IN THE HIGH COURT OF KARNATAKA AT BENGALURU DATED THIS THE 10^{TH} DAY OF MAY, 2022

BEFORE

THE HON'BLE MR. JUSTICE M. NAGAPRASANNA CRIMINAL PETITION No.6875 OF 2020

BETWEEN:

1. SRI SUSHIL GOEL

2. SMT. MONISHA DANGE

3. M/S UNICORN MEDITECH

REPRESENTED BY ITS PROPRIETOR SRI THYAGARAJAN.

... PETITIONERS

(BY SRI DESU REDDY G., ADVOCATE)

AND:

STATE AT THE INSTANCE OF DRUGS INSPECTOR - 1, BENGALURU CIRCLE - 3, BENGALURU,

REPRESENTED BY STATE PUBLIC PROSECUTOR, AMBEDKAR VEEDHI, BENGALURU – 560 001.

... RESPONDENT

(BY SMT.YASHODHA K.P., HCGP)

THIS CRIMINAL PETITION IS FILED UNDER SECTION 482 OF CR.P.C., QUASH THE ENTIRE PROCEEDINGS IN SPL.C.C.NO.154/2020 ON THE FILE OF THE LEARNED PRL.CITY CIVIL AND SESSIONS JUDGE AT BENGALURU FILED AGAINST THE PETITIONERS FOR THE ALLEGED VIOLATION OF SECTION 18(a) AND P/U/S 27(a) AND VIOLATION OF AND SECTION 18(a)(i) AND 22(I) (cca) WHICH IS P/U/S 27(a) AND 22(3) OF DRUGS AND COSMETICS ACT.

THIS CRIMINAL PETITION HAVING BEEN HEARD AND RESERVED FOR ORDERS ON 01.04.2022, COMING ON FOR PRONOUNCEMENT THIS DAY, THE COURT MADE THE FOLLOWING:-

ORDER

Petitioners are before this Court calling in question proceedings in Special C.C.No.154 of 2020 pending before the Principal City Civil and Sessions Judge at Bangalore arising out of complaint filed under Section 200 of the Cr.P.C. for violation

of Sections 18(a)(i) and 22(i)(cca) punishable under Section 27(a) and 22(3) of the Drugs and Cosmetics Act. 1940 ('the Act' for short).

- 2. Heard Sri. Desu Reddy G., learned Counsel for petitioners and Smt. K.P.Yashodha, learned High Court Government Pleader for respondent.
- 3. Brief facts leading to the filing of the present petition, as borne out from the pleadings, are as follows:-

It appears that on 12-07-2020 information was received by the Assistant Drugs Controller from the Superintendent of Minto Hospital, Bengaluru alleging that cataract surgeries had been carried out at the Hospital on 9-07-2019 and the patients who underwent cataract surgeries had developed eye infection. The said information was taken by the Assistant Drugs Controller and visited the hospital to investigate the matter. One Dr. K.M. Dakshayini hands over a letter to the respondent mentioning names of drugs which were used during cataract surgeries and

also informed that consumables and drugs that were used in the cataract surgeries were sent to gram stain, culture sensitivity to microbiology laboratory and culture sensitivity report was given by the Department of microbiology, Victoria Hospital on 12.07.2019 which yielded pseudomonas aueroginosa growth in drug Hydroxypropyl Methylcellulose Ophthalmic Solution USP (OCCUGEL 2%) Batch No.OUV190203 date of Mfg.Feb.2019 Date of Exp. Jan.2021 manufactured by M/s Ophtechnics Unlimited.

- 4. It is after the report that was received and finding that the subject drug was not of standard quality, proceedings were instituted against the petitioners and several other accused for offences punishable under Section 27(a) of the Act for alleged violation of Section 18(a)(i) of the Act. The petitioners 1 and 2 are Proprietors/Directors of the 3rd petitioner M/s.Unicorn Meditech, the manufacturer of the subject drug and other drugs.
- 5. Alleging violation of Section 18(a)(i) of the Act which becomes punishable under Section 27(a) of the Act, a complaint

is registered by the respondents invoking Section 200 of the Cr.P.C. The complaint, though is at great length, does not indicate the role of the petitioners to be in the day-to-day affairs of manufacturing of drugs in the company. Unless this is spelt out, the offences against the petitioners cannot be driven home, is the consistent view taken by this Court in plethora of judgments right from the year 2000.

6. A Co-ordinate Bench of this Court in the case of **SANJAY G. REVANKAR v. STATE BY DRUG INSPECTOR**, **U.K.DISTRICT, KARWAR**¹ has held as follows:

"Taking into consideration the Director, Manager, Secretary or other Officers of a Company are made vicariously liable to the collective action of a Company, who itself would be an accused in the offences like one on hand, there are certain restriction and preventive measures placed by the Legislation itself for making them co-accused along with the Company. Prima facie requirement is that complainant to substantiate requirements like the present accused is, to show he is in-charge of, or responsible for the conduct of the business of the Company, be it in any capacity and if he is the Director, Manger, Secretary or. Officer of the Company it should be averred and shown that the offence took place with his consent or connivance

¹ILR 2002 KAR 475

or is also attributable to the neglect on the part of such person (Director, Manager, Secretary and other Officer). Keeping in view, the observations of the Apex Court in the case of Shyam Sunder v. State of Haryana which are to the following effect:—

"More often it is common that some of the partners of the firm may not even be knowing of what is going on day-to-day in the firm. There may be partners, better known as sleeping partners who not required to take part in the business of the firm. There may be ladies and minors who were admitted for the benefit of partnership. They may not know anything about the business of the firm. It would be a travesty of justice to prosecute all partners and ask them to prove under the proviso to sub-section (1) that the offence was committed without their knowledge. It is significant to note that the obligation for the accused to prove under the proviso that the offence took place without his knowledge or that he exercised all due diligence to prevent such offence arises only when the prosecution establishes that the requisite condition mentioned in sub-section (1) is established."

(emphasis supplied)

It is to be noted that unlike the first information as required under Section 154 Cr. P.C. which need not be elaborate and contain all the history of the case, this complaint under Section 200 Cr. P.C. filed for specific and substantial offences under, the independent acts like Drugs and Cosmetics Act. In the present case it is the public servant on his own investigation in respect of commission of offences under the Act lodges a complaint under Section 200 Cr. P.C. In such an event the accused person who is to be vicariously liable and this aspect he may come to know only after taking of cognizance and issuance of process against him and only when he can either state that he does not fall either under Clause (1) of Sections 34 of the Act viz., that he is not a person-in-charge of, and was responsible to the assets of the Company or the alternate

arguments that even though he is the Director, Manager, Secretary or other Officer of the Company, it is not shown that the offence was committed with his consent or connivance or is attributable to any neglect on his part. As observed by the Apex Court in the case of G.L. Mehta⁹ followed in the Gupta v. D.N. subsequent pronouncements in the case of Shyam Sunder v. State of Haryana merely because a person is a Director may not be concerned with day to day working of the Company and as such only because of his holding of position, he cannot be straightaway arrayed as accused unless prima facie there is averment to clearly indicate what exactly is the role played by such Director, which resulted in the commission of the offence.

In the present case petitioners (accused Nos. 4 to 6, 8) are the Directors of the Company. There is no specific averment about the role of each of Directors except baldly stating in the complaint that these are the Directors of accused No. 1/Company and hence they are to be held responsible for the day to day affairs of the firm or company. In my view, this would not be a sufficient averment. From the words used in the complaint for example at para-7 that accused Nos. 4 to 6 are working partners of the firm and are held responsible for the day to day affairs indicate that the complainant wants to infer the fact that merely because such person is a director, he is deemed to be responsible for the commission of the offence. As observed by the Apex Court in the aforesaid decisions, there are number of different types of partners in a firm or a Company. He may be working partner, sleeping partner or partners who are minors. Merely because he is a partner, it cannot be straighaway inferred that he is responsible for the day to day working or he is in-charge of and responsible for the very operation of the Company and more so towards the commission of the crime in question. Nodoubt the proviso to Section 34(1) leaves it open to such co-accused to prove before the trial Court such offence was committed without his knowledge or inspite of his exercising due diligence in proving the commission of such

offence but that is at the trial stage. As observed by the Apex Court in the case of Pepsi Foods Limited v. Special Judicial Magistrate¹⁰ if there is absence of such prima facie allegation or averment why the person should be asked to undergo the agony of a criminal trial and make him to prove the fact which was not even averred basically by the complainant in his complaint filed under Section 200 Cr. P.C. Hence, in my view, that apart from saying that the co-accused is holding certain posts like Director, Manager, or Secretary or any other officer of his Company - the main accused, it must be clearly averred in the complaint itself as to whether he was in-charge of the Company or its affairs and how he was concerned with the commission of the offence Taking into consideration the pronouncements of the Apex Court in this regard in respect of similar provisions arising under the different special enactments creating liability on the partners of a firm or Directors of a Company, I hold that the complainant in his complaint should mention and aver the details as to how the particular vicarious liable person or accused is concerned with the commission of the crime itself and unless and until the same is done, merely because he is a Director or an Officer cannot be held to be straight away as an accused."

(Emphasis supplied)

Subsequently, another Co-ordinate Bench in the case of **RITESH**

v. STATE OF KARNATAKA² has held as follows:

"RE: POINT No. 1:

17. It has been contended by the complainant that "Ferrous Sulphate tablet NFI" is a drug within the meaning of Section 3(b) of the Act which has been manufactured and sold and it is not of standard quality thus attracting

² ILR 2011 KAR 5927

Section 18(a)(i) of the Act. In the complaint at paragraphs 6 to 10 it has been alleged as under:

"That the accused persons are responsible for conducting the business of A 1 factory".

- 18. Again at paragraphs 30(2) to 30(6) it has been alleged by the prosecution that Accused persons being the Directors of accused No. 1 and responsible for the conduct of business of A-1 are responsible for the omission and commission of offence and as such it has been contended that there is vicarious liability.
- 19. In the light of averments made in the plaint when the contention raised by Learned Advocates appearing for the parties are examined by taking into consideration the judgments referred to supra. It is noticed that in Rajiv Khurana's case it has been held that, it is incumbent upon the complainant to state how a Director who is sought to be proceeded as an accused was incharge of business of the company are responsible for the conduct of company's business and it has been further held that complainant has to aver in the complaint that accused was incharge and was responsible for the conduct of the business of the company. It has also been held averments made in the complaint should be clear and specific. The Hon'ble Supreme Court in Pepsico Holdings Pvt Ltd. case referred to supra referring to the earlier judgments has held that Directors who are incharge of day to day affairs of the company are vicariously liable and a mere bald statement that a person was the Director of the company would not suffice and it was found on facts that a particular Director had been nominated to be the person incharge and responsible for the company for the conduct of its business and he alone being responsible for day to day affairs, proceedings against others cannot be proceeded with and as such quashed the proceedings against the appellants therein.

- 20. Yet again in Dinesh B. Patel's Case the Hon'ble Supreme Court was considering the very same provision namely Section of 34(2) of the Act, and it has been held therein that paragraph 6 of the complaint would disclose that directors therein had manufactured the medicine for sale in breach of the act and thus it was held that it is a punitive offence. While examining the facts therein at paragraph 9 it has been held as under:
 - "9. In our opinion, the averments in Paras 4, 5, 6 and 8 of the complaint cannot be described as bald statements. The emphasised portion in Para 6 of the complaint suggests manufacturing of the medicine by the company and its Directors. The averments in all these paras would have to be read together and para 6 of the complaint would have to be read in the light of the other averments. It seems that in the reported decision in the Complaint, there was no link pleaded in the Directors and the manufacturing process. That is not the situation here. This was a case of the manufacture of the drug for human consumption and, after it was tested in laboratory, was found to be defective since there was a growth of fungus, which is a very serious matter related to public health".
- 21. A perusal of the complaint filed against the petitioners in the instant case would disclose that only an assertion has been made in the complainant that petitioners have committed offence by manufacturing and selling the drugs that are not of standard quality. It is nowhere stated in the complaint as to the role of petitioners in either participating in the day to day affairs of the A-1 industry and as to their actual role in manufacturing the drugs in question. It would also be of relevance to note at this juncture itself that license issued to A-1 factory would specifically state as to who are the persons namely persons who are engaged in the manufacture and it is specifically stated therein the approved expert staff of A-1 factory and testing officials and laboratories engaged in testing and certifying the drug manufactured by A-1

industry are specified in the License granted who can be construed as persons manufacturing the drugs in question

- 22. Thus, on examination of facts namely the averments made in the complaint and the case laws extracted herein above, I am of the considered view that the averments made in the complaint regarding the role and responsibilities of the petitioners not being specific precise, they cannot be proceeded against and complaint does not reveal that petitioners herein were in-charge and responsible for the conduct of the business of A-1 firm except a bald and vague statement made in the complaint stating that petitioners were the Directors of the firm and they were in-charge of day to day affairs when the license issued goes to show the persons involved in the manufacturing process as someone else. In that view of the matter, I am of the considered view that Learned Magistrate was not justified in taking cognizance of the offence alleged against petitioners herein and issuing summons.
- 23. Accordingly point No. 1 is answered in favour of the petitioners and against respondent/complainant."

(Emphasis supplied)

Both these judgments were interpreting Section 34 of the Act. Section 34 of the Act deals with offence committed by a Company. Unless specific role is attributed to the Directors or Partners of the Company in the process of manufacturing, they cannot be hauled into criminal proceedings, as vicarious liability

would come about only when there are particular instances narrated in the complaint.

- 7. The narration in the complaint, in the case at hand, insofar it pertains to the petitioners, is absolutely vague. There is nothing in the narration that would point at the role of the petitioners in the day-to-day manufacturing of drugs in the Company. Unless the petitioners do have an active role in the preparation and manufacture of drugs, which are alleged to be of sub-standard quality, the petitioners cannot be drawn in to these proceedings.
- 8. In the light of the judgments rendered by the Coordinate Benches of this Court interpreting Section 34 of the
 Act, the impugned proceedings cannot be continued against the
 petitioners, as there is no narration in the complaint that would
 touch upon the offences against the petitioners for their role in
 the manufacture of drugs. Vague statements with regard to
 them being Partners or Directors of the Company cannot by

itself bring the petitioners to the web of these proceedings. The narration in the entire complaint insofar as it pertains to the petitioners is as follows:

- *"*3. That Accused No.1, M/s Total Health care, Plot No.17, Ambota, Sector 5, Parwanoo, Dist. Solan, Himachal Prudesh, 173220, India is a partnership firm, engaged in manufacturing and sale of drugs. Company possesses Drug manufacturing licenses in Form 25 and 28 bearing no.MNB/05/168 and MB/05/169 dated 10.08.2005 issued by Drugs Controlling Licensing Authority, Himachal cum Pradesh, renewed in Form 26 and valid unto 09.08.2020. the Product-Hydroxypropyl Methylcellulose ophthalmic Solution USP (OCCUGEL 2%), No.OUV190203, Date of Mfg:Feb.2019, Date of Exp.:Jan.2021 was manufactured by them under loan license on behalf of M/s**Ophtechnics Unlimited** havina registered office at Plot No.2209, DLF City, Phase-IV, Gurgaon, Haryana (A-3) and committed offences described here under.
- 4. That, Accused No.2 Sri Sushil Goel, is one of the partner of M/s Total Health care, Plot No.17, Ambota, Sector 5, Parwanoo, Dist. Solan, Himachal Pradesh, 173220, India (A-1) and A 2 is responsible for the offences described here under.
- 5. That, Accused No.3 Smt.Monisha Dange, Proprietor of M/s Ophtechnics Unlimited having registered office at Plot No.2209, DLF City, Phase-IV, Gurgaon, Haryana.

The firm possesses Loan License in Form-28-A bearing No.SL-MB/2011-70 dated 02.03.2012 issued by Drugs Controlling Authority, Licensina Himachal cum Pradesh, renewed in Form 26-A and valid upto 01.03.2022. The Loan License is granted to manufacture their products at A-1 firm and having product permission to manufacture "Hudroxypropyl Methylcellulose ophthalmic Solution USP" (OCCUGEL 2%), at the parent company A-1. Hence A 3 is responsible for the offences described here under.

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50. That, by the investigation conducted in this matter, it is established that, Accused A1, A2, A3, A4 and A5 have manufactured, analysed and sold the impugned batch of drug to A6, who in turn supplied the said batch of drug to Modi Eye Hospital, Bangalore 02. The same drug was used during cataract surgery carried out on 09.07.2019 in Minto Hospital and on postoperative day infection was observed in eyes of the patients who underwent cataract surgery, all the operation theatre instruments, drugs used during surgery and patients samples were sent Microbiology, Department of Victoria Hospital Campus, Bangalore-02. From the reports of Department of Microbiology, Victoria Hospital, Bangalore it is indicated that the impugned batch of drug used in operative procedure showed Gram negative Bacilli and Culture Showed Pseudomonas aeruginosa Organism. The same organism was observed in aqueous tap and vitreous tap of the patients samples as per the

reports issued by Department Microbiology, Victoria Hospital, Bangalore -02 and caused loss of eye sights of 14 patients. Which is Grievous hurt within the meaning of Section 320 of the Indian Penal Code (45 of 1860). The legal sample of impugned batch of drug was drawn from the stores of Minto Hospital, Bangalore-02 for the purpose of Test or Analysis and same was declared as Not of Standard Quality by Drugs Testing Laboratory, Bangalore and also by the appellate laboratory i.e., Central Drugs Laboratory, Kolkata with respect to 'Sterility' and 'pH'.

.......

II.Accused No.2 Sri Sushil Goel, is one of the partner of M/s Total Health Care, Plot No.17, Ambota, Sector 5, Parwanoo, Dist. Solan, Himachal Pradesh, 173220, India (A-1) he is responsible for having manufactured and having sold the subject 'Not of Standard Quality" drug, which has caused grievous hurt upon usage has violated which Section 18 (a)(i)punishable under Section 27 (a) of the said Act and by not submitting the partnership deed he has violated Section 22(1) (cca) of the said Act, which is punishable under Section 22 (3) of the Said Act.

III. No.3 Monisha Accused Smt. Dange, **Proprietor** of M/s**Ophtechnics** Unlimited having registered office at Plot No.2209, DLF City, Phase-IV, Gurgaon, Haryana, The Drug-Hydroxypropyl Methylcellulose Solution ophthalmic USP(OCCUGEL 2%), Batch No. OUV190203. Date Mfg.:of Feb.2019, Date of Exp.:Jan.2021 drug) impugned was manufactured on her behalf at A-1 firm. A-3 have entered into agreement with A1for manufacture, sale and distribution of several drugs including the impugned drug. A 3 supplied the impugn drug to A-6. Thereby, A-3 is responsible for manufacturing and selling the impugned drug which has caused grievous hurt upon usage and has violated Section 18 (a)(i) which is punishable under Section 27 (a) of the said Act."

This can hardly meet the test of vicarious liability being fixed on the petitioners and the interpretation of this Court as aforequoted. 9. For the aforesaid reasons, I pass the following:

ORDER

- (i) The Criminal Petition is allowed and the proceedings in Special C.C.No.154 of 2020 pending before the Principal City Civil and Sessions Judge, Bangalore City stand quashed qua the petitioners.
- (ii) It is made clear that the observations made in the course of this order is applicable only to the accused/petitioners and the same shall not influence or bind any other proceedings pending against any other accused.

The application I.A.No.1/2020 stands disposed, as a consequence.

Sd/-JUDGE

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