IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on :23.11.2017

Pronounced on : 21.12.2017

Coram:

THE HON'BLE DR.JUSTICE G.JAYACHANDRAN

Crl.R.C.No.1643 of 2016
and
Crl.M.P.No.13523 of 2016

1.M/s.Tristar Formulations Pvt. Ltd.,
Rep. By its Executive Director,
Mr.Asaithambi, Puducherry.

2.Asaithambi

.. Petitioners

/versus/

The Inspector of Police,
C.B.I., ACB, Chennai. .. Respondent

Criminal Revision Petition is filed under Section 397 Read With Section 401 of Criminal Procedure Code, 1973, praying to set aside the Order dated 19.09.2016 passed by the Hon'ble Special Judge (Hon'ble Principal Distrit Judge), Puducherry in Cr.M.P.No.1025 of 2016 in Spl.C.C.No.8 of 2014.

For Petitioners : Mr.AR.L.Sundaresan, Senior Counsel
for Mr.T.D.Selvan Babu

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

O R D E R

This petition is arising out of the order made in C.M.P.No.1025 of 2016 in Spl.C.C.No.8 of 2014 on the file of the Special Court, Puducherry.

2. The 1st petitioner, who is arrayed as A2 is the Company by name M/s Tristar Formulations (P) Ltd. The 2nd petitioner, who is arrayed as A3 in Spl.C.C.No.8 of 2014 is the Executive Director of the 1st petitioner-company. Both the petitioners had filed Crl.M.P.No.1025 of 2016 in Spl.C.C.No.8 of 2014 before the Special Judge, Puducherry for discharge the petitioners/accused from the charges levelled against them and the same was dismissed on 19.09.2016. Against which, the petitioners have filed the present revision petition to set aside the order of the trial Court dated 19.09.2016 and pass such further or other orders.

3. This revision petition is filed on the ground that they have obtained license for manufacturing and trading of drugs from the Drugs Controller, Puducherry on 27.02.2004 valid for 5 years and renewed periodically. However, criminal case is registered against them as if 9 drugs are new drugs as per the Drugs and and Cosmetics Rules, 1945 and to manufacture those drugs prior approval from the Drug Controller General of India, New Delhi is mandatory. Instead of getting his approval

and payment of prescribed fees, license to manufacture these drugs had been obtained from the 1st accused, thereby caused wrongful loss and cheated the revenue of the Central Government to the tune of Rs.4,50,000/-. Final report has been filed for prosecuting the Licensing Authority-cum-Controlling Authority, P.Rajkumaran[A-1]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.

4. The contention of the petitioners is that the charge sheet mentioned 9 drugs are not new drugs as alleged in the final report. The license for manufacturing these drugs was obtained between 2005 and 2006 from the then Drugs Controller Mr.Deenadayalan and the 1st accused only renewed the license on its expiry during the year 2009-2010. By then, the products were in the market for more than 4 years and A1 is the Competent Authority to renew the 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. 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 petitioners during the year 2005-2006. The Court below failed to appreciate the charge that

Government of India was cheated to the tune of Rs.50,000/- for each drug and Rs.4,50,000/- in total is bad, illegal and does not stand scrutiny of law. Even as per Rule 122-D of Drugs & Cosmetics Rules, 1945, the fee payable is only Rs.15,000/- for a new FDC drug and the petitioner's drugs are FDC drugs and not new FDC drugs.

5. Further contention of the petitioners is that the Court below failed to appreciate that the charges are wrongly made and are unsustainable for having been made without regard to product approval namely, ECOSPRIN, OSTEOCERIN, TRIGLYCOMET, RISE-PLUS, LIPIKIND all have been granted to petitioner as early as 2005 and 2006 and not in 2009 or 2010 & 2011 as stated. The lower Court failed to appreciate that the charge as against the product under name POLYTORVA 2.5 KIT and POLYTORVA 5 KIT is ill-founded as the same does not fall under new drug by any criteria since two separate medicines, a capsule and a tablet are packed in single pack as a kit and the question of obtaining prior approval under Rule 122-E or paying fee of Rs.50,000/- or Rs.15,000/- does not arise at all in the case. The Court below failed to consider that the charge against the 1st petitioner/2nd accused is not maintainable as it is a Company, which is a corporeal person against whom the charge of

criminal conspiracy under S.120-B or cheating under S.420 IPC that require mens rea cannot stand. Therefore, the petitioners cannot be mulcted with criminal liability. The trial Court ought not have taken cognizance of the complaint. Therefore, the order dismissing the discharge petition is liable to be set aside.

6. Per contra, the learned Special Public Prosecutor for CBI Cases would submit that the final report in this case discloses that, 9 drugs of Fixed Dose Combination[FDC] were allowed to be manufactured by the petitioners without approval from the Drugs Controller General of India [DCG(I)] and without applying for approval by paying Rs.50,000/- fees. It is confirmed from the Drugs Controller General of India [DCG(I)] office through letter dated 19.08.2013 that the petitioners have not applied for approval in respect of these 9 drugs and were not approved by his office during 2009-2011. Through the investigation, it is found that Shri.P.Rajkumaran(A1) himself cancelled the licence issued to the petitioners company M/s Tristar Formulations Private Limited for the manufacture of FDC Citicoline 500 mg+Methylcobalamin 750 mcg+Folic acid 750 mcg/Pyriodoxine Hydrochloride 1.5 mg Nervijen CT table and Diobetrol -3D on the ground that permission was not obtained from the

DCG(I), New Delhi. When the petitioners filed a Form-44 for permission to manufacture and market FDC of Metformin + Glimepiride + Ploglitazone. The Drugs Controller General (India), New Delhi vide letter No.3835/27.01.2012 File No.4-29/2003-DC (Pt.Tri) dated 07.09.2012 rejected the proposal/not granted permission for the proposal. Whiel so, license has been obtained to these drugs in connivance with A1 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. Since sufficient materials are available to prosecute the accused and likelihood of convicting them is bright, this petition 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 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 about 9 drugs which are FDC drugs and prior approval of DCG(I) is a mandatory requirement.

14. Per contra, the learned Senior counsel appearing for the petitioners contents that the license for production of 9 drugs was accorded to their company viz., M/s Tristar Formulations Pvt. Ltd., as early as 2006. These drugs are Fixed Dose Combination [FDC] drugs, for which first approval was accorded 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. In this case, the 1st accused has only renewed the license which was already granted. This by itself show they are not new drugs as defined under the Rule 122-E.

15. 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.

16. 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.

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

18. The sum and substance of the submission on behalf of the petitioners is that, the licenses obtained by them from the State Licensing Authority much prior to 01.10.2012 and it 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 [DCG(I)] for grant of approval. Due to apprehension expressed by the manufactures of these drugs, the Government of Puducherry has also issued the 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 with similar plea few other manufactures have also

approached it. Hence, there is no substance to sustain the prosecution against the petitioner.

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

20. 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 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.

21. 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. The statements of witnesses relied by the prosecution discloses violation of licensing procedure. Thus, prima facie case to prosecute is available on record.

22. 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, when the First Information Report was registered and final report filed pursuant to the investigation.

23. The facts of the case as found in the final report 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.

24. 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.

25. No doubt, though the Drugs and Cosmetics Act, 1940 provides for Penal action and the prosecution agency has not laid the final report invoking those provisions, it is for the judicial officer, who has taken cognizance of the offence to apply his mind and frame appropriate charges under appropriate law, based on the materials placed by the prosecution. Hence, the plea raised by some of the petitioners in the connected matter does not carry any merit.

26. The trial Court, while considering the discharge petition, has gone through the records and concluded that there is a prima facie case for framing charge. On deeper scrutiny of the records, this Court is unable to arrive at any other view other than the view of the trial Court.

27. For the reason, this Court finds that there is no reason to

interfere with the order of the trial Court. Hence, this Criminal Revision Case is dismissed. Consequently connected Miscellaneous Petition is closed.

21.12.2017

Index:yes/no
Internet:yes/no
speaking order/non speaking order
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To
1.The Hon'ble Special Judge, Puducherry.
2.The Inspector of Police, CBI, ACB, Chennai.
3.The Special Public Prosecutor for CBI Cases, High Court, Madras.

Dr.G.Jayachandran,J.

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Pre-delivery order made in
Crl.R.C.No.1643 of 2016
and
Crl.M.P.No.13523 of 2016

21.12.2017