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.1642 of 2016
and
Crl.M.P.No.13522 of 2016

1.M/s.Accent Pharma
Rep. By its Managing Partner,
A.Mohammed Sulaiman.

2.A.Mohammed Sulaiman .. Petitioners

/versus/

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

Criminal Revision Petitions are 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 District Judge), Puducherry in Cr.M.P.No.1309 of 2015 in Spl.C.C.No.13 of 2015.

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.1309 of 2015 in Spl.C.C.No.13 of 2015 on the file of the Special Court, Puducherry.

2. The 1st petitioner, who is arrayed as A3 is the Company by name M/s Accent Pharma. The 2nd petitioner, who is arrayed as A4 in Spl.C.C.No.13 of 2015 is the Managing Partner of the 1st petitioner-company. Both the petitioners had filed Crl.M.P.No.1309 of 2015 in Spl.C.C.No.13 of 2015 before the Special Judge, Puducherry for discharge the petitioners/accused from the charges levelled against him and the same was dismissed on 19.09.2016. Against which, the petitioners have filed the present revision petition.

3. This petition is filed to set aside the order passed by the trial Court in their discharge petition and to pass appropriate order. According to the petitioners, a false criminal case is registered against them on the premise that 130 drugs, which they are manufacturing are all new drugs as per the Drugs and and Cosmetics Rules, 1945. While for manufacturing of those drugs requires prior approval from the Drug Controller General of India, New Delhi, without getting the said approval and without paying

prescribed requisite fee of Rs.15,000/- for each drug, petitioner-Company has obtained license from the 1st accused, P.Rajkumaran, Licensing Authority and manufacturing the same, thereby caused wrongful loss and cheated the revenue of the Central Government to the tune of Rs.19,50,000/- thereby committed offences under Section 120-B r/w 420 IPC and 13(2) r/w 13(1)(d) of Prevention of Corruption Act, 1988.

4. The Learned Senior Counsel for the petitioners submitted that, the petitioners company involved in pharma manufacturing in Pondicherry since 2006 manufacturing various Fixed Dose Combination[FDC] drugs under valid license. Initially they had their manufacturing unit at Thirubuvanam and later, shifted to Mettupalayam. The license to manufacture the drugs, which are mentioned in the charge sheet was originally granted by one Deenadayalan and Dhansekaran, the then Lincensing Authorities. No new license was granted by the 1st accused [P.Rajakumaran]. He had only renewed the old license due to shift of manufacturing premises from Thirubuvanam to Mettupalayam during the year 2009. The drugs, which are manufactured by the petitioners, are in the market for more than 4 years. Therefore, it is not a new drug as defined under the Act and Rules. The petitioners have obtained their

license to manufacture these drugs strictly in compliance of the procedure prescribed under Rule 69 of the Drugs and Cosmetic Rules 1945.

5. The drugs are not new drugs as per the definition under Rule 122 (E). They are in the market for more than 4 years. Further, 25 drugs which are listed in the final report, are approved drugs by the Drugs Controller General of India DCG(I) under different brand names, much prior to filing of the First Information Report and chargesheet. That apart, some of the Fixed Dose Combination [FDC]drugs, which are found in the charge sheet while attempted to be banned in the year 2007, the Hon'ble High Court has stayed the attempt in W.P.No.35777 to 35781 of 2007 and the matter is still pending. Therefore, the criminal prosecution does not carry any fundamental ingredients to frame charges against the petitioners. More so, when the Central Government itself has floated the scheme for approval of all Fixed Dose Combination[FDC] drugs, by notification dated 15.01.2013 and availing the opportunity, the petitioners have already applied to the Drugs Controller General of India DCG(I) by paying requisit fees. In the light of the above fact, the prosecution should have closed the complaint as mistake of fact or atleast the trial court considering the materials placed before it, ought to have discharged the

petitioners. Having declined to do so, the present revision petition.

6. The contention of the petitioners is that the charge sheet mentioned 130 drugs are not new drugs as alleged in the final report. The license for manufacturing these drugs was obtained during 2006 from Mr.Deenadayalan and Mr.Dhanasekaran, who are the predecessors in office to the 1st accused. They were 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. The 1st accused in this case has only renewed the license. 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.

7. In response to the above plea, it is contended by the learned Special Public Prosecutor for CBI cases appearing for the respondent that, 130 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 petitioners herein, in connivance with the 1st accused [P.Rajkumaran] who was Licensing Authority-cum-Controlling Authority, during October 2009 to July 2011, had obtained license and thereby cheated the Government, without paying requisite fees and caused wrongful loss of revenue to the Government of India to an extent of Rs.19,50,000/-.

8. In pursuance of the said conspiracy, the 2nd accused (Dr.Dilip Kumar Baliga) had accorded administrative approval and license has been issued by A1 for the petitioners company 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

14. 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)

15. 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 130 drugs.

16. Contrarily the petitioners content that out of 130 drugs, 97 drugs have already been approved by the Drugs Controller General of India [DCG(I)] 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 [DCG(I)] has already granted permission for other manufacturers and the

said permission is granted more than four years ago. Therefore, they do not fall within the definition of new drugs.

18. 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.

18. 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.

19. 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 cases they are

awaiting approval. Meanwhile, the respondent has registered a case against them and filed charge sheet for the alleged offence under Section120-B r/w 420 IPC and Section 13(2) r/w 13(1)(d) of Prevention of Corruption Act, 1988, which is unsustainable.

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

21. 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 [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 with similar plea few other manufactures have also approached it. Hence, there is no substance to sustain the prosecution against the petitioner.

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

23. 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. Though the petitioners content that A1 only renewed the existing license after change of address to Mettupalayam and it is not new drug and 25 drugs out of 130 drugs approval already granted by the Drugs Controller General of India DCG (I) before 2010, are all facts to be established in the course of trial. Even if few or more such drugs are excluded in trial, if even one drug is found to have been manufactured in violation of the Rules, the prosecution will sustain. Therefore, while considering the merits of the case, on a discharge petition, prima facie material is suffice to continue the prosecution.

24. The materials placed before this Court prima facie discloses violation of the Drugs and Cosmetics Act, 1940 and Rules 1945 in granting manufacturing license for FDC drugs to the petitioner's company. This violation is 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.

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 for 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 the market for more than four 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 was 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 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. 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 the petitioners in this regard does not carry any merit.

29. The trial Court, while considering the discharge petition, has gone through the records and concluded that the statement of witnesses implicate the petitioners with specific allegation and there is a prima facie case for framing charge and has also taken note of the subsequent development, pointed out by the petitioners' counsel and has held that the

trial Court cannot undertake a roving enquiry at this stage.

30. For the aforesaid 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

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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.1642 of 2016
and
Crl.M.P.No.13522 of 2016

21.12.2017