IN THE HIGH COURT OF DELHI AT NEW DELHI

% Judgment delivered on: 17.09.2018

\+ **W.P. (C) 1257/2018 & CM No. 5226/2018**

INTAS PHARMACEUTICALS LIMITED & ANR ...Petitioners

Versus

UNION OF INDIA & ANR ...Respondents

Advocates who appeared in this case:

For the Petitioners :Mr Akhil Sibal, Senior Advocate with Mr Shamik Bhatt and Mr Parminder Singh.

For the Respondents :Mr Ravi Prakash, CGSC and Mr Nitish Gupta and Ms Anshula.

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HON'BLE MR JUSTICE VIBHU BAKHRU

JUDGMENT

VIBHU BAKHRU, J

1. The petitioners have filed the present petition under Article 226 of the Constitution of India, *inter alia*, impugning an order dated 16.01.2018 (hereafter 'the impugned order') passed by the National Pharmaceuticals Pricing Authority (hereafter 'NPPA') demanding a sum of ₹86,66,045/- (₹73,58,964/- as overcharged amount plus ₹13,07,081/- as interest till 31.01.2018). The said demand is founded on the basis that petitioner no.1 (hereafter 'INTAS') has manufactured and sold its product, Ceftas 400 Tablets (hereafter referred to as 'Ceftas') at a price in excess of the ceiling price fixed for Cefixime 400 mg tablets. The said demand relates to sales made during the

period April 2016 to September 2017.

2. Schedule-I of the Drugs (Price Control) Order, 2013 (hereafter 'DPCO-2013') includes Cefixime 400 mg tablets. INTAS claims that even though Ceftas contains Cefixime 400 mg, it is not included in Schedule-I to the DPCO-2013 and is not a *'scheduled formulation'*. INTAS claims that this is so because Ceftas 400 is a Dispersible tablet, which is a "*novel formulation, completely distinct and seperate from the conventional/plain Cefixime tablets"*.

3. Thus, the principal controversy involved in the present case is whether Ceftas 400 – which is admittedly a dispersible tablet (DT formulation) containing Cefixime 400 mg – is included within the relevant entry relating to Cefixime in Schedule – I to the DPCO-2013 read with the explanation (2) to the said schedule.

Factual Background

4. INTAS – a pharmaceutical company – was incorporated under the Companies Act, 1956 and is, *inter alia*, engaged in manufacturing and marketing pharmaceutical products.

5. INTAS manufactures a pharmaceutical product – Ceftas 400 mg Tablet – which is a dispersible formulation. The Active Pharmaceutical Ingredient (API) in the product is 'Cefixime', which is a semisynthetic cephalosporin antibacterial drug for treating bacterial infections of urinary tract, skin and soft tissue, ear, bone, blood etc. It is also used to prevent infections after surgery.

6. DPCO-2013 is issued by the Central Government under Section 3 of the Essential Commodities Act, 1955. It provides the list of price controlled drugs, procedure for fixation of price of drugs, method of implementation of prices. The National List of Essential Medicines, 2015 (hereafter 'NLEM 2015') is included as Schedule-I to the DPCO-2013.

7. On 29.03.2016, NPPA issued a notification bearing S.O. No. 1254(E) in exercise of its powers under the DPCO-2013 revising the ceiling price of Cefixime-400 mg to ₹20.48 per tablet. This was further revised to ₹20.88 per tablet with effect from 01.04.2017 by a notification dated 1.04.2017. Thereafter, by a notification dated 30.06.2017, the same was reduced to ₹20.02 per tablet.

8. On 04.08.2017, NPPA issued a notice to INTAS alleging that INTAS was not following the prices fixed under notification bearing S.O. No. 1039(E) dated 01.04.2017 in relation to Ceftas 400 mg Tablet.

9. By the said notice, INTAS was directed to furnish quantitative details in respect of Ceftas 400 duly certified by a Chartered/Cost Accountant. The respondents claim that INTAS failed to comply with the said notice and did not provide the data as required.

10. On 18.08.2017, NPPA issued a show cause notice alleging that INTAS has overcharged an amount of ₹62,54,252/- for its formulation, Ceftas 400 and calling upon INTAS as to why action should not be taken against it for charging in excess of the ceiling

price. This amount alleged to have been overcharged was determined on the basis that INTAS had charged a price of ₹122/- for 5 tablets against the ceiling price of ₹20.48/- for 1 tablet (that is, ₹102.40/- for 5 tablets on pro-rata basis from 01.04.2016) for the period April, 2016 till June, 2017.

11. On 24.08.2017, INTAS responded to the notice dated 04.08.2017 issued by NPPA stating that Ceftas 400 is a dispersible formulation and is different from the conventional Cefixime 400 mg Tablet. It claimed that Ceftas is not covered under the ceiling price fixed vide notification dated 01.04.2017; therefore, it should be treated separately. Thereafter, on 01.09.2017, INTAS responded to the show cause notice dated 18.08.2017 reiterating its stand that Ceftas 400 was distinct from the Cefixime 400 mg Tablet and is not covered under various notifications issued by NPPA.

12. NPPA did not accept the aforesaid contention and, on 06/09.11.2017, issued a Demand Notice to INTAS demanding ₹84,78,542/- on account of overcharged amount alongwith interest within thirty days from the receipt of the aforesaid notice.

13. Aggrieved by the aforesaid Demand Notice, the petitioners filed a Writ Petition (bearing no. W.P.(C) 11072/2017 in this Court, *inter alia*, complaining that INTAS was not afforded an opportunity to be heard. The said petition was disposed of by an order dated 13.12.2017 setting aside the impugned demand notice dated 06/09.11.2017 and further directing NPPA to decide afresh after affording the petitioners

a hearing.

14. In compliance with the aforesaid order, NPPA issued a notice dated 14.12.2017 calling upon INTAS for a hearing on 27.12.2017. Thereafter, representatives of INTAS appeared before the NPPA and submitted written submissions on their behalf contending that the product (Ceftas 400 mg) is not a scheduled formulation.

15. NPPA rejected the aforesaid submission made on behalf of INTAS and raised a demand of ₹86,66,045/- on account of the amount charged by INTAS in excess of the maximum permissible price for the drug in question.

Submissions

16. The petitioners have assailed the impugned order, essentially, on two grounds. First, that the pharmaceutical drug – Ceftas 400 mg Tablet – manufactured by INTAS does not fall within the scope of Schedule-I to DPCO-2013 as Ceftas is a dispersible tablet and distinct from the conventional Cefixime 400 mg tablet. It is submitted by the learned counsel for the petitioners that only the conventional Cefixime tablets (200 mg and 400 mg) are included in Schedule-I to the DPCO-2013. It was further contended that the ceiling price fixed under DPCO-2013 cannot be determined on the basis of API, but can only be done for a formulation notified under Schedule-I to DPCO-2013. If a particular formulation is covered under Schedule-I to DPCO-2013, it would not necessarily imply that other formulations having the same API are also deemed to be included under Schedule-I to DPCO-2013.

17. Second, it is submitted by the learned counsel for the petitioners that dispersible Ceftas tablet is a non-scheduled formulation, and therefore ceiling price for the said formulation cannot be fixed. In any event the price fixed for conventional Cefixime tablets cannot be applied to dispersible Ceftas tablets, as Ceftas 400 mg Tablet is a unique, novel, distinct and separate product from Cefixime 400 mg Tablet and has novel drug delivery system.

18. The respondents contested the aforesaid submissions advanced on behalf of the petitioners. The learned counsel for the respondents submitted that INTAS was not following the ceiling price fixed by NPPA and was selling their product at a higher price. INTAS was charging an amount of ₹122.00/- for five tablets against the ceiling price of ₹102.10/- for five tablets (that is, ₹20.48/- per tablet) fixed vide notification dated 29.03.2016.

19. It is also submitted by the learned counsel for the respondents that the product manufactured by INTAS contains API/bulk drug 'Cefixime' of a particular dosage, form and strength specified in Schedule-I to DPCO-2013 and, therefore, is a scheduled formulation within the meaning of Clause 2(zb) of DPCO-2013. He submitted that the ceiling price fixed by NPPA applies to all forms of Cefixime 400 mg whether in the form of conventional or dispersible tablets and no distinction can be made on the basis of the nature of the tablet.

20. Explanation (1) to Schedule-I of DPCO-2013 states that any dosage form of the medicine, which has the same strength and route of

administration should be considered as included. In the present case, the dosage form is the same; that is, a tablet, therefore, the dispersible tablets containing the formulation 'Cefixime' are included in Schedule-I to DPCO-2013. It is also submitted that when a formulation is identical to a scheduled formulation in terms of API, dosage and strength, it cannot fall out of price control merely because it has a non-conventional or new drug delivery system.

Reasons and Conclusion

21. At the outset, it is relevant to refer to paragraph 8(1) of DPCO-2013, which reads as under:-

> "8. **Maximum retail price**.- (1) The maximum retail price of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling price notified by the Government plus local taxes wherever applicable, as under:
>
> **Maximum Retail Price = Ceiling Price + Local Taxes as applicable**..."

22. It is apparent from the above that in terms of the DPCO-2013, the obligation to adhere to a ceiling price notified by the Government is applicable only in respect of a "*scheduled formulation"*. In view of the above, the principal question that falls for consideration of this Court is whether the formulation in question is a *"scheduled formulation"*.

23. The expression "scheduled formulation" is defined under sub-clause (zb) of paragraph 2(1) of DPCO-2013, which reads as under:

"(zb) "**scheduled formulation**" means any formulation, included in the First Schedule whether referred to by generic versions or brand name."

24. It is relevant to state that DPCO-2013 had been issued in exercise of powers conferred under Section 3 of the Essential Commodities Act, 1955 and as per the National Pharmaceutical Pricing Policy-2012 (hereafter 'NPPP-2012'). One of the principal objectives of NPPP-2012 is to "*put in place a regulatory framework for pricing of drugs so as to ensure availability of essential medicines at reasonable prices*". DPCO-2013 is a welfare legislation (*albeit* delegated) and the same must be interpreted in a purposive manner to further its object. Thus, the provisions of DPCO-2013 must be interpreted in a manner so as to ensure inclusion of essential medicines as opposed to being interpreted in a restrictive manner so as to exclude formulations from the scope of expression "Scheduled Formulation". (See: ***Union of India and Anr. v. M/s. Swiss Garnier Life Sciences & Ors.: (2013) 8 SCC 815.***

25. In the present case, the central controversy is whether Ceftas 400 is included in Schedule-I to the DPCO-2013. Admittedly, Ceftas 400 contains Cefixime. Entry 6.2.1.8 of Schedule-I to the DPCO-2013 is relevant and reads as under:-

6.2.1.8	Cefixime	S,T	Tablet 200 mg Tablet 400 mg Oral liquid 50 mg/5 ml Oral liquid 100 mg/5 ml

26. At this stage, it would be relevant to refer to the stand of NPPA as is reflected in the impugned order. According to NPPA, once a formulation is mentioned in Schedule-I, it would include all versions of the said medicine irrespective of the form or the drug delivery system. In case conventional and non-conventional versions are separately mentioned, the same would be considered separately for determining their ceiling prices. If the drug delivery system is not separately mentioned, all versions of the formulations would be considered as included. The relevant extract of which is set out below:-

> "4. When there is no separate mention in the NLEM regarding the Drug delivery system, all versions of the scheduled drug in question are clubbed together irrespective of the Drug Delivery System for arriving at the ceiling price under the prescribed simple average price formula. If there is a separate mention of conventional and non-conventional versions, the two versions are considered separately for arriving at their respective ceiling prices. Underlying principle here being that of the "essentiality" of a drug, which is measured from therapeutic and intended use point of view and hence, no drug can fall out of price control merely because it involves a New Drug Delivery System. It certainly cannot be argued that the DPCO, 2013 considers Scheduled Drugs with innovative delivery system as non-essential or that it is not interested in making them affordable to all including poor masses. It should be noted that a Drug Delivery System is only a subset of the dosage form and cannot override it. Hence, merely because a tablet is a specialised tablet with Novel Drug Delivery System does not make it cease to be a tablet.
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> 5. As a matter of fact, exclusion of Scheduled Drug from price control merely on account of Drug Delivery System,

would result in jeopardising the entire DPCO framework, and would remove a large number of Scheduled Drugs from price control because they may adopt specialised Drug Delivery System such as SR (sustained release), ER (Extended release), CR (controlled release), DR (Delayed release), DT (dispersible tablet), ET (effervescent tablet), CTB (chewable tablet), IFPD (inlay tablet), PGS (gelatine coated or polymer coated gelatine), BLM (bilayered), ECT (enteric coated), etc. The issue of differential pricing factoring Drug Delivery System is totally out of context and not a part of existing pricing policy."

27. INTAS does not dispute that Ceftas 400 contains Cefixime of the strength of 400 mg. Its case is that Ceftas 400 is excluded from the Schedule by virtue of Explanation (2) to Schedule-I of the DPCO-2013. The said Explanation reads as under:-

> "(2) Innovation in medicine must be encouraged. The formulations developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/ controlled release etc. should be considered as included only if specified in the list against any medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing, etc."

28. In view of the aforesaid Explanation, NPPA's contention that all versions of formulations listed in Schedule-I to DPCO-2013 have to be considered as included irrespective of the Drug Delivery System, is unsustainable. Schedule – I of DPCO-2013 was amended on 10.03.2016. The aforesaid Explanation was introduced in on the basis of the report of the Core Committee for Revision of the National List of Essential Medicines-2015. The relevant extract of the said report reads as under:-

"**Incremental Innovation**
The Committee deliberated in detail about the issue of inclusion of improved formulations of a medicine developed through incremental innovation involving technology. The Committee considered that such formulations including novel drug delivery systems like lipid/liposomal formulations modified release formulations like sustained release, controlled release etc. of a medicine, which are developed to overcome certain disadvantages associated with the use of conventional formulations, will be considered included **only if** specified in the list against any medicine."

29. It is apparent from the plain language of Explanation (2) to Schedule-I of the DPCO-2013 indicates that improved formulations that have been developed through incremental innovation involving technology for overcoming disadvantages associated with conventional forms would not be read as included in the National List of Essential Medicines-2015 (which is appended as Schedule-I to DPCO-2013). The said Explanation expressly illustrates its import by referring to Sustained Release (SR) and Controlled Released (CR) formulations. Admittedly, controlled release and sustained release are drug delivery systems. Thus, formulations involving innovative drug delivery system, unless expressly included in Schedule-I of the DPCO-2013, are excluded from the schedule. Similarly, formulations which are developed through incremental innovations, which are significant improvement over conventional forms, would not be read as included in Schedule-I of DPCO-2013, unless specifically mentioned. If such a formulation is excluded from Schedule-I of

DPCO-2013, it also falls outside the definition of the expression 'scheduled formulation'.

30. In view of the above, the contention that all versions of the formulations irrespective of the drug delivery system or innovation are included in Schedule-I of the DPCO 2013 is erroneous.

31. INTAS claims that Ceftas 400 is a dispersible formulation and is completely different, distinct and separate from the conventional Cefixime tablets. It is further contended that Ceftas 400 has been developed through innovation and is a significant improvement over the conventional form.

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.

VIBHU BAKHRU, J

SEPTEMBER 17, 2018
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