IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on: 23.07.2018	Pronounced on: 31.07.2018

Coram

The Honourable Dr.Justice G.JAYACHANDRAN

Criminal Revision Case Nos.624 to 627 of 2018
in
Criminal Miscellaneous Petition Nos.7354 to 7361 of 2018

1. P.Kalavathy
   Managing Partner,
   M/s.Huntra Labs

2. G.Pakkirisamy,
   Partner,
   M/s.Huntra Labs ...Petitioner/Accused[A2 & A3]
   in Crl.R.C.No.624 of 2018

1. M/s.Bonn Schtering Bio Sciences
   Represented by
   Umarani & Bharathidasan

2. Umarani,
   Managing Partner,
   M/s.Bonn Schtering Bio Science,

3. Bharathidasan
   General Manager,
   M/s.Bonn Schtering
   Bio Sciences, ...Petitioners/Accused [A3 to A5]
   in Crl.R.C.No.625 of 2018

1. M/s. Life Care Formulations Pvt. Ltd.,
   Represented by E.Srinivsan

2. Mr.E.Srinivasan,
   Managing Director,
   M/s. Life Care Formulations (P). Ltd., ...
Petitioner/Accused[A2 & A3]
   in Crl.R.C.No.626 of 2018

1. M/s.Medzone Pharmaceuticals Pvt. Ltd.,
   Rep. by Mr.Alexander Jesudasan

2. Alexander Jesudasan,
   Executive Director,
   M/s.Medzone Pharmaceuticals(P).Ltd., ...
   Petitioner/Accused[A2&A3]
   in Crl.R.C.No.627 of 2018

/versus/

State, rep. by The
Inspector of Police
CBI/ACB/Chennai,
Chennai. ... Respondent/Complainant
in Crl.R.C.No.624 to 627 of 2018
R.C.MA.1 2013 A 0051,
R.C.MA.1 2013 A 0050 &
R.C.MA.1 2013 A 0056

PRAYER: Criminal Revision Petitions are filed under Section 397(1) and 401 of Criminal Procedure Code, to set aside the order dated 26.02.2018 made in Crl.M.P.Nos.1172, 1174, 1179, 1181 of 2015 in Special C.C.No.22, 17, 19, 23 respectively on the file of the learned Special Judge (under the Prevention of Corruption Act, 1988) Puducherry.

For Petitioners : Mr.R.Shanmugasundaram, Sr.Counsel
in Crl.R.C.No. 624 to 627 of 2018 for Mr.S.Manuraj

For Respondent : Mr. K.Srinivasan,
in all the cases Special Public Prosecutor [C.B.I]

C O M M O N O R D E R

Brief facts leading to these batch of revision petition are as below:-

2. Based on source information, the respondent CBI/ACB/Chennai registered Cr.No.RC 50(A) 2013 CBI/ACB/Chennai and Cr.No.RC 51(A) 2013/CBI/ACB/Chennai on 30.11.2013 and 27.12.2013 respectively against Shri.P.Rajkumaran the then Licensing Authority, Department of Drugs Control, Ministry of Health, Pondicherry and other Private Drug Manufactures, alleging that they have committed criminal conspiracy, cheating and criminal misconduct by public servant. To wit, Rajkumaran the Drug Licensing Authority had in connivance with respective drug manufactures at Pondicherry without approval from DGCI, granted licence to manufacture several drugs which are Fixed Dose Combination [FDC] drugs and fall under New Drugs Category as defined under Section 122 E of Drugs and Cosmetic Act. Further, they failed to pay requisite fees to DC&GI for getting approval for manufacturing Fixed Dose Combination [FDC] drugs.

3. On completion of investigation, in the above two complaints, three charge sheets each were filed and taken on file by the trial Court.

4. The petitioners in Crl.RC.No.624 of 2018 are the 2nd and 3rd accused in C.C.No.22 of 2015. The charge against them is that, they are Managing Partner and Partner of M/s Huatra Drugs entered into conspiracy with P.Rajakumaran [A-1] while he was working as Licensing Authority, without submitting requisite Form 44 and without paying requisite fees of Rs.15,000/- for each FDC and without obtaining mandatory permission/approval from the DCGI had dishonestly obtained license from licensing Authority to manufacture 59 FDC drugs knowing fully well the competent authority to approve manufacturing of new drug is DCGI and not the state licensing Authority.

5. The petitioners in Crl.RC.No.625 of 2018 are the A-3, A-4, A-5 in Special C.C.No.17 of 2015. The charge against them is that, they are Managing Partner and General Manager of M/s.Bonn Schtering Bio Science entered into conspiracy with P.Rajakumaran [A-1] while he was working as Licensing Authority, without submitting requisite Form 44 and without paying requisite fees of Rs.15,000/- for each FDC and without obtaining mandatory permission/approval from the DCGI had dishonestly obtained license from licensing Authority to manufacture 183 FDC drugs knowing fully well the competent authority to approve manufacturing of new drug is DCGI and not the state licensing Authority.

6. The petitioners in Crl.RC.No.626 of 2018 are the 2nd and 3rd accused in Special C.C.No.19 of 2015. The charge against them is that, they are Managing Partner of M/s. Life Care Formulations Pvt. Ltd., entered into conspiracy with P.Rajkumaran [A-1] while he was working as Licensing Authority, without submitting requisite Form 44 and without paying requisite fees of Rs.15,000/- for each FDC and without obtaining mandatory permission/approval from the DCGI had dishonestly obtained license from licensing Authority to manufacture 92 FDC drugs knowing fully well the competent authority to approve manufacturing of new drug is DCGI and not the state licensing Authority.

7. The petitioners in Crl.RC.No.627 of 2018 are the 2nd and 3rd accused in Special C.C.No.23 of 2015. The charge against them is that, they are Company and Executive Director of M/s. Medzone Pharmaceuticals Pvt. Ltd., entered into conspiracy with P.Rajkumaran [A-1] while he was working as Licensing Authority, without submitting requisite Form 44 and without paying requisite fees of Rs.15,000/- for each FDC and without obtaining mandatory permission/approval from the DCGI had dishonestly obtained

license from licensing Authority to manufacture 49 FDC drugs knowing fully well the competent authority to approve manufacturing of new drug is DCGI and not the state licensing Authority.

8. This issue involved in all these Revision Petitions is one and the same. Hence, common order is passed. The petitioners herein filed petition under Section 239 of Cr.P.C before the trial Court for discharge, but failed. Hence the present revision petitions are filed.

9. The learned Senior appearing for the revision petitioners would submit that the entire basis of the prosecution is misconceived. The revision petitioners are not public servants,to attract provision of Prevention of Corruption Act, 1988. They have not deceived any person they did not dishonestly induced to deliver any property to attract offence under Section 420 I.P.C. The petitioner being in trade of manufacturing drugs, applied for license to manufacture certain drugs and obtained license from A-1 after furnishing necessary documents and required fees. The licensing authority found the application in order and had issued license. A new procedure for obtaining approval to manufacture New drugs/FDC drugs being introduced through inter-departmental circular over riding the existing legislation passed by the Parliament and Rules framed there under. Such procedure is bad in law for want of legal sanction. In any event it will not attract penal provisions.

10. The further points canvassed in support of the revision petitioner are; The case of the prosecution regarding estimated loss at the time of registering First Information Report and after investigation vary to a vast extend this exposes the source of the information, which form base of the FIR is false. When DCGI which is the Agency to regulate manufacturing and marketing drugs have thought fit to allow the manufacturing of these drugs subject to application for post approval on or before 30.08.2013. The First Information Report registered on 30.11.2013, thereafter is baseless. Further when in the opinion of DCGI the license obtained by the petitioners from SLA is rectifiable and no penal action under Drugs and Cosmetic Act warrants, prosecution for cheating has no legs to stand.

11. Further, the learned Senior Counsel would also content that, a combined reading of Rules 69, 75 and 76 of the Drugs and Cosmetic Rules make clear the procedure to obtain license for manufacturing drug, one has to make application to the licensing Authority and not to DCGI. Under Rule 22 it is the licensing authority who has to give approval and not the DCGI. If the Government, wants to

vest the authority of granting approval for New drugs with DCGI then the rule has to be amended and placed before the Parliament. In this case, without amending Rule, merely based on the suggestion of Central Drug Standard Control (CDSCO), the DCGI had thought fit to direct the manufactures of New drug particularly FDC that hereinafter DCGI will be the authority and for any license granted by SLA prior to 01.10.2012 in respect of FDC drugs, the manufactures should apply and get approval from DCGI within a period of 18 months. The variation in procedure without amending Rules though not sustainable, the drug manufactures like the petitioners herein have already made application to DCGI seeking approval and DCGI is in turn issuing approvals in phased manner.

12. The Rules duly placed before the Parliament can be changed only by the procedure established under law. Amended Rule not placed before Parliament within the time stipulated cannot be enforced. It is nonest in law. So breach of such amended Rule cannot be base for prosecution. It is submitted that the above legal proposition is settled by Supreme Court by confirming the judgment of Karnataka High Court in KT Uthappa and other vs state of karnataka;

13. Per contra, the learned Special Public Prosecutor for C.B.I would submit that, the points raised by the petitioners herein are no more res integra in view of the judgment of this Court passed in

1. M/s. Tristar Formulations Vs. Inspector of Police, CBI in Crl.R.C.No.1643 of 2016 dated 21.12.2017.
2. Dr.Dilip Kumar Baliga Vs. The Inspector of Police, C.B.I, ACB, Chennai in Crl.R.C.Nos.1598 to 1613 of 2016 dated 02.08.2017.
3. M/s. Accent Pharma vs. The Inspector of Police, C.B.I, ACB, Chennai in Crl.R.C.No.1642 of 2016 dated 21.12.2017.
4. M/s. Daeiou Pharmaceuticals Private Limited vs. The Inspector of Police, C.B.I/ACB/Chennai dated 21.12.2017.
5. M/s. Lessac Research Lab (P) Ltd., vs. Inspector of Police, CBI/ACB/Chennai in Crl.R.C.No.596 of 2015 dated 21.12.2017.

14. Smt. Geetha Shyamsundar vs. The Inspector of Police, CBI/ACB/SPE, Chennai in Crl.O.P.No.23912 of 2017 dated 21.12.2017. Wherein similarly placed manufactures approached this Court against dismissal of their discharge petitions. Similar grounds were raised and negatived. The instruction given by DCGI on 15.01.2013 is not in variation to existing Rule or an amendment to the Rules. It is only reiteration of the existing Rules and reminder to the manufactures and SLA that manufacturing of new drugs cannot be approved without undergoing safety and efficacy test by

CDSCO. The SLA should ensure whether prior approval granted by licensing authority defined under Section 21 (b) of Drugs and Cosmetic Act is accompanied with the license application made for manufacturers. Therefore, the judgment cited by the learned counsel does not apply to the facts of the case.

15. The Learned Special Public Prosecutor would further submit that, this Court has gone into the merits of the prosecution case and has held grounds to frame charge, available. These petitioners besides other offence also charged for conspiracy. In the absence of any legal or factual issue other than what canvassed earlier by the similarly placed accused, the same issue cannot be re-agitated through other drug manufactures.

16. No doubt, as it is pointed by the learned Special Public Prosecutor, this Court has occasion to consider petitions similar to the revision petitions now under consideration. The submissions made by the Revision Petitioner herein in this regard and had in detailed dealt and order passed tracing the genesis of Drugs and Cosmetic Rules, 1940, the definition of new drugs/Fixed Dose Combination [FDC], procedure to accord approval and grant of licence to manufacture and market. In those batch of revision petitions, this Court has examined the relevant Rules framed under Drugs and Cosmetic Act and had arrived at a conclusion that any new drug inclusive of Fixed Dose Combination has to be first tested for safety and efficacy. Thereafter, approval in the prescribed form shall be issued by the Licensing Authority. Based on the approval, manufactures shall apply for licence.

17. In all these cases now under consideration, and the cases were orders passed on 21.12.2017, the allegation made out in the final report is that the licence to manufacture and market had been given by the State Licensing Authority P.Rajkumaran [A1]. The Director of Health and Family Welfare Services, Government of Pondicherry, Dr.Dilip Kumar Baliga had authorised P.Rajkumaran [A1] in all these cases, to accord approval. Therefore, the State Licensing Authority who has accorded licence, the Director who has delegated power to accord approval and the manufactures who has obtained licence to manufacture new drugs dishonestly are all arrayed as accused. In all these cases, another learned Judge of this Court as mentioned earlier [Justice P.Velmurugan] on 02.08.2017 had dismissed Crl.R.C.Nos.1598 to 1613 of 2016 filed by Dr.Dilip Kumar Baliga [Director of Health and Family Welfare Services, Government of Pondicherry] who is the common accused in all the Calendar Cases. Later, this Court has passed orders in Crl.R.C.No.1643 of 2016 dated 21.12.2017 dismissing the Revision Petitions filed by following "Pharma Companies" and its representatives.

i). M/s Tristar Formulations Pvt Ltd.,
ii). M/s. Accent Pharma
iii) M/s. Daeiou Pharmaceuticals Pvt Ltd.,
iv). M/s. Lessac Research Lab (P) Ltd.,
v). M/s. GuruFcure Pharmaceutical Company.

18. The learned Senior Counsel has again reiterated the points in a different perception. Therefore, this Court, in addition to the reasons assigned in its earlier order wish to add the following reasons for dismissal of these revision petitions.

19. None of the rules framed under Drugs and Cosmetics Act had been tinkered, altered or modified by the later communication of DCGI issued on 15.01.2013 and thereafter. There is a specific mention in the letter dated 15.01.2013, that it is only a reiteration of the existing Rules.

20. According to the Rules as it exists, no new drug can be manufactured without clearing the Safety and Efficacy test. Approval for manufacturing and marketing of new drugs shall be accorded by the licensing authority. Any application seeking approval shall accompany fees of Rs.15,000/- for each drugs. The Forms for applying approval is prescribed under statue. On obtaining approval, the manufactures has to apply for grant of licence to manufacture and market. While applying for licence, the application should accompany the approval granted by the Licensing Authority as defined under Rule 21 (b).

21. The case of the prosecution against these Revision Petitioners is very specific that they have obtained license from Rajkumaran [A1], the State Licensing authority without appropriate approval. They have not applied for licence along with the order of approval issued by competent authority. They have not paid requisite fees for considering the approval application. The act of Dilip Kumar Baliga, Director of Health and Welfare Service, Government of Pondicherry, delegating the power to P.Rajkumaran [A1] for issuing approval. The act of issuing license to manufacture and market by P.Rajkumaran [A1]. Knowing fully well, the manufactures obtaining approval and licence from a person who is not competent to issue licence to manufacture new drugs are the materials placed by the prosecution against these petitioners.

22. The reiteration of rules in existence and pointing out the violation; giving breather to the manufactures to rectify the violation by getting approval from authority competent are not defence or reasons to

discharge the Criminal Revision Petitioners. The prosecution has made out a prima facie case against these manufactures that the product for which they have obtained license from P.Rajkumaran [A1] had not cleared the test of safety and efficacy. The licence to manufacture is not accompanied with appropriate approval and the manufactures were given approval without remittance of requisite fees.

23. It was pointed on behalf of the petitioners that the final report indicates that the manufactures had conspiracy to cheat Government of India in connivance with the public servants namely RajKumaran, the State Licensing Authority and Dr.Dilip Kumar Baliga. No other penal provision is invoked against them. More particularly the penal provisions under Drugs and Cosmetic Act, is not charged.

24. The final report filed by the police indicating the provisions of law violated is not the final say in a criminal prosecution. It is the Magistrate who to frame charge has to decided what are the penal provisions attracted, on reading the final report and documents filed along with the final report. If there are prima facie materials to show that the drugs which are listed in the final report are manufactured and marketed, without undergoing the process of safety and efficacy test, the trial Court, may later even frame charge under relevant sections in Indian Penal Code or Drugs and Cosmetic Act dealing with the offences affecting the public health, safety etc., which the Court on appeal cannot comment upon.

25. For the aforesaid reasons, the Criminal Revision Petition Nos.624 to 627 of 2018 are dismissed. Consequently, connection Miscellaneous Petitions are closed.

Sd/-
Assistant Registrar(CS)

//True Copy//

Sub Assistant Registrar

bsm

To

1. The Special Judge (Principal sessions Judge)
Prevention of Corruption Act, Puducherry

2. The Inspector of Police
CBI/ACB/Chennai, Chennai.

3. The Special Public Prosecutor [C.B.I],
High Court, Madras.

+4 copies to MRS.MANURAJ Advocate SR.NO. 52145,52146,52147, 25418

CC TO :

THE SECTION OFFICER,
CRIMINAL SECTION,
HIGH COURT
MADRAS

Pre-delivery order made in
Crl.R.C Nos.624 to 627 of 2018
in Crl.M.P.Nos.7354 to 7361 of 2018

GJ(CO)
ASK(21/08/2018)