

IN THE HIGH COURT OF JUDICATURE AT PATNA
Civil Writ Jurisdiction Case No.17257 of 2017

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1. M/s Omega Biotech Limited, 1608 Dewan Hall Building Bhagirath Place, Delhi- 110006 having its manufacturing unit at 7th Mile Stone Saliyar, Dehradun Road, Roorkee, Uttrakhand-247667 through its authorized Power of Attorney Holder, Sri Shahi Ranjan Singh, S/o Sri Binod Prasad Singh, residing at Mohanpur, Near Devi Asthan Mandir, Punaichak, P.S.- Shastri Nagar, Patna- 23.
 2. Sashi Ranjan Singh, S/o Sri Binod Prasad Singh, Residing at Mohanpur, Near Devi Asthan Mandir, Punaichak, P.S.- Shastri Nagar, Patna- 23, authorized Power of Attorney Holder of M/s Omega Biotech Limited.

... .. Petitioner/s

Versus

1. The State of Bihar.
2. The Principal Secretary, Health Department, of Bihar, Patna.
3. The Drug Controller, Bihar, Patna.
4. The Bihar Medical Services and Infrastructure Corporation Ltd. through its Managing Director, 5th Floor, Biscoman Bhawan, Gandhi Maidan, Patna- 1.
5. The Managing Director, Bihar Medical Services and Infrastructure Corporation Ltd., 5th Floor, Biscoman Bhawan, Gandhi Maidan, Patna- 1.
6. The General Manager (Proc), Bihar Medical Services and Infrastructure Corporation Ltd. Floor, Biscoman Bhawan, Gandhi Maidan, Patna- 1.

... .. Respondent/s

with

Civil Writ Jurisdiction Case No. 16089 of 2017

Bihar Drugs And Pharmaceutical Manufacturer Association Through Its President Sanjiv Rai having its Office Jeskay Pharmo-Chem Private Limited, Opposite Karlo Automobiles, Boring Road, P.S.-S.K. Puri, District-Patna-800001.

... .. Petitioner/s

Versus

1. The State of Bihar through the Chief Seretary, Bihar, Patna.
2. The Principal Secretary, Department of Health, Bihar, Patna
3. The State Drugs Controler, Bihar, Patna.

... .. Respondent/s

Appearance :

(In Civil Writ Jurisdiction Case No. 17257 of 2017)

For the Petitioner/s : Mr. Rajeev Kumar Singh, Adv.
Mr. Sita Ram Prasad, Adv.

For the Respondent/s : Mr. AC to GA10

For Respondents 4,5 & 6 : Mr. Prabhat Kumar Singh, Adv.

(In Civil Writ Jurisdiction Case No. 16089 of 2017)

For the Petitioner/s : Mr. Shekhar Singh, Adv.
Mr. Sumit Kumar. Adv.
Mr. Satyendra Rai, Adv.

For the State : Mr. Aditya Nath Jha, AC to SC -18

For Intervenors : Mr. Vishwajeet Kumar Mishra, Adv.

CORAM: HONOURABLE JUSTICE SMT. NILU AGRAWAL
ORAL ORDER

5 25-07-2018

Heard learned counsel for the petitioners, learned



counsel appearing on behalf of the Respondent- Bihar Medical Services and Infrastructure Corporation Limited (hereinafter referred to as the BMSICL) as well as the State of Bihar.

An intervenor application has been filed by a NGO which is I.A. No. 9401 of 2017 in CWJC No. 16089 of 2017 in support of the Memo No. 857 (15) dated 07.09.2017 issued by the State Drug Controller Bihar, Patna.

Considering the nature of the relief sought for, I.A. No. 9401 of 2017 is allowed and be treated as part of the writ application.

For the sake of convenience, CWJC No. 17257 of 2017 is taken up first. I.A. No. 8899/17 has been filed in which challenge has been put to letter no. 3147 issued by the BMSICL dated 25.11.2017 as contained in Annexure-10 by which the Corporation has stopped supply, sale-purchase, stock and distribution of supply of Ofloxacin Oral Suspension IP in pursuance to the order dated 07.09.2017 and to take back all unused medicines. I.A. No. 8899/17 is allowed.

Petitioners have prayed for the following reliefs:

“(a) To quash the order contained in memo no. 857 dated 07.09.2017 issued by the Drug Controller, Bihar (Resp. No.-3), so far it relates to Ofloxacin, whereby and where under, he has issued direction that sale-purchase, stock,



use and distribution of Ofloxacin for pediatric use has been banned with immediate effect. A copy of memo dated 07.09.2017 is annexed as ANNEXURE-1 to this application.

(b) To direct the respondents, especially respondent No.-4 to 6, to accept the supply of Ofloxacin oral suspension IP for which purchase order has issued in favour of petitioner pursuant to Tender Notice No-BMSICL/DRUGS/1505 and accordingly pay the amount as well as per the agreement.

(c) To direct the respondent to pay the amount of the Ofloxacin oral suspension IP which has already been supplied to respondents no.- 4to 6 pursuant to the order dated 11.08.2017 issued in favour of petitioner.”

The petitioners have also challenged letter no. 3147 dated 25.11.2017 which is consequential to the order dated 07.09.2017 issued by BMSICL which is challenged in IA No. 8899/17.

Petitioners in CWJC No. 17257 of 2017 have challenged the order issued by the Drug Controller, Bihar Patna vide Memo No. 857 dated 07.09.2017 by which restrictions have been imposed not to offer for sale-purchase, stock and distribution of medicines formulation of Levofloxacin and Ofloxacin meant for paediatric use. Petitioners have challenged



the subsequent order issued by Letter No. BMSIC/55035/01-2017/3147 dated 25.11.2017, Annexure-10 to I.A. No. 8899 of 2017 by which petitioners have been asked to stop sale-purchase, stock, use and distribution of Levofloxacin and Ofloxacin and directed to take back all the unused Ofloxacin Oral Suspension IP and not to supply the remaining Ofloxacin Oral Suspension IP.

Facts of the case is that the petitioners was issued a letter of intent by the Respondent- BMSICL vide letter dated 06.03.2017, Annexure-3 and supply orders vide Supply Order No. BMSIC/40020/05-2017/1664, Annexure-8 was placed for supply of 14 types of drugs including Ofloxacin Oral Suspension IP. Supplies were made in pursuance to purchase order dated 27.03.2017, 12.04.2017 and 11.08.2017 (Annexures- 6 to 8) and in pursuance to the agreement dated 27.03.2017, Annexure-5.

Learned counsel for the petitioners submits that all of a sudden the said Drug Controller issued the impugned order dated 07.09.2017, Annexure-1 and such restrictions and constraints imposed is not as per the mandatory requirement under Section 18 of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the Act). He submits that the order



dated 07.09.2017 has already been quashed by a co-ordinate Bench of this Court in CWJC No. 4422 of 2018 vide order dated 07.05.2018. He further submits that Annexure-10 dated 25.11.2017, which has been issued by Respondent No. 4-BMSICL is also not as per the mandatory requirement as the State Government by notification in the official gazette in this behalf can impose such restrictions and constraints. He submits that the said order dated 25.11.2017 impugned as Annexure-10 has been issued in pursuance to the Memo No. 857 (15) dated 07.09.2017, without such notification by the State Government in the official gazette which is not in consonance with the mandatory requirements under Section 18 of the Act, which is extracted below:

“18. Prohibition of manufacture and sale of certain drugs and cosmetics.- From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—

(a) [manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,] or distribute-

[(i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;



[(ii) any cosmetic which is not a standard quality, or is misbranded, adulterated or spurious;]

[(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof [the true formula or list of active ingredients contained in it together with the quantities, thereof];]

(iv) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims [to prevent, cure or mitigate] any such disease or ailment, or to have any such other effect as may be prescribed;

(v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;]

(b) [sell, or stock or exhibit or offer for sale,] or distribute any drug [or cosmetic] which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

(c) [manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,] or distribute any drug [or cosmetic], except under, and in accordance with the conditions of, a license issued for such purpose under this



Chapter:

Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:

Provided further that the [Central Government] may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the [manufacture for sale or for distribution, sale, stocking or exhibiting or offering for sale] or distribution of any drug or class of drugs not being of standard quality.”

Considering that the order passed by the Drug Controller dated 07.09.2017 has already been quashed by this Court in CWJC No. 4422 of 2018 dated 07.05.2018, Annexure-1 is quashed. Annexure-10 is also quashed as the mandatory requirements of Section 18 of the Act has not been followed.

The State Government is at liberty to issue necessary notification in terms of Section 18 of the Act, if so advised.

Respondent -BMSICL is directed to make payment of supplies already made by the petitioners.

It goes without saying that whatever supplies have



been made by the petitioners, they are entitled for payment of the same within a period of three months from the date of receipt of a copy of this order. The security amount which has been deposited with regard to the Drug in question i.e. Ofloxacin Oral Suspension IP would also be returned to the petitioners.

In CWJC No. 16089 of 2017 the petitioner as an association has challenged Memo No. 857 (15) dated 07.09.2017 which has already been quashed by this Court in CWJC No. 4422 of 2018 vide order dated 07.05.2018.

Thus, CWJC No. 16089 of 2017 is allowed in terms of the order dated 07.05.2018 passed in CWJC No. 4422 of 2018.

Both the writ applications are allowed.

(Nilu Agrawal, J)

Arjun/Pragya

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