HIGH COURT OF PUNJAB AND HARYANA AT CHANDIGARH ****

CRM-M-15224-2023 Reserved on 03.05.2023 Pronounced on 11.07.2023

Sunita Dhawan & Anr.

... Petitioners

VS.

UOI ... Respondent

CORAM: HON'BLE MR.JUSTICE SANDEEP MOUDGIL

Present: Mr. Keshav Pratap Singh, Advocate for the petitioners

Ms. Gurmeet Kaur Gill, Sr.Panel Counsel for UOI

Sandeep Moudgil, J.

(1). The petitioners seek grant of anticipatory bail in complaint No.1 dated 03.03.2022 (Annexure P1), under Sections 32/16/17-A(f)/17-B(d)/18(a)(i)/ 18(a)(vi) & 18(c) of Drugs and Cosmetics Act, 1940 read with Sections 27(b)(1), 27(c), 27(d), 36-AC of the said Act.

(2). Brief facts of the case are that the complainant-Drug Inspector on the directions of Deputy Drugs Controller (I) Sub Zone Baddi vide letter No.NZ/BD-SZO/PUN/OFOR/2019-20/467-469 dated 18.6.2020 for necessary sampling of sanitizer for the testing and analysis from various area of Punjab viz. Mohali, Kharar and Zirakpur on 18.6.2020 constituted a team comprising two drugs Inspectors of CDSCO- Sub Zone Baddi i.e. the present complainant and Mr. Sanjay Aggarwal alongwith Ms. Manpreet Kaur, DCO (Mohali-I) Punjab who visited the site of M/s Gupta Medical Hall, situated at SCO 32, Phase 1 Mohali on 18.6.2020 for necessary sampling to ensure the quality of the available stock of Sanitizers at the level of end user. Accordingly, the complainant had drawn the samples of the Sanitizer/Handrub from M/S Gupta Medical Hall, which was manufactured by the petitioner-firm i.e. M/s Dr.Edwin

Lab Plot No.517, Industrial Area Phase IX SAS Nagar Mohali. Further as per the allegations made against the petitioners in this complaint and the documents attached therewith, the petitioners were involved in manufacturing, sale and distributing the drugs, which have been found to be not of standard quality as per the report of Government Analyst. It has also been reported that the sample does not conform to claim as per IP 2018 with respect to the "identification" and the "Assay of Isopropyl Alcohol" and "sample contains 77.43% v/v Methanol, while the label claim is Isopropyl Alcohol IP 70 w/v".

- Medical Hall and in reply, said firm has disclosed the said batch was procured from M/s Shelom Pharma SCF-9 Phase 6 Mohali vide invoice No.346 dated 18.6.2020 and that the drug/product in question was sold out to the end user. Then, complainant issued notice to the representative of M/s Shelom Pharma and in reply, the said firm disclosed that it was procured from the petitioner-firm M/s Edwin Lab and thereafter, complainant issued notice dated 11.9.2020 to petitioner-firm M/s Dr. Edwin Lab, but the said firm did not respond or submit any reply to the notice. Thereafter, the petitioners approached the trial court seeking anticipatory bail however, the same has been rejected by the trial court vide orders dated 17.02.2023.
- (4). Learned counsel for the petitioners contended that the petitioners had sent a communication to State Drugs Controlling-cum-Licensing Authority on 24.07.2018 specifying that full authority was given to one Shailendra Mishra, Approved Manufacturing Chemist to take all decisions regarding production/manufacturing of medicine who even accepts his liability. Therefore, it is clear that the petitioners were not incharge or responsible for the

conduct of the business of the firm and as such they have no role in the preparation and manufacture of the drugs which is against the law laid down in *Sri Sushil Goel vs. State at the instance of Drugs Inspector*.

- (5). It is averred that the petitioners had no personal knowledge in respect of alleged seizure of sample of pure handrub/sanitizer as no search/seizure of alleged samples were made from the premises of the petitioners. None of the petitioners were present at the spot and as such they have no direct or indirect connection with the alleged seizure of samplers of drugs etc. In the alleged seizure report, the respondents have failed to report the number of alleged pieces of "pure handrub plus" sanitizers allegedly displayed at the retail shop. Besides the factum of adulteration and substandard quality of the hand sanitizer is yet to be ascertained.
- (6). Learned counsel for the petitioners further contended that Section 34 of the Drugs Act provides that every person who was in charge of and responsible for the conduct of business, at the time of commission of an offence under the Drugs Act, is deemed guilty of the offence. *Proviso* to Section 34 of the Drugs Act enumerates that a person shall not be liable for punishment under the Drugs Act, if he proves that the offence was committed without his/her knowledge. It is further contended that the petitioners cannot be prosecuted since it must be proven that the offence under the Act has been committed with his consent and connivance. Further, no prior investigation was carried out as to who is responsible for the adulterated sanitizer in view of the fact that the petitioners being the Director cannot be only held liable for adulteration as technical manpower is involved in the manufacture of such chemical solution.

- (7). He relied upon Section 34 of the 1940 Act to submit that there are no allegations in the complaint against them which spell out a case wherein the petitioners were incharge and were responsible for the conduct of the business of the firm and as per Section 34(1) of the Act, every persons at the time of office, should be incharge of and responsible for the conduct of the business. There is no allegation in the complaint that the petitioners were in charge and responsible for the conduct of the business of the firm and the complaint is nothing but an abuse of process of law as has been held by the Supreme Court in *State of Karnataka vs. Pratap Chand (1981) 2 SCC 335*.
- (8). Reliance has been placed on (i) Pepsico India Holdings P.Ltd. vs. Food Inspector & Anr. (2011) 1 SCC 176; (ii) State of Haryana vs. Brij Lal Mittal (1998) 5 SCC 343; (iii) State of NCT of Delhi vs. Rajiv Khurana (2010) 11 SCC 469; (iv) M/s Pepsi Foods Ltd. vs. Special Judicial Magistrate (1998) 5 SCC 749 as well as the Karnataka High Court judgment in *Ritesh vs. The State of Karnataka 2011(25) RCR (Crl.) 354* to contends that the director of the company cannot be held responsible since the only assertion has been made in the complaint is that the petitioners have committed offence by manufacturing and selling the drugs that are not of standard quality, however, it is nowhere stated in the complaint as to the role of petitioners in either participating in the day to day affairs of the firm/company and as to his actual role in manufacturing the drugs in question. The Karnataka High Court referred to *State of NCT of Delhi Vs Rajiv Khurana 2011 (1) SCC (Crimes)* 195 and 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 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."

- (9). The further contention raised by learned counsel for the petitioners is that in a complaint against a Company and its Directors, the complainant has to indicate in the complaint itself as to whether the Director(s) concerned were either in charge of or responsible to the Company for its day-to-day management, or whether they were responsible to the company for the conduct of its business. Mere bald statement that a person was a Director of the Company against which certain allegations had been made is not sufficient to make such Director liable in the absence of any specific allegations regarding his role in the management of the Company.
- (10). Lastly, it is submitted that the co-accused namely Suraj Kumar Gupta from whose shop the samples and another co-accused Shiv Bhushan Jha have been granted the concession of bail by the trial court vide orders dated 01.03.2023 and 03.03.2023. He claims parity with the co-accused being on a better footing.

- (11). On the other hand, Ms. Gurmeet Kaur Gill, Sr.Panel Counsel for Union of India contended that the petitioners were indulged in malpractice and making undue money by fraudulent means, even during the period of pandemic COVID-19, and at that time, the Disaster Management Act was in vogue. She countered the contention of the petitioners and argued that in case of offences committed by a company against society at large, the Director who has accrued benefit from such 'overt act' ought to be held liable.
- (12). Learned counsel for UOI further argued that principles of vicarious liability are not attracted in the present case as production of the Drugs is not related to managing the affairs of the company. Given the nature of the offence, this is a case for strict liability and as such, the petitioners are not liable to be extended the concession of anticipatory bail, as sought for.
- of this nature are 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 petitioners being the Director, cannot claim that he was not directly involved in the product of the drugs, when the decision to produce the drugs itself is the outcome of their decision. Therefore, the case of Director signing the cheque on behalf the Company and the case of Director participating in the decision to produce sub-standard drugs are not one and the same to hold that the petitioners is not involved in day-to-day affairs of the Company.
- (14). It is further submitted by counsel of the UOI that the petitionerfirm without obtaining the test report of the raw material from the raw material

supplier and without any conformity verification for the quality of the raw material, manufactured the product in question and without testing of the final product, launched it in the market with the ulterior motive to enrich themselves at the cost of lives of public at large. During investigation, Ms. Ayushi Dhawan, partner of the above said firm was present and was unable to provide the necessary information and documents on demand as per rules. After completing all the scrutiny, investigation and correspondence under the Act, complainant has found that the petitioners being manufacturing firm and active participants as also the supplier/wholesaler and distributor (s)/retailer(s) of the drugs in question, which have been declared as not of standard quality, they are liable for punishment for the offences committed under the Act.

- (15). Having heard learned counsel for the parties and after going through the record, this Court does not find any merit in the contentions raised by the petitioners.
- (16). The Drugs and Cosmetics Act, 1940 came into force on 10.04.1940. It is an existing law when the Constitution came into force. In the year 1982 there was an amendment to this Act, the statement of Objects and Reasons for the said Amendment, explains the purpose of the Act as below:-

"Amendment Act 68 of 1982- Statement of Objects and Reasons:-

The Drugs and Cosmetics Act, 1940, regulates the import into, manufacture, distribution and sale of drugs and cosmetics in the country. The problems of adulteration of drugs and also of production of spurious and sub-standard drugs are posing serious threat to the health of the community. It is, therefore considered necessary to amend the Drugs and Cosmetics, Act, so as to impose more stringent penalties on the anti-social elements indulging in

the manufacture or sale of adulterated or spurious drugs or drugs not of standard quality which are likely to cause death or grievous hurt to the user. This opportunity is also being availed of to incorporate certain other provisions on the other aspects of effective control on the manufacture, distribution, sale of drugs and cosmetics on the basis of experience gained in the working of the Act."

- (17). Section 34 of the Drugs Act which deals with offences by companies reads as under:-
 - (34) Offences by companies:- (1) Where an offence under this Act has been committed by a company, every person who at the time the offence was committed, was in charge of and was responsible to the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act f he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

- (2) Notwithstanding anything contained in sub section (1), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of or is attributable to any neglect on the part of any director. manager, secretary or other officer of the company, such director, manager. secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly."
- (18). In State of NCT of Delhi through prosecuting Officer, Insecticide Government of NCT, Delhi. Vs Rajiv Khurana 2011 (1) 8CC (Crimes) 195, the Supreme Court held that "the ratio of all these cases is that the complainant is required to state in the complaint how a Director who is

sought to be made an accused, was Incharge of the business of the company or responsible for the conduct of the company's business. Every Director need not be and is not Incharge of the business of the company. If that is the position with regard to a Director, It is needless to emphasise that in the case of non-Director officers, it is all the more necessary to state what were his duties and responsibilities in the conduct of business of the company and how and in what manner he is responsible or liable".

- (19). It further concluded that "unless clear averments are specifically incorporated in the complaint, the respondent cannot be compelled to face the rigmarole of a criminal trial".
- In Pepsico India holdings Vs Food Inspector & Another, the (20).Supreme Court considered as to whether the presence of 0.00 1 mg of Carbofuran per litre found in the sweetened carbonated water, manufactured by the Appellant-Company, can be said to be adulterated as per Rule 65 of the 1955 Rules and under Section 2(ia) (h) of the 1954 Act, particularly in the absence of any validated standard of analysis provided for under the 1954 Act or 1955 Rules and on the question of liability of the Directors of the Company with respect to an offence alleged to have been committed by the Company, it held that the "the High Court went beyond the ratio of the decision of this Court in **S.M.S Pharmaceuticals Ltd.'s** case (supra) upon holding that the principles set out in the said decision could not be understood in any mechanical or rigid manner. It was held that "in a complaint against a Company and its Directors, the Complainant has to indicate in the complaint itself as to whether the Directors concerned were either in charge of or responsible to the Company for its day-to-day management, or whether they were responsible to the Company

for the conduct of its business. A mere bald statement that a person was a Director of the Company against which certain allegations had been made is not sufficient to make such Director liable in the absence of any specific allegations regarding his role in the management of the Company".

(21). The Supreme Court in <u>State of Haryana vs. Brij Lal Mittal</u> (supra) while dealing with the vicarious liability of a person for being prosecuted for offence committed by the company, held that:-

"It is thus seen that the vicarious liability of a person for being prosecuted for an offence committed under the Act by a company arises if at the material time he was in-charge of and was also responsible to the company for the conduct of its business. Simply because a person is a director of the company it does not necessarily mean that he fulfills both the above 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. From the complaint in question we, however, find that except a bald statement that the respondents were directors of the manufacturers, there is no other allegation to indicate, even prima facie, that they were in-charge of the company and also responsible to the company for the conduct of its business."

Supreme Court observed that the averment in a complaint that an accused is a director and that he is in charge of and is responsible to the company for the conduct of the business of the company, duly affirmed in the sworn statement, may be sufficient for the purpose of issuing summons to him. But if the accused is not one of the persons who falls under the category of 'persons who are responsible to the company for the conduct of the business of the company', then merely by stating that 'he was in charge of the business of the company' or

- 11 -

by stating that 'he was in charge of the day to day management of the company' or by stating that he was in charge of, and was responsible to the company for the conduct of the business of the company', he cannot be made vicariously liable under Section 141(1) of the Act.

(23).Even though Section 34 of Drugs Act makes all the persons concerned with the company which is the principal accused vicariously liable; there must be definite averment in the complaint as to the role of each of the person arrayed as co-accused with the help of principles of vicarious liability. It is apparent that vicarious liability of persons for being punished for an offence committed under the Act by a company arises, if at the material time, he was in charge of, and was also responsible to the company for the conduct of its business (as per Section 34(1) of the Act). Otherwise also under Section 34(2) of the Act, where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any Director, Manager, Secretary or other officer of the company, each of them would be deemed guilty of the offence. If one peruses the provisions of Section 34(1) and (2) of the Drugs Act independently, what can be made out is that in Subsection (1) of Section 34 of the Drugs Act, every person who is shown to be in charge of, and was responsible to the company for the conduct of its business is deemed to be guilty. The use of the words 'every person' means it is irrespective of what is the position held by the said person whether be it as a Director, Manager, Secretary or any other officer of the company. If it is prima facie shown by the prosecution that such person was in charge of, and was responsible to the company for the conduct of its business by applying the

- 12 -

principles of vicarious liability, he is deemed to be guilty of the offence and <u>liable to be proceeded against</u>. The *proviso* to said Sub-section (1) shows that even if such *prima facie* material is shown, it is open for the person so accused and charged to prove that irrespective of his being in charge of, and responsible towards the company for its conduct or business, the offence was committed without his knowledge or was done in spite of best diligence or preventive actions taken by him to prevent such offence. Hence the basic material and averment required so far as Sub-section (1) of Section 34 of the Act is concerned is to prima facie show that the particular person/accused is in charge of, and was responsible to the company for the conduct of its business. Through this clause though almost every person connected with the company may be arrayed as accused and be prosecuted, be it the Director, Manager, etc., in its wisdom the legislature has added the second clause to this section creating specific vicarious liability so far as Director, Manager, Secretary and other officers are concerned also and this provision starts with non obstante clause. Under Sub-section (2) of Section 34 of the said Act, apart from showing that the accused person is a Director, Manager, Secretary or other officer of the company, it must be shown or proved that the offence has been committed with his consent or connivance or is attributable to any neglect on the part of such Director, Manager, Secretary or other officer of the company.

Having said so, there are certain restrictions and preventive measures placed by the legislation itself for making them co-accused along with the company. Prima facie requirement is that the complainant to substantiate the basic 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

- 13 -

and if he is the Director, Manager, Secretary or officer of the company it should be averred and shown that the offence took place with his consent or connivance or is also attributable to the neglect on the part of such person viz.Director.

- (25).In the present case, admittedly, the sampling of sanitizer in the area of Mohali, Kharar and Zirakpur, samples were taken from M/s Gupta Medical Hall, Phase-1 Mohali. Samples of hand sanitizers made by M/s Dr. Edwin Lab were not found to be of standard quality as per report of Government analyst. These were mentioned to contain "Assay of Isopropyl Alcohol" and sample contains 77.43% v/v Methanol which is poisonous. M/s Gupta Medical Hall disclosed that batch was procured from M/s Shelom Pharma, SCF 9, Phase 6 Mohali and sold to users. M/s Shelom Pharma further reported that product was procured from M/s Dr. Edwin Lab. In reply, M/s Dr. Edwin Lab admitted that during manufacturing of product, the quality control employees were absent and accused firm without obtaining test report of raw material and without testing final product had launched the product in the market. Ms. Ayushi Dhawan and Sunita Dhawan are partners of the firm, while Parmodh Dhawan who is owner of M/s Shelom Pharma is also their family member. It is also an admitted fact that the petitioners could not produce any report with regard to the testing or show any material before this Court.
- (26). However, thereafter vide letter dated 29.9.2020, M/s Edwin Lab has admitted that during manufacturing of the above said product, the quality control employees were absent in the laboratory to perform the testing of raw material, as well as finished product. It also comes out that petitioners were partners of the firm which manufactured the hand sanitizers which was

- 14 -

launched during Covid-19 Pandemic and was not only of sub-standard quality, but was also found to contain 77.43% v/v Methanol which was poisonous. The firm has admitted that no proper testing of raw material and finished product was undertaken. By any stretch of imagination, it is expected from the petitioners and its company to verify and test the contents of the hand sanitizer and ensure that the same is utilizable by the masses which are already facing the anathema of pandemic. Even otherwise, the petitioners have to face the music of its mis-action because ultimately, the product which was allegedly purchased by the petitioners and its company, has been found to be adulterated and substandard.

- (27). The argument of the petitioners is also misplaced to aver that the order passed by the trial court is absolutely silent as to on which basis, the provisions of Section 18(a)(i) of the Drugs are made out against the petitioners. The trial court, at the very first instance, is not expected to carry out any investigation at its own level since such an issue is required to be ascertained during trial. The trial court is only required to see if *prima facie* offence, as alleged, is made out against the petitioners or not.
- (28). Thus it is clear that product was launched without proper testing only to earn huge profits during the time of crisis when people were scared due to onset of Covid-19 pandemic. The petitioners had thus played with the lives of the people for their personal gains. Due to seriousness of the matter, the punishment provided under various provisions of Drug and Cosmetic Act is also very high. Simply because the petitioners have been summoned in a complaint case is no ground to grant them benefit of anticipatory bail. The

CRM-M-15224-2023

- 15 -

allegations against the petitioners are very serious. Moreover, main complaint is pending before the trial court.

- (29). Thus, on examination of facts namely the averments made in the complaint and the case laws extracted herein above, this Court, *prima facie*, is of the considered view that the averments made in the complaint regarding the role and responsibilities of the petitioners are specific and precise, and in these circumstances, the trial court was justified in taking cognizance of the offence alleged against petitioners and rejecting the prayer for anticipatory bail of the petitioners.
- (30). In view of above discussions, this Court is of the considered opinion that the petitioners does not deserve to be granted the concession of anticipatory bail, at this stage.
- (31). Dismissed.

11.07.2023 V.Vishal

1. Whether speaking/reasoned?2. Whether reportable?

(Sandeep Moudgil) Judge

Yes/No Yes/No