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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

+ W.P.(C) 3273/2019 and CM Nos. 15056/2019 & 15057/2019

BIOCON LTD

..... Petitioner

Through: Mr K. Datta, Mr Ashish Verma and
Mr Arnav Sanyal, advocate.

versus

UNION OF INDIA & ORS

..... Respondents

Through: Mr Ashim Sood, CGSC and Mr Tarun
Krishnakumar, Advocates for R-1, 2
and 3.

CORAM:

HON'BLE MR. JUSTICE VIBHU BAKHRU

ORDER

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03.04.2019

1. The petitioner has filed the present petition, *inter alia*, impugning an order dated 22.02.2019 (No. 31015/40/2018- hereafter the 'impugned order') passed by respondent no.1, rejecting the petitioner's review petition filed under paragraph 31 of the Drugs (Price Control) Order, 2013 (hereafter 'the DPCO'). The petitioner had preferred the aforesaid review petition against the notification dated 23.11.2017, bearing SO No. 3727 (E), issued by the National Pharmaceutical Pricing Authority (NPPA), fixing the retail price of the drugs, 'Blistro Trio 1', containing Metformin Hcl (SR/ER/PR) 500 + Voglibose 0.2 mg + Glimepride 1mg tablet and 'Blistro Trio 2', containing Metformin Hcl (SR/ER/PR) 500+Voglibose 0.2mg+Glimepride 2mg tablet.

2. The petitioner has also impugned the demand notices dated 08.06.2018 and 25.05.2018, whereby the petitioner was called upon to pay sums of ₹42,61,555/- and ₹67,63,579/-, as the amounts allegedly

overcharged by the petitioner, inclusive of penalty and interest.

3. The drugs in question – ‘Blistro Trio 1’ and ‘Blistro Trio 2’ –are manufactured by Hetero Labs Limited. The petitioner had entered into an agreement with Hetero Labs Ltd. for marketing and distribution of the said drugs and has been marketing the same pursuant to the said agreement.

4. None of the components of the drugs in question, namely, Metformin Hcl (SR/ER/PR) 500, Voglibose and Glimepride were listed in the National List of Essential Medicines - 2011 (NLEM-2011) and, therefore, were not scheduled formulations. However, Metformin in the conventional form was listed in NLEM-2011, and was a ‘scheduled formulation’.

5. The petitioner states that Hetero Labs Ltd. had obtained an approval on 27.03.2014, in Form I as per paragraph 15 of the DPCO, in respect of the formulations in question. The said approval was granted vide the notifications [S.O. No. 936 (E) and S.O. No. 938(E)], dated 27.03.2014.

6. The petitioner received show cause notices alleging that the petitioner had launched the drugs in question, without obtaining prior approval under the DPCO. The said show cause notices were premised on the basis that the drugs in question were new drugs within the meaning of paragraph 2(u) of the DPCO, and the petitioner required a prior approval under paragraph 15 of the DPCO. It is the petitioner’s case that Metformin Hcl (SR/ER/PR) 500 was not a scheduled formulation at the material time, since it was not included in NLEM-2011, which was incorporated as Schedule-I to the DPCO. According to the respondents, since Metformin in the conventional form was included in the NLEM-2011, all other dosage forms of the said

medicine would also fall within the definition of a scheduled formulation under the DPCO.

7. Concededly, the aforesaid issue is squarely covered in favour of the petitioner by an earlier judgment of this Court in *Sanofi India Ltd. and Anr. v. Union of India and Ors.: W.P.(C) 7589/2018 & other connected matters*, decided on 20.03.2019.

8. In view of the above, the present petition is allowed and the impugned order dated 22.02.2019, and the impugned demand notices dated 08.06.2018 and 25.05.2018 are set aside.

9. All pending applications are also disposed of.

VIBHU BAKHRU, J

APRIL 03, 2019
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