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CrI.OP.No.729 of 2022

IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 28.11.2023

CORAM:

THE HONOURABLE MR.JUSTICE **G.K.ILANTHIRAIYAN**

CrI.OP.No.729 of 2022

and

CrI.MP.Nos.278 & 280 of 2022

- 1.M/s.Global Ophthalmic Private Limited,
Through its Directors,
Shri.S.Dhandapani, Shri.D.Govindaraji and Shri.N.K.Arumugam,
Factory at Plot No.03, First Main Road, Sri Ramasamaji Nagar Extn,
Vellanoor Village, Ambattur Taluk, Thiruvallur District, Chennai
- 2.S.Dhandapani
- 3.D.Govindaraji
- 4.N.K.Arumugam

... Petitioners

Vs.

Union of India,
Represented by its Drugs Inspector & Medical Devices Officer,
Shri.N.K.Jayasenthil,
Office of the Deputy Drugs Controller(India),
Central Drugs Standard Control Organization,
South Zone, 2nd Floor, Shastri Bhawan Annex,
Chennai 600 006

... Respondents

PRAYER:

Criminal original petition is filed under Section 482 of Cr.P.C. to call for



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all the records and to quash all the proceedings in CC.No.200 of 2021 on the file of the learned Chief Judicial Magistrate, Thiruvallur.

For Petitioners : Mr.A.Nagarajan
for Mr.S.Senthil Murugan

For Respondent : Mr.S.Diwakar,
Central Government Senior Panel Counsel

ORDER

This criminal original petition has been filed to quash the proceedings in CC.No.200 of 2021 on the file of the learned Chief Judicial Magistrate, Thiruvallur, thereby taken cognizance for the offence under Sections 27(c) and 27(d) of Drugs and Cosmetics Act, 1940.

2. The respondent filed complaint for the contravention of Sections 18(a)(i) r/w 17-B(c) and 17(c) punishable under Sections 27(c) and 27(d) of Drugs and Cosmetics Act, 1940 (hereinafter called as 'the Act'). The accused are licenced to manufacture for sale or distribution Intraocular lens(medical devices) under different brand names 'Glovision, Proxylenz, Hema-fold,



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Asprolenz, Accuravue, Hyphoflex and Hyphovue' under the Drugs and

Cosmetics Act in Form No.28 vide licence No.TN 00003111 dated 14.03.2012

valid upto 13.03.2017 issued by the Licencing Authority, Director of Drugs

Control, State of Tamilnadu and approved by the Drugs Controller General

(India), Central Licencing Authority. While pending application for their

renewal of licence, the complaint was received from one, Dhaval K Shukla,

President of United States IOL, Inc. by the email dated 06.08.2018 and

07.08.2018 alleging that the accused has involved in manufacture and selling

the counterfeit versions of their intraocular lenses. On receipt of the said

complaint, joint investigation was conducted in the premises of the accused and

found 482 pieces of US IOL intraocular lenses about which received complaint.

The following brands of intraocular lenses were not licenced to the accused for

manufacture under the licence:

S. No.	Product name	Information on the label	Quantity in No's
1	US IOL One Sterile Intraocular Lens	US IOL Inc. 2500 Sandersville Road, Lexington, Kentucky 40511	482
2	Envision Intraocular Lens	Envision Corporation 1308 Monte Vista Avenue Upland, California 91786, USA	895
3	US Vision Intraocular Lens	US Vision Inc, 1522 Monroe Street, River Forest, IL 60305 (USA), Tele Fax: 708 7719820	283



S. No.	Product name	Information on the label	Quantity in No's
4	Asprolenz-BLF Negative Aspheric Aberration Free Foldable Intraocular Lens	Manufactured for Ophthalmic Medical Inc, 49 S.OAK, AV.Fords, NJ. 08863, USA Neutral Code: TN/DRUGS/TN00003111	778
5	Flexiol Acrylic Foldable Intraocular Lens	Manufactured for US Ocular Devices L.L.C. 16842, Sieera Vista Way, CA 90703, USA Neutral Code: TN/DRGS/TN00003111	2161
6	I focus Intraocular lens	Manufactured for U.S.Optics Inc. 150 Arovista Circle, Brea, CA 92821, USA Neutral Code: TN/DRGS/TN00003111	966

3. The representative of the complainant brought the sample of the product in order to verify the genuineness of the product manufactured by the accused. The investigation officer found the printed packaging materials for three products found stocked which are not permitted for manufacture by the accused. It also observed that the accused did not have manufacturing licence for the above six brands of intraocular lenses as required under Section 18(c) of the Act. They had manufactured spurious products of the six brands of intraocular lenses and it is violation of Sections 18(a)(i) and 17-B of the Act and Rules, 1945. On receipt of the said complaint, the Chief Judicial



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Magistrate, Tiruvallur has taken cognizance in CC.No.200 of 2021 and it is pending for trial.

4. The learned counsel for the petitioners would submit that the petitioners are arrayed as A1 to A4. The impugned prosecution has been initiated on the basis of the complaint submitted by one, Dhaval K Shukla who is none other than a competitor of the petitioners. The main contravention as alleged by the respondent is that the petitioner had no licence to manufacture intraocular lens. They had manufactured spurious and misbranded product. He raised grounds that (i) the trial court i.e. the learned Chief Judicial Magistrate, Tiruvallur has no jurisdiction to take cognizance since the contraventions as alleged by the respondent are triable by the Court of Sessions, (ii) the respondent failed to comply with the mandatory provisions as contemplated under Sections 25(3) & 25(4) of the Act. Accordingly, the respondent ought to have sent before the laboratory and after obtaining report, the petitioners may be given opportunity to refer the product for further analysis before the Central Laboratory. Without even receipt of any report from the Laboratory, the respondent initiated prosecution as against the petitioners and (iii) the petitioner's licence for manufacturing of the products as alleged by the respondent was duly renewed from 14.03.2017 to 13.03.2022 by the



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competent authority. The complaint lodged by the respondent is only based on the report submitted by the petitioner's competitor by name Dhaval K.Shukla representing for US IOL.

5. Heard, the learned counsel appearing on either side.

6. On perusal of the counter, revealed that the petitioners were granted licence only till 13.03.2017 and for renewal of their licence from 14.03.2017, it was pending from the authority. As on date, the Central Licensing Authority, Office of DCG(I) Medical Devices and Invitro-diagnostic Devices Division, CDSCO, Ministry of Health and Family Welfare, Government of India have not notified any authorised testing laboratory for testing / analysis of the intraocular lens. The samples which were seized from the petitioners ought to have been sent for analysis. It is relevant to extract provision under Section 25 of Drugs and Cosmetics Act hereunder:

25 Reports of Government Analysts

(1) The Government Analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.



(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A, and shall retain the third copy for use in any prosecution in respect of the sample.

(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under section 18A has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused: cause the sample of the drug or cosmetic produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or



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analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

(5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct.

7. Thus, it is clear that the samples which have been seized to be sent to the Government Analyst for testing or analysis. On receipt of the report from the analyst, the accused shall be given opportunity to send another sample for testing or analysis by the Central Drugs Laboratory. In the case on hand, admittedly the respondent did not send the products which were seized from the petitioners for analysis. Without doing so, the respondent cannot come to conclusion that the lens which were seized from the petitioners are spurious and misbranded. The said conclusion was arrived at only by comparison, that too by the competitor Dhaval K.Shukla from US IOL. Further, admittedly the license of the petitioners was duly renewed from 14.03.2017 to 13.03.2022. Therefore, they had valid licence at the time of seizure of the products from the petitioners to manufacture under the drugs other than those specified in Schedule C, C(1) and X. As stated supra, as per Section 52 in the Drugs and



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Cosmetics Rules, 1945, the Drug Inspector shall have to take samples manufactured on the premises and send them for testing or analysis in accordance with these rules. Admittedly no samples were sent to any laboratory for testing or analysis. Insofar as the ground raised by the petitioner that the Chief Judicial Magistrate, Tiruvallur has no jurisdiction to try the complaint lodged by the respondent, it is relevant to extract provision under Section 32 of the Drugs and Cosmetics Act hereunder:

32 Cognizance of offences

(1) No prosecution under this Chapter shall be instituted except by—

(a) an Inspector; or

(b) any gazetted officer of the Central Government or a State Government authorised in writing in this behalf by the Central Government or a State Government by a general or special order made in this behalf by that Government; or

(c) the person aggrieved; or

(d) a recognised consumer association whether such person is a member of that association or not.

(2) Save as otherwise provided in this Act, no court inferior to that of a Court of Session shall try an offence punishable under this Chapter.]



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(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence against this Chapter.

8. Therefore, the contravention of Sections 18(a)(i) r/w 17-B of the Act as alleged by the respondent is coming under Chapter IV of the Act. Hence, no court inferior to that of a Court of Sessions shall try the offence punishable under this Chapter. This Court already held in respect this issue that though the learned Magistrate entertained the complaint and had taken cognizance, it shall be tried only by Court of Sessions. Therefore, the learned Magistrate has got jurisdiction to take the complaint on file and after taking cognizance, the same shall be made over before the competent jurisdictional court i.e. Court of Sessions for trial. Therefore, this ground is answered against the petitioners.

9. In view of the above discussion, no prosecution can be lodged as against the petitioners since no contravention committed by the petitioners. Accordingly, the entire proceedings in CC.No.200 of 2021 on the file of the learned Chief Judicial Magistrate, Thiruvallur is quashed and this criminal original petition is allowed. Consequently, connected miscellaneous petitions are closed.



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G.K.ILANTHIRAIYAN, J.

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