IN THE HIGH COURT AT CALCUTTA
CRIMINAL REVISIONAL JURISDICTION
APPELLATE SIDE

The Hon'ble **JUSTICE BIBEK CHAUDHURI**

IA No.:CRAN/1/2021
In
CRR 553 of 2021

M/s Celebrity Biopharma Limited & Ors.

-Vs-

Union of India

For the Petitioners: Mr. Anirban Dutta, Adv.,
Mr. Sumit Biswas, Adv.,
Mr. Sarangam Chakraborty, Adv.,
Mr. Shashwat Nayak, Adv.,
Ms. Rajashree Bhowmick, Adv.

For the Union of India: Mr. Rajdeep Mazumder, Adv.,
Mr. Pritam Roy, Adv.

Heard on: 22 June & 30 June, 2022.
Judgment on: 06, September, 2022.

BIBEK CHAUDHURI, J. : –

1. Petitioner No.2 to 6 are directors of petitioner No.1 company under the name and style of M/s. Celebrity Biopharma Limited. Petitioner No.7 is the Deputy Manager, quality assurance of the petitioner No.1 company. The petitioners have prayed for quashing of proceeding in connection with Complaint Case No.C-156 of 2020 pending before the learned Metropolitan Magistrate, 13th Court, Calcutta whereby, the petitioner has

been charged for violation of Section 18(a)(i) and Section 27 of the Drugs and Cosmetics Act, 1940 and all orders passed in the aforesaid complaint case including order dated 28th January, 2020 passed by the learned Magistrate.

2. The petitioner No.1/company is engaged in manufacturing and distribution of pharmaceutical medicines through various supply chain. Petitioner Nos.2 to 6 being the director of the said company are not engaged in manufacturing and distribution process of drugs. However, they are involved in overall administration and finance of the said company. Petitioner No.7 is the Deputy Manager of the quality assurance team of the said company which consists of appointees by the Drug Controller cum license authority for quality assurance, formulation, process validation and various declarations which are required in terms of the Drugs and Cosmetics Act, 1940 (hereafter described as the said Act). The quality assurance team of the said company consists of officers having various designations and they are responsible for formulation of Drug and/or declaration which are to be made in respect of specific drug. Manufacturing and distribution of any drug go through a rigorous process, viz.,

(i) Conceptualization of a drug leading to formulation and/or preparation of analytical method, validation of protocol cum report.

(ii) Disclosure of the formulae and the process through which a drug is to be made.

(iii) Formulation standard operating procedure for every batch which will be manufactured followed by a certificate of analyses for every batch.

(iv) Preparation of finished products specification reports, testing and verification by the quality control team of the company.

(v) Finalization of all such records.

(vi) Procurement of drug license from the State Drug Controller/licensing authority and lastly,

(vii) Preparation of stability study report by the quality control team after the drug is released in the market.

3. On compliance of all the above measures, the petitioner No.1/company had got approval from the Health and Welfare Department of Baddi, Himachal Pradesh for manufacturing of a drug in the name and style of "Aceclofenac and Paracetamol Suspension" on and from 1st December 2015 to 11th February, 2018. After complying of all the process as aforesaid, the company started production of the said drug. Certificate of analysis for the said drug was prepared by the quality team based on specifications which have been approved by the Drug Controlling Authority while issuance of the drug license. However, the specifications are not a stipulated declaration as per any Rules or Regulations, but these are the declaration of the range within which a result should lie. The concerned test results in respect of a particular batch of medicine is reflected on the certificate of analysis under result column and are final outcome of the tests which is conducted by the quality team of the

petitioner/company. Pursuant to manufacturing testing and dispatch of a particular batch, it is up to the suppliers who use various modes and transportation to transfer a medicine to the retail chain.

4. It is alleged by the petitioners that the company received a letter dated 2nd April, 2018 from the office of the Drug Inspector, CDSCO (East Zone) Kolkata wherein the petitioner/company was directed to show cause and also to stop manufacturing and distribution of "Ashycloflam P", on the ground that the drug was reported to be of non-standard quality with respect to batch number CPAO 610026 manufactured by the petitioner No.1 company. Along with the said letter the petitioner/company was served with a Government Analyst Report dated 27th February, 2018. The petitioner/company sent a reply in writing on 19th May, 2018 disputing the contention of the Drug Inspector, CDSCO (East Zone), Kolkata and denying the product to be of non-standard quality. The opposite party No.2 in turn sent a letter dated 13th June, 2018 requiring the petitioner/company for testing of the drug in question by a Government Analyst. The petitioner/company however denied the drug to be tested by the Government Analyst on the ground that certificate of analysis was duly prepared in respect of every batch. Under the direction of the Deputy Drug Controller, India, the Drug Inspector, CDSCO Sub-Zone Baddi and the Drug Inspector, Baddi, Himachal Pradesh inspected the company premises and the process of manufacturing of the said drug control in question. On conclusion of investigation it was observed, "On the basis of the above observation and

documents furnished by the firm, inspecting team is of the opinion that the firm has added the required quantity of bulk drug. In the Government Analyst Report as per the specification, pH limit is mentioned as 5.5 to 6. However, in the finished products of COA of the manufacturer, the specification is mentioned as 5.0 to 6.5." Subsequently, on or about 13th March, 2020 the petitioners received summons from the court of the learned Metropolitan Magistrate, 13th Court, Calcutta directing them to appear before the said court for violation of the provision of Section 18(a)(i) and Section 27 of the said Act. The petitioners subsequently came to know that upon a complaint filed by the opposite party No.2, the learned Chief Metropolitan Magistrate, Calcutta took cognizance of the offence under Section 27 of the Act for violation of Section 18(a)(i) of the said Act on 18th January, 2020. It is urged by the petitioners that the petitioner/company did not commit any offence under the said Act and complaint under Section 27 is not maintainable against them. It is also contended on behalf of the petitioners that the learned Chief Metropolitan Magistrate, Calcutta, took cognizance of the offence against the petitioners without following the mandatory provision of Section 202 of the Cr.P.C.

5. Under such circumstances, the petitioners have prayed for quashing of the complaint filed against them.

6. Mr. Rajdeep Mazumder, learned Advocate for the opposite party submits that under Chapter (iv) of the Drugs and Cosmetics Act the manufacturer of a drug has the bounden duty to comply with the

standard set out in the second schedule of the Act. It is also submitted by him that the standard of qualities are fixed by the government after due deliberation and after consulting a committee of competent persons. It is for them to give due allowance for probable errors before fixing a standard. When a standard has been fixed, it is to be observed strictly. If the manufacturer fails to observe the standard quality, while manufacturing a drug, the same will fall under the category of misbranded drug within the meaning of Section 17 of the said Act and the manufacturer is liable for penal action under Section 18(a)(i) of the said Act. In the instant case pH limit as per the Government Analyst Report of the seized drugs in question ought to have been 5.5 to 6. However, in the finished product of COA of the manufacturer, the specification was mentioned as 5.0 to 6.5. Thus, manufacturer's COA was not in conformity with the COA of the Government Analyst Report with regard to pH percentage of the drug. It is also submitted by Mr. Mazumder that it is immaterial as to whether pH factor of the drug in question was within the limit of the Government Analyst Report or not. As soon as pH specification mentioned in the COA of the manufacturer varies from the Government Analyst Report, Section 18(a)(i) attracts and the petitioner cannot escape from facing trial for violation of specific provisions of the said Act in relation to "misbranded drugs".

7. The learned Advocate for the petitioner, on the other hand, contended that pH factor of the drug was found to be 5.8 which is within the normal limit of Government Analyst Report. Therefore, consumption

of the said drug would not be fatal for any patient who might be prescribed to take the said drug. As pH factor of the drug was within the limit of the Government Analyst Report the petitioners cannot be held liable for prosecution under Section 18(a)(i) of the said Act.

8. It is also urged by the learned Advocate for the petitioners that indisputably the petitioners carry on business of manufacturing drugs outside the jurisdiction of the learned Chief Metropolitan Magistrate, Kolkata. Therefore, it was the bounden duty of the learned Magistrate, where the accused is residing at a place beyond the area in which he exercises his jurisdiction, to postpone the issue of process against the accused, and either inquire into the case himself or direct an investigation to be made by a Police Officer or by such other person as he thinks fit, for the purpose of deciding whether or not there is sufficient ground for proceeding. In the instant case before issuance of process the learned Magistrate did not take recourse to Section 202 of the Code of Criminal Procedure. Therefore, issuance of process against the petitioners without complying with the provisions of Section 202 of the Cr.P.C is bad in law and liable to be quashed.

9. I have duly considered submission made by the learned Counsels for the parties in support of their cases.

10. In **Sri Kamalesh Purkait & Anr. vs. Sri. Sambhunath Dey, Drug Inspector & Anr.** reported in **(2000) 3 Cal LT 424** a question came up before a Coordinate Bench as to whether a proceeding under Sections 23(4)(iii), 27 and 28A of the Drugs and Cosmetics Act is liable to be

quashed for non compliance of mandatory provision regarding disposal of the portions of sample.

11. The Bench while replying the issue in affirmative held that Sub-Section (4) of Section 23 of the said Act directs Drugs Inspector the manner in which he is to dispose of the portions of sample taken by him and Clause (iii) of Sub-Section (4) of Section 23 of the Act in specific terms provides that the Drug Inspector is to send the third portion of the sample to the manufacturer. When the statute has directed that the portions of sample are to be disposed of in a particular way, the Drug Inspector has to follow the said directions and he cannot act in a different way. Therefore, the Drug Inspector in not complying with the said procedure violated the mandatory provisions of law and thereby causing serious prejudice to the accused vitiating the entire proceeding.

12. It is also not out of place to mention that petitioner No.1 is a private limited company of which petitioners No.2-6 are the Directors and petitioner No.7 is the Deputy Manager, quality assurance of the said company. It is avert by the petitioners that they are not engaged in manufacturing process of drugs manufactured in the said company. They are only responsible for the administrative job. In **Sham Sunder & Ors vs. State of Haryana** reported in **(1989) 4 SCC 630,** the Hon'ble Supreme Court was pleased to hold that before impleading the Directors of a company or partners of a partnership firm in a criminal case, it is the duty of the learned Magistrate to consider as to whether they are really involved in the process of commission of offence. There may be a sleeping

partner or a Director of a company without taking part in manufacturing process of the material. In such a case it would be a travesty of justice to prosecute such partner or director and ask them to prove that the alleged offence was committed without their knowledge. In other words, in the absence of specific averment in the petition of complaint, criminal liability against the petitioners cannot be presumed. In a subsequent decision in **State of Haryana vs. Brij Lal Mittal & Ors.** reported in **(1998) 5 SCC 343,** the Hon'ble Supreme Court was pleased to hold that on the allegation of commission of offence by the company the directors cannot be made vicariously liable.

13. Coming to the factual aspect of the case it is not disputed that the drug in question was within the specific limit as to the pH factor because on scientific examination it was found that the said drug contains pH 5.8, while the government's specification is 5.5 to 6. Under such circumstances, the said drug cannot be disqualified under the banner of "misbranded drug". On non compliance of Section 202 of the Cr.P.C, I like to record that in **Vijay Dhanuka & Ors. vs. Najima Mamtaj & Ors.** reported in **AIR 2014 SC (Supp) 756,** the Hon'ble Supreme Court was pleased to hold that Section 202 contemplates postponement of the issue of the process in a case where the accused is residing at a place beyond the area in which he exercises his jurisdiction and thereafter to either inquire into the case by himself or direct an investigation to be made by a Police Officer or by such other person as he thinks fit. The word "shall", in a case where the accused is residing at a place beyond the area in which

he exercises his jurisdiction makes the provision mandatory and the learned Magistrate cannot issue any process without such inquiry. The above decision was followed in the following subsequent decisions:-

i) **Udai Shankar Awasthi V. State of U.P & Anr : (2013) 2 SCC 435.**

ii) **National Bank of Oman vs. Marakara Abdul Aziz & Anr. : (2013) 2 SCC 488.**

iii) **Abhijit Pawar vs. Hemant Madhukar Nimbalkar & Anr. : (2017) 3 SCC 528.**

iv) **Shyamal Kanti Goswami vs. Ashim Mukherjee : (2014) 2 CHN 136.**

v) **Trend Bags & Anr. vs. State of Bengal & Anr. : (2017) 1 CCrLr (Cal) 60.**

vi) **S.S Binu vs. State of West Bengal : (2018) SCC OnLine Cal 1741.**

vii) **Birla Corporation Ltd. Adventz Investments & Holdings Ltd. & Ors : (2019) 16 SCC 610.**

viii) **Re: Expeditious Trial of Cases u/s 138, NI Act, 1881 : 2021 SCC OnLine SC 325**

ix) **Sunil Todi vs. State of Gujrat : 2021 SCC OnLine SC 1174.**

14. In view of the above discussion I find substance in the submission made by the learned Advocate for the petitioner and the revisional application succeeds.

15. The proceeding, being complaint case No.156 of 2020 presently pending before the 13th Court of the learned Metropolitan Magistrate, Calcutta be quashed.

16. The parties are at liberty to act on the server copy of this order.

(Bibek Chaudhuri, J.)