IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on : 23.11.2017

Pronounced on : 21.12.2017

Coram

THE HONOURABLE DR.JUSTICE G.JAYACHANDRAN

Crl.O.P.No.23912 of 2017
and
Crl.M.P.No.13841 and 13842 of 2017

Smt.Geetha Shyamsundar .. Petitioner

/versus/

State rep.by
The Inspector of Police,
CBI:ACB:SPE,
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.6 of 2015 on the file of the Special Court, Puducherry and quash the same in so far as the petitioner/4th accused is concenred.

For Petitioner :Mr.Sai Krishnan

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

O R D E R

This petition is arising out from the case in Special C.C.No.6 of 2015 on the file of the Special Court, Puducherry.

2. Smt.Geetha Shyamsundar, the petitioner herein is the Proprietrix of M/s GuruFcure a Pharmaceutical Company, 4th accused in the above Spl.C.C.No.6 of 2015.

3. This petition is filed to quash the complaint on the ground that she has duly obtained license for manufacturing and trading of drugs from the Competent Authority. However, criminal case is registered against her on the premise that 59 drugs, which they are manufacturing are new drugs as per the Drugs and and Cosmetics Act, 1940. Manufacturing of those drugs requires prior approval from the Drug Controller General of India, New Delhi, but without getting the said approval and 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.8,85,000/-. 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] and the Drugs Inspector & the Licensing Authority-cum-Controlling Authority M.Dhanasegaran [A-3] all public servants along with the petitioner 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.

4. The contention of the petitioner is that the charge sheet mentioned 59 drugs are not new drugs as alleged in the final report. The license for manufacturing these drugs was obtained between 2009 and 2012 from the 1st and 3rd 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. The drugs are not new drugs as alleged in the complaint but, these drugs are available in the market for long period of time even prior to grant of license to the petitioner. Therefore, the petitioner cannot be mulcted with criminal liability. Hence, the complaint deserves to be quashed.

5. In response to the above plea, it is contended by the learned Special Public Prosecutor for CBI cases appearing for the respondent that, 59 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 petitioner herein, in connivance with the 1st accused [P.Rajkumaran] and the 3rd accused [M.Dhanasegaran], who were 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.

6. In pursuance of the said conspiracy, the 2nd accused (Dr.Dilip Kumar Baliga) had accorded administrative approval for 59 drugs for which license has been obtained 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 petitioner and others. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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)

13. The allegation against the petitioner 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 333 drugs. Out of 333 drugs, 193 drugs have already been approved by the Drugs Controller General of India [DCGI] and/ or 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 [DCGI] has already granted permission for other manufacturers and the said permission is granted more than for a period of four years before. Therefore, they do not fall within the definition of new drugs.

14. Whereas, 9 drugs among 294 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 59 drugs, 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 counsel appearing for the petitioner contents that the license for production of 59 drugs was accorded to their company viz., M/s GuruFcure between 2009 and 2012. These drugs are Fixed Dose Combination [FDC] drugs, for which first approval was accorded by the Drugs Controller General of India [DCGI] 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 counsel appearing for the petitioner

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 [DCGI]. 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 [DCGI] 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 petitioner herein is that pursuant to the communication dated 05.07.2013, they have submitted their application for approval of Drugs Controller General of India [DCGI] and for some cases, they have received approval and for some cases they are awaiting approval. 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 counsel appearing for

the petitioner 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 (DCGI), till the final decision has been taken in this regard.

20. The sum and substance of the submission on behalf of the petitioner is that, the licenses obtained by them from the State Licensing Authority is well within their competency and legal. Even otherwise, in the light of the subsequent development, they have applied to the Drugs Controller General of India [DCGI] 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 counsel appearing for the petitioner 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 are arrayed as accused 1,2 and 3. 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 [DCGI] 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 [DCGI], 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 to A3 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 is not only resulted in marketing drugs, which were not properly tested for its efficacy, but also evidently clear that by not getting approval from the Drugs Controller General of India [DCGI], 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 [DCGI] on or before 30.08.2013 will not exonerate the criminal liability on the petitioner 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 counsel appearing for the petitioners, in the identical matter, 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, 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 is 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[DCGI] which provides opportunity for manufactures to get approval for their products by applying to DCGI 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 Petitions are closed.

21.12.2017

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.23912 of 2017
and
Crl.M.P.Nos.13841 and
13842 of 2017

21.12.2017