

IN THE HIGH COURT OF DELHI AT NEW DELHI

* **Date of decision: 27th February, 2020**
+ W.P.(C) 2261/2020

LUPIN LTD.

..... Petitioner

Through:

Mr. Amit Sibal, Sr. Advocate with
Mr. Vivek Sarin, Mr. Satish C.
Kaushtik, Mr. Dibya Prashant Singh &
Mr. Manish Sharma, along with the
Petitioner (M-9013407227)

versus

UNION OF INDIA AND ORS.

..... Respondents

Through:

Mr. Kirtiman Singh, CGSC with Mr.
Rohan Anand, Advocate for R-1 to 3
(M-9968791199)

CORAM:

JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh, J. (Oral)

CM APPL. 7889/2020 (for exemption)

1. Allowed, subject to all just exemptions. Application is disposed of.

W.P.(C) 2261/2020 & CM APPL. 7888/2020

2. Issue notice to the Respondents returnable on 1st April, 2020.

3. Mr. Kirtiman Singh, Id. Standing Counsel accepts notice for

Respondents No.1, 2 and 3. Respondents No.4 and 5 are proforma parties.

4. The present writ petition raises an important question in respect of the

interpretation of Para 32 of the Drug Price Control Order, 2013 (*hereinafter*

DPCO).

5. An amendment was introduced in 2019 under Para 32 which reads as

under:

“32. Non-application of the provisions of this order in certain cases. - The provisions of this order shall not

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8. Pursuant to the rejection of the reply to the show cause notice, a letter dated 2nd January, 2020 has been issued by the NPPA calling upon the Petitioner to provide data since the launch. A perusal of the minutes of meeting where the decision was taken as also the letter dated 2nd January, it is entitled to the exemption.

7. The NPPA thereafter issued a show-cause notice dated 11th October, 2019 which was replied to by the Petitioner on 6th November, 2019. However, the NPPA has now taken the stand that there was an obligation on the Petitioner to apply for an exemption under Para 32(i), prior to launching the product itself and the Petitioner could not have made a presumption that it is entitled to exemption as per Para 32(i).

6. The said provision has been called to question inasmuch as the Petitioner had, in December 2018 launched a fixed dose combination (FDC) of Empagliflozin and Metformin Hydrochloride drug without seeking the prior permission of National Pharmaceutical Pricing Authority (*hereinafter 'NPPA'*) on the premise that the said product was patented. The Petitioner's case is that it has an arrangement with the Patentee i.e., Respondents 4 & 5 who have been granted a product patent in respect of the Fixed dose combination (FDC). Thus, it is entitled to exemption as per Para 32(i).

Provided that the provision of this paragraph shall apply only when a document showing approval of such new drugs from Drugs Controller General (India) is produced before the Government."

*...
country.
its commercial marketing by the manufacturer in the
period of five years from the date of commencement of
under the Indian Patent Act, 1970 (39 of 1970), for a
(i) A manufacturer producing a new drug patented
apply to, -*

Court Master
High Court of Delhi
New Delhi
Sharma

Rahul/A.S.

FEBRUARY 27, 2020

**JUDGE
PRATHIBA M. SINGH**

SP/

Master.

11. A copy of this order be given *dasti* under signatures of the Court approach this Court for interim relief.

10. Considering the legal issue involved in this petition, the date for furnishing of the data as sought for by the NPPA from the Petitioner, vide letter dated 2nd January, 2020 is extended beyond the next date fixed by this Court and no coercive measures shall be taken against the Petitioner. If any price is notified by the NPPA in the meantime, the Petitioner is permitted to

interpretation of Para 32 within a period of two weeks.
3rd January, 2019, the NPPA is directed to file its stand in respect of the needs to be settled, as it is a new amendment which has been introduced on in India. Since the issue of the applicability and the operation of Para 32(i) the NPPA, if the pharmaceutical product has been granted a product patent defined under Para 2(n) can launch the product merely after an intimation to exemption under Para 32(i), prior approval is needed or any manufacturer as 9. The question that has arisen is whether in order to avail of an permission to avail the exemption as being 'audacious'.

2020 shows that there has been no examination of the case of the Petitioner on merits. The NPPA terms the Petitioner's launch without seeking