**IN THE HIGH COURT OF JUDICATURE AT MADRAS**

**Reserved on : 23.11.2017**

**Pronounced on : .12.2017**

**Coram**

**The Honourable Dr.Justice G.Jayachandran**

**Crl.O.P.No.27254 of 2016**
**and**
**Crl.M.P.No.13842 of 2016**

1.M/s Daeiou Pharmaceuticals Private Limited,
R.S.No.158/3, Pondy-Villupuram Main Road,
Villianur,
Puducherry,
Rep.by R.Raghunaathan

2.R.Raghunaathan,
Director,
M/s Daeiou Pharmaceuticals Private Limited,
R.S.No.158/3, Pondy-Villupuram Main Road,
Villianur, Puducherry. .. Petitioners

/versus/

The Inspector of Police,
CBI
ACB,
Chennai. .. Respondent



Criminal Original Petition filed under Section 482 of the Criminal Procedure Code praying to call for the records in Spl.C.C.No.2 of 2015 on the file of the Special Court under P.C.Act, 1988, Principal Sessions Judge, Puducherry and quash the same in so far as the petitioners/3rd and 4th accused are concerned.

For Petitioners :Mr.R/Yashod Vardhan, Sr.C for
Mr.S.Ajikumar

For Respondent :Mr.K.Srinivasan,
Spl.PP for CBI Cases

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ORDER

This petition is arising out from the case in Special C.C.No.2 of 2015 on the file of the Special Court under the P.C. Act, 1988, Puducherry.

2. The 1st petitioner, who is arrayed as 3rd accused in Spl.C.C.No.2 of 2015 is the Company by name M/s DAEIOU Pharmaceuticals Private Limited Company and the 2nd petitioner, who is arrayed as 4th accused in Spl.C.C.No.2 of 2015, is the Director of the 1st petitioner-company.

3. This petition is filed to quash the complaint on the ground that the 1st petitioner-Company represented by the 2nd petitioner/A4 [Shri R.Raghunathan] has obtained general license for manufacturing and trading of drugs from the Competent Authority during the year 2010 from the Licensing Authority, the 1st accused. However, criminal case is registered against them on the premise that they are manufacturing new drugs and as per the Drugs and Cosmetics Rules 1945 manufacturing of

any new drugs requires prior approval from the Drug Controller General of India, DCG(I), New Delhi, but without getting the said approval, the first accused has granted license in violation of direction given by the Director General of Health and Services, New Delhi.

4. Though they have applied for grant of license in the manner known to law and as per the procedure, alleging that without paying prescribed requisite fee of Rs.15,000/- for each drug, petitioner-Company has indulged in manufacturing the same, thereby caused wrongful loss and cheated the revenue of the Central Government to the tune of Rs.30,50,000/-, the impugned final report has been filed for prosecuting the Licensing Authority-cum-Controlling Authority, P.Rajkumaran[A-1], Director of Health and Family Welfare Service, Puducherry, Dr.Dilip Kumar Baliga [A-2] all public servants along with the petitioners herein for the offence under Section 120-B r/w 420 IPC and 13(2) r/w 13(1)(d) of Prevention of Corruption Act, 1988.



5. The contention of the learned Senior Counsel appearing for the petitioners is that the charge sheet mentioned 201 drugs are not new drugs as alleged. The license for manufacturing these drugs was obtained during the year 2010 from the 1st accused, who are the Competent

Authority to grant license. The law does not require prior approval from the Drugs Controller General of India, New Delhi for grant of license in respect of these drugs. Therefore, the obligation for paying fee of Rs.15,000/- for each drug does not arise, since the notification for prescribed fee of Rs.15,000/-each drug, came into force only in the year 2013, which is much later to the date of obtaining license. These drugs are not new drugs as alleged in the complaint. These drugs are available in the market for long period of time even prior to grant of license to the petitioners. Therefore, the petitioners cannot be mulcted with criminal liability. Hence, the complaint deserves to be quashed.

6. In respect to the above plea, it is contended by the learned Special Public Prosecutor for CBI cases appearing for the respondent that, 201 drugs out of 257 drugs listed in the final report are Fixed Dose Combination [FDC]/new drugs as defined in Rule 122-E of the Drugs and Cosmetics Rules, 1945. Though knowing fully well that the approval of the Drugs Controller General of India, New Delhi, is required and for such approval, payment of Rs.15,000/-per drug is mandatory, the 2nd petitioner herein, in connivance with the 1st accused [P.Rajkumaran], who was Licensing Authority-cum-Controlling Authority, during the relevant point of time, had obtained license and thereby cheated the Government, without

paying requisite fees and caused wrongful loss of revenue to the Government of India.

7. In pursuance of the said conspiracy, the 2nd accused (Dr.Dilip Kumar Baliga) had accorded administrative approval for 85 drugs. For the rest of drugs, the 1st accused had granted license illegally, without subjecting to safety and efficacy test and clinical test, as stipulated in the Drugs and Cosmetics Act/Rules for safeguarding the health of the consumers/patients. In such circumstances, after due investigation, the final report has been filed against this petitioners and others for conspiracy and cheating. Since sufficient materials are available to prosecute the accused and likelihood of convicting them is bright, this petition for quash is liable to be dismissed.

8. The factual and legal matrix involved in this petition are as under:-



The State in order to regulate the import, manufacture, distribution and sale of drugs enacted the Drugs and Cosmetics Act, 1940 under the Government of India Act, 1935. Being the "existing law" as defined by the Constitution of India under Article 366(x), has been adopted and in force post Independence. In 1962, the word 'Cosmetics' was also included along

with Drugs. Since the case arose from the Union Territory of Pondicherry, it is relevant to point out that as far as the Union Territory of Puducherry is concerned, the Act got extended by virtue of Regulation 7 of 1963.

9. Under this Act, no new drugs shall be manufactured for sale, unless it is approved by the Licensing Authority as defined under Rule 22. To get the approval, the applicant namely, manufacturer of new drug has to make an application in Form-44 to the Licensing Authority and it shall be accompanied by the fee prescribed.

10. The said Licensing Authority, after being satisfied that the drug, if approved to be manufactured, shall be effective and safe for use in the country, shall issue approval in Form 46/46A as the case may be subject to the condition that while applying for approval to manufacture of any new drug to the State Licensing Authority, the applicant shall produce the application along with evidence that the drug for the manufacturer of which application is made, has already been approved by the Licensing Authority in Rule 21.

11. As per the Rule 21(b) of the Drugs and Cosmetics Rules 1945, the Licensing Authority means the authority appointed by the Central

Government to perform the duties of the licensing authority under these Rules and includes any person to whom the powers of the licensing authority is delegated under Rule 22. Similar regulation and restriction are imposed regarding import and manufacture of Fixed Dose Combination [FDC] of two or more drugs as defined in Clause (c) of Rule 122E. In case of Fixed Dose Combination [FDC], the fees prescribed is Rs.15,000/-. The applicant for FDC drugs shall furnish the information and dates as required in Appendix VI of Schedule 'Y' of the Rules.

12. Rule 122-E of Drugs and Cosmetics Rules, 1945 defines a new drug includes Fixed Dose Combination [FDC] drugs which are combination of two or more drugs, individually approved earlier in certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz., indications, dosage, dosage form (including sustained release dosage form) and route of administration.



13. The Explanation of Rule 122-E indicates that a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier.(as the statute stood prior to 07.11.2013)

14. The allegation against the petitioners as found in the final report is that the petitioner-Manufacturing company had obtained license from the Licensing Authority in the Department of Drugs Control, Puducherry for 257 drugs. Out of 257 drugs, 9 drugs have already been approved by the Drugs Controller General of India [DCG(I)] and are listed in Indian Pharmacopeia (IP) and conforms to the requirement under Rule 122E of the Drugs and Cosmetics Rules, 1945. For these drugs, the Drugs Controller General of India [DCG(I)] has already granted permission for other manufacturers and the said permission is granted more than four years before. Therefore, they do not fall within the definition of new drugs. 40 drugs are repeated in the list of 257 drugs. 4 products not endorsed. Whereas, 3 drugs among 257 for which the Hon'ble Madras High Court has granted stay on the premises that they are not new drugs and the matter is sub-judiced. For the remaining 201 drugs[257-(40+9+3)+4], the license for manufacturing given by the State Licensing Authority is not in consonance with the Act and Rules and the same has been issued to the petitioner-Company as a consequence of conspiracy.

15. Per contra, the learned Senior counsel appearing for the petitioners contents that the license for production of all these drugs was

accorded to their company viz., M/s Daeiou Pharmaceuticals Pvt.Ltd. in the year 2010. These drugs are not new drugs. As Fixed Dose Combination [FDC] drugs, first approval was accorded to these drugs by the Drugs Controller General of India [DCG(I)] long back and had been included in the India Pharmacopeia for more than four years prior to license granted to the petitioner's company. Therefore, these drugs do not fall within the scope and meaning of new drug. The Licensing Authority for these drugs are the State Licensing Authority, who are appointed by the Central Government to perform the duty of Licensing Authority by delegation of power.

16. Further, the learned Senior counsel appearing for the petitioners submitted that just prior to the registration of First Information Report by the prosecution Agency, The Director of Health and Family Welfare Service, Central Drugs Standard Controller Organisation vide his communication dated 15.01.2013, has directed all the States/Union Territory of Puducherry to ask the concerned manufacturers to prove within a period of 18 months, the safety and efficacy of Fixed Dose Combination [FDC] drugs, which has been allowed before 01.10.2012 on the strength of the license given by the State Licensing Authority, without the permission of the Drugs Controller General of India [DCG(I)]. Failing

which such Fixed Dose Combinations (FDC) will be considered being prohibited for manufacture and marketing in the country.

17. This communication has been issued, in view of the fact that the manufacturing license for sale of Fixed Dose Combinations [FDC], which fall within the definition of the term 'new drug' in the country were granted by the State Licensing Authority without due approval by the Licensing Authority as defined under Rule 21(b). In continuation of this letter, the Directorate of General of Health Service issued a communication dated 05.07.2013 wherein he has expressed that the State Licensing Authority have issued manufacturing licenses for a very large number of Fixed Dose Combinations [FDC] drugs, without prior clearance from Central Drugs Standard Control Organisation [CDSCO]. This has resulted in the availability of many Fixed Dose Combinations (FDC) in the market which have not been tested for efficacy and safety. This can put patients at risk. Though the manufactures were requested to prove the safety and efficacy of the said Fixed Dose Combination[FDC], where the State Authority has accorded license prior to 01.10.2012, within in a period of 18 months. Hardly few manufacturers have sought for the Drug Controller and General of India [DCG(I)] permission. Therefore, the Drug Controller and General India has fixed the upper limit for receiving such application

as 30th August 2013.

18. It is the contention of the petitioners herein is that pursuant to the communication dated 05.07.2013, they have submitted their application for approval of Drugs Controller General of India [DCG(I)] and for some cases, they have received approval and for some products they are awaiting approval. Rest of the products they have already stopped the manufacturing. Meanwhile, the respondent has registered a case against them and filed charge sheet for the alleged offence under Section 120-B, 420 IPC and Section 13(2) r/w 13(1)(d) of Prevention of Corruption Act, 1988, which is unsustainable.

19. In support of the said statement, learned Senior counsel appearing for the petitioners also referred the Official Memorandum of Government of Puducherry, Health Department dated 16.03.2015 which states that the issue of cancellation of manufacturing licenses of Fixed Dose Combination [FDC] drugs, which were issued before 01.10.2012 was taken up with the Ministry of Health and Family Welfare, Government of India and it has been referred that the product licenses in respect of drugs for which the manufactures have already submitted their application along with all requisite data and information for proving safety and efficacy, are

not to be suspended/cancelled for not obtaining prior approval from The Drugs Controller General of India [DCG(I)], till the final decision has been taken in this regard.

20. The sum and substance of the submission on behalf of the petitioners is that, the licenses obtained by them from the 1st accused State Licensing Authority is well within his competency and legal. Even otherwise, in the light of the subsequent development, they have applied to the Drugs Controller General of India [DCG(I)] for grant of approval. Due to apprehension expressed by the manufactures of these drugs, the Government of Puducherry has issued Official Memorandum dated 16.03.2015 wherein, it has assured that the manufacturing shall not be cancelled/suspended for drugs obtained license prior to 01.10.2012. Hence, there is no substance to sustain the prosecution against the petitioner.



21. Heard the learned Senior counsel appearing for the petitioners and the learned Special Public Prosecutor (for CBI cases) appearing for the respondent.

22. The statute as well as the communications referred by counsels

reveals that on the date of complaint, the petitioner-company were manufacturing Fixed Dose Combination[FDC] drugs on the strength of license granted by the State Licensing Authority, who is arrayed as accused 1. The combined reading of Rule 122-E as it stood before the amendment and Rule 21(b) and the statement of witnesses recorded by the prosecution indicates that the first accused Mr.Rajkumaran, Licensing Authority-cum-Controlling Authority, Department of Drugs Control, Puducherry, had granted the license for manufacturing of new drugs, without following legal provision. The license to manufacture the drugs, without approval of the Drugs Controller General of India [DCG(I)] is illegal. The form furnished by the manufacturers for obtaining license is also not in accordance with the statute. It is also seen from the record that when it was brought to the notice of the State Licensing Authority (A1) about the illegal grant of permission for manufacturing Fixed Dose Combination [FDC] drugs without prior approval of the Drugs Controller General of India [DCG(I)], he has cancelled the license for some of the products. But, they have not cared to rectify the illegality in respect of remaining drugs. It is the case of the prosecution that A1 and A2 in violation of law had accorded license for manufacturing Fixed Dose Combinations [FDC] to the petitioner's-company and few more other companies which are operating in Puducherry.

23. The materials placed before this Court prima facie discloses violation of the Drugs and Cosmetics Act, 1940 and Rules 1945 in granting manufacturing license to the petitioner's company. This violation not only resulted in marketing drugs, which was not properly tested for its efficacy, but also evidently clear that, by not getting approval from the Drugs Controller General of India [DCG(I)], there is revenue loss to the Union of India, due to evasion of processing fee of Rs.15,000/- per product. The subsequent communication to regularise the manufacturer of Fixed Dose Combination[FDC] drugs and attempts taken by the Union of India, expecting manufacturer to get approval from the Drugs Controller General of India [DCG(I)] on or before 30.08.2013 will not exonerate the criminal liability on the petitioners and the co-accused, who are knowingly manufacturing drug on the strength of license issued by incompetent person and without paying requisite process fee.



24. In support of the contention, the learned Senior counsel appearing for the petitioners, had cited the following judgments of the Hon'ble Supreme Court:

(i) ***Hira Lal Hari Lal Bhagwati v. C.B.I., New Delhi dated 02.05.2003*** wherein the Hon'ble Supreme Court taking note of Kar Vivad Samadhan Scheme 1998, which has provided amnesty

for violation of Customs had observed as:

"Section 415 of the Indian Penal Code deals with cheating. To hold a person guilty of cheating as defined under Section 415 of the Indian Penal Code, it is necessary to show that he has fraudulent or dishonest intention at the time of making the promise with an intention to retain the property. In other words, Section 415 of the Indian Penal Code which defines cheating, requires deception of any person (a) inducing that person to: (i) to deliver any property to any person, or (ii) to consent that any person shall retain any property OR (b) intentionally inducing that person to do or omit to do anything which he would not do or omit if he were not so deceived and which act or omission causes or is likely to cause damage or harm to that person, anybody's mind, reputation or property. In view of the aforesaid provisions, the appellants state that person may be induced fraudulently or dishonestly to deliver any property to any person. The second class of acts set forth in the Section is the doing or omitting to do anything which the person deceived would not do or omit to do if he were not so deceived. In the first class of cases, the inducing must be fraudulent or dishonest. In the second class of acts, the inducing must be intentional but not fraudulent or dishonest.

In view of the aforesaid provisions of law, as the Customs Duty has been paid by the GCS, there is no fraudulent or dishonest intention on the part of the GCS or its office bearers to retain the property. Moreover, there is no inducing on the part of the GCS or its office bearers intentionally to retain the property in view of the fact that the Customs Duty has been paid by the GCS and, therefore the ingredients of the offence of cheating are missing for issuing the process against the appellants and, therefore, the same, in our view, is liable to be quashed and set aside."

(ii) ***C.Chenga Reddy & Others v. State of Andhra Pradesh reported in [CDJ 1996 Sc 1567],*** the relevant portion reads as under:

> "On a careful consideration of the material on the record, we are of the opinion that though the prosecution has established that the appellants have committed not only codal violations but also irregularities by ignoring various circulars and departmental orders issued from time to time in the matter of allotment of work of jungle clearance on nomination basis and have committed departmental lapse yet. non of the circumstances relied upon by the prosecution are of any conclusive nature and all the circumstances put together do not lead to the irresistible conclusion that the said circumstances are compatible only with the hypothesis of the guilt of the appellant and wholly incompatible with their innocence. In Abdulla Mohammed Pagarkar v. State (Union Territory of Goa, Daman and Diu), [1980] 3 SCC 110, under somewhat similar circumstances this Court opined that mere disregard of relevant provisions of the Financial Code as well as ordinary norms of procedural behaviour of government officials and con-tractors, without conclusively establishing, beyond a reasonable doubt, the guilt of the concerned officials and contractors, may give rise to a strong suspicion but that cannot be held to establish the guilt of the accused. The established circumstances in this case also do not establish criminality of the appellants beyond the realm of suspicion and, in our opinion, the approach of the trial court and the High Court to the requirements of proof in relation to a criminal charge was not proper. That because of the actions of the appellants in breach of codal provisions, instructions and procedural safeguards, the Stale may have suffered financially, particularly by allotment of work on nomination basis without inviting tenders, but those acts of omission and

commission by themselves do not establish the commission of criminal offences alleged against them.

25. The statute is very clear while defining new drugs by including Fixed Dose Combination (FDC) of one or more drugs, though individually approved earlier in certain claim, but combined for the first time in a fixed ratio, it becomes new drug and it requires the compliance of protocol prescribed under the statute. Invariably, in all the batch of petitions decided today by this Court the pharmaceutical companies claim that the Fixed Dose Combination [FDC] drugs which they are manufacturing are combination of two or more drugs individually approved earlier. Therefore, they do not fall within the meaning of new drug or they have been in market for more than years in the said combination and thus, lost the character of new drug. Whether the said claim is correct, is subject matter of the trial. Admittedly, on the date of registering the First Information Report, none of the pharmaceutical companies, which are before this Court by way of revision petition or by original petition, had obtained approval from the Drugs Controller General of India [DCG(I)]. Therefore, there is material evidence indicating violation of the Rule in force as well as deception at the time of the First Information Report registered and final report filed pursuant to the investigation.

26. The facts of the case is not just cheating the State but, also it involves safety and health of the common man. The drug, which has not been approved for sale in the manner known to law, but licensed to manufacture by violating the established law, without proving its safety and efficacy, cannot be considered as omission or violation of Code and Law, which can be condoned by subsequent conduct.

27. The Government of Puducherry, in its official memorandum dated 16.03.2015, taking into consideration of the representation made by the manufacturers and the earlier communications of the Drugs Controller General of India[DCG(I)] which provides opportunity for manufactures to get approval for their products by applying to [DCG(I)] on or before 30.08.2013, had also made it very clear that this concession is without prejudice to any case/trial/proceeding relating to unapproved Fixed Dose Combinations [FDC] Institute in Drugs and Cosmetics Act, 1940 and Rules, 1945 provision of Corruption Act or other laws arising out of Union Territory of Puducherry.

28. Hence, this criminal original petition fails and liable to be dismissed. Accordingly, this Criminal Original Petition is dismissed. Consequently connected Miscellaneous Petition is closed.

..12.2017

Index:Yes/No
Internet:Yes/No
Speaking order/non speaking order
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To
1.The Inspector of Police, CBI:ACB:SPE, Chennai.
2.The Special Public Prosecutor (CBI cases), High Court, Madras

Dr.G.Jayachandran,J.

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Pre-delivery order made in
Crl.O.P.No.27254 of 2016 &
Crl.M.P.No.13842 of 2016



..12.2017