegations against A2 to A4, which is mandatory under Section 34 of the Act. It was further submitted that the license that was issued by the designated authority for manufacture and sale / distribution of drugs specifically gives the names of persons who are involved in the manufacturing and testing. To substantiate the same, Form 28 and Form 26 that were issued in favour of A1-Company was brought to the notice of this Court and it was further informed by virtue of the communication dated 26.06.2018, that the license was extended from 20.06.2018 to 19.06.2023. Such extension was made by taking into consideration the earlier license issued under Form 26 which specifically names the persons who are responsible for manufacturing and testing. The learned counsel submitted that the persons on whom the responsibility has been placed under the license are the persons who are incharge of manufacturing and testing of drugs and they are the ones who should be made as accused persons. It was further



contended that if the Director is made as an accused, the requirement under Section 34 of the Act must be satisfied.

7. Per contra, Mr.M.Karthikeyan, learned Standing counsel appearing on behalf of the respondent submitted that sufficient averments were made in the complaint as against the accused persons. That apart, learned counsel by pointing out to paragraph 13 of the complaint submitted that the investigation team was not able to gather the particulars and the same has been specifically mentioned in the complaint. In view of the same, it was contended that the mandate under Section 34 of the Act has been fulfilled and that the accused persons must face the trial before the Court below.

8. The allegations made against the petitioners in the complaint is as follows:

“4. The complaint further submits that the 1st Accused is manufacturer of the drug Telmisartan Tablets IP 40 mg (Telmiral 40) Batch No.: 78TML18002, Manufacturing Date: NOV. 2018, Expiry Date: JUN. 2020 running under the name and style of M/s.Crescent Therapeutics Ltd., Khasra No.587/588, Beside Jharmajri, Village Kunjhal, Baddi, Tehsil Nalagarh, Distt. Solan – 173 205, Himachal Pradesh.



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5. The complainant further submits that, 2nd accused Shri. Vijay Kumar Joshi Director of M/s.Crescent Therapeutics Ltd., (presently known as M/s.Sanctus Global Formulations Ltd.), Khasra No.587/588, Beside Jharmajri, Village Kunjhal, Baddi, Tehsil Nalagarh, Distt. Solan – 173 205, Himachal Pradesh, 3rd Accused, Shri.Vinod Kumar Joshi Director of M/s.Crescent Therapeutics Ltd., (presently known as M/s.Sanctus Global Formulations Ltd.), Khasra No.587/588, Beside Jharmajri, Village Kunjhal, Baddi, Tehsil Nalagarh, Distt. Solan – 173 205, Himachal Pradesh, 4th accused, Shri.Sahil Joshi, M/s.Crescent Therapeutics Ltd., (presently known as M/s.Sanctus Global Formulations Ltd.), Khasra No.587/588, Beside Jharmajri, Village Kunjhal, Baddi, Tehsil Nalagarh, Distt. Solan – 173 205, Himachal Pradesh. Above said directors of M/s.Crescent Therapeutics Ltd., (presently known as M/s.Sanctus Global Formulations Ltd.), Khasra No.587/588, Beside Jharmajri, Village Kunjhal, Baddi, Tehsil Nalagarh, Distt. Solan – 173 205, Himachal Pradesh are responsible persons for the manufacturing and conduct of business of the Accused No.1 at the time when the drug in question was manufactured, i.e. Month of November 2018. (Copy of letter received from Deputy Registrar of Companies Punjab and Chandigarh along with its enclosers is enclosed as Annexure-3)”

9. Insofar as the first petitioner (A1) is concerned, the proceedings will have to go on and there is no scope for interfering with the proceedings. The



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only issue to be considered is as to whether A2 to A4 will have to undergo the trial before the Court below.

10. The averments made in the complaint and which has been extracted *supra*, shows that the mandate under Section 34 of the Act has not been fulfilled. The complaint does not state as to how A2 to A4 are incharge and responsible for running the day-to-day affairs of A1-Company.

11. The recent judgment of this Court in Crl.O.P.No.11184 of 2019, dated 12.10.2022 was brought to the notice of this Court. Learned Single Judge of this Court had an occasion to deal with the scope of Section 34 of the Act. The learned Single Judge after considering the law and issue came to the following conclusion:

“24. The offences and the offenders in the case of this nature is manufacturing and distribution of sub-standard drugs by a Company which is managed by its Board of Directors. The decision to manufacture the drugs is the collective decision of the Board of Directors. Therefore, the Directors cannot claim that they are not directly involved in the product of the drugs, when the decision to produce the drugs itself is the out come of their decision. Therefore, the case of Directors signing the cheque on



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behalf the Company and the case of Directors participating in the decision to produce sub-standard drugs are not one and the same to hold that these petitioners are not involved in day-to-day affairs of the Company.”

12. It is also brought to the notice of this Court that there is a recent judgment of the Hon’ble Apex Court on this issue in the case of ***Lalankumar Singh and Others vs. State of Maharashtra*** reported in ***2022 SCC OnLine SC 1383*** and the relevant portions are extracted hereunder:

“33. It can thus be seen that there are no specific averments insofar as the present appellants are concerned. It is further to be noted that the present appellants are neither the managing director nor the whole-time directors of the accused company.

34. It is further to be noted that, in accordance with the provisions of Rule 76 of the said Rules read with Form 28, the Accused Nos.9 and 10 have specifically been approved by the licensing authority in Form 28, Accused No.9 was approved as a person under whose active direction and personal supervision the manufacture would be conducted as required under sub-rule (1) of Rule 76 of the said Rules. Similarly, Accused No.10, who was approved as a head of the testing unit, was to be in-charge



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for carrying out the test of the strength, quality and purity of the substances as may be required under the provisions of Part X of the said Rules. We are therefore of the considered view that the complaint is totally lacking the requirement of Section 34 of the said Act.”

13. The Apex Court while dealing with the scope on Section 34 of the Act has rendered the following finding:

“28. It could thus clearly be seen that this Court has held that merely reproducing the words of the section without a clear statement of fact as to how and in what manner a director of the company was responsible for the conduct of the business of the company, would not ipso facto make the director vicariously liable.”

14. In terms of the above finding, the Apex Court applied the facts of that case and came to a conclusion that there are no specific averments against the Directors as mandated under Section 34 of the Act.

15. The above judgment of the Hon’ble Apex Court is binding on this Court. Therefore, the judgment of the learned Single Judge in Crl.O.P.No.11184 of 2019, dated 12.10.2022 cannot be pressed into



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operation, in the light of the judgment of the Hon'ble Apex Court referred to *supra*.

16. It is apparent from the above judgment that the Hon'ble Apex Court has also considered the relevant Form that is issued at the time of granting license to the company and has dealt with the same in paragraph 34 of the judgment. The Hon'ble Apex Court has held that the person whose name has been approved under the relevant Form must be the person who is incharge for carrying out the test of the strength, quality and purity of the drug as required under the relevant Rules. The Hon'ble Apex Court held that the same was lacking in the said case and hence the requirement under Section 34 of the Act was not fulfilled.

17. In the instant case, the license that was given to A1-company under Form 28 on 20.06.2008 specifically names the technical staff who are incharge of the manufacturing and testing of drugs. This license was valid upto 2013. Thereafter, the license was renewed under Form 26 on 11.07.2013 and even in the said Form, the competent technical staff



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responsible for manufacturing and testing have been named. This renewal of license was given till 2018 and thereafter it was extended upto 19.06.2023.

18. It is clear from the above that the approved technical staff has already been fixed under the relevant Form and it is quite surprising that the respondent did not add them as accused persons in the complaint. The Hon'ble Apex Court in the above judgment has made it very clear that it is these technical staff who have been identified, must be incharge of carrying on the test and ensuring the quality maintained in the drugs.

19. The respondent has mechanically added A2 to A4 as accused persons. A2 to A4 are not the persons who have been named in the license that was given to A1-company and that position continues even when it was renewed from time to time. That apart, there are no sufficient allegations against A2 to A4 in the complaint as mandated under Section 34 of the Act. The Hon'ble Apex Court has held that a mere reproduction of the words found in Section 34 of the Act, without a clear statement as to how and in what manner A2 to A4 were responsible for the conduct of the business of the A1-company, is not enough to rope in them as accused persons.



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20. In the light of the above discussions, continuation of the proceedings as against the petitioners 2 to 4 (A2 to A4) will amount to abuse of process of Court, which requires the interference of this Court in exercise of its jurisdiction under Section 482 of Cr.P.C.

21. In the result, this Criminal Original Petition is partly allowed and the proceedings as against the petitioners 2 to 4 (A2 to A4) in C.C.No.343 of 2021 on the file of the XV Metropolitan Magistrate Court, George Town, Chennai are hereby quashed. The proceedings as against A1 shall go on and the Court below shall complete the proceedings within a period of three months from the date of receipt of a copy of this order. Consequently, connected miscellaneous petition is closed.

02.08.2023

Index : Yes
Internet : Yes
Speaking Order/Non-Speaking Order
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To

1.The Drugs Inspector,
Union of India,
Office of the Deputy Drugs Controller (India),
Central Drugs Standard Control Organization,
2nd Floor, Shastri Bawan, Annexe,
26, Haddows Road,
South Zone, Chennai – 600 006.

2.The Public Prosecutor,
High Court, Madras.



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N. ANAND VENKATESH, J.

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