



December 2022

Madras high court holds that all directors are vicariously liable for offences under the Drugs and Cosmetics Act, 1940

Recently Madras High Court (“**Madras HC**”) has held in the case of **Vikas Rambal v. State of Madras**¹ that all the directors are vicariously liable under the Drugs and Cosmetics Act, 1940 (“**Drug Act**”) for the sub-standard drugs manufactured by a company and the directors cannot claim that they are not directly involved in the production of drugs.

The Madras HC has deviated from the settled position of law that vicarious liability cannot be fastened upon directors or officials, who are not involved in the day-to-day affairs of a company.

Brief Facts

The Drugs Inspector, Udumalpet initiated prosecution proceedings against the Petitioner Nos. 2 to 5, who were directors of Sunrise International Labs Limited, Petitioner No. 1 (“**Company**”), engaged in the manufacture of Carbimazole Tablets which were found to be of sub-standard quality (“**Drugs**”). Accordingly, summons were issued against the Petitioners (“**Summons**”). The Petitioners approached the High Court for quashing the Summons.

Petitioner Nos. 2, 3 and 5 (“**Investor Directors**”) argued that they are not directly involved in the day-to-day affairs of the Company, and Petitioner Nos. 2 and 3 are not even resident in India.

The Investor Directors submitted that Section 34² of the Drug 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 Drug Act, is deemed guilty of the offence. The proviso to Section 34 of the Drug Act enumerates that a person shall not be liable for punishment under the Drug Act if he proves that the offence was committed without his/her knowledge.

The Investor Directors contended that they cannot be prosecuted since it must be proven that the offence under the Act has been committed with their consent and connivance.

The State countered the contentions of the Investor Directors and argued that in case of offences committed by a company against society at large, all Directors who have accrued benefit from such act ought to be held liable. The State further argued that principles of vicarious liability are not attracted in the present case as production of the

¹ 2022 SCC OnLine Mad 4822

² As Section 34 of the Drugs & Cosmetics Act, 1940 where an offence under the Act is 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 conduct of the business of the company as well as the company shall be deemed to be guilty of the offence. Explanation to the said provision provides that company means a body corporate, and it includes a firm or other association of individuals.

Drugs is not related to managing the affairs of the Company. Given the nature of the offence, this is a case for strict liability.

Issue

Whether all the directors of a pharmaceutical company are vicariously liable under the Drug Act for the offence of production of sub-standards pharma products?

Findings of Madras HC

After considering the submissions of the parties and analyzing the position of law, the Madras HC held that:

- a) The offence in the present case is that of manufacturing and distributing sub-standard Drugs by the Company which is managed by its board of directors. Any decision to manufacture a drug is a collective decision of the board of directors. Hence, a director cannot claim that it was not directly involved in the manufacture of the drug when it is a direct outcome of the director's decision to permit such manufacturing.
- b) A Director who has approved the manufacturing of a drug at the Board level cannot claim that he/she was not involved in the day-to-day affairs of the company to evade liability under the Act.

JSA Comment

The Supreme Court of India, in various decisions, has laid down a set of guiding principles that hold prominence in ascertaining whether the director of a company is liable to be prosecuted for the offence charged or otherwise.³

It is now settled that a director/official can be held liable for an offence by a company if:

- (1) There is evidence of the individual's active role coupled with criminal intent;
- (2) The director / official is in charge of and responsible for the conduct of business of the company at the relevant time when the offence was committed, and not on the basis of merely holding a designation or office in a company.

Therefore, the liability of directors or officials depends on the role they play in the affairs of a company and not on designation or status.

The present judgement may not be correct law and is likely to be set aside on appeal as:

- a) Madras HC has not discussed the settled position of law for liability of a director/official of a company, which is laid down in the catena of judgments referred above.
- b) The Madras HC discussed the judgement of the Supreme Court in *S.P. Mani and Mohan Dairy*⁴ wherein the Court interpreted Section 141 of the Negotiable Instruments Act, 1881 ("**NI Act**") and held that criminal liability is attracted only on those officials who at the time of commission of the offence, were in charge of or responsible for the conduct of the business of the firm. Despite observing that Section 141 of the NI Act and Section 34 of the Act are *pari materia*, the High Court held that the nature of offence under the NI Act (dishonour of cheque) and Drugs & Cosmetics Act (production of sub-standard act) operate in different spheres.

³ Sunil Bharti Mittal v CBI MANU/SC/0016/2015 ; Pooja Ravinder Devidasani v State of Maharashtra & Ors MANU/SC/1328/2014; SEBI v Gaurav Varshney (2016) 14 SCC 430; National Small Industries v Harmeet Singh Paintal (2010) 3 SCC 330; K.K. Ahuja v V.K. Vora and Another (2009) 10 SCC 48

⁴ S.P. Mani and Mohan Dairy v. Snehalatha Elangovan, 2020 SCC OnLine 1238.

- c) The issue of vicarious liability of director/officials of a company even under the Drug Act are no longer *res integra* as the Supreme Court has previously decided a similar issue in the case of *State of Karnataka v. Pratap Chand*⁵. In this case, the Supreme Court has interpreted Section 34 of the Drug Act and held that a director or official held liable should be a person in overall control of the day-to-day affairs of the company or there should be evidence of the individual's active role coupled with criminal intent.

One will have to wait and see how the Supreme Court deals with this one!

Healthcare Practice

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JSA also has substantial experience in matters relating to regulation of foods, drugs, medical devices, cosmetics, product packaging, and dangerous chemicals. Our attorneys advise manufacturers on Indian labelling questions, national rules for testing and review of new products, reporting of safety information, and proceedings relating to product withdrawals. We regularly advise clients on regulatory standards governing advertising, the distinction between advertising and labelling and the differing regulatory standards that apply to each, and the roles of the states and self-regulatory mechanisms. JSA has been actively involved in advising clients with respect to regulation of nutrition and health claims in food advertising.

We also have extensive experience in litigating cases in courts and administrative agencies in the healthcare sector.

This Prism has been prepared by:



Dheeraj Nair
Partner



Angad Baxi
Senior Associate



Avni Sharma
Associate

⁵ MANU/SC/0237/1981: (1981) 2 SCC 335,



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