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

\+ **W.P.(C) 10837/2017 and CM APPL. 44445/2017**

INTAS PHARMACEUTICALS LIMITED AND ANR. ..... Petitioners

Through: Mr Akhil Sibal, Senior Advocate with Mr Rishi Agarwala, Mr Pradeep Chindra, Mr Parminder Singh, Mr Parinay T. Vasandani, Ms Aarushi Tiku, Advocates.

versus

UNION OF INDIA AND ANR. ..... Respondents

Through: Mr Dev P. Bhardwaj, CGSC for UOI.

CORAM:
HON'BLE MR. JUSTICE VIBHU BAKHRU

O R D E R

% 12.04.2019

1. The petitioners have filed the present petition, *inter alia*, impugning an order dated 07/13.11.2017, whereby the petitioners have been called upon to pay a sum of ₹61,72,373/- on account of the price overcharged by the petitioners in respect of its formulation 'Cloba MT 5 mg tablets' containing Clobazam-5mg. The said amount is inclusive of interest calculated up to 30.11.2017. The petitioners also impugn an order dated 27.12.2017 passed by the National Pharmaceuticals Pricing Authority (hereafter 'NPPA'), whereby the petitioners' contention that the drug 'Cloba MT 5mg' is outside the purview of the Drugs (Price Control) Order, 2013 (hereafter 'DPCO-2013'), was rejected.

2. Although, Clobazam 5mg is a scheduled formulation and is included in the National List of Essential Medicines 2015 – which is

incorporated as Scheduled-I to the DPCO-2013 – the petitioner claims that its drug has a novel delivery system, inasmuch as, it is a mouth dissolving tablet (MDT). It is claimed that MDT formulations cater to specific needs of geriatric patients who have difficulties in swallowing or have dysphagia or risk of chocking or hand tremors and deterioration in eye-sight, hearing, memory etc. The petitioners claim that its drug is inherently unique and is completely distinct and different from the conventional Clobazam tablet.

3. The petitioner relies on Explanation (2) to Schedule-I of the DPCO-2013 and contends that by virtue of the said explanation, novel drug delivery systems are not to be considered as included in Schedule-I of DPCO-2013, if the same are not specifically mentioned. It is stated that Schedule-I only includes the conventional form of Clobazam and not the MDT version of the said formulation.

4. The learned counsel appearing for the parties state that the present controversy is covered by the decision of this Court in ***Intas Pharmaceuticals Limited and Anr. v. Union of India and Anr.: W.P.(C) 1257/2018, decided on 17.09.2018.*** The said decision was rendered in the context of a drug 'Ceftas 400 Tablet'. Although, the said drug contained Cefixime which is a scheduled formulation, the petitioner claimed that 'Ceftas 400' is a disbursable tablet which is a novel formulation completely distinct and separate from the conventional Cefixime tablet.

5. The operative part of the said decision is set out below:-

> "32. A plain reading of the impugned order indicates that

NPPA has proceeded on the basis that irrespective of the incremental innovation or the novelty of the drug delivery system, all versions of the formulations would be included. As noticed above, this contention is unsustainable. This is also the view expressed by this Court in ***Modi-Mundipharma Pvt. Ltd. v. Union of India & Ors: W.P.(C) 11802/2016, decided on 17.07.2018*** and ***Indoco Remedies Limited v. Union of India and Anr: W.P.(C) 7597/2018, decided on 26.07.2018***.

33. In this view, NPPA has not proceeded to examine whether the petitioner's claim that Ceftas is a novel formulation and totally different, distinct and separate from the conventional Cefixime tablets. NPPA has not examined whether it is a significant improvement, developed through innovative technology, over the conventional Cefixime 400mg tablet.

34. This Court is of the view that it would be necessary for the NPPA to examine these aspects in order to determine whether Ceftas is included in Schedule-I of DPCO-2013.

35. The import of Explanation (2) to Schedule-I of the DPCO-2013 is to clarify that medicines, which have added qualities and attributes that are substantial enough to render the said medicine dissimilar to the one entered in Schedule-I of DPCO-2013 are excluded from the scope of Schedule-I. It would, thus, be essential for NPPA to also examine whether the different delivery system (as claimed by INTAS) is a substantial improvement with significant therapeutic advantages so as to consider the product materially different from a conventional version. Clearly, minor changes or minor improvements would not be sufficient to exclude such formulations from Schedule-I of the DPCO- 2013.

36. In view of the above, the impugned order is set aside and the matter is remanded to the NPPA to consider afresh in the light of the observations made herein. The pending

application also stands disposed of."

6. In view of the above, the impugned orders dated 7/13.11.2017 and 27.12.2017 are set aside and the matter is remanded to NPPA to consider it afresh in the light of the observations made in ***Intas Pharmaceuticals Limited and Anr***. (*supra*).

7. The pending application is disposed of.

8. The parties are left to bear their own costs.

VIBHU BAKHRU, J

APRIL 12, 2019
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