Cipla Limited (Local Depot) vs The State Of Jharkhand. .. ..Opp. ... on 10 October, 2023

Author: Gautam Kumar Choudhary

Bench: Gautam Kumar Choudhary

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IN THE HIGH COURT OF JHARKHAND AT RANCHI
Cr. M. P. No. 641 of 2021

Cipla Limited (Local Depot). .... Petitioner(s)
Versus
The State of Jharkhand. .. ..Opp. Party(s)
With
Cr. M. P. No. 1792 of 2020
1.Lokesh Kumar Turkar
2.Jai K. Mishra
3.Tirupati Lifesciences, a Partnership Firm registered under the Indian Partnership Act, 1932 and having its registered office at Village Surajpur, District- Sirmour, H.P.
.... Petitioner(s)
Versus
The State of Jharkhand. .. ..Opp. Party(s)

.....

CORAM :HON'BLE MR. JUSTICE GAUTAM KUMAR CHOUDHARY .....

For the Petitioner(s) : M/s J.S. Singh, Mukesh Kr. Banka, & Girish Mohan Singh, Advocates (in Cr.M.P. No. 641/21) Mr. Vimal Kirti Singh, Sr. Advocate (in Cr.M.P. 1792/20) For the State : APP .....

Oral Order 06 / Dated : 10.10.2023 Heard, learned counsel for the parties.

1. Order taking cognizance in Cosmetic Case No. 2094 /2015 under Sections 27(b)(ii), 27(c) and 27(d) of the Drugs and Cosmetics Act, 1940 (For short DCA) and under Section 420 IPC, against the petitioners is under challenge in both these Cr. M. Ps involve common questions of law and therefore they have been heard together and shall be disposed of by a common order. Petitioner in Cr. M. P. No.641 of 2021 is the licenced saler of the seized samples of Alzivit tablets and Petitioner no.3 in Cr. M. P. No. 1792 of 2020 is the Partnership Firm claiming to be a manufacturer of food supplements/ Nutraceuticals.

2. On 10.01.2015, the Drug Inspector seized 300 tablets of Alzivit Multi-vitamin tablets at M/s Drug

Inn, Ranchi manufactured by M/s Tirupati Life Sciences (Petitioner) and marketed by Cipla House.

3. As per the prosecution case the active ingredients present in the seized drugs were much more than prescribed under DCA and the related Rules. The allegations are that the composition of the said Product exceeded therapeutic dose as under :-

> a. Vitamin B6 Therapeutic dosage contained in the seized product was 20 mg whereas permissible range was 1.5 mg to 3 mg;

b. Folic Acid Therapeutic range is 1 mg to 1.5 mg whereas in product it was 0.8 mg;

c. Vitamin B12 Therapeutic dosage range is 5 mcg to 15 mcg whereas in product it in 0.5 mg (500 mcg).

4. Active ingredients exceeded limits as prescribed in Schedule V and also that the said product comes under purview of Section 3(b)(i) of the Drugs and Cosmetics Act, 1940 and hence, it was a drug and not food, whereas the same was being sold under the FSSAI License no.10012062000165 as a food items only and not a Drug. Hence, offence has been committed under Section 17-B, 18(a)(i), 18(a)(iii), 18(a)(vi), 18(c) punishable under Section 27(b)(ii), 27(c) and 27(d) of the Drugs and Cosmetics Act, 1940.

5. Food License is being used for manufacturing drug which is punishable under Sections 420 and 423 of IPC.

6. Alzivit contained high volume of various ingredients which had side effects and excessive consumption was dangerous to life, marketing it as dietary substance was is contravention to Section 17-B, 18(a)(i), 18(a)(iii), 18(a)(iv) and 18(b) and 18(c) of Drugs and Cosmetics Act, 1940 which is punishable under Section 27(b)(ii), 27(c) and 27(d) of the Drugs and Cosmetics Act, 1940 and under section420 and 423 IPC.

7. Immediately after receiving of the said complaint, learned Addl. Chief Judicial Magistrate, Ranchi on the basis of prosecution report filed by the Drug Inspector-II, Ranchi took cognizance of the offence under Sections 27(b)(ii), 27(c) and 27(d) of the Drugs and Cosmetics Act, 1940 against the accused persons including the petitioner.

8. Earlier the order taking cognizance dated 22.08.2015 of learned AJC-II, Ranchi was set aside by the co-ordinate Bench of this Court on 16.03.2020 in Cr. M. P. No.3897 of 2019 and the case was remanded back to the ld. Court of AJC-II, Ranchi, for passing order afresh and in pursuant thereto again the Ld. AJC-II, the impugned order taking cognizance has been passed on 30.04.2020.

9. Impugned order is challenged mainly on the ground that the said product did not come within the category of drug, but being a multi-vitamin was a food supplement being produced under a licence issued by competent authority. Since it was not a drug, therefore offence under DCA will not make out.

10. Specific plea taken on behalf of the Petitioner in Cr.M.P. No.641 of 2021 is that M/s Tirupati Life Sciences is the manufacturer of the tablet in question named as Alzivit (multi-vitamin tablet) and Cipla Limited (the petitioner herein) was only the marketer of the said product. Plea of the Petitioner is raised on the following counts:

> Firstly, the petitioner is only the marketer of the product and not the manufacturer and marketer cannot be held liable to the violations committed by the manufacturer of the product. The term Marketer is not defined under the Drugs & Cosmetics Rules, 1945 nor the law casts upon any liability on the marketer who sells the product manufactured by a third party. It is humbly submitted that the Ministry of Health and Family Welfare Vide GSR No.101
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> (e) Dated 11.02.2020 published notification amending the provisions of Drugs and Cosmetics Rules, 1945 which are known as the Drugs & Cosmetics (Amendment) Rules, 1945 which came into effective from 01.03.2021. By virtue of the said Amendment the legislature for the first time inserted Rule 84D, pursuant to which the marketer is made liable for the quality and regulatory compliances.
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> "84E. Responsibility of marketer of the drugs.- Any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliance along with the manufacturer under these rules."

Secondly, there was non-compliance of mandatory provisions of the Drugs and Cosmetics Act, 1940.

Thirdly, the product is not a drug and even otherwise would fall under the exemption specified in Schedule K of the Drugs and Cosmetics Rules, 1945, wherein it stated that drugs which are falling under Clause (b)(i) of Section 3 of Drugs and Cosmetics Act, 1940 not intended for medicinal use are exempted under all the provisions of Chapter IV of the Act. Moreover, Ministry of Health and Family Welfare has clarified that Vitamin B6, Vitamin B12 and Folic Acid fall within the purview of 'Health Supplements'. Therefore, it is amply clear that the said seized product 'ALZIVIT' is 'FOOD' and not a 'DRUG'. Fourthly, there is no report, research paper or any investigation report to support the claim that Alzivit had any kind of side effects which were fatal in nature.

11. It is argued on behalf of the Petitioner in Cr. M. P. No. 1792 of 2020 that accused no.3 is a partnership Firm which runs under the name and style of M/s Tirupati Life Sciences (herein-after accused Firm or petitioner no.3) with operations in Paonta Sahib (H.P.) and is manufacturing food supplements Nutraceuticals under valid licence. It has all necessary licences and valid approvals from the Food Safety and Standards Authority of India (hereinafter FSSAI). M/s Tirupati Group (Hereinafter Parent Entity) engaged in the business of outsourcing its manufacturing activities to all its group entities having appropriate licenses and valid approvals for the products manufactures /marketed under their names.

12. In absence of any test report, all the aforesaid allegations are based merely on surmise and conjecture and no specific overt act has been attributed to the petitioners including M/s Tirupati

Life Sciences, the petitioner no.3 herein.

13. Learned APP for the State has opposed the prayer.

14. At the stage of cognizance the probative value of the materials in support of the allegations made is not to be scrutinized. But the materials should be sufficient to fulfil the ingredients of the offence.

15. Whether seized sample of Alzivit tablets will come under the category of drugs or cosmetics to make out a prima facie case under DCA is the central issue in the instant petition. The second related issue is whether the sample has been seized in conformity to the procedural requirements under Section 23 and Section 25 of the Drugs and Cosmetics Act, 1940.

Section 3(b)(i) of the Drugs and Cosmetics Act, 1940 defines a 'drug' as including 'all medicine for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any diseases or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes."

Section 22(1)(b)(i) of the Food Safety and Standards Act, 2006 deals with the definition of "foods for special dietary uses or functional foods or nutraceuticals or health supplements" and states that a product that is labelled as such ought not to be represented for use as a conventional food. It has been held in Chimanlal Jagjivan Das Sheth v. State of Maharashtra, 1962 SCC OnLine SC 16 The said definition of "drugs" is comprehensive enough to take in not only medicines but also substances intended to be used for or in the treatment of diseases of human beings or animals. Section 25 of the Drugs and Cosmetics Act, 1940 says that the Government Analyst is required to send the test report to the Inspector whereby the Inspector is required to deliver a copy of the report to the person from whom the sample was taken, and retain another copy for use in the prosecution of the sample. None adherence to the procedural requirements is by itself a ground to quash the criminal prosecution as held in Laborate Pharmaceuticals India Ltd. v. State of T.N., (2018) 15 SCC 93

6. A reading of the provisions of Sections 23(4) and 25 of the Act would indicate that in the present case the sample having been taken from the premises of the retailer had to be divided into four portions; one portion is required to be given to the retailer; one portion is required to be sent to the Government Analyst and one to the court and the last one to the manufacturer whose name, particulars, etc. is disclosed under Section 18-A of the Act. In the present case, admittedly, one part of the sample that was required to be sent to the appellant (manufacturer) under Section 23(4)(iii) of the Act was not sent. Instead, what was sent on 22-3-2012 was only the report of the Government Analyst. When the part of the sample was not sent to the manufacturer, the manufacturer could not have got the same analysed even if he wanted to do so and, therefore, it was not in a position to contest the findings of the Government Analyst.

16. It is not in dispute that each container is clearly labelled with the words "NOT FOR MEDICINAL USE". Therefore, seized Alzivit (multi-vitamin) tablet will not come under the definition of drug and is instead covered by Section 22(1)(b)(i) of the Food Safety and Standards Act, 2006.

17. The second issue is pertaining to whether the sample seized has been seized as per the procedural safeguards under Section 23 and Section 25 of the Drugs and Cosmetics Act, 1940. Section 23(4) of the Drugs and Cosmetics Act, 1940 mandates that samples of the drugs should be divided by the drug inspector in four portions and one of the portion is to be sent to the Government Analyst for test or analysis.

18. In the present case there is nothing on record to suggest that sample has been sent to the Government Analyst for test or analysis, and the same is not disputed by the opposite party in the counter-affidavit. It is evident that the procedural safeguards under Section 23 and 25 of the Act were not followed in the present case. Under the aforesaid facts and circumstance of the case it is apparent that in absence of a report of drug analysis, there is no prima facie case that the seized samples came within the category of drugs for which the penal provisions of DCA could apply.

Accordingly, the entire criminal proceeding including the order taking cognizance dated 30.04.2020 passed by learned Addl. Judicial Commissioner- II, Ranchi in connection with Drugs & Cosmetics Case No.2094 of 2015 is quashed so far the petitioners above-named are concerned. Both the aforesaid Cr.M.Ps. are allowed.

(Gautam Kumar Choudhary, J.) Sandeep/ Uploaded.