



W.P.Nos.15460 and 15463 of 2021

IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 16.04.2024

CORAM :

THE HONOURABLE MR. JUSTICE G.K.ILANTHIRAIYAN

W.P.Nos.15460 and 15463 of 2021 and
W.M.P.Nos.16395, 16396, 16397 and 16389 of 2021

M/s.GlaxoSmithKline Pharmaceuticals Limited,
Represented through its
Power of Attorney holder,
Rajgopal Bhutada,
Dr.Annie Besant Road,
Worli, Mumbai – 400 030

Also at,
Southern portion of ground and first floor,
No.144, Poonamallee,
High Road, Valappanchavadi,
Chennai – 600 077

...Petitioner in
both WPs

-Vs-

1.The Senior Drug Inspector,
Office of the Drug Control Department,
Tiruvallure Zone,
Tiruvallore – 602 003
Tamil Nadu.

2.The Commissioner of Food Safety,

1/12



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Food Safety and Drug Administration Department,
Tamil Nadu,
Office of the Commissioner of Food Safety,
5th Floor, DMS Office Building,
259, Anna Salai, DMS Campus,
Teynampet, Chennai – 600 006

3.The State of Tamil Nadu,
Represented by its Secretary,
Department of Health and Family Welfare,
Fort St.George, Chennai – 600 009

4.Orchid Pharma Limited,
Orchid Towers,
313, Valluvarkottam High Road,
Nungambakkam, Chennai – 600 034

...Respondents in
both WPs

Prayer in W.P.No.15460 of 2021: Writ Petition filed under Article 226 of the Constitution of India for issuance of a Writ of Certiorari calling for the records of the respondent No.1 comprised in order dated 1st July 2021 in Form 15 and to quash the same as illegal, arbitrary and violative of the fundamental rights of the petitioner.

Prayer in W.P.No.15463 of 2021: Writ Petition filed under Article 226 of the Constitution of India for issuance of a Writ of Certiorarified Mandamus calling for the records of the respondent No.1 in order dated 14th July 2021 in Form 16 and quash the same as illegal, arbitrary and violative of the fundamental rights of the petitioner and consequently quash the memo dated 14th July 2021 issued by the respondent No.1 and consequently direct the



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respondent No.1 to handover the subject drugs to the petitioner.

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For petitioner
(in both WPs)

: Mr.Sathish Parasaran
Senior Counsel for
M/s.Arva Merchant

For Respondents 1 to 3
(in both WPs)

: Mr.P.Kumaresan
Additional Advocate General
assisted by Mr.E.Sundaram
Government Advocate

COMMON ORDER

These writ petitions have been filed challenging the order passed by the first respondent dated 01.07.2021 and 14.07.2021 thereby ordered not to disburse the stocks which are in petitioners possession for a period of 20 days from the date of the order dated 01.07.2021 and thereby seized the stock of drugs under section 22(1) (c) of the Drugs and Cosmetics Act, 1940 from the premises of the petitioner.

2. The petitioner engaged in the business of manufacturing and marketing several drugs, including, amongst others, manufacturing and marketing of various fixed dose combinations. The 4th respondent company operates across segments like anti-infectives, anti-inflammatory, central



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nervous system (CNS), Cardio-Vascular segment (CVS), nutraceuticals and other oral and sterile products. The 4th respondent obtained manufacturing license in Form 28 for manufacture of various drugs. Under license bearing No.696 of 2001 for a period of five years till 01.01.2008. The license was described as M/s.Orchid Health care (a division of Orchid Chemicals & Pharmaceuticals Limited). Accordingly, manufacturing of licensed drugs is to be carried out by the 4th respondent at the premises bearing No.B-77, SIDCO Industrial Estate, Alatchur, Kanchipuram District. Subsequently the said license was renewed till 01.01.2023. The petitioner had executed the Loan License Agreement with the 4th respondent on 05.09.2013 and thereby 4th respondent agreed to manufacture certain drugs for and on behalf of the petitioner as per the standards and specifications of the petitioner and in accordance with the manufacturing instructions and standard operating procedure of the petitioner. The terms of the Loan Licensed Agreement was extended from time to time and it was valid till 09.07.2021. Thereafter, a fresh loan agreement was executed between the petitioner and the 4th respondent on 15.07.2021 for the period till 09.07.2024. Thereafter, the petitioner obtained a loan license in Form-28A



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dated 21.04.2014. By virtue of the said license, the petitioner was granted loan license to manufacture certain drugs on the premises of the 4th respondent. The Loan License also authorized the manufacture for sale by way of wholesale dealing by the petitioner for storage for sale by the petitioner. The loan license was extended for further period of five year on 01.03.2019 on payment of retention fees. While being so, in the year 2016 the name of the 4th respondent was changed from 'Orchid Chemicals & Pharmaceuticals Limited to 'Orchid Pharma Limited'. It was also carried out in the license of the 4th respondent and the Loan License of the petitioner. On 01.07.2021, the first respondent inspected the petitioner's premises and passed an order in Form 15 under section 22(1)(c) of the Drugs and Cosmetics Act requiring the petitioner not to dispose certain drugs lying at the petitioner's premises contravention of Section 18 of Drugs and Cosmetics Act. Subsequently, order in Form 15 dated 01.07.2021, was valid only for a period of twenty days from the date of the issue thereof. Those drugs were seized by the first respondent under section 22(1)(c) of the Act from the petitioner's premises.



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3. The learned senior counsel appearing on behalf of the petitioner submitted that the petitioner came to know about the reasons for Form 15 dated 01.07.2021, there has been a change in the constitution of the petitioner and despite such change, the petitioner has not obtained a fresh license in the name of the petitioner with the changed constitution. As a result, the change in the constitution of the 4th respondent and basis the fresh license issued to the 4th respondent due to change in constitution, the petitioner ought to have applied for a fresh license as well. Though, the petitioner submitted detailed representation to the 1st respondent explaining that there had been no change in the constitution of the petitioner operating under the Loan License with respect to the drug manufacturing premises or the license number or the name of the entity in the Form 28 issued to the 4th respondent as fresh license. Therefore, the petitioner did not violated any provisions of the Drugs and Cosmetics Act. There has been no change in the constitution of the petitioner. There is some facts in relation to the change in constitution of the 4th respondent. A petition was filed for declaring the 4th respondent as insolvent was filed before the National



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Company Law Tribunal and the same was allowed and an interim resolution professional was appointed to take charge of the erstwhile management of the 4th respondent. Thereby corporate Insolvency Resolution Process (CIRP) was initiated against the 4th respondent. The National Company Law Tribunal by an order dated 27.06.2019 the resolution plan submitted by M/s.Dhanuka Laboratories Limited, which was approved by the Committee of Creditors and held to be in compliance of Section 30(2) of the Indian Bankruptcy Code. The said order was challenged before the National Company Law Appellate Tribunal. The NCLAT passed an order dated 13.11.2019 and allowed the appeal and set aside the order passed by the NCLT. Thereafter, it was challenged before the Hon'ble Supreme Court of India. The Hon'ble Supreme Court of India passed an order dated 28.02.2020 thereby allowed the appeal and set aside the NCLAT's judgment dated 13.11.2019, thus, upholding the Resolution Plan submitted by M/s.Dhanuka Laboratories Limited. Therefore, the board of Directors of the 4th respondent was reconstituted and change in the shareholding pattern of the 4th respondent had also taken place. Further M/s.Dhanuka Laboratories Limited became major shareholder of the 4th respondent. In



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pursuant to the change in constitution, the 4th respondent informed the same to the respondents 1 to 3 and on inspection the license in form 28 was granted on 28.12.2020. Though, it does not require any fresh license. Without prejudice, the petitioner obtained fresh license.

4. The learned Additional Advocate General appearing for the respondents 1 to 3 filed counter and submitted that the 4th respondent was granted license in Form 28 in the premises situated at B-77, SIDCO Industrial Estate, Alathur, Kancheepuram District. Due to change of constitution, the 4th respondent was issued fresh license in Form 28 with effect from 31.03.2020. Due to change in constitution, the license which was granted to the 4th respondent was canceled by an order dated 28.12.2020. On 01.07.2021, an inspection was carried out at the petitioner's premises and noted that the 4th respondent was granted a fresh manufacturing license in Form 28 dated 02.01.2003 by canceling the previous license as a result the license issued by the petitioner Form 28A dated 21.04.2013 is deemed to be canceled as per Rule 78A(1) of the Drugs and Cosmetics Act, 1940. Since change in constitution of the 4th



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respondent was made due to petition filed before the NCLT for declaring the 4th respondent as Insolvent under Insolvency and Bankruptcy Code, 2016.

In pursuant to which M/s.Dhanuka Laboratories Limited submitted resolution plan and the same was approved, due to which the said concerned became a major shareholder and accordingly the change in constitution of 4th respondent had taken place on implementation of the resolution plan. Therefore, the petitioner did not apply for fresh license, since the previous license of the principal manufacture was canceled due to the change in constitution and granted a fresh license in Form 28(A).

5. Though, the petitioner submitted detailed representation explaining the above said position, the first respondent failed to consider and seized the drugs which were ordered not to disburse for 20 days and subsequently seized all the drugs which were not allowed to disburse. That apart, the petitioner was not given any opportunity of personal hearing before issuance of Form 16 dated 14.07.2021. Further, the license of Form 28A is completely independent and the petitioner's license has been issued under Rule 76-A of the Drugs Rules. Rule 76 and Rule 76A are independent



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provisions and a license issued by petitioner and the 4th respondent under these provisions are not connected with each other. Therefore, upon constitution of 4th respondent, the 4th respondent only to require obtain fresh license with the change in constitution. Therefore, no license is required to be obtain by the petitioner.

6. In view of the above, the impugned order passed by the first respondent dated 01.07.2021 and 14.07.2021 cannot be sustained and liable to be quashed. Accordingly, the impugned order passed by the first respondent dated 01.07.2021 and 14.07.2021 are quashed. Accordingly, these writ petitions are allowed. Consequently, connected miscellaneous petitions are allowed. No costs.

16.04.2024

Index : Yes/No
Speaking/Non-Speaking order
Neutral Citation : Yes/No
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- 2.The Commissioner of Food Safety,
Food Safety and Drug Administration Department,
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- 3.The Secretary,
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Fort St.George, Chennai – 600 009



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