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

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Decided on: 17th February, 2021

+ **W.P.(C) 2162/2021**

ASTRAZENECA PHARMA INDIA LIMITED Petitioner

Through: Mr.Amit Sibal, Sr.Adv. with
Mr.Krishna Sharma, Mr.Jayakrishnan KR,
Mr.Navnit Kumar and Ms.Archita Phookun,
Advocates

Kirtiman singh CGSC, for Respondents – UOI

Versus

**THE NATIONAL PHARMACEUTICAL
PRICING AUTHORITY & ORS.**

..... Respondents

Through: Mr.Kirtiman Singh, CGSC with
Mr.Waize Ali Noor Adv, Mr.Rohan Anand,
Ms.Taha Yasin, Advs.

CORAM:

HON'BLE THE CHIEF JUSTICE

HON'BLE MS. JUSTICE JYOTI SINGH

JUDGMENT

: **D.N.PATEL, Chief Justice (Oral)**

Proceedings in the matter have been conducted through video conferencing.

C.M.No.6284/2021 (exemptions)

Allowed, subject to all just exceptions.

The application is disposed of.

W.P.(C) No.2162/2021 & C.M.No.6283/2021(stay)

1. This writ petition has been preferred with the following prayers:-

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- “(a) Pass an appropriate writ, order or declaration quashing the Gazette Notification dated February 27, 2019 issued by the Respondent No.1/NPPA;*
- (b) Pass an appropriate writ, order or declaration quashing the Show-Cause Notice dated October 14, 2020 issued by the Respondent No.1 /NPPA;*
- (c) Pass an appropriate writ, order or declaration quashing the Order dated January 13, 2021 passed by the Respondent No.1/NPPA; and*
- (d) Pass any other or further order(s) which this Hon'ble Court deems fit in the interest of justice.”*

2. At the outset, learned Senior Counsel appearing for the petitioner invited our attention to the order dated 13th January, 2021 issued by Respondent No.1/NPPA (Annexure P-4 to the Writ Petition) whereby Respondent No.1 has directed the petitioner to furnish CA certified data for sale of the formulation concerning the drug in question. Attention is also drawn to the communication dated 4th February, 2021 (Annexure P-24 to the Writ Petition) whereby the petitioner has, in response to the order dated 13.01.2021, supplied the necessary details to Respondent No.1.

3. It is thus submitted by the learned Senior Counsel for the Petitioner that it would suffice for the disposal of this writ petition if the respondents are directed to decide the show cause notice afresh in accordance with law, and taking into account the various details and the requisite data supplied by the petitioner vide its communication dated 4th February, 2021. It is nevertheless the contention of the Petitioner that the various grounds averred in the present writ petition together with the points urged in the replies given by the petitioner, *inter alia*, would clearly evidence that the Gazette Notification dated 27.02.2019 issued by invoking para 19 of Drug Price

Control Order, 2013 (hereinafter referred to as 'DPCO, 2013') is beyond the scope of National Pharmaceuticals Pricing Policy, 2012 as well as para 32 of the DPCO, 2013. It is submitted that OSIMERTINIB is a patented product qualifying for exemption for five years from the date of commencement of its commercial marketing in India. Para 32 (i) of DPCO, 2013 stipulates that the provisions of the said order shall not apply to a manufacturer producing a new drug patented under the Indian Patent Act, 1970 for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country. These amendments were introduced on 03.01.2019 i.e. prior to the impugned Notification to encourage innovation and research. The Petitioner has a product patent covering the molecule OSIMERTINIB (TAGRISSO) and the same is valid for twenty years i.e. upto 24.07.2032. The Show Cause Notice dated 14.10.2020 and the impugned order dated 13.01.2021 are thus illegal and deserve to be quashed.

4. We have heard learned senior counsel for the Petitioner and learned counsels for the Respondents. We have perused the order dated 13.01.2021 and it is clear that Respondent No.1 has directed the Petitioner to furnish CA certified data before issuing a Demand Notice. Relevant part of the said order reads as under:-

“6. Based on the abovementioned facts, the company has overcharged in sale of Tagrisso 80mg tablet. The company has not submitted details of quantity sold since 08th March, 2019 duly certified by Chartered Accountant as sought vide Show Cause Notice dated 14th October, 2020. Therefore, the company is once again directed to furnish CA certified data for sale of the formulation in reference in the Annexure attached herewith within 15 days of receipt of this order,

failing which demand notice will be issued based on market data available with NPPA.”

5. As per the submissions of learned Senior Counsel appearing for the Petitioner, the details required and sought for by Respondent No.1 have already been supplied by the Petitioner vide communication dated 4th February, 2021. Apart from the various grounds urged to challenge the Show Cause Notice and the impugned order, learned Senior Counsel also highlighted that the respondents have no power, jurisdiction and authority to issue the aforesaid Show Cause Notice and raise a demand on the Petitioners.

6. Since the matter still rests at a stage where requisite information and data has been sought by Respondent No.1 and the decision is yet to be taken, we hereby direct Respondent No.1/NPPA to pass a fresh order taking into account the information given in the communication dated 4th February, 2021 by the petitioner and also the various contentions raised in the present writ petition including the reply(s) filed by the petitioner. The Authority will also consider the issue of jurisdiction raised herein and needless to state that the decision so taken on all counts shall be in accordance with law and after giving adequate opportunity of being heard to the petitioner.

7. Till the decision is taken by Respondent No.1, it shall not raise any demand against the petitioner with regard to the issues in question. In case the Petitioner is still aggrieved by the decision rendered by Respondent No.1, it shall have the liberty to challenge the same in accordance with law in the appropriate Forum.

8. With these observations, the writ petition is disposed of along with the pending application.

CHIEF JUSTICE

JYOTI SINGH, J

FEBRUARY 17, 2021

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