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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

Reserved on: 17th May, 2023
Pronounced on: 06th September, 2023

\+ CRL.M.C. 3424/2011

M K HAMEID & ANR. ..... Petitioners

Through: Mr. Arvind Nigam and Mr. Maninder Singh, Senior Advocates with Mr. Waize Ali Noor, Mr. Mansimran Singh and Ms. Nidhi Jain, Advocates.

versus

STATE THR. ABHIJIT SINGH ..... Respondent

Through: Mr. Aman Usman, APP for the State.
Mr. Sundeep B.J., Assistant Drug Controller.

CORAM:
HON'BLE MR. JUSTICE AMIT SHARMA

JUDGMENT

AMIT SHARMA, J.

1. The present petition under Section 482 of the Code of Criminal Procedure, 1973 (hereinafter referred to as 'CrPC') seeks quashing of CC no. 46/04 titled 'State through Sh. Abhijit Ghosh Drugs Inspector vs. Sh. Virender Sindhwani & Ors.' and all other consequential proceedings emanating therefrom, pending before the Court of the learned Metropolitan Magistrate, Rohini, Delhi, including the order dated 06.12.2010 (hereinafter referred to as 'impugned order') by which the learned Metropolitan Magistrate has taken cognizance of offences under Sections 18(a)(i) and 27(d)

of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as 'the Act') and summoned the accused persons including the petitioners herein.

1.1. It is noted that by separate judgments of the same date, this Court has disposed of similar petitions filed on behalf of the petitioners herein, in relation to separate complaints filed by the respondent with respect to different batches of drugs. The facts and circumstances of the said petitions are similar to the present petition and the same contentions have been raised on behalf of the parties. Details of the said petitions are as under:

i. CRL.MC. 4332/2011 pertaining to CC No. 44/04 arising out of complaint dated 06.12.2010.
ii. CRL.MC. 4334/2011 pertaining to CC No. 47/04 arising out of complaint dated 06.12.2010.
iii. CRL.MC. 4335/2011 pertaining to CC No. 48/04 arising out of complaint dated 06.12.2010.
iv. CRL.MC. 4336/2011 pertaining to CC No. 45/04 arising out of complaint dated 06.12.2010.

Background

2. Petitioner no. 1 is the Joint Managing Director of M/s Cipla Ltd - a leading pharmaceutical company and petitioner no. 2 is its Chairman and Managing Director. The subject complaint dated 06.12.2010 was instituted at the instance of Sh. Abhijit Ghosh, Drugs Inspector, Drugs Control Department, Government of NCT of Delhi, seeking initiation of prosecution against the accused persons named therein, including the petitioners, for commission of offences under Sections 18(a)(i) and 27(d) of the Act. Briefly stated, the facts of the case are as under:

i. As on November 2007, M/s Cipla Ltd. (accused no. 7) was a company within the meaning of Section 34 of the Act. The drug namely, 'Ibugesic' Ibuprofen Oral Suspension B.P. (hereinafter referred to as 'the Drug'), which is a drug within the meaning of Section 3(b) of the Act was manufactured by M/s Mistair Health and Hygiene Pvt. Ltd. (accused no. 11) on the basis of a loan license granted to M/s Cipla Ltd. At the relevant point in time, petitioner no. 1 (accused no. 8) was the Joint Managing Director and petitioner no. 2 (accused no. 9) was the Chairman and Managing Director of M/s Cipla Ltd. and were in-charge of the conduct of day to day business of the said company.

ii. It was stated that on 16.07.2008 a sample of the Drug from batch no. CM 7451, Mfd. 11/07, Exp. 10/2010, manufactured by M/s Cipla Ltd. was taken by the complainant for test/analysis from the premises of M/s Galaxy Chemist (accused no. 1, hereinafter referred to as 'vendor') as per the procedure laid down in Section 23 of the Act. Intimation on Form-17 and one sealed portion of the sample was handed over to the vendor.

iii. On the same day, i.e., 16.07.2008, a portion of the sampled drug was forwarded to the government analyst, as per the procedure laid down in Rule 57 of the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as '1945 Rules').

iv. *Vide* test report no. F.2/(24)/TR/DTL-358/08 dated 02.02.2009, the government analyst declared the sample as ***'not of standard quality'*** as it did not ***"conform to claim as per BP with respect to test for assay (content of ibuprofen)"*** inasmuch as it was found to contain 44.51% of Ibuprofen as against the claim of 100 mg/5 ml.

v. On further enquiry made on 13.02.2009, Virender Sindhwani, i.e., the proprietor of the vendor informed the complainant that the said batch of the Drug was supplied to his firm by M/s Unique Pharma (accused no. 2, hereinafter referred to as 'distributor') *vide* invoice no. SB-1580 dated 16.05.2008.

vi. On 13.02.2009, a copy of the report of the government analyst was supplied to the vendor.

vii. In terms of Section 23(4)(iii) and 25(2) of the Act, on 19.02.2009, the complainant sent one portion of the sample alongwith the test report of the government analyst to the distributor. The same was not challenged and therefore, it is alleged that the same was conclusive evidence of the facts stated therein as per the provisions of Section 25(4) of the Act.

viii. On 19.02.2009, Sh. Ranjan Kumar Garg, the proprietor of the distributor revealed that the aforesaid batch of the Drug was supplied to them by M/s Janak Medicos (accused no. 3) *vide* invoice no. 5271 dated 03.05.2008.

ix. On 20.02.2009, Mr. Ravi Pal Udar, Partner (accused no. 4) at M/s Janak Medicos informed the complainant that the Drug was supplied to them by M/s Cipla Ltd. from its sales depot located at Mandoli Village, Delhi.

x. On 20.02.2009, enquiries were made at the Delhi depot of M/s Cipla Ltd. and it was revealed that the Drug was supplied to them from the Indore depot of the said company *vide* stock transfer invoices no. D/2257 and D/2316 dated 01.03.2008 and 10.03.2008, respectively.

xi. On 18.11.2009 and 19.11.2009, enquiries made with M/s Mistair Health and Hygiene Pvt. Ltd. revealed that the Drug was manufactured

by them on the basis of loan license granted to M/s Cipla Ltd. for sale and distribution. It was confirmed that the aforesaid batch of the Drug was supplied to M/s Cipla Ltd. at their Pune depot on 04.12.2007 and 05.12.2007. The said position was also not disputed by Mr. Santosh S. Naik, who was the authorised person of M/s Cipla Ltd. at M/s Mistair Health and Hygiene Pvt. Ltd.

xii. On 05.04.2010, the complainant wrote a letter to M/s Cipla Ltd. requesting for details in relation to the management of the said company and persons in-charge for the conduct of the business of the firm during the period of manufacture of the Drug.

xiii. *Vide* letter dated 23.06.2010, in response to the aforesaid letter dated 05.04.2010, M/s Cipla Ltd. informed the complainant that on the date of the manufacture of the Drug, Mr. Talat Fakhri (accused no. 10) was responsible for the conduct the day to day business of the company. A copy of the Power of Attorney issued by petitioner no. 1 in favour of Mr. Talat Fakhri was submitted alongwith the said letter.

xiv. On 06.12.2010, the learned Metropolitan Magistrate took cognizance on the complaint for offences under Sections 18(i)(a) and 27(d) of the Act and summoned all the accused persons named in the complaint, including the present petitioner for 04.04.2011.

Submissions on behalf of the Petitioners

Non-compliance with Section 23 of the Act

3. Learned Senior Counsel appearing on behalf of the petitioners submitted that the complaint dated 06.12.2010 and any proceedings instituted in pursuance of the same stand vitiated on account of non-compliance with the mandatory provisions of Section 23 of the Act which provides as under:

"**23. Procedure of Inspectors**.—(1) Where an Inspector takes any sample of a drug or cosmetic under this Chapter, he shall tender the fair price thereof and may acquire a written acknowledgement therefor.

(2) Where the price tendered under sub-section (1) is refused, or where the Inspector seizes the stock of any drug or cosmetic under clause (*c*) of Section 22, he shall tender a receipt therefor in the prescribed form.

(3) Where an Inspector takes a sample of a drug or cosmetic for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked:

Provided that where the sample is taken from premises whereon the drug or cosmetic is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that where the drug or cosmetic is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug or cosmetic be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows—

(*i*) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

(*ii*) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug or cosmetic]; and

(*iii*) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under Section 18-A.

(5) Where an Inspector takes any action under clause (*c*) of Section 22,—

(*a*) he shall use all despatch in ascertaining whether or not the drug or cosmetic] contravenes any of the provisions of Section 18 and, if it is ascertained that the drug or cosmeticdoes not so contravene, forthwith revoke the order passed under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized;

(*b*) if he seizes the stock of the drug or cosmetic, he shall as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof;

(*c*) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug or cosmetic, he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

(6) Where an Inspector seizes any record, register, document or any other material object under clause (*cc*) of sub-section (1) of Section 22, he shall as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof."

3.1. It was submitted that as per the complaint, it is an admitted position that the respondent had sent a sealed portion of the sample as per Section 23(4)(iii) and the original report of the government analyst in terms of Section 25(2) of the Act to the distributor. It was submitted that in the same paragraph of the complaint, it has been stated that as per Section 25(3) of the Act, the distributor was given an opportunity to challenge the report. Since the report was not challenged, it attained finality and is conclusive evidence of the facts stated therein.

3.2. It was submitted that the respondent also does not dispute the fact that the prosecution against the petitioners and M/s Mistair Health and Hygiene Pvt. Ltd. is based on the fact that the aforesaid report is conclusive evidence on account of the same not being challenged by the distributor. It was further submitted that it is also an admitted position that Sections 23(4)(iii) and 25(3) were not complied with inasmuch as the sample of the Drug or an opportunity to challenge the report of the government analyst were not provided to the petitioners or to M/s Mistair Health and Hygiene Pvt. Ltd.

3.3. Attention of this Court was drawn to a judgment of the Hon'ble Supreme Court in **Amery Pharmaceuticals and Ors. v. State of Rajasthan,**

(2001) 4 SCC 382, wherein the term 'conclusive' as employed in Section 25(3) of the Act was interpreted and it was held as under:

> "**24.** The extent of the implication of the words "such evidence shall be conclusive" as employed in Section 25(3) of the Act has to be understood now. Section 4 of the Evidence Act says that when one fact is declared by the said Act to be conclusive proof of another "the court shall, on proof of one fact, regard the other as proved, and shall not allow evidence to be given for the purpose of disproving it". The expression "conclusive evidence" employed in Section 25(3) of the Act cannot have a different implication as the legislative intention cannot be different. Such an import as for the word "conclusive" in the interpretation of statutory provisions has now come to stay. If so, what would happen if the manufacturer is disabled from challenging the facts contained in the document which would visit him with drastic consequences when he is arraigned in a trial? Any legal provision which snarls at an indicted person without affording any remedy to him to disprove an item of evidence which could nail him down cannot be approved as consistent with the philosophy enshrined in Article 21 of the Constitution. The first effort which courts should embark upon in such a situation is to use the power of interpretation to dilute it to make the provision amenable to Article 21."

3.4. It was further contended that the procedure prescribed under Section 23 of the Act has to be mandatorily followed by the Drugs Inspector while taking samples of the subject drug or medicine. If the sample is taken from a retailer or a person whose name has been disclosed under Section 18A of the Act, the Inspector shall divide the same into four portions, seal and mark them and allow the person from whom the sample was taken to add his own seal or mark. It was submitted that as per Section 23(4)(iii) of the Act, the third portion of the sample is required to be provided to the person whose name, address, etc., have been disclosed pursuant to the exercise conducted under Section 18A of the Act. It was submitted that a perusal of Section 18A makes it abundantly clear that the purpose of the said provision is to disclose the

name of the manufacturer of the subject drug and extend a fair opportunity to the said manufacturer for exercising his rights provided for in the Act. The provision of Section 18A is applicable on every person who is not a manufacturer or its agent for distribution.

3.5. It was submitted that it is thus, incumbent upon the Inspector to seek disclosure under Section 18A of the Act from every person/entity in the supply chain till such Inspector reaches the person who discloses the name of the manufacturer and by way of invoices, substantiates that he had purchased the subject drug from the manufacturer itself or its agent for distribution. Upon such disclosure, the Inspector has to then provide a portion of the sample and the report in terms of Sections 23(4)(iii) and 25(2) of the Act respectively. Section 18A of the Act provides as under:

> "**18-A. Disclosure of the name of the manufacturer, etc**.—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."

3.6. As far as the facts of the present case are concerned, learned Senior Counsel submitted that it is not in dispute that the respondent had interpreted Section 18A of the Act to mean that since the vendor had disclosed the name of the distributor, the statutory rights under Section 23(4)(iii) and 25(2) accrued only in favour of the distributor and not the manufacturer of the Drug or the petitioners herein.

3.7. It was submitted that in terms of the settled legal position, one portion of the sample was to be sent to the manufacturer. As per the complaint, both - M/s Cipla Ltd. and M/s Mistair Health and Hygiene Pvt. Ltd. are responsible for the manufacture of the Drug, however, it is an admitted case that neither

of them were supplied with a portion of the sample or a copy of the report of the government analyst which is a clear infraction of the mandatory safeguards incorporated in the Act. Learned Senior Counsel submitted that such violations completely vitiate the complaint and any proceedings emanating therefrom. In support of the said contention, learned Senior Counsel placed reliance on the decision of the Hon'ble Supreme Court in **Laborate Pharmaceuticals India Limited and Ors. v. State of Tamil Nadu, (2018) 15 SCC 93**, and in particular, on the following paragraphs thereof:

> "6. A reading of the provisions of Sections 23(4) and 25 of the Act would indicate that in the present case the sample having been taken from the premises of the retailer had to be divided into four portions; one portion is required to be given to the retailer; one portion is required to be sent to the Government Analyst and one to the court and the last one to the manufacturer whose name, particulars, etc. is disclosed under Section 18-A of the Act. In the present case, admittedly, one part of the sample that was required to be sent to the appellant (manufacturer) under Section 23(4)(iii) of the Act was not sent. Instead, what was sent on 22-3-2012 was only the report of the Government Analyst. When the part of the sample was not sent to the manufacturer, the manufacturer could not have got the same analysed even if he wanted to do so and, therefore, it was not in a position to contest the findings of the Government Analyst. In the present case, the sample was sent to the appellant manufacturer on 10-8-2012 and on 13-9-2012 the appellant had indicated its desire to have another part of the sample sent to the Central Laboratory for reanalysis. This was refused on the ground that the aforesaid request was made much after the stipulated period of 28 days provided for in Section 25(3) of the Act.
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> 7. The cognizance of the offence(s) alleged in the present case was taken on 4-3-2015 though it appears that the complaint itself was filed on 28-11-2012. According to the appellant the cough syrup had lost shelf life in the month of November 2012 itself. Even otherwise, it is reasonably certain that on the date when cognizance was taken, the shelf life of the drug in question had expired. The Magistrate, therefore, could not have sent the sample for reanalysis by the Central Laboratory.

8. All the aforesaid facts would go to show that the valuable right of the appellant to have the sample analysed in the Central Laboratory has been denied by a series of defaults committed by the prosecution; firstly, in not sending to the appellant manufacturer part of the sample as required under Section 23(4)(iii) of the Act; and secondly, on the part of the Court in taking cognizance of the complaint on 4-3-2015 though the same was filed on 28-11-2012. The delay on both counts is not attributable to the appellants and, therefore, the consequences thereof cannot work adversely to the interest of the appellants. As the valuable right of the accused for reanalysis vested under the Act appears to have been violated and having regard to the possible shelf life of the drug we are of the view that as on date the prosecution, if allowed to continue, would be a lame prosecution.

9. Consequently and for the reasons alluded we are of the view that the present would be a fit case to interdict the criminal trial against the appellant-accused. We order accordingly. Therefore, CC No. 263 of 2015 pending on the file of the XVth Metropolitan Magistrate, George Town, Chennai is hereby quashed. The appeal is allowed and the order of the High Court is set aside."

Non-compliance with Section 25 of the Act

4. Learned Senior Counsel appearing on behalf of the petitioners contended that the fact that Section 25 of the Act was not complied with by the respondent also vitiates the proceedings arising out of the complaint dated 06.12.2010. Section 25 of the Act provides as under:

"**25. Reports of Government Analysts**.—(1) The Government Analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis under sub-section (4) of Section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken and another copy to the person, if any, whose name, address and other particulars have been disclosed under Section 18-A, and shall retain the third copy for use in any prosecution in respect of the sample.

(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars

have been disclosed under Section 18-A has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug or cosmetic produced before the Magistrate under sub-section (4) of Section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

(5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct."

4.1. It was submitted that it is an admitted case that the report of the government analyst was never sent to M/s Cipla Ltd. or to M/s Mistair Health and Hygiene Pvt. Ltd. in terms of Section 25(2) of the Act. Learned Senior Counsel submitted that the report was received by M/s Cipla Ltd. annexed alongwith a show cause notice dated 31.03.2009 sent to them by some other department and not under Section 25(2) of the Act and therefore, since M/s Cipla Ltd. has been sought to be proceeded against as the manufacturer of the Drug, the Inspector has failed to comply with the aforesaid provision. In support of his argument, learned Senior Counsel placed reliance on a judgment of the Hon'ble High Court of Gujarat in **Rajesh Ramanlal Shah and Ors. v. State of Gujarat and Ors., MANU/GJ/2756/2019**, wherein it has been held as under:

"30...Therefore, manufacturer having not notified such intention under section (3) of Section 25 of the Act after receipt of the report on the

ground that one portion of sample was not furnished to him, cannot successfully then argue that he is deprived of valuable right under sub section (4) of Section 25 of the Act after filing of the complaint against it. However, in the said decision the Supreme Court has recognized the right under sub-section (4) of Section 25 of the Act to be a valuable right of the accused. Thus, the decision relied on by the learned Senior Counsel Mr. Amin will not come to his help, on the contrary, on facts, it helps the accused.

31. The contention raised by Mr. Amin, learned Public Prosecutor and Senior Counsel, that the document produced by the petitioners at page No. 30 reveals that vide communication dated 15.11.2014 a copy of analyst's report was served to him as referred in the communication addressed to the Manufacturer, within 28 days of the receipt thereof, it was incumbent upon the applicants to notify their intention to adduce evidence in controversion of the report. According to Mr. Amin, learned Senior Counsel, declaration of intention vide communication dated 25.12.2014 or 28.12.2014 by the petitioners is surely beyond 28 days as provided under sub section (3) of the Section 25 of the Act and therefore, it was never incumbent upon the Drug Inspector to send the sample for retest to the Central Drugs Laboratory, is also required to be rejected. Since the communication which is produced by the petitioner dated 15.11.2014 is a notice issued under sub rule (2) of Rule 85 of the Rules by the Central Licence Approving Authority asking manufacture as to why licence is not suspended or cancelled, is not a compliance, that too, by the Drug Inspector under sub-section (2) of Section 25 of the Act. Mere supply of copy of the test report of Government Analyst, that too, by Central Licence Approving Authority while issuing show cause notice for suspension/cancellation of licence, the person may be well within contemplation that instead of initiating prosecution, the authority rests contended issuing show cause notice for suspension or cancellation of the license. At any rate, for search, seizure, drawing sample etc., the Drug Inspector is empowered. Therefore, each and every compliance right from drawing sample till filing of the prosecution, the Drug Inspector is empowered. Therefore, even if it is presumed that by communication dated 15.11.2014 issued by the Licencing Authority, the document which is produced by the petitioners, accused were made aware of the report of the Government Analyst, they are not obliged to declare their intention to adduce evidence in controversion of the report, to the Central Licence Approving Authority as it is to be notified to the Inspector as per Section 25(3) of the Act. Since Central Licence Approving Authority is not supposed to have the portion of sample to be submitted to the Court, in no

> case even if the manufacturer notifies his intention to adduce evidence in controversion thereof, it is supposed to send the same to the Central Drugs Laboratory. Therefore, the Act provides furnishing of the copy of the government analyst report by the Drug Inspector alone. Initiating any other action, by any of the officer of the Food and Drugs Administration will not be presumed to be compliance under sub-section (2) of Section 25 of the Act.
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> At any rate, neither the complaint refers about the said communication nor is prosecution able to point out the date on which it is received by the petitioners. It is only within 28 days of receipt of the same, the petitioners are supposed to notify their intention to adduce evidence in controversion of the government analyst report. Therefore, it can not be successfully argued that communication dated 15.11.2014 which is a show cause notice for suspension or cancellation of licence to be construed as compliance under sub-section (2) of Section 25 of the Act, that too, by the Drug Inspector, as held aforesaid. Hence prosecution is required to be quashed for denial of the opportunity under Section 25(4) of the Act."

4.2. Without prejudice to the aforesaid argument, it was submitted that even if it was assumed that the report supplied to M/s Cipla Ltd. by way of the show cause notice dated 31.03.2009 is sufficient for compliance of Section 25(2) of the Act, by way of a letter dated 18.04.2009, M/s Cipla Ltd. sufficiently controverted the report of the government analyst as per Section 25(3) of the Act within 28 days of its receipt alongwith their own in-house report of analysis of the reserve sample of the Drug from the same batch. Reliance in this regard was placed on a judgment of the Hon'ble High Court of Manipur in **Indchemie Health Specialties Private Limited and Ors. v. Union of India, Ministry of Health and Family Welfare and Ors., MANU/MN/0019/2019**, wherein it was held as under:

> 38. A reading of the provision section 25(3) and 25(4) of the Act, it is clear that the intention of the legislature is to enable the accused to adduce evidence in controversion of the report. There is no need to ask for a re-testing as suggested by the respondents' counsel.
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> 40. Tested on the above principles laid down by the Hon'ble Supreme Court, in the present case, the petitioners have adduced evidence to controvert the report of the Government Analyst. And therefore, the requirement of Under section 25 (3) and 25 (4) is satisfied. The consequence is that the prosecution ought to have sent the report to the Government drug laboratory for test by the competent authority, namely, the director or his duly authorized person specified in rule 3 and 6 r/w Form 2 extracted above. The failure to place the report in controversion before the Court, is a violation of provision of law. The breach will entitle the petitioners in this case to plead for quashing the proceedings which is inherently defective.

Non-compliance with the guidelines under the Drugs and Cosmetics (Amendment) Act, 2008

5. Learned Senior Counsel submitted that guideline number 7 of the Guidelines For Taking Action On Samples Of Drugs Declared Spurious Or Not Of Standard Quality Formulated Under The Drugs And Cosmetics (Amendment) Act, 2008 ('2008 Guidelines') mandate that the State Drug Control Departments must constitute screening committees to examine the investigation report of the cases where prosecution is sought to be launched. It is further mandated that the said prosecution is to be launched only after considering the recommendations of the screening committee.

5.1. Learned Senior Counsel submitted that a bare perusal of the complaint dated 06.12.2010 does not disclose that the matter was ever placed by the screening committee as mandated by the 2008 Guidelines. Attention of this Court was drawn to a judgment of the Hon'ble High of Madras in **CRL.OP. Nos. 4419, 4420 and 4595 of 2017 and CRL.M.P. Nos. 3300, 3302, 3303, 3469 and 3470 of 2017**, titled **'Y.K. Hamied and Ors. v. State'**, whereby the Court quashed a criminal complaint under the Act on the ground that requisite sanction was not sought by the Drugs Inspector from the screening committee

before prosecution was initiated. While quashing the complaint, the Hon'ble High Court of Madras held as under:

> "16.There is no record to show that the show cause notice and the replies thereto were placed before the Screening Committee. There is no such reference in the sanction order also. The learned Magistrate had also not examined whether, the mandatory procedure had been adhered to the respondent / complainant. There is also no record to show that the replies to the show cause notice were examined in their proper perspective. Since there is a violation of these mandatory requirements, it is only just that cognizance which had been taken by the learned Magistrate of the complaint filed by the respondent is quashed."

Section 34 of the Act

6. Learned Senior Counsel submitted that merely because petitioner no. 1 is the Joint Managing Director and petitioner no. 2 is the Chairman and Managing Director of M/s Cipla Ltd. does not mean that they can automatically be prosecuted by virtue of Section 34 of the Act. Section 34 of the Act provides 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 if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.
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> (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.

Explanation.—For the purposes of this section—

(*a*) "company" means a body corporate, and includes a firm or other association of individuals; and

(*b*) "director" in relation to a firm means a partner in the firm."

6.1. It was submitted that Mr. Talat Fakhri, in favour of whom a Power of Attorney was executed by petitioner no. 1 was the person responsible for the conduct of the day to day affairs of M/s Cipla Ltd. Learned Senior Counsel submitted that it is also an admitted position that the Drug in question was manufactured by M/s Mistair Health and Hygiene Pvt. Ltd. on the basis of a loan license.

6.2. In support of the aforesaid contentions, reliance was placed on the following judgments:

i. Cheminova India Limited v. State of Punjab, 2021 SCC OnLine SC 573.

ii. State of H.P. v. Shri Nand Kishore and Ors., 2011 (2) Drugs Case (DC) 308.

iii. M/s Hwizal Laboratory Pvt. Ltd. & Ors. v. State of Rajasthan, 2009 (1) Drugs Case (DC) 265.

iv. Umesh Sharma, Managing Director, M/s. Aristo Pharmaceuticals Ltd., v. S.G.Bhakta, Drugs Inspector and Ors., (2003) Drugs Case 1.

v. Sanjay G. Revankar v. State by Drugs Inspector, Uttar Kannada District, Karwar, (34) 2002 Drugs Case 163.

vi. State of Haryana v. Brij Lal Mittal & Ors., (1998) 5 SCC 343.

vii. Adarsh Marwah & Ors. v. Nehar Ranjan Bhattacharya & Anr., Judgement of the High Court of Delhi dated 15.03.1990 in Crl. Misc. (M) 1867 of 1989.

viii. Municipal Corporation of Delhi v. Ram Kishan Rohtagi & Ors., (1983) 1 SCC 1.

ix. State of Karnataka & Ors. v. Pratap Chand & Ors., (1981) 2 SCC 335.

x. Ashoke Mal Bafna v. Upper India Steel Mfg. & Engg. Co. Ltd., (2018) 14 SCC 202.

xi. Castrol (India) Ltd. v. State of Karnataka, (2018) 17 SCC 275.

xii. Pooja Ravinder Devidasani v. State of Maharashtra, (2014) 16 SCC 1.

xiii. G.N. Verma v. State of Jharkhand & Anr., (2014) 4 SCC 282.

Rules 69A and 79 of the Drugs and Cosmetics Rules, 1945

6.3. Attention of this Court was drawn to Rule 69-A of the 1945 Rules which stipulates that before grant of a loan license, the licensing authority is required to satisfy itself that the manufacturing unit has adequate equipment, staff, capacity for manufacture and facilities for testing to undertake the manufacture on behalf of the applicant for a loan license. Attention of this Court was further drawn to Rule 79 which states that before a loan license is granted, the licensing authority shall cause the proposed manufacturing establishment to be inspected by one or more inspectors with or without an expert in the field. Learned Senior Counsel submitted that the provisions concerning a loan license contained in the 1945 Rules would require approval of the Office of the Drugs Inspector for manufacture of the drug in question by M/s Mistair Health and Hygiene Pvt. Ltd. with approved scientific and supervisory staff.

Section 202 of the CrPC

7. Learned Senior Counsel submitted that in the present case, both the petitioners reside outside the territorial jurisdiction of the Court of the learned Metropolitan Magistrate before whom the trial in the present case is pending.

However, a perusal of the summoning order dated 06.12.2010 reflects that no enquiry prior to issue of process in terms of Section 202 has been conducted by the learned Metropolitan Magistrate. Section 202 of the CrPC provides as under:

> "**202. Postponement of issue of process**.—(1) Any Magistrate, on receipt of a complaint of an offence of which he is authorised to take cognizance or which has been made over to him under Section 192, may, if he thinks fit, and shall, in a case where the accused is residing at a place beyond the area in which he exercises his jurisdiction, postpone the issue of process against the accused, and either inquire into the case himself or direct an investigation to be made by a police officer or by such other person as he thinks fit, for the purpose of deciding whether or not there is sufficient ground for proceeding:
>
> Provided that no such direction for investigation shall be made,—
>
> (*a*) where it appears to the Magistrate that the offence complained of is triable exclusively by the Court of Session; or
>
> (*b*) where the complaint has not been made by a Court, unless the complainant and the witnesses present (if any) have been examined on oath under Section 200.
>
> (2) In an inquiry under sub-section (1), the Magistrate may, if he thinks fit, take evidence of witnesses on oath:
>
> Provided that if it appears to the Magistrate that the offence complained of is triable exclusively by the Court of Session, he shall call upon the complainant to produce all his witnesses and examine them on oath.
>
> (3) If an investigation under sub-section (1) is made by a person not being a police officer, he shall have for that investigation all the powers conferred by this Code on an officer in charge of a police station except the power to arrest without warrant."

7.1. Learned Senior Counsel placed reliance on the following judgments:

i. In Re: Expeditious Trial of Cases Under Section 138 of the Negotiab;le Instruments Act, 1881, 2021 SCC OnLine SC 325.

ii. Abhijit Pawar v. Hemant Madhukar Nimbalkar & Anr., (2017) 3 SCC 528.

iii. Mohammad U.L. Rehman v. Khazir Mohammad Tunda & Ors., (2015) 12 SCC 420.

No prima facie case against the Petitioners

8. Learned Senior Counsel submitted that although proviso 'a' to Section 200 of the CrPC provides for an exemption from recording pre-summoning evidence in a case where a private complaint is filed by a public servant in discharge of his official duties; it is settled legal position that it is incumbent upon the Magistrate to apply his mind to see whether on the basis of the allegations made in the complaint and the evidence placed on record, a *prima facie* case for taking cognisance and summoning the proposed accused is made out or not.

8.1. Learned Senior Counsel submitted that just because a complaint is filed on behalf of a department of the Government, it does not constitute an automatic exemption of the applicability of the mandatory provision of Section 200 of the CrPC. It was submitted that a perusal of the impugned order reflects that the learned Metropolitan Magistrate did not examine the complainant before taking cognisance and has treated the present case to be considered as one where there is an automatic exemption from compliance of Section 200 of the CrPC.

8.2. Learned Senior Counsel drew the attention of this Court to a judgment of the Hon'ble Supreme Court in **Dayle De'souza v. Government of India through Deputy Chief Labour Commissioner and Anr., 2021 SCC OnLine SC 1012** and in particular, the following paragraphs thereof:

> "**38.** Equally, it is the court's duty not to issue summons in a mechanical and routine manner. If done so, the entire purpose of laying down a detailed procedure under Chapter XV of the 1973 Code gets frustrated. Under the proviso (a) to Section 200 of the 1973 Code, there

> may lie an exemption from recording pre-summoning evidence when a private complaint is filed by a public servant in discharge of his official duties; however, it is the duty of the Magistrate to apply his mind to see whether on the basis of the allegations made and the evidence, a *prima facie* case for taking cognizance and summoning the accused is made out or not. This Court explained the reasoning behind this exemption in *National Small Industries Corporation Limited* v. *State (NCT of Delhi)* :
>
> "12. The object of Section 200 of the Code requiring the complainant and the witnesses to be examined, is to find out whether there are sufficient grounds for proceeding against the accused and to prevent issue of process on complaints which are false or vexatious or intended to harass the persons arrayed as accused. (See *Nirmaljit Singh Hoon* v. *State of W.B.*) Where the complainant is a public servant or court, clause (a) of the proviso to Section 200 of the Code raises an implied statutory presumption that the complaint has been made responsibly and bona fide and not falsely or vexatiously. On account of such implied presumption, where the complainant is a public servant, the statute exempts examination of the complainant and the witnesses, before issuing process."
>
> **39.** The issue of process resulting in summons is a judicial process that carries with it a sanctity and a promise of legal propriety."

8.3. It was submitted that the rationale behind Section 200 of the CrPC is that before criminal law is set in motion against any person, the satisfaction of a criminal court in relation to the existence of a *prima facie* case is mandatory. It follows that it is only upon discharge of the unequivocal obligation upon the court of carefully examining the contents of the complaint and the material placed on record in its support, a Judge, after duly recording reasons for his satisfaction, can dispense with the examination of the complainant and witnesses before issuance of summons.

8.4. Learned Senior Counsel further submitted that nothing contained in the impugned order shows that the learned Metropolitan Magistrate has applied

his mind to the facts of the case to determine whether a *prima facie* case is made out against the proposed accused or not.

Submissions on behalf of the State

Responsibility of M/s Cipla Ltd. and the Petitioners

9. Learned APP for the State submitted that M/s Cipla Ltd. is a 'manufacturer' in terms of Section 3(b) of the Act. Attention of this Court was drawn to a letter dated 20.02.2009 addressed by M/s Cipla Ltd. to the Drugs Inspector admitting that batch No. CM 7451 of the Drug was manufactured at their Kolhapur plant. Learned APP of the State drew the attention of this Court to a letter dated 23.06.2010 addressed by M/s Cipla Ltd. stating that a Power of Attorney was executed by petitioner no. 1 in favour of Mr. Talat Fakhri making him responsible for conduct of the day to day business of M/s Cipla Ltd. It was submitted that Section 34 of the Act provides that in case of an offence committed by a company, every person responsible for the conduct of the business of the company at the time of the commission of the offence shall be liable to be proceeded against and punished accordingly. It was submitted that the import of Section 34 of the Act includes Directors of the company as well, which in this case are the petitioners. Therefore, it was submitted that the Magistrate was required to only formulate a *prima facie* view in relation to the commission of the offence and has not erred in summoning the petitioners.

Compliance with Section 23 of the Act

10. Learned APP for the State submitted that the procedure prescribed in Section 23 of the Act was duly followed.

10.1. Four samples of the Drug were collected from the vendor:

i. The first portion of the sample was handed over to the person/chemist from whom the sample was collected under his acknowledgment.

ii. Second portion of the sample was sent to the government analyst for testing.

iii. The third portion of the sample, as per Section 23(4)(iii) of the Act was handed over to the person/firm whose name was disclosed under Section 18A, i.e., the distributor.

iv. The fourth portion of the sample is to be produced before the Court before which the proceedings have been instituted in respect of the drugs, in case the report of the government analyst is challenged under Section 25(3) of the Act. In the present case, the said fourth portion of the sample is in the possession of the Investigating Officer as case property as the report was never challenged.

10.2. Learned APP for the State submitted that as far as Section 23(4)(iii) of the Act is concerned, the same was complied with the moment a portion of the sample to provided to the distributor from which the vendor had bought the drug. To substantiate this argument, learned APP for the State drew the attention of this Court to the following paragraph of **Amery Pharmaceuticals (*supra*)**:

> "**16.** Thus, in a case where the drug or medicine has passed from the manufacturer to a wholesaler (a distributor) and then to a retailer, the obligation of the Inspector (who takes the sample from a retailer) as for giving portions of the sample would end up by giving it to the retailer and also to the distributor (from whom the retailer bought the drug)."

10.3. Reliance was further placed on a judgment of the Hon'ble High Court of Punjab and Haryana rendered in **CRM-M-23426 of 2022** titled **'Varun Kapoor and Ors. v. State through Drugs Inspector, Amritsar'**, wherein

the Hon'ble High Court, after referring to **Amery Pharmaceuticals (*supra*)** and **Laborate Pharmaceuticals (*supra*)** has clearly distinguished the entitlement of a manufacturer in reference to obtaining a portion of the sampled drug and has held as under:

> "9. As observed by Hon'ble Supreme Court, in Amery Pharmaceuticals Vs. State of Rajasthan (supra), as per Section 25(2) of the Act, Inspector shall deliver one copy of the report to the person from whom the sample was taken, another copy of the report to person whose name and address have been disclosed to the Inspector, whereas third copy shall be retained by the Inspector for use in any prosecution in respect of the sample.
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> 11. It is contended by learned counsel for the petitioners that the petitioner- manufacturer has been disabled from controverting the finding of the government analyst in this case because he was not provided the portion of the sample, which was taken by the Drug Inspector on 30.01.2018. Contention of learned counsel is that the petitioner could challenge the report by notifying his intention to the trial Court or the Drug Inspector to adduce evidence in controversion of the report only in case a portion of the sample was sent to him. It is further urged that name of the petitioner – manufacturer was duly mentioned in Form 17, despite which compliance of Section 23(4)(iii) of the Act was not made.
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> 13. A reading of the above-said provision to be read with Section 25 of the Act already reproduced, would indicate that after taking the sample, the Inspector is required to hand over one portion of sample in sealed condition to the person from whom he takes it (retailer in this case); second portion is required to be sent to the government analyst for test/ analysis; another portion is required to be produced in the Court before which proceedings are to be instituted in respect of the drug and the last sample is required to be sent to the person, whose name, address and other particulars have been disclosed under Section 18-A of the Act.
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> 15. A bare perusal of the above-said provision would reveal that a person, who is neither the manufacturer of the drug nor the agent for distribution, is required to disclose to the Inspector, the name, address and other particulars of the person from whom he acquired the drug or the cosmetic. It is important to notice here itself that requirement of Section 18A is to disclose the name, address and other particulars of the

person from whom the concerned person has acquired the drug. It is not the requirement of law that the concerned person has to disclose the name of the manufacturer. He is only to disclose the particulars of the person from whom he acquired the drug or cosmetic."

Compliance with Section 25 of the Act

11. Learned APP for the State submitted that Section 25 of the Act has also been complied with.

11.1. It was submitted that Section 25(2) of the Act provides that one copy of the report shall be provided to the person from whom the sample was collected and one to the person whose name has been disclosed under Section 18A of the Act. In the present case, the entity whose name was declared under Section 18A is the distributor, to which the report of the government analyst was admittedly supplied in original on 19.02.2009.

11.2. Learned APP for the State further submitted that as per the judgment of the Hon'ble Supreme Court in **Amery Pharmaceuticals** (***supra***), the manufacturer can also avail himself of the remedy provided for in Section 25(4) of the Act by requesting the Court to send a portion of the sample to be tested at the Central Drugs Laboratory. Since M/s Cipla Ltd. never expressed their interest to adduce evidence to dispute the report of the government analyst, they cannot at this stage plead that their right to challenge the report was violated. It was further submitted that M/s Cipla Ltd. could also have challenged the report by directly approaching the Court under Section 25(3) of the Act, as the enquiry in relation to the sampled Drug was made at their Delhi Depot by the concerned Drugs Inspector in the year 2009, which is well before the expiry date of the batch of the Drug.

Loan Licence

12. Learned APP for the State submitted that the loan licence, on the basis of which M/s Mistair Health and Hygiene Pvt. Ltd. was manufacturing the drug, was granted to M/s Cipla Ltd. It was urged that Rule 69A of the 1945 Rules provides that a loan licence may be issued by the concerned Licensing Authority to an applicant who intends to avail the manufacturing facilities owned by a licensee in term of form 25 of the 1945 Rules.

12.1. It was submitted that in the present case, M/s Cipla Ltd. has used the manufacturing facilities of M/s Mistair Health and Hygiene Pvt. Ltd. to manufacture, sell and distribute the Drug. The loan license was granted to M/s Cipla Ltd. after complying with the mandatory requirements of the 1945 Rules. As per the said rules, the loan licensee, i.e., M/s Cipla Ltd. is the actual manufacturer of the Drug and its liability is at par with M/s Mistair Health and Hygiene Pvt. Ltd.

12.2. Attention of this Court was drawn to a Technical Agreement entered into between M/s Cipla Ltd. and M/s Mistair Health and Hygiene Pvt. Ltd., wherein it was agreed that a representative of M/s Cipla Ltd. would be responsible for supervision and certification of the manufacture of the products, periodic validation of manufacturing systems, equipment and operations, periodic validation of the products, review of all documentation relating to the batches to be sent to the principal and any other duties as assigned. As per the said agreement, M/s Cipla Ltd. was also responsible for confirming the stability of the products and quality control.

Guidelines under the Drugs and Cosmetics (Amendment) Act, 2008

13. As far as the compliance with the 2008 Guidelines is concerned, it was submitted that the said guidelines are only recommendatory in nature and are

not mandatory. Neither the Act nor the 1945 Rules mandate the constitution of a Screening Committee as recommended in the 2008 Guidelines. It was submitted that different States have formulated different mechanism to facilitate a thorough examination of the case before prosecution is initiated under the Act. In the State of Delhi, all cases are screened by the Legal Cell of the Department before any prosecution is initiated, the said screening process is regulated by internal departmental guidelines/procedure which may vary from State to State.

Rejoinder on behalf of the Petitioners

14. Learned Senior Counsel appearing on behalf of the petitioners submitted that the reliance placed by the State on paragraph 16 of **Amery Pharmaceuticals (*supra*)** is misconceived. It was submitted that the said paragraph cannot be read in isolation and the judgment has to be read as a whole. It was the contention of the learned APP for the State that the said paragraph states that if the Drug has passed on from the manufacturer to the distributor and then to a retailer, then the obligation of the Inspector would be completed by giving a portion of the sampled Drug to the retailer and the distributor. It was submitted that the aforesaid paragraph 16 of **Amery Pharmaceuticals (*supra*)** in fact records the submission of the respondent department therein and is not the ratio laid down by the Hon'ble Supreme Court. Learned Senior Counsel reiterated that reliance placed on paragraph 16 of the said judgment to contend that the mandatory requirement under Section 23(4)(iii) has been satisfied is entirely misconceived and unsustainable.

14.1. Learned Senior Counsel further submitted that Section 18A was incorporated to enable the concerned department/investigating officer to reach

the actual manufacturer of a drug which is the subject matter of an investigation. It was submitted that compliance with Section 18A is vital in order to distinguish a genuine manufacturer from the manufacturer of a counterfeit/spurious drug. Essentially, the procedure in Section 18A compels the retailers and distributors to disclose the details of their purchase until such time that the identity of the original manufacturer is revealed. Therefore, it is submitted that it would be misconceived to say that the requirement of Section 18A of the Act was satisfied when the name of the distributor was disclosed by the vendor.

14.2. Learned Senior Counsel further submitted that if the interpretation accorded by the State to paragraph 16 of **Amery Pharmaceuticals (*supra*)** is accepted, it is likely to create an anomalous and dangerous situation, especially in cases where counterfeit drugs are involved. For the sake of argument, it was submitted that in an event where a counterfeit drug is sampled during an investigation, and then declared as 'not of standard quality', the sample and the report of the government analyst in terms of Sections 23(4)(iii) and 25(2) of the Act read with paragraph 16 of **Amery Pharmaceuticals (*supra*)** will only be required to supplied to the retailer and the distributor. If such a course of action is accepted as sufficient of compliance of Section 18A of the Act, the investigating agency would proceed to initiate prosecution against the actual manufacturer without even having to supply it with a portion of the sample and giving it an opportunity to test it or challenge the report. In such a case, the actual manufacturer will confronted with a situation where it will be prosecuted on the basis of an inconvertible report in relation to a drug which was not actually manufactured

by it. Learned Senior Counsel submitted that such an interpretation would defeat a legislative intent behind Sections 23(4)(iii), 25(2) and 18A of the Act.

14.3. Without prejudice to the aforesaid arguments, learned Senior Counsel submitted that upon a bare reading of **Amery Pharmaceuticals (*supra*)**, a clear position emerges which unequivocally recognises the right of a manufacturer whose name has been disclosed under Section 18A of the Act and also of a manufacturer which is impleaded at a subsequent stage under Section 32A of the Act to be entitled to the safeguards incorporated in Sections 23 and 25 of the Act. Attention of this Court was drawn to the following paragraphs of **Amery Pharmaceuticals (*supra*)**.

> "**26.** In *Vetcha Venkata Raju* v. *State of A.P.* [1994 Drugs Cases 94 (AP)] a manufacturer was prosecuted in a situation similar to the present case and he was convicted by the trial court which was confirmed by the Sessions Court. He raised a contention before the High Court of Andhra Pradesh that he was precluded from exercising a valuable right to get the sample examined by the Central Drugs Laboratory as provided under Section 25(4) of the Act because the portion of the sample or copy of the report was not supplied to him. As against the said contention the Public Prosecutor in that case pointed out that any other manufacturer also would be under such a disability if he is prosecuted in exercise of the powers under Section 32-A of the Act because there is no provision for serving him with a copy of the report in such a situation. A Single Judge of the Andhra Pradesh High Court, in the wake of the above contentions, observed that if the manufacturer is prosecuted by impleading him as per Section 32-A of the Act he cannot claim the right to be supplied with a copy of the report of the Government Analyst, but if he is prosecuted in consequence of the disclosure made under Section 18-A such manufacturer would be entitled to a portion of the sample as well as a copy of the report of the Government Analyst. According to learned Single Judge, failure to supply such things to the manufacturer who was made an accused as per Section 18-A could cause prejudice to him. But no such prejudice can be caused by (*sic* to) a manufacturer impleaded under Section 32-A of the Act, according to the learned Single Judge. Consequently the conviction and sentence passed on the manufacturer in that case were set aside by the High Court.

> **27.** We are unable to understand the rationale in drawing a hiatus between a manufacturer who is arraigned as an accused at the first instance itself and another manufacturer who is arraigned in exercise of the powers under Section 32-A of the Act, as regards his right to challenge a document purporting to be the report of the Government Analyst. The right to challenge the report must, as of right, be available to both such manufacturers who are prosecuted for the offence."

14.4. As far as the reliance placed by the State on the judgment rendered by the Hon'ble High Court of Punjab and Haryana in **Varun Kapoor (*supra*)** is concerned, learned Senior Counsel submitted that in the said case, despite the receipt of the report from the Drugs Inspector, the manufacturer did not challenge the same within the 28 days as per the mandate of Section 25(3) of the Act. It was for that reason that the Court had concluded that the reliance placed by the petitioners therein on **Laborate Pharmaceuticals (*supra*)** was misplaced. Be that as it may, it was submitted that the Hon'ble High Court of Punjab and Haryana had also not considered the judgment of **Amery Pharmaceuticals (*supra*)** in its entirety, and especially, paragraphs 26 and 27 thereof.

Analysis

15. Heard learned counsel for the parties and perused the record.

Compliance of Section 18A, 23 and 25 of the Act

16. A learned Division Bench of the Hon'ble High Court of Himachal Pradesh, in **Kiran Dev Singh v. State, 1990 SCC OnLine HP 56**, while answering a reference in the context of similar circumstances, observed and held as under:

> "**2.** The complaint says that a sample of Furalin suspension (Batch No. Red) manufactured by Rose Chem, haying a license under the provisions of Drugs and Cosmetics Act, 1940 (briefly the Act; was found to be of non-standard quality in the report dated September 28,

1988, by the Government Analyst, Punjab. The sample said to have been drawn from the supply of Furalin suspension, a drug for Diarrhoea, made by Kiran Dev Singh to the Sub Centre Stores, Public Health, Mandi, on the basis of an order which had been secured by M/s. Easter Pharmaceuticals Laboratory, Parwanoo, from the Chief Medical Officer, Mandi. The allegation in the complaint further is that the sample having been found to be of a drug which was not of standard quality, the Incharge of the Sub Centre Stores was intimated about the fact by the Drug Inspector vide letter dated October 4, 1988. The Incharge was required to disclose the name of the person from whom he had received the drug. The Incharge disclosed the name of Easter Pharmaceuticals Laboratory, Parwanoo through his letter of October 6, 1988 and supplied the purchase invoice. In this purchase invoice no batch number of the drug was found mentioned.

3. A copy of the report of analysis of the drug sample was furnished to M/s Easter Pharmaceuticals Laboratory, Parwanoo. A part of the sample, which had been collected by the Drug Inspector on January 21, 1988, at the Sub Centre Storesh, Mandi, was also supplied to M/s Easter Pharmaceuticals Laboratory, Parwanoo. No such copy of the report of the Analyst or part of the sample was, however supplied to Kiran Dev Singh, who learnt about the case on receiving of the process from the court of the. Chief Judicial Magistrate, Mandi.

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7. The basic question which arises for determination is whether there is an obligation upon the Drug Inspector, under the provisions of the Act, to furnish a part of the sample and a copy of the report of the Analyst to a manufacturer of the drug in question or not. Some provisions of the Act merit a look in this connection.

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14. The provisions noticed above make one thing amply clear. And, it is that where the *manufacturer* of a drug, which is found to be lacking in the requisite standard of quality, can be traced, he is ultimately to be held responsible for the supply of such a drug and, thus liable for prosecution. Where, as in a case covered by Section 19, the plea of warranty put forward by a person from whose possession the Inspector takes the sample or by a person who supplies the drug to such a person, is coming forward as an acceptable plea of defence, the ultimate liability for breach of the provisions of Section 18 rests upon the manufacturer.

15. If the intendment of the Act is to get hold of the manaufacturer of a drug, which is lacking in necessary standards of quality, it is absolutely clear that such a manufacturer should have

effective opportunity for a defence to the effect that the drug manufactured by him, out of which was drawn the sample, is not lacking in the necessary standards of quality. If such a defence is available to the manufacturer, it is obvious, that he should have access to a part of the sample drawn from his product as well as to the report describing it as lacking in standards of quality, within a reasonable period to enable him to exercise the right of adducing evidence in controversion of the report of the Analyst which describes his product as lacking in necessary standards of quality.

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19. True it is that a; literal reading of the provisions may lead to the conclusion that the obligation cast upon the Inspector under section 24(4) would stand discharged where he-forwards a part of the sample to the person whose identity is disclosed finder section 18A and that in case the person whose identity is so disclosed is different from the manufacturer, it would not be necessary for the Inspector to forward a part of the sample (or a copy of the report as envisaged by Section 25(3)) to the manufacturer yet, having regard to the scheme of the Act discussed above, it would be incumbent upon the Inspector to make a part of the sample, as also a copy of the report of the analyst, available to the manufacturer.

20. A perusal of the judgment in *Manager, Medical Pharmaceutical Processors* (supra), would show that the learned Chief Justice was of opinion that a manufacturer cannot claim any right which is not given to him under the aforesaid provisions of the Act. With utmost respect to the learned Chief Justice, the view taken by him proceeds on a literal reading of the provisions without having regard to the scheme of the Act and the basic principle of law that person who is likely to be affected adversely by initiation of cirminal proceedings against him for the breach of the provisions of the Act must legitimately have an effective opportunity for his defence within the four corners of the Act. The prosecution of a manufacturer in respect of a drug, of whiz sample is drawn by the Inspector, is likely to result in the penalties envisaged by the Act, in case it is found that the drug manufacturer by him was lacking in the requisite standard of quality contemplated under the Act. **The object of the Act clearly being to get at the manu facturer of the drug, which is found lacking in the necessary standards of quality, for ensuring the availability of drug of standard quality to the actual consumer, it is consistent with the concept of justice that such a manufacturer whose drug is found by the Analyst to be lacking in the necessary standards of quality, should know about it and have**

an opportunity of getting the sample rechecked by analysis by the Director, Central Drugs Laboratory and thus put forward his defence, if any, effectively. This can only be ensured by reading the provisions of the Act in a manner that would lead to the conclusion that it is incumbent upon the Inspector to make available a copy of the report of the Analyst and a part of the sample to the manufacturer, where his identity becomes known before he is actually proceeded against from the initial stages by being made a party to the complaint filed by the Inspector.

21. There may be occasions where identity of the manufacturer becomes known later, during the pendency of the trial. In that situation, he can only be brought before the Court in exercise of power under section 32A. In such a case, it may not be necessary that the report of the Analyst or any part of the sample of the drug in question be made available to him. The report would be read against him as well. Law in this respect has been clearly laid down by the Supreme Court in *V.N. Kamdar* v. *Municipal Corporation, Delhi* [AIR 1973 SC 2246.] and *Bhagwan Dass Jagdish Chander* v. *Delhi Administration* [AIR 1975 SC 1309.] , while dealing with an identical provision contained in Section 20A of the Provision of Food Adulteration Act, 1954. **In a case, however, where the manufacturer is before the Court from the inception of the proceedings, there seems no legitimate ground to take the view that he should not be provided with a copy of the report of the Analyst or a part of the sample to enable him to defend himself by seeking the examination afresh of the sample by the Director, Central Drugs Laboratory.**

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24. The dictum of the Supreme Court has been relied upon by a learned single Judge of the Punjab and Haryana High Court in *Cyanamid India Limited*v. *The State of Haryana* [1989 C.C.C. 60 (HC).] for his view that a manufacturer of insecticides can claim to be furnished with a copy of the report of the Analyst even though there is no specific provision entitling him to do so under the, Insecticides Act, 1968. The learned Judge also sought support from the decision in the case of *Mr. H. Lange* v. *The State of Punjab* [1986 (1) PLR 262.] . In view of what we have stated above, it appears clear that the decision in *Manager Medical Parmaceatical Processors, Amritsar* v. *State of H.P.* (supra) does not lay down the correct law. **The provi sions of the Act, when read in the light of the scheme thereof, lead to the unmistakable conclusion that it is incumbent upon the Drug Inspector to make, a copy of the report of the Analyst as also a part**

of the sample, available to the manufacturer where his identity becomes known before he is actually proceeded against from the initial stages by being made a party to the complaint filed by the Inspector. This is the mandate of law lest the manu facturer is deprived of an effective opportunity for a defence to the affect that the drug manufactured by him, out of which the sample was drawn, is not lacking in necessary standard of quality. The manufacturer should have access to the report and a, part of the sample drawn, from his product within a reasonable period to enable him to exercise the right of adducing evidence in controversion of the report of the analyst which describes his product as lacking in necessary standards of quality."

(emphasis supplied)

18. In the present case, the following dates will be relevant:

i. **16.07.2008** - Samples were taken as per the procedure prescribed in Section 23 of the Act. One portion of the sample was given to the firm from which the sample was collected, i.e., the vendor, under acknowledgment on Form-17. One portion of the sample was sent to the government analyst under Section 23(4)(i) of the Act.

ii. **02.02.2009** - The government analyst declared the sample as 'not of standard quality'.

iii. **13.02.2009** - A copy of the report of the government analyst was sent to the firm from which the sample was collected, i.e., the vendor, under Section 25(2) of the Act.

iv. **13.02.2009 -** The vendor informed the complainant that the drug was supplied to them by the distributor.

v. **19.02.2009** - One portion of the sample and a copy of the report was sent to the entity whose name, as per the complaint, was disclosed by the vendor under Section 18A of the Act, i.e., the distributor.

vi. **19.02.2009 -** Enquiries made with the distributor revealed that the drug was supplied to them by M/s Janak Medicos.

vii. **20.02.2009** - After relevant enquiries from M/s Janak Medicos, it was revealed that the drug was supplied to them by M/s Cipla Ltd. from its depot at Mandoli Village, Delhi and investigation was conducted at the Delhi depot of M/s Cipla Ltd.

viii. **18.11.2009 to 19.11.2009** - Enquiries made with M/s Mistair Health and Hygiene Pvt. Ltd. revealed that the Drug was manufactured by them on loan license from M/s Cipla Ltd.

ix. **05.04.2010 -** The complainant wrote a letter to M/s Cipla Ltd.

x. **23.06.2010 -** In response to the letter dated 05.04.2010, M/s Cipla Ltd. informed the complainant that Mr. Talat Fakhri was responsible for the conduct of day to day business of the company.

xi. **06.12.2010 -** The subject complained was filed.

xii. **06.12.2010 -** The learned Metropolitan Magistrate took cognizance of offences under Sections 18(a)(i) and 27(d) of the Act and summoned the accused persons, including the petitioners.

19. The subject complaint has been filed for commission of offences under Sections 18(a)(i) and 27(d) of the Act, which provide as under:

> "**18. Prohibition of manufacture and sale of certain drugs and cosmetics**.—From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, 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;
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>
> **27. Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter.—**Whoever, himself or by any other person on his behalf,

manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes,—

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(d) 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.."

A perusal of the aforesaid provisions demonstrates that it is the responsibility of the manufacturer, primarily, to ensure that the drugs manufactured by it are of standard quality and the manufacturer is liable for manufacture, sale etc. of a drug which does not comply with the requisite standards.

20. The case of the prosecution is that in view of Section 18A of the Act, disclosure of the person/concern given by the vendor, from where the sample is collected is sufficient compliance thereof and so the sample collected under Section 23(4)(iii) and report under Section 25(2) of the Act was supplied to the said person/concern, which in the present case is the distributor. Learned APP, in support of the aforesaid stand of the prosecution placed reliance on **Amery Pharmaceuticals (*supra*)**, and in particular, paragraph 16 thereof, wherein it has been recorded that disclosure by a primary source from where the sample is collected is sufficient compliance of Section 18A of the Act.

21. It is pertinent to note that in the present case, disclosure in terms of Section 18A of the Act was made while filling out Form-17. On the said form, it has been categorically mentioned that the Drug was manufactured by ***"M/s Cipla Ltd., MIDC, Shiroli, Kolhapur - 416122"***. It is a matter of record that the Drugs Inspector noted the name of the manufacturer which was published

on the label of the drug. In these circumstances, the Drugs Inspector had knowledge about the identity of the manufacturer at the time of seizure of sample from the retailer itself and therefore, the requirement of disclosure under Section 18A of the Act was thus, satisfied. The facts in the present case are similar to the facts in **Kiran Dev Singh (*supra*)**, wherein it has been held as under:

> "**22. It was also urged on behalf of the State that in the present case, the identity of the manufacturer, that is, M/s Rose Chem was not disclosed under section 18A at all. The identity of the manufacturer was known from the label of the drug and is also mentioned in the details filled in by the Drug Inspector in the prescribed form XVII. If that be so, as it seems, the claim of the manufacturer to be furnished with a copy of the report of the Analyst and a part of the same would stand on firmer ground. There is no doubt, in such a situation, of the source from which the drug in question has emanated.** The manufacturer is brought before the court for trial on that account. For an effective defence, therefore, the manufacturer would, in these circumstances, have a right to supplied with a copy of the report of the Analyst and a part of the sample of the drug in question. Apart from any thing else, such a claim would be well founded on the principles of natural justice."
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> (emphasis supplied)

22. Similarly, as noted hereinbefore, under the Act, the manufacturer is prosecuted is on account of the drug lacking requisite standard, being the ultimate responsibility of the manufacturer. In this scenario, such a manufacturer should have the requisite opportunity to demonstrate that the drug manufactured by him, of which the sample was drawn, is not lacking in standards of quality and therefore, access to a portion of the sample as well as the report within the time frame prescribed under the Act is a valuable right. It may be further noted that this aspect can be further inferred from the Act

itself. In this regard, the following observations in **Kiran Dev Singh (*supra*)** are relevant:

> "**16.** There is intrinsic indication in the Act itself which leads to this conclusion. The indication is contained in sub-section (3) of Section 23 read earlier, **The first proviso to that sub-section says that where the sample is taken from the premises wherein the drug is being manufactured, it shall be necessary to divide the sample into three portions only and the earlier part of this section says that the Inspector shall divide the sample into four portions. This discloses the legislative intent of a sample being necessarily made available to a manufacturer of the drug in question in unmistakable terms. A look at sub-section (4) of Section 23 reinforces this conclusion.** It provides that apart from the person from whom the sample is taken, one portion is to be sent to the Government Analyst for analysis, the other shall be produced before the court before which the proceedings, are instituted in respect of the drug and the third is to be sent to the person, if any, whose identity is disclosed under section 18A.
>
> **17. In case the sample is drawn from the store of the manufacturer, he gets. a part thereof. Where it is drawn from a place other than a manufacturer's store, the fourth part of the sample is meant for a person whose identity is disclosed under section 18A.**
>
> **18. Under section 18A, disclosure of identity is to be by a person from whom the sample is drawn by the Inspector. If it is the manufacturer of the drug or his-agent for distribution, there is no necessity or requirement of such a disclosure. The disclosure is contemplated in other cases alone. Such a provision, as contained in Section 18A, also suggests that the identity of the manufacturer of the drug is being aimed at by the legislature for the purpose of ensuring compliance with the provisions of the Act in regard to the standard of quality.**"
>
> (emphasis supplied)

It is pertinent to note that the aforesaid decision rendered by a learned Division Bench of the Hon'ble High Court of Himachal Pradesh in **Kiran Dev Singh (*supra*)** was duly taken note of by Hon'ble Supreme Court in **Amery Pharmaceuticals (*supra*)** and the ratio of **Kiran Dev Singh (*supra*)**

was not set aside. In the present case, as noted hereinabove, disclosure under Section 18A of the Act came into effect at the time when the samples were seized. As a sequitur, the provisions of Section 23(4)(iii) and Section 25(2) of the Act were required to be complied with. the Following the judgment in **Kiran Dev Singh (*supra*)**, this Court is of the opinion that the provision of Section 24(4)(iii) and Section 25(2) of the Act have not been complied with. It may further be noted that it is an admitted case that the samples which are now with the Court in terms of Section 23(4)(ii) of the Act are beyond their expiry date and the same cannot be sent for analysis during the course of trial, even if the manufacturer is given such an opportunity.

23. In view of the aforesaid discussion, the contention on behalf of the petitioners regarding non-compliance of the 2008 guidelines need not be examined.

Section 34 of the Act

24. Without prejudice to the aforesaid findings, it is noted that in the present complaint, the relevant averments in relation to the present petitioners are as under:

> "10. That, as on November 2007, Mr. M. K. Hameid (Accused No.8), Dr Y.K. Hameid (Accused No. 9) and Mr. Talat Fakhri (Accused No. 10) were Joint Managing Director, Chairman & Managing Director and the Attorney respectively of the company Mis Cipla Ltd. (Accused No.7) and in that capacity, were the persons in charge of and responsible for the conduct of day to day business of the said company.
>
> xxx
>
> 21. That Mis Cipla Ltd., (Accused No.7), in response to the letter of the complainant dated 05.04.2010 informed vide letter dated 23.06.2010 that Mr. Talat Fakri (Accused No.10) was responsible for the conduct of day to day business of the company as on the date of manufacture of 'The Drug' and submitted copy of Power of attorney issued by Mr. M. K. Hameid (Accused No. 9) in favour of Mr. Talat

Fakri (Accused No.10). They also submitted copy of Memorandum and Articles of Association of M/s Cipla Ltd., (Accused No 7)."

Section 34 of the Act provides for prosecution of a company and of the person who, at the time when the alleged offence was committed was in charge and responsible for the conduct of the day to day business of the said company. In the present case, it is an admitted case, as stated in Para 21 of the complaint, that the complainant was informed that Mr. Talat Fakhri was the person responsible for conduct of the day to day affairs of the company on the date of manufacturing of the drug. The Power of Attorney executed by petitioner no. 1 in favour of Mr. Talat Fakhri was provided to the complainant, which is also a relied upon document.

25. The Hon'ble Supreme Court, in **State of Haryana v. Brij Lal Mittal, (1998) 5 SCC 343,** held as under:

"**8.** Nonetheless, we find that the impugned judgment of the High Court has got to be upheld for an altogether different reason. Admittedly, the three respondents were being prosecuted as directors of the manufacturers with the aid of Section 34(1) of the Act which 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 if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence."

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 fulfils 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**."
>
> (emphasis supplied)

In view of the Power of Attorney executed in favour of Mr. Talat Fakhri, which has also been relied upon by the prosecution, this Court is of the opinion that in order to establish the vicarious liability of the present petitioners, apart from a bald assertion in the complaint, some more material was required to be placed on record demonstrating that the petitioners played an active role in the day to day business of M/s Cipla Ltd. at the relevant time.

26. In **S.P. Mani and Mohan Dairy v. Dr. Snehalatha Elangovan, 2022 SCC OnLine SC 1238**, the Hon'ble Supreme Court, while dealing with a similar provision, i.e., Section 141 of the Negotiable Instruments Act., 1881, held as under:

> "**40.** The principles discernible from the aforesaid decision of this Court in the case of *Ashutosh Ashok Parasrampuriya* (supra) is that the High Court should not interfere under Section 482 of the Code at the instance of an accused unless it comes across some unimpeachable and incontrovertible evidence to indicate that the Director/partner of a firm could not have been concerned with the issuance of cheques. This Court clarified that in a given case despite the presence of basic averments, the High Court may conclude that no case is made out against the particular Director/partner provided the Director/partner is able to adduce some unimpeachable and incontrovertible evidence beyond suspicion and doubt.

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47. Our final conclusions may be summarised as under:—

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d.) If any Director wants the process to be quashed by filing a petition under Section 482 of the Code on the ground that only a bald averment is made in the complaint and that he/she is really not concerned with the issuance of the cheque, he/she must in order to persuade the High Court to quash the process either furnish some sterling incontrovertible material or acceptable circumstances to substantiate his/her contention. He/she must make out a case that making him/her stand the trial would be an abuse of process of Court."

27. In the present case, it is an admitted case that a Power of Attorney has been executed in favour of Mr. Talat Fakhri by petitioner no. 1, which is a document relied upon by the prosecution. Therefore, there is an unimpeachable document to demonstrate that the petitioners herein were not in-charge of day to day business of M/s Cipla Ltd. at the relevant time and therefore, cannot be held liable by virtue of Section 34 of the Act. As per the case of the prosecution itself, in light of the aforesaid Power of Attorney relied upon by the complainant, Mr. Talat Fakhri is the person who would be liable in terms of Section 34 of the Act. It is pertinent to note that this aspect was ignored by the learned Metropolitan Magistrate while issuing summons to the present petitioners under Section 200 of CrPC. The learned Metropolitan Magistrate ought to have considered the fact that Mr. Talat Fakhri was the person who was in charge of the conduct of day to day business of M/s Cipla Ltd. It was the duty of the learned Metropolitan Magistrate to examine the said fact before issuing summons to the present petitioners. Even if the complainant, being a public servant, was exempted from being examined, documents placed on record ought to have been considered by the learned Metropolitan Magistrate. In view thereof, the

summoning order dated 06.12.2010 is not sustainable *qua* the present petitioners.

Section 202 of the CrPC

28. Learned Senior Counsel for the petitioners contended that an enquiry was mandatorily required to be conducted by the learned Metropolitan Magistrate since the present petitioners reside outside the territorial jurisdiction of the learned Metropolitan Magistrate. It is noted that Section 202(1) provides that the magistrate, shall, in a case where the accused is residing at a place beyond the area in which he exercises his jurisdiction, postpone the issue of process against the accused, and either inquire into the case himself or direct an investigation to be made by a police officer or by such other person as he thinks fit, for the purpose of deciding whether or not there is sufficient ground for proceeding. It is further noted that the proviso to the said provision itself provides as under:

> "Provided that no such direction for investigation shall be made,—
> (*a*) where it appears to the Magistrate that the offence complained of is triable exclusively by the Court of Session; or
> (*b*) where the complaint has not been made by a Court, unless the complainant and the witnesses present (if any) have been examined on oath under Section 200."

The present complaint would be covered under the aforesaid proviso (b) as the complainant and witnesses were not examined on oath under Section 200 of the CrPC on account of the fact that the present complaint was made by a public servant and therefore, the present case is covered by proviso (a) to Section 200 of the CrPC which provides as under:

> "Provided that, when the complaint is made in writing, the Magistrate need not examine the complainant and the witnesses—
> (a) if a public servant acting or purporting to act in the discharge of his official duties or a Court has made the complaint;..."

In view of the above, the said contention advanced on behalf of the petitioners is not sustainable.

Conclusion

29. The final conclusions of this Court may be summarised as under:

i. The identity of the manufacturer was known at the time the sample of the Drug was seized, as recorded in Form-17 filled out by the Drugs Inspector. Identity of the manufacturer was thus disclosed from the retailer itself and the same will amount to a disclosure under Section 18A of the Act. As a sequitur, a portion of the sample and report of the government analyst had to be sent to the manufacturer, as mandated in Section 23(4)(iii) and Section 25(2) of the Act. Sending the sample and the report to the distributor instead of the manufacturer in the present case was not a compliance of Section 23(4)(iii) and Section 25(2) of the Act.

ii. Without prejudice to the above, in view of the Power of Attorney executed in favour of Mr. Talat Fakhri by petitioner no. 1, it is concluded that the petitioners were not responsible for the conduct of day to day business of M/s Cipla Ltd. and hence, cannot be prosecuted or held vicariously liable by virtue of Section 34 of the Act.

iii. In the facts of the case, non-compliance of Section 202 of the CrPC is not made out.

30. In view of the aforesaid reasons, the present petition is allowed.

31. CC no. 46/04 titled 'State through Sh. Abhijit Ghosh Drugs Inspector vs. Sh. Virender Sindhwani & Ors.' (arising out of the complaint dated 06.12.2010) and all other consequential proceedings emanating therefrom,

pending before the Court of the learned Metropolitan Magistrate, Rohini, Delhi are quashed *qua* the present petitioners, i.e., Sh. M.K. Hameid and Dr. Y.K. Hameid.

32. The petition is allowed and disposed of accordingly.

33. Pending applications, if any, also stand disposed of.

34. Judgment be uploaded on the website of this Court, *forthwith.*

AMIT SHARMA
JUDGE

SEPTEMBER 06, 2023/*sn/nk*