

HONOURABLE Dr. JUSTICE B.SIVA SANKARA RAO

CRIMINAL PETITION Nos.1377 & 9767 of 2017

COMMON ORDER:

The respective sole petitioners i.e., Mr. Amit Ghare in CrI.P.No.1377 of 2017 is A.8 and Mr. Ashish Mallella in CrI.P.No.9767 of 2017 is A.9 are among the 12 accused in the PRC.No.32 of 2014, viz., A.1 is M/s. Celon Labs Limited, Hyderabad (for short 'Celon') represented by its MD Sri K.V.Ravindra, Hyderabad-A.2, A.3-M/s. Seven Pharma Labs Limited of Peru (local address at Venkatapuram, Khammam District), A.4-Bheemireddy Muralikrishna Reddy, Promotor of Seven Pharma, A.5-K.Rami Reddy, Director of Seven Pharma, Hyderabad, A.6-M/s. Alkem Laboratories Private Limited, Mumbai (for short 'Alkem Labs') represented by its MD BDN Singh-A.7, Mumbai, one Amith Ghare, Head International Business, Alkem Labs, Mumbai-A8 petitioner in CrI.P.No.1377 of 2017, Ashish Mallella, Assistant Manager, International Business Exports, Alkem Labs, Mumbai-A9, N.Veer Raju, QA Senior Executive of M/s Celon Labs as A.10, A.Venugopal Rao, employee of Intech Printing Press Private Limited, Kukatpally as A.11 and Vindogh Kumar Upadyaya, Vice President, Operations of M/s. Celon Labs at Hyderabad-A.12.

2. The PRC.No.32 of 2014 proceedings are outcome of the complaint of the Drugs Inspector, Balanagar Zone, Ranga Reddy District (respondent herein), filed before the learned IX

Metropolitan Magistrate, Cyberabad at Miyapur. The learned Magistrate has taken cognizance for the offences punishable under Section 32(1) of the Drugs and Cosmetics Act, 1940 (for short 'the Act') for the violation of Section 17B(e) of the Act and the rules framed thereunder which violation stated punishable under Section 27(c) of the Act, by allotted the PRC.No.32 of 2014 to commit the case the Court of Sessions. The petitioners maintained the two petitions in seeking to Quash said cognizance order supra

3. The contentions which are common in both the petitions in seeking to quash the said proceedings impugning the complaint with 16 witnesses cited and 92 documents referred in the complaint from which cognizance taken against 12 accused for the offences among other supra are that, the accusation mentioned in the complaint so far as the accused concerned is for altering/re-labeling ALCLAV-625 mg tablets to ALCLAV-FC without license by violation of 17-B(e) of the Act and the Rules thereunder, A.6 & A.7 manufactured ALCLAV-625 mg without manufacturing license also liable for violation of Section 18(c) of the Act read with Rules, A.6 & A.7 violated Section 18(a)(vi) r/w license conditions in Form-28 Clause (3) r/w condition No.4 Clause (ii) of Form-21B of the Act and Rules thereunder and A.1 to A.5 stocked ALCLAV-625 mg at unlicensed premises, violated Section 18(c) of the Act and the Rules made there under and the punishment provided respectively is under Sections 27(C), 27(b)(ii), 27(c)

and 27(b)(ii) of the Act on the 4 counts supra, are unsustainable and no offences made out against them.

4. The averments in the quash petitions are that M/s. Alkem Labs entered into distribution agreement dated 15.02.2010 with M/s. Seven Pharma Peru company incorporated and registered in Peru and pursuant to the terms of distribution agreement, Seven Pharma, Peru agreed to import the products manufactured by Alkem Labs to market, distribute and sell said products, exclusively within the territory of Peru and said Seven Pharma, Peru arrayed as A.3 and the Distribution Agreement as per the terms of Distribution Agreement, the title to the products supplied by the Alkem Labs to Seven Pharma, Peru under said Distribution Agreement was to pass on to Seven Pharma, Peru, when said products delivered by Alkem Labs using the nominated mode of transport either by air or sea for being placed on the vessel at the port, for the purposes of export. In order to fulfil its obligations under the terms of Distribution Agreement and to export its products to Seven Pharma, Peru, the Alkem Labs obtained requisite manufacturing license to export its products, including the drug "ALCLAV 625 MG" and the samples of said drug ALCLAV-625 mg also sent to the Drug Control Laboratory, Hyderabad for analysis on 18.04.2012 vide Form-18 that was declared as Standard Quality by the Government Analyst on 08.06.2012. As per the terms of the said Distribution

Agreement, Seven Pharma, Peru was required to obtain all consents, licenses and approvals, as may have been necessary in connection with the import, sale, distribution and promotion of the products manufactured by the Company, within the territory of Peru. Seven Pharma, Peru accordingly had obtained the requisite license to import the products manufactured by the Company, and had complied with requisite registration of the products under local Peruvian law. Seven Pharma, Peru had *inter alia* obtained a product registration bearing No. 18119 issued by DIGIMED (Ministry of Health, Peru) Peru for importing the said drug ALCLAV-625 mg. In terms of the said Distribution Agreement, Seven Pharma, Peru placed Purchase Orders from time to time on the Company for purchase of its products. Accordingly, in terms of the said Distribution Agreement and as per the relevant Purchase Orders placed by Seven Pharma, Peru, the Company began supplying its products to Seven Pharma, Peru since in and around 2010. On 06.12.2010, Seven Pharma, Peru placed Purchase Order bearing No. 008-2010 for procurement of 24,999 strips (each strip containing 10 tablets) of ALCLAV-625 mg (hereinafter referred to as "**Consignment**") from the Company. As per the terms of the said Purchase Order placed by Seven Pharma, Peru, and in terms of the understanding arrived at under the said Distribution Agreement, the Company took steps to deliver the said Consignment to Seven Pharma, Peru. In respect of

the above Consignment, the Company raised two invoices along with the packing list pertaining to ALCLAV 625 mg i.e. (i) Invoice No. 10003723 (for Batch No. 0151285 with quantity of 5040 strips) dated 19.01.2012; and (ii) Invoice No. 10003724 (for Batch No. 0151285 and Batch No. 1150018 with aggregate quantity of 19,959 strips) dated 19.01.2012 on Seven Pharma, Peru. Seven Pharma, Peru paid the entire consideration for the Consignment to the Company. When the Consignment was ready for dispatch, Seven Pharma, Peru instructed the Company to handover the Consignment to SDV International Logistics (hereinafter referred to as the "**Agent**"), its agent located at Hyderabad. As instructed, the Company agreed to ship the Consignment on 28.01.2012 to the said Agent at Hyderabad. Since the entire consideration for the Consignment was paid to it, and the Company had supplied the Consignment as instructed by Seven Pharma, Peru to the Agent, the Company treated the relevant transaction as completed. In terms of the said Distribution Agreement, the title to the products had transferred to Seven Pharma, Peru at the time when the Company shipped the goods to the Agent on the instructions of Seven Pharma, Peru and the Company was no longer concerned with them. While matters stood thus, the Company received a letter dated 07.05.2012 from the Respondent informing it of the seizure of the Consignment by the Respondent at Hyderabad. *Vide* the said letter dated 07.05.2012, the Respondent requested the Company to

furnish copies of the documents as required under Section 18-B and Section 22(1)(cca) of the Act for carrying out further investigation. Vide its letter dated 07.05.2012, the Company replied to the aforementioned letter and furnished the documents requested for by the Respondent. On 10.05.2012, the Respondent addressed a letter to the Petitioner requesting the Petitioner to furnish certain additional documents mentioned therein. On the same day i.e. on 10.05.2012 the Company replied to the aforesaid letter by furnishing the information/documents requested by the Respondent. Copies of the said letters addressed to the Respondent on 07.05.2012 and 10.05.2012 (without the enclosures thereto) are filed herewith as **Annexure No. 5** and **Annexure No. 6**. The Respondent, without proper investigation and verification of documents furnished by the Company, falsely implicated the Petitioner by filing the impugned Complaint *inter alia* against the Petitioner on the file of the Hon'ble IX Metropolitan Magistrate, Cyberabad at Miyapur under Section 32 (1) of the Act. Upon a perusal of the Complaint, the Company learnt that the Agent had after taking delivery of the said products from the Company, handed over the same to Seven Pharma, Peru at the premises of Ceylon Labs Ltd, where it appears from the Complaint that the label ALCLAV-625 printed on the tablet strips of ALCLAV-625 mg, manufactured by the Company was erased by using Nova-delete p solution and reprinted as ALCLAV-FC by means of screen printing.

5. From above facts, the contentions in both the quash petitions are that:

5(i). There is not even a single averment in the impugned Complaint against the respective Petitioner/s, save and except at paragraph 24 thereof, where it has been simply stated that Accused No. 1 to Accused No. 12, which includes the respective Petitioner/s herein, have violated Section 17-B(e) of the Act and the Rules and are punishable under Section 27(c) of the Act. In this regard, section 17-B (e) of the Act contemplates that a drug shall be deemed to be a spurious drug if it purports to be the product of a manufacturer of whom it is not truly a product. It is submitted that the identity of the manufacturer company of the product is not disputed in the impugned Complaint. Although the Respondent alleges a violation of Section 17B (e) of the Act, it does not state the manner in which the Consignment, which was seized by it, purports to have been manufactured by a manufacturer other than the Company. Therefore, the allegation of violation of Section 17B (e) of the Act is without any basis in law and is patently false and incorrect. Although the allegations in the impugned Complaint pertaining to the Petitioners is limited to an alleged violation of Section 17-B(e) of the Act, nevertheless the Petitioners dealing with the allegations pertaining to the Company, hereinafter, with a view to underline that the impugned Complaint does not reveal any offence even against

the Company. The allegation in the impugned Complaint that the Company did not have a valid license to manufacture ALCLAV-625 mg during the relevant period and therefore violated Section 18 (c) of the Act is also not correct. Section 18(c) of the Act prohibits the manufacture for sale or for distribution, or sell or stock or exhibit or offer for sale or distribute any drug except under and in accordance with the conditions of the license. At the outset, the Company had a valid license bearing No. DD/422 for manufacturing ALCLAV-625 mg which was issued to it on 17.03.2004 by the Drugs Licensing Authority, UT of Daman & Diu, Daman and the same was renewed on 01.07.2009 and was valid till 16.03.2014. Thus, it is clear that the Company has manufactured a drug product, namely, ALCLAV 625 mg. under a valid product permission and drug manufacturing license. Therefore, the allegation that the Company did not have the manufacturing license for ALCLAV-625 and the Company has violated Section 18 (c) of the Act is baseless and totally incorrect. In so far as the events which have occurred after the Agent took delivery of the said product from the Company are concerned, the Company cannot be held responsible, as the title in the said product had already passed on to Seven Pharma, Peru when the products were shipped to the Agent on the instructions of Seven Pharma, Peru. The Company was not in connivance with Seven Pharma, Peru, even assuming that the said drugs were stored

at the warehouse of Seven Pharma, Peru with the knowledge of the Company, as per the Hon'ble Bombay High Court in **State of Maharashtra v. Ghanshyam K Zaveri**¹, prosecution under Section 18(c) of the Act is not attracted to a case where the drug has been stored for export to a foreign country and is not meant for immediate sale in India. The Hon'ble High Court relying on the decision of the Supreme Court in **Mohd. Shabbir v. State of Maharashtra**² has observed,"... *Thus, it is very clear from the judgment of the Apex Court that the respondents must be shown to have stocked the drug in question for sale. The question then arises whether the drug meant for exporting and consequently for sale in the foreign country would amount to contravention of the provisions of Section 18(c) of the Act. It cannot be doubted that the provisions of the Act in question are applicable in India. Secondly, the drug seized from the airport meant for export to a foreign country cannot be said to have been stored for immediate sale. Thirdly, the sale of the drug was not banned in the foreign country to which it was meant for export. Fourthly, it was not in dispute that the Central Government had given permission for export of the drug abroad as the Central Government had given NOC for the manufacture of the said drug for the purpose of export...*"

¹ (2001) 2 Mah LJ 506

² AIR 1979 SC 564

5(ii). In so far as the allegation that the Company has violated Section 18(a) of the Act read with the conditions of license in Form 28 Clause (3) read with Form 21B-4(ii) of the Rules and therefore violated Section 18(c) of the Act is concerned, Clause (3) of Form 28 stipulates that the license authorizes the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the license subject to conditions applicable to licenses for sale. The conditions for sale of drugs are stipulated in Form 21-B of the Rules. Condition 4(ii) of Form 21B stipulates that no sale of any drug shall be made for the purpose of resale to any person not holding the requisite license to sell, stock or exhibit for sale or distribute the drug. It is submitted that in view of the fact that the Consignment was being manufactured for export, the rules and regulation particularly conditions of license mentioned in the Complaint, which are aimed at domestic resale and consumption, are not applicable to the Company. As per current industry practice, the export of pharmaceutical products is regulated by the requirements imposed by the Importing Country. It is pertinent therefore to note that Seven Pharma, Peru had obtained the requisite registration of the products under Peruvian Law. It is therefore submitted that there is no violation of any of the conditions of the license in Form 28 Clause (3) read with Form 21B- 4(ii) of the Rules as alleged in the Complaint. It is submitted that as stated above, the Company had entered

into a Distribution Agreement with Seven Pharma, Peru. Pursuant to the said Distribution Agreement, Seven Pharma, Peru agreed to purchase products manufactured by the Company, to market, distribute and sell the said products exclusively in the territory of Peru. In the light of this, it is submitted that the Company did not violate any conditions of either manufacture or sale of ALCLAV-625 to Seven Pharma, Peru.

5(iii). After receiving payment of the entire consideration from Seven Pharma, Peru, the Company ceased to be the owner of the Consignment and was only holding the Consignment in his capacity as a bailee. Therefore, on receiving the specific instructions from Seven Pharma, Peru, the Company sent the Consignment to the Agent of Seven Pharma, Peru at Hyderabad. In fact, the Respondent in the Complaint also stated that Seven Pharma, Peru paid the consideration for the Consignment to the Company and that the Company sent the material to Hyderabad only on the instructions of Seven Pharma, Peru and not on its own volition. In view of the above stated admitted facts and further in view of the averments made in the Complaint, no offence has been committed by the Company.

5(iv). The allegation made in the Complaint that the Consignment which was seized was diverted to Hyderabad by the Company with an intention to change the name of the

Consignment from ALCLAV-625 to ALCLAV-FC is baseless and devoid of any merit.

5(v). The activity of exports is not regulated under the provisions of the Act. As per the industry practice at present, export of drugs and cosmetics is regulated as per the requirements of the importing country. In fact, recognizing this lacuna under the provisions of the Act, the Central Government sought to expressly regulate exports for the first time vide the provisions of the Drugs and Cosmetics (Amendment) Bill, 2013. When the said Bill was introduced in the Rajya Sabha, the Rajya Sabha referred the Bill to the Parliamentary Standing Committee on Health and Family Welfare for examination and report. During the course of examination, the Parliamentary Standing Committee invited representations from various stakeholders and experts from various medical professions on the provisions of the Bill. In their representations to the Parliamentary Committee, the stakeholders raised various objections to the regulation of exports under the provisions of the Bill. The Parliamentary Committee after due deliberations, concluded that no regulation on the export of drugs would be necessary. The Committee was of the view that if export of drugs is brought within the ambit of the Act and/or the Rules, it will adversely affect export of drugs and put domestic pharmaceutical manufacturing units/exporters at a serious disadvantage. The Committee therefore decided that the word export may be

omitted from the provisions of the Bill. In the absence of regulation of exports under the Act, the Company cannot be held responsible for the aforesaid acts and/or omissions.

5(vi). The composition of ALCLAV 625 mg and ALCLAV-FC is the same. It is submitted that as has already been admitted in the impugned Complaint, the said ALCLAV 625 mg had already been declared as a standard quality drug by a Government Analyst vide Form 13 dated 08.06.2012. Therefore, there was no public health impact, from the alleged re-branding, which in any event the Company and the Petitioner are not involved in or concerned with. Even assuming but not contending that an offence is disclosed against the Company, the Petitioner, in the circumstances set out hereinafter, cannot be made vicariously liable for the same. It is submitted that in the entire Complaint there is not even a single averment against the Petitioner herein, save and except at paragraph 24 thereof, where it has been simpliciter stated that Accused No. 1 to Accused No. 12, which includes the Petitioner herein, have violated Section 17-B(e) of the Act and the Rules and are punishable under Section 27(c) of the Act. A perusal of the impugned Complaint would further reveal that there is no averment in the impugned Complaint, even remotely indicated the role and/or responsibility of the Petitioner, either within the Company or in the commission of the alleged offences under the Act and the Rules. Significantly, there is no averment in the impugned

Complaint indicating that the Petitioner was in-charge of and/or responsible for the conduct of the business of the Company, to bring the Petitioner within the fold of the deeming fiction operating under Section 34(1) of the Act. In the absence of specific averments made in the Complaint, the Petitioners respectively cannot be held liable for prosecution along with the Company under the Act.

5(vii). In the course of hearing the counsel for the petitioners respectively while reiterating the same sought for quashing the said cognizance order so far as the petitioners respectively concerned.

6. The contentions of the learned Public Prosecutor representing the Drug Inspector-respondent (complainant) are that the very labelling in India squarely comes under Section 17(B)(d) of the Act. The very complaint averments in all make out the specific case against the respective accused that was rightly taken cognizance and there is nothing to quash the cognizance order against any of the accused including the petitioners. It is not even their case in the quash petition of they have no knowledge but for no violation made by them. If known once it is their duty to disclose to the authorities to prevent misbranding which is an offence referred supra, it is nothing but connivance with other accused and thereby liable and sought for dismissal of the quash petitions.

7. Heard both sides and perused the material on record.

8. In deciding the lis, it is necessary to mention that the learned Magistrate has taken cognizance so far as petitioners A8&9 concerned for the offences punishable under Section 32(1) of the Act for the violation of Section 17B(e) of the Act and the rules framed there under which violation stated punishable under Section 27(c) of the Act, by allotted the PRC.No.32 of 2014 to commit the case the Court of Sessions, which is the subject matter of impugment. From the above, it is needful to read Section 17B of the Act.

9. Before reproducing Section 17B of the Act, coming to the very scheme of the Act, out of the 38 sections with sub-sections in V chapters, chapter IV deals with manufacture, sale and distribution of drugs and cosmetics and of which, Section 16 deals with 'standards of quality', Section 17 deals with 'misbranded drugs', 17A deals with 'adulterated drugs', 17B deals with 'spurious drugs', besides 17(C) to (E) deals with misbranded, spurious and adulterated cosmetics. Section 27 of the Act with amendment by Act 26 of 2008 to Section 17B, w.e.f.10.08.2009 deals with **penalty for manufacture, sale, etc., of drugs in contravention of this Chapter, and speaks that** 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, any drug deemed to be adulterated under Section 17-A or spurious under Section (17-B and which) when used by any person for or in the diagnosis, treatment, mitigation,

or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of Section 320 of the India Penal Code (45 of 1860), solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be (punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more). First proviso speaks of payment of compensation out of the fine amount to the person who used the said drug supra. Second proviso speaks the person is dead to pay the fine amount realised from the convict to the relatives of the dead person. Section 27-B speaks punishment for Section 17-A not covered by Section 27-A or 18C. Section 27-C speaks that any drug deemed to be spurious under Section 17-B, but not being a drug referred to in clause (a) shall be punishable with imprisonment not less than seven years but which may extend to life and with fine which shall not be less than three lakh rupees or three times the value of the drugs confiscated, whichever is more. Section 27(c) thereby speaks any drug spurious under Section 17-B irrespective of not used is itself punishable as supra. Section 27(d) deals with 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 there under, 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 Rs.20,000/-.

10. Section 17B of the Act, which defines-Spurious drugs—read as follows:

17B. Spurious drugs — For the purposes of this Chapter, a drug shall be deemed to be spurious,—

(a) if it is manufactured under a name which belongs to another drug; or

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

11. Among Section 17B of the Act, the offence proper mentioned as sub clause (e) referred supra and the core to establish is a drug shall be deemed to be spurious if it purports to be the product of a manufacturer of whom it is not truly a product. The decision placed reliance by the petitioners of the Bombay High Court in **State of Maharashtra v. Ghanshyam K Zaveri supra**, did not deal with Section 17B of the Act and as such no way relevant to decide application of Section 17B of the Act or not. It was for

prosecution under Section 18(c) of the Act is held not attracted to a case where the drug has been stored for export to a foreign country and is not meant for immediate sale in India, how far it is applicable to other accused is not necessary to decide herein.

12. Now to decide the attracting or not of Section 17B of the Act against the petitioners supra as A8 & A9, it is necessary to mention gist of the Complaint averments which speak that:

12(i). The complainant Aravind Kumar(LW1), Drugs Inspector duly authorized under Section 21 of the Act to launch prosecution under Section 32 of the Act for any contravention of the provisions of the Act and rules made there under with jurisdiction over entire State of Andhra Pradesh (composite State), presently working as Drugs Inspector, Balanagar, R.R.District and also he holds Full additional charge of the post of Drugs Inspector, Sherlingampally. LW.2-M.Hemalatha is Drugs Inspector, Qutubullapur also appointed under Section 21 of the Act.

12(ii). Said Hemalatha, Drugs Inspector-LW2 on 31-03-2012, during inspection in the R&D centre of M/s. Celon Labs Ltd, at ALEAP Industrial Estate, Plot No.123 & 124 near Pragathinagar, Gajularamaram, R.R. District found some secondary packaging material of the ALCLAV-FC in quantity of 4300 in the premises of said firm, LW2-Hemalatha asked the firm to produce for verification the processing/packaging/

manufacturing records, distribution details and licenses/ approvals/permissions if any for the product ALCLAV-FC and served notice dated 31-03-2012 to K.V.Ravindra (A2) under section 221(cca) of the Act.

12(iii). On 02.04.2012, with reference to the inspection report and enquiry of Qutubullapur, Drugs Inspector, Ms.M.Hemalatha (LW2), Mr. K.V.Ravindra (A2), Authorized signatory of A.1 submitted a letter to M.Hemalatha-LW2 stating that the consignment of the secondary packing material in the R&D centre of M/s. Celon labs Ltd (A1), was received on behalf of the M/s. Seven Pharma SAC, Peru/Hyderabad (A3) for text verification of technical information and stated that M/s. Seven Pharma SAC Peru/Hyderabad (A3) is one of the group of companies of the M/s. Celon labs Ltd (A1), conducting distribution of finished formulations exporting to different countries. Based on the information received by LW2, on 14.04.2012 at 10.30 A.M, along with LW1-Aravind Kumar, one M.Sreenivasulu-LW.3 and five other Drug Inspectors namely K. Anil Kumar, K. Anvesh, Jayalakshmi, Amity Mary George and N.Prashanthi inspected the premises of M/s. Shirdi Sai Nilayam, D.No.2-48/24, Plot No.24, Flat No.202, Telecom Nagar, Gachibowli under the supervision of three Assistant Directors namely T.Naganarayana Rao, K. Rajabhanu-LW 14 and A.Visala and at that time N.Veer Raju-A10 and A.Venugopal-A11 and 20 other workers were present in the premises and found huge

quantities of 24,999 strips of ALCLAV-625 & ALCLAV-FC tablets of B.Nos.0151285 & 1150018 manufactured by M/s. Alkem Labs, Daman were stocked in the premises which is an unlicensed premises.

12(iv). At the time of Inspection supra, it was found label ALCLAV-625 printed on the tablet strips of ALCLAV-625mg tablets of B.Nos.0151285 & 1150018 manufactured by M/s. Alkem Labs was erased by using **Nova delete-p** solution and reprinted as ALCLAV-FC by screen printing with the help of A.Venugopal-A11 and 20 other workers under the supervision of N.Veer Raju-A10, Senior Incharge of M/S. Celon Labs.

12(v). On enquiry N.Veer raju (A10) stated that this premises belongs to M/s. Seven Pharma and the stock also belongs to them and the stocks of the drugs received from M/s. Celon Labs warehouse and he furnished the Airway bill and two Invoices raised by M/s. Alkem Labs-A6 in favour of M/S. Seven Pharma SAC, Peru. The physical stocks and quantities mentioned in the invoices were tallied.

12(vi). The complainant-Aravind Kumar-LW1 when enquired A10 as to whether the premises holding any Drug license for stocking of drugs for sale, he replied of they don't have any license. LW1 drawn four Drug samples out of the said 24,999 tablet strips from the place of offence under Form 17 & 17A acknowledged by A10 and were sent for analysis to Drugs Control Laboratory, Hyderabad in Form-18 on

18.04.2012 and remaining stocks of drugs supra were seized along with printed mono cartons, tools, materials and documents listed in Form-16 under cover of panchanama and served on A10 by obtaining acknowledgement of the proceedings conducted in the presence of the witnesses namely K.Sanjeev-LW5 and G.Anjaiah-LW6. LW1-Aravind Kumar collected statements of A10 and found supervising the job of erasing the name, printing, labelling and packing of ALCLAV-625 mg tablets to ALCLAV-FC tablets and A. Venugopal (Screen printing technician) at the said premises, above said seized drugs, materials, tools and documents recorded in Form-16 was deposited before the IX Metropolitan Magistrate, Miyapur on 16.04.2012 in C.P.R.No.135/2012.

12(vii). On that day, M.Sreenivasulu, Drug Inspector, Malkajgiri-LW3 visited the premises of M/s. SDV International Logistics Ltd. and enquired about the Air way bill No.589-37078930 which was seized on 14.04.2012 from the premises of Seven Pharma SAC situated at Shiridi Sai Nilayam supra of Gachibowli and on enquiry. LW3-M.Sreenivasulu, Drug Inspector, addressed a letter to G.B.Sastry (LW8), Branch Manager, M/S. SDV International Logistics Ltd., for which G.B.Sastry-LW8 in his letter of even date stated that 209 boxes of ALCLAV-625 mg tablets delivered to Mr.B.Rama Rao of M/S. Celon Labs on 28.01.2012 and instructions for the shipment of the cargo from Mumbai to Hyderabad was given by M/s. Seven Pharma

SAC Peru/Hyderabad (A3) to M/s. Alkem Labs (A6) Mumbai. As per which the cargo was assigned to Hyderabad on M/s. SDV International Logistics Ltd., to take delivery at Airport and the same was handed over to M/s. Seven Pharma at M/s. Celon Labs, Plot No.2, ALEAP Industrial Estate, Near Pragathinagar, Gajularamaram, Hyderabad.

12(viii). LW1-Aravind Kumar on enquiry found the consignment of 209 boxes of ALCLAV-625 were sent from Mumbai to Hyderabad through Skylink Freight forwarders, Mumbai (Issuing Carrier agent) vide Air way bill No.589-3707 8930 by M/s. Alkem Labs-A6 (Consignor), Mumbai to M/s. SDV International Logistics Ltd (Consignee), situated at 2nd floor, Victoria castle, S.P Road, Secunderabad and said consignment of 209 boxes of ALCLAV-625 delivered to B.Rama Rao-LW4 (Ware house, Executive, Celon Labs Ltd at M/s. Celon Labs-A1 situated at Plot No.2, ALEAP Industrial Estate, Near Gajularamaram, Hyderabad, on instructions of Mr. Vinodh Kumar Upadyaya-A12. On 17-04-2012, LWs.1 & 2 supra visited Intech printing press, situated at Plot No.56, ALEAP Industrial estate, Near Pragathinagar, Gajularamaram, Hyderabad. K.V.Ravindra (A2) was present at the time of inspection, addressed a letter to LW1 and furnished relevant documents pertaining to ALCLAV-FC monocartons. LW1 on enquiry found that the monocartons of the ALCLAV-FC monocartons were printed at Intech Printing

press on purchase order of the M/s. Seven Pharma SAC Peru/Hyderabad (A3), vide No.01/2012, dated 10.01.2012.

12(ix). On 19-04-2012, LW2 along with LW1 inspected the premises of M/s. Celon Labs, situated at Plot No.123 & 124, ALEAP industrial Estate, Near pragathinagar, Gajularamaram, Hyderabad and on Inspection of them found 4299 monocartons of ALCLAV-FC that were seized by LW2 vide Form-16 and deposited before the VI Metropolitan Magistrate, Medchel. LW1 on investigation found the Monocartons of ALCLAV-FC that were seized with stock of drugs (ALCLAV-625 & ALCLAV-FC after conversion from ALCLAV-625) at Shiridi Sai Nilayam of Gachibowli supra and Monocartons of ALCLAV-FC seized at M/S. Celon Labs-A1 on 19-04-2012 at ALEAP, Industrial Estate, Plot No.123 & 124, Near Pragathinagar, Gajularamaram, are one and same. On investigation at M/s. Alkem Laboratories Ltd, Daman-A6 by LW1, LW3 and K.Raja Bhanu-LW14 with Girish S.Vaghela-LW13, Drug Inspector, UT of Diu & Daman on 07-05-2012 & 08-05-2012 found the samples of ALCLAV-625 & its monocartons seized at Hyderabad and the reference samples of M/s. Alkem Labs, Daman were compared and confirmed of one and same by the QA personnel G.Sunder (QA Asst. General Manager of M/s. Alkem Labs, Daman).

12(x). It was also observed that M/s. Alkem Labs-A6 sold 25,000 strips of ALCLAV-625 mg tablets to M/s. Seven Pharma-A3 vide Purchase order 008-2010 dated 06-12-2010

and payment made to M/s. Alkem Labs-A6 by M/s.Seven Pharma-A3 on 21.01.2011. M/s. Alkem Labs-A6 (Consignor) raised two Invoices with Packaging List pertaining to ALCLAV-625 vide Invoice Nos.10003723 (B.No.0151285, Qty:5040) & 10003724 (B.No.0151285 & 1150018, Qty:19,959), dated 19-01-2011 to M/s.Seven Pharma-A3 (Consignee), situated at Calle Monterry 341 OF, 704, Chacarilla-Santiago De Surco-URB, Peru. But the invoices that raised to Peru were diverted to Hyderabad by M/s.Alkem Labs, Mumbai (A5) on instructions of B. Muralikrishna Reddy (A4) of M/s. Seven Pharma SAC, Peru/Hyderabad (A3) and subsequently the 209 shippers of ALCLAV-625 mg tablets sent to M/s.SDV International Logistics, Hyderabad from Mumbai through Skylink Frieght forwarders, Mumbai vide Air way supra dated 25-01-2012 and from Hyderabad (Airport) the shippers were transported to the premises of M/s. Celon Labs Ltd (A1) at Plot No.2, Near Pragathinagar, Gajularamaram, on 28-01-2012 and the stocks received by B.Ramarao (Ware House, Executive) of M/s. Celon Labs on the instructions of Mr. Vinodh kumar Upadyaya (A12) (Vice President, M/S. Celon Labs). Mr. Vinodh Kumar Upadyay (A12) deputed N.Veerraju (A10), to supervise the repacking and other operations at Shiridi Sai Nilayam, Gachibowli supra on indent made by N.Veerraju to B.Rama Rao-LW4 in six spells and same found at Shirdi Sai Nilayam, Gachibowli, where those were being repacked/Labelled thus being manufactured with the

personnel of M/s. Celon Labs, Hyderabad. The M/s. Celon Labs-A1 or M/s. Seven Pharma-A3 does not hold any valid license to stock the drugs for sale and also licenses for repacking and labelling. The premises for repacking/re-labelling of ALCLAV-625 tablets to ALCLAV-FC at Shiridi Sai Nilayam supra was arranged by Mr.Guruprasad (LW15) on behalf of M/s. Seven Pharma (A3), who had taken the premises on rent from Mr. Venkateshwara Rao (LW16), neighbour of the Building owner K.M.Rathnakumari (LW 12).

12(xi). The Drug samples sent to Drug Control Laboratory, Hyderabad for analysis on 18-04-2012 in Form-18 was declared as Standard quality by the Government Analyst in Form-13, dated 08-06-2012, that was furnished to N.Verraju by 15-06-2012 and attested copy of the analytical reports in Form 13 also furnished to M/s. Alkem Labs on 04-07-2012. The statements of the witnesses and the documents collected containing the incriminating material connecting all the accused to the offences charged as referred supra hence to take on file and to try the accused.

13. From the above, it is crystal clear from the very complaint averments with basis to frame a charge so far as against A6 for the offence supra, as Section 17B(e) of the Act attracts, leave about other 5 offences and so far as against the petitioners attracting of said offence concerned is undisputedly they are working under A6.

14. Coming to the other contention of no allegations to fasten vicarious liability against them along with A6 Company concerned, Section 34 under Chapter V of the Act necessary to refer, reads as follows:

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.

(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.

14(i). The wording of Section 34 of the Act is similar to Section 141 of the Negotiable Instruments Act. The law in this regard is clearly settled from several expressions of the Apex Court and also of this Court.

14(ii). The Constitutional bench in **Standard Chartered Bank V. Directorate of Enforcement**³ held that Company can be prosecuted and convicted for an offence which requires a minimum sentence of imprisonment. Though it was held that it is not expressing any opinion on the question whether a Corporation could be attributed with requisite Mensrea to prove the guilt the same is later clarified by the subsequent expression of the Apex Court in **Iridium India Telecom Ltd. V. Motorola Inc.**⁴ referring to the several expressions of the American and England Courts in paras 59 to 64 of the expression page Nos.98 to 100 in nutshell that a Company in many ways be like a human body they have a brain and nerve centre which controls what they do. Some of the people in the Company are mere servants and agents who are nothing more than hands to do the work and cannot be said to represent the mind or will. Others are directors and managers who represent directing the mind and will of the Company and control what they do. The state of mind of these managers is the state of mind of the Company and is treated the law as such. The fault of the manager will be the personal fault of the Company. The knowledge and intention must be imputed to the body corporate. It was concluded therefrom by referring to **Standard Chartered Bank** para No.6 supra of a Company is liable to be prosecuted and punished for criminal offences in deviation to the earlier

³ (2005)4 SCC 530

⁴ (2011)1 SCC 74

authorities in India of Corporations cannot commit a crime, for generally accepted modern rule is that except for such crime as a corporation is held incapable of committing by reason of the fact that they involve personally with malicious intent, a corporation may be subject to indictment or other criminal process, although the criminal act is committed through its agent. The criminal intent of the alter ego of the Company that is the personnel group of persons that guide, the business of the Company would be imputed to the Company/corporation. It was the observation in ***Iridium*** supra that was again followed in latest three Judge bench expression of the Apex Court in ***Sunil Bharti Mittal V. C.B.I.***⁵ It was observed in ***Sunil Bharti Mittal*** (supra) that the corporate entity, an artificial person acts through its officers, directors, managing director, chairman etc, if such fact continues an offence involving Mensrea it would normally be evident and action of that individual who would act on behalf of the Company in particular in relation to criminal conspiracy. However, the cordial principle of criminal jurisprudence is that there is no vicarious liability unless the statute specifically provides so. An individual who has perpetrated the commission of an offence on behalf of a Company can be made as an accused along with the Company, if there is sufficient material on his active role. Second situation is knowledge it may be implicated is in those

⁵ (2015)4 SCC 609

cases where statutory regime itself attracts the doctrine of vicarious liability by specifically incorporating by such a provision. It is at para No.44 of **Sunil Bharti Mittal** supra and other expression of the Apex Court in **Aneeta Hada (II) V. Godfather Travels & Tours (P) Ltd**⁶ held that the group of persons that guide the business of the company if the criminal intent that would be imputed to the body corporate and in this back drop Section 141 of the N.I.Act has to be understood. Such a position is therefore because of statutory intendment making it a deemed fiction.

14(iii). In **Sunil Bharti Mittal** supra it also referred the three Judge bench expression of the Apex Court in **S.M.S.Pharmaceuticals Ltd. V. Neeta Bhalla**⁷. In **S.M.S.Pharma** supra at para No.8 it is observed that there is no universal rule that a Director of a Company is in-charge of its every day affairs. It all depends upon the respective roles assigned. A company have managers or secretaries for different Departments and may have more than one Manager or Secretary. In **Aneeta Hada** supra it is observed with reference to Section 141 of N.I.Act that the deeming fiction makes the functionaries of the Companies to be liable as its own signification.

14(iv). Thus, the words as well as the Company used therein makes it absolutely and unmistakably clear that when the Company can be prosecuted, then the only persons

⁶ (2012)5 SCC 661

⁷ (2005)8 SCC 89

mentioned in the other categories could be vicariously liable for the offence subject to the averments in the petition and proof thereafter. In **S.M.S Pharmaceuticals** (three Judge bench) supra also it is made clear with reference to section 141 of the N.I.Act that it is necessary to aver that at the time the offence was committed, the person accused was in-charge of and responsible for conduct of business of the Company and without this averment being made in the complaint, the requirements of Section 141 of the N.I.Act cannot be said to be satisfied. A clear case should be spelled out in the complaint against the persons sought to be made liable to show as in charge of and responsible to the Company for the conduct of its business. Every person connected with the Company thereby shall not fall within the ambit of Section 141 of the N.I.Act but of those persons who were in charge of and responsible for the conduct of business of the Company at the time of commission of the offence. The liability arises on account of conduct or act or omission on the part of a person and not merely on account of holding an offence or a position in a Company. The complaint therefore must disclose the necessary facts which make a person liable, specifically aver that at the time of offence committed, the person accused was in charge of and responsible for conduct of the business of the company. A director cannot be deemed to be in charge of and responsible to the Company for the conduct of the business for no deemed liability of a Director

from that status, unless the aforesaid requirement of Section 141 of the N.I.Act has been averred as a fact in the complaint.

14(v). The other expression of the Apex Court two Judge bench in **National Small Industries Corporation V. Harmeet Singh**⁸ also by referring to **Parekh** and **S.M.S.Pharmaceuticals** supra among other expressions held that vicarious liability on the part of any Director or other person as in charge and responsible to the conduct of business be specifically averred, though same is not required against a Managing Director. Even later expression in **Poojari Ravinder Devi Dasani V. State of Maharashtra**⁹ reiterates the same.

15. From above legal position, coming back to facts, A.6-M/s. Alkem Laboratories Private Limited, Mumbai (for short 'Alkem Labs') is representing by its MD BDN Singh-A.7, Mumbai and Mr.Amith Ghare-A8 petitioner in Crl.P.No.1377 of 2017, is the Head, International Business of A6-Alkem Labs, Mumbai and Mr. Ashish Mallella-A9 petitioner in Crl.P.No.9767 of 2017, is the Assistant Manager, International Business Exports of A6-Alkem Labs, Mumbai and same is not in dispute. However that itself is insufficient to fasten vicarious liability from the status without any specific allegations against them as responsible for day to day affairs. The complaint averments so far as the petitioners concerned, speak that did not specifically speak how they are

⁸ (2010)3 SCC 330

⁹ AIR 2015 SC 675

responsible for day to day affairs at the time of commission of the offence to make them vicariously liable along with A.6 represented by its MD-A7 to make them also liable as A.8 & A.9 which is a pre-requisite to fasten vicarious liability, for nothing to show from the wording of Section 34 of the Act supra by virtue of their status and working under A.6 they are liable vicariously along with A.6.

16. Having regard to the above though Section 17(B)(e) clearly speaks of a drug shall be deemed to be spurious that purports to be a product of manufacture of whom it is not truly a product and attracts from the averments in the complaint in so far as A.6 represented by A.7, coming to the petitioners to array as A.8 & A.9 being connected with A.6, for no any specific allegations in the complaint as to how they are vicariously liable along with A.6, the cognizance order against the petitioners no way sustains. However, it is made clear as laid down in **Sunil Bharati Mittal** supra that in the course of trial if there is any material showing their role as responsible to the day to day affairs to fasten liability along with A.6, this order is not a bar for the learned trial Judge to invoke Section 319 Cr.P.C. subject to factual foundation of the standard laid down in **Hardeep Singh Vs. State of Punjab**¹⁰.

17. Accordingly and in the result and subject to the above observations, the Criminal Petitions are allowed by

¹⁰ AIR 2014 SC1400

quashing the proceedings in so far as against the petitioners as A.8 & A.9 in PRC.No.32 of 2014 supra.

Miscellaneous petitions, if any, shall stand closed.

Dr. B. SIVA SANKARA RAO, J

Date: 29.03.2019
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