

# Intas Pharmaceuticals Limited & Anr vs Union Of India & Anr on 14 March, 2023

**Author: Tushar Rao Gedela**

**Bench: Tushar Rao Gedela**

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\* IN THE HIGH COURT OF DELHI AT NEW DELHI  
+ W.P.(C) 2836/2023, CM APPL. 10931/2023 & CM APPL.  
10930/2023

INTAS PHARMACEUTICALS LIMITED & ANR.

..... Petitioners

Through: Mr. Anshuman Sharma, Advocate.

versus

UNION OF INDIA & ANR.

..... Respondents

Through:

Mr. Kirtiman Singh, CGSC with  
Vidhi Jain and Ms. Manmeet  
Sareen, Advocates.

CORAM:

HON'BLE MR. JUSTICE TUSHAR RAO GEDELA

ORDER

% 14.03.2023 [ The proceeding has been conducted through Hybrid mode ]

1. Petitioner challenges the order dated 16.02.2023, whereby the respondent has raised a demand on the manufacturing/marketing of scheduled formulation "Valprol CR 200 TABLET" 10's, Each Film coated controlled released Tablet Contains: Sodium Valproate 200 mg - at a price higher than notified ceiling price and calculated the demand to Rs. 3,49,91,568/- on the issue of overcharging on the batches sold and an amount of Rs. 3,53,40,742/- is an interest calculated up to 28.02.2023 @ 15 % per annum on the said overcharged amount.

2. Learned counsel appearing for the petitioner submits that though the generic molecule of Sodium Valproate is covered under the Drug Price Control Order, 2013, however, the delivery system represented by the control release, the innovated molecule by the petitioner does not fall within the excepted category under the schedule, therefore, the demand cannot be raised therein.

3. Mr. Anshuman Sharma, learned counsel for the petitioner submits that the petitioner is covered under explanation 2 of Schedule 1 of the Drugs (Price Control) Order 2013 and submits that such demand could not have been raised by the respondent.

4. Learned counsel draws attention of this Court to page 31 annexure P-2 particularly to item 27 to submit that the petitioner has a licence to manufacture VALPROL-CR-200 controlled release tablets of sodium valproate and valproic acid.

5. Drawing attention to the explanation of schedule 1 of DPCO - 2013, learned counsel submits that the explanation too contained in schedule 1 stipulates that the innovation in medicine must be encouraged and different formulations should be considered differently for the purposes such as procurement policy pricing etc.

6. On that basis, learned counsel submits that since the VALPROL-CR-200 manufactured by the petitioner comes within the innovative medicine, the non-consideration of the same while passing the impugned demand notice would vitiate the demand raised therein.

7. Learned counsel draws attention to page 107 of the present petition, which is the judgment passed by the co-ordinate bench of this Court in a case pertaining to the very same petitioner and in particular, learned counsel brings attention of this Court to para 32 and 33 to submit that the observations made in para 32 and 33 are directly applicable to the present case too.

8. Learned counsel submits that in the aforesaid case, the impugned order of demand was set aside. Para Nos. 32 and 33 of the W.P.(C) 1257/2018 decided on 17.09.2018 is extracted hereunder for the purposes of convenience :-

"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."

9. Learned counsel also refers to the judgment placed at page 120 passed by the co-ordinate bench of this Court in W.P.(C) 11037/2018, wherein, in an identical situation, in respect of another formulation manufactured by the petitioner, that is, Nitrofurantoin 100 mg Sustained Release Tablet, was considered as not being a formulation covered in the schedule to the Drugs (Price Control) Order, 2013. The said order was an interim order in respect of the stay which was granted without any conditions.

10. Learned counsel also refers to the order dated 12.06.2020 in W.P.(C) 3510/2020, in its own case, whereby on the similar basis, the demand notice was stayed without any conditions.

11. On the other hand, Mr. Kirtiman Singh, learned CGSC appearing for the respondent submits that the DPCO 2013 and the schedule attached thereto would not be applicable in the case of the

petitioner for the reasons that the schedule itself was inserted in the year 2015 and came into effect from 11.03.2016.

12. Mr. Singh learned CGSC, submits that the violation is prior to 2015 particularly of the year 2013, therefore, it will be covered under the DPCO of 1995, and consequently, the petitioner would not get the benefit of the explanation which was inserted subsequently, insofar as the batches prior to 2015 are concerned.

13. Learned counsel also submits that the delivery systems like Controlled Release, Sustained Release and Extended Release are deliverables which are not new or innovative to the market and have been existing for decades now, to urge that there is no new innovativeness in the product manufactured by the petitioner.

14. Mr. Singh, Learned counsel also submits that the delivery systems would not take away the fact that such drugs are being used for manufacture of medicines which are covered by the DPCO and the demand which has been raised is sustainable in law.

15. Mr. Singh also submits, without prejudice to his rights and contentions, that insofar as the demand pertaining to the period prior to 2015 is concerned, the same would, in any case, not be covered under the exemption sought under the schedule introduced in 2015 in DPCO of 2013.

16. Learned counsel also relies upon a number of judgments of this Court to submit that in similar circumstances, the co-ordinate benches have directed deposit of the amounts raised in the demand notices as pre-condition to grant of stay.

17. Learned counsel also submits that the price which was determined by the National Pharmaceutical Pricing Authority ('NPPA'), considered the prices available in the market of similar products, i.e., CR Tablets, and, therefore, the submission that innovativeness was not considered by the NPPA is without any merits.

18. On a perusal of the impugned order, prima facie, it appears that the impugned order has not considered the applications of the schedule to the DPCO 2013, insofar as the batches post the year 2015 is concerned and the demand on over-charging has also included within its ambit period w.e.f., 2015 through till January 2018, which appears, prima facie, to be unsustainable insofar as the contentions of the petitioner are concerned.

19. However, the period prior to the insertion of the Schedule to the DPCO 2013, prima facie, may not have the benefit of the same since then issue whether it is applicable retrospectively is yet to be determined. At the interim stage of admission itself, no such firm conclusion can be drawn.

20. Considering the fact that the demand for overcharging is over Rs.3 cores and the fact that the interest thereon can be ascertained only when such overcharging is found as a fact, it is deemed appropriate to stay the operation of the impugned demand notice, subject to the petitioner depositing a sum of Rs. 2 Crores before this Court within two months from today.

21. Reply, if any, be filed within six weeks. Rejoinder thereto, if any, be filed within six weeks thereafter.

22. List on 21.09.2023.

TUSHAR RAO GEDELA, J MARCH 14, 2023/nd