$~35

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

\+ **W.P.(C) 3912/2018 and CM APPL. 15431-15433/2018 & 28990/2018**

LUPIN LIMITED ..... Petitioner

Through: Mr Amit Sibal, Senior Advocate with Ms Archana Sahadeva, Ms Namita Kochhar, Ms Surbhi Singh and Mr Luv Virmani, Advocates.

versus

UNION OF INDIA & ORS ..... Respondents

Through: Mr Ripu Daman Bhardwaj, CGSC with Mr Mohit Bhardwaj, GP and Ms Sabhya Jain, Advocates for R-1 to 3.

CORAM:
HON'BLE MR. JUSTICE VIBHU BAKHRU

O R D E R

% 10.05.2019

VIBHU BAKHRU, J

1. The petitioner has filed the present petition, *inter alia*, impugning the notifications SO No. 1039 (E) dated April 01, 2017; SO No. 2058 (E) dated June 30, 2017 and; SO no. 1461 (E) dated April 02, 2018, issued by respondent no. 3 (National Pharmaceutical Pricing Authority – hereafter 'NPPA'), to the extent that they fix the ceiling prices of the formulations Budesonide (A) + Formoterol (B) and Tiotropium in Dry Powdered Inhalation (hereafter 'DPI') dosage forms. The said notifications are hereafter referred to as the impugned notifications.

2. The controversy involved in the present petition relates to the manner in which the prices have been fixed for the subject formulations in DPI

dosage form. There is no dispute that the subject formulations are included in Schedule 1 of the Drugs (Prices Control) Order, 2013 (hereafter 'the DPCO') and, therefore, are scheduled formulations within the meaning of Clause (zb) of Section 2(1) of the DPCO. Thus, concededly, NPPA is empowered to fix the ceiling prices for the subject formulations under the DPCO. The petitioner claims that that the ceiling process of the DPI dosage forms, as notified under the impugned notifications, have not been computed in accordance with the provisions of the DPCO.

Factual Context

3. The petitioner is a pharmaceutical company and is, *inter alia*, engaged in the manufacture and sale of the subject formulations, namely, Budesonide (A) + Formoterol (B) Inhalation in the Dry Powdered Inhalation (DPI) Dosage Form and Tiotropium Inhalation in the Dry Powered Inhalation (DPI) Dosage form. The subject formulations are life saving drugs and are used for treating Chronic Obstructive Pulmonary Disease (COPD) and Asthma. The subject formulations are manufactured in four dosage forms. The dosage forms relevant to the controversy in this petition are Metered Dosage Inhalation (MDI) and Dry Powder Inhalation (DPI).

4. Indisputably, the two dosage forms – MDI and DPI – are materially different. The medicine in MDI dosage form is delivered by a handheld device (Metered Dosage Inhalers) which delivers a specific amount of medication in aerosol form. The Metered Dosage Inhaler consists of a pressurized canister inside a plastic case with an attached mouthpiece. The medication is delivered by pressing on the device which releases the

medication from the pressurized canister. The user is required to correspond the inhalation of his breath with the release of the medicine for the medication to be delivered directly into the lungs of the user. MDI uses a chemical propellant for pushing the medication out of the device (inhaler).

5. The subject formulations in DPI dosage form are delivered through a separate kind of device (a dry powder inhaler). There are several models of this device. The user is required to inhale through the said device for administration of the medicine. The medication does not use any chemical propellant. The device is not pressurized. The DPI dosage is in a form of powder consisting of micronized drug blended with large carrier particles which enhance the flow, reduce aggregation and aid in dispersion.

6. Apart from the MDI and DPI forms there are two other delivery systems, namely, Breath Actuated Inhalers (BAI) and Nebulizers. However, the said forms are not relevant for the controversy raised in this petition.

7. It is not disputed that the technology involved in the two delivery systems, namely MPI and DPI, are different and the two forms of the subject formulations are available at different price points.

8. In terms of the DPCO, NPPA notified the ceiling price of the formulation Budesonide (A) + Formoterol (B) inhalation in MDI form by including the same in SO 1560 (E) dated April 27, 2016. Thereafter, NPPA notified the ceiling price of Tiotropium Inhalation in DPI Dosage form by SO 1687 (E) dated May 09, 2016. The NPPA also published working sheets on April 20, 2016 and May 09, 2016, indicating the computation of the ceiling price for the formulations of Budesonide + Formoterol and

Tiotropium respectively. The relevant entries in the tabular statement included in the price notification dated April 27, 2016, are set out below:-

Sl. No.	**Name of the Scheduled Formulation**	**Strength**	**Unit**	**Ceiling Price (Rs)**
xxxx	xxxx	xxxx	xxxx	xxxx
32	Budesonide Respirator Solution for use in Nebulizer	Budesonide-0.5mg/ml	1ml	9.93
33	Budesonide Respirator Solution for use in Nebulizer	Budesonide-1mg/ml	1ml	11.98
xxxx	xxxx	xxxx	xxxx	xxxx
xxxx	xxxx	xxxx	xxxx	xxxx
46	Budesonide Inhalation	Budesonide-100 mcg/Dose	Each Metered Dose	1.22
47.	Budesonide Inhalation	Budesonlde-200mcg/Dose	Each Metered Dose	1.50
48.	Budesonide + Formoterol Inhalation	Budesonide-400 mcg+Formoterol -6 mcg/Dose	Each/Metered Dose	2.74
49	Budesonide + Formoterol Inhalation	Budesonide-200 mcg + Formoterol-6 mcg/Dose	Each Metered Dose	2.19
50.	Budesonide + Formoterol Inhalation	Budesonide-100 mcg + Formoterol-6	Each Metered Dose	1.74

		mcg/Dose		

9. The relevant entries in the tabular statement included in the price notification dated May 9, 2016 are set out below:-

Sl.No.	**Name of the Scheduled Formulation**	**Strength**	**Unit**	**Ceiling Price (Rs.)**
xxxx	xxxx	xxxx	xxxx	xxxx
36.	Tiotropium Inhalation	Tiotropium-18mcg/Dose	Each Metered Dose	2.29
37.	Tiotropium Inhalation	Tiotroplum-9mcg/Dose	Each Metered Dose	2.16
xxxx	xxxx	xxxx	xxxx	xxxx

10. As is apparent from the above, the subject formulations in the DPI dosage form were not specifically mentioned in the price notifications dated April 27, 2016 and May 09, 2016.

11. On April 01, 2017, NPPA issued the impugned price notification revising the ceiling prices of various formulations on the basis of the annual Wholesale Price Index (WPI) in terms of Section 16 of the DPCO. In terms of the said impugned notification, the ceiling prices of the subject formulations, as fixed in the earlier notifications, were also revised. However, in a material departure from the earlier notifications, the impugned notification also mentioned the DPI dosage form against the subject formulations. The relevant entries in the tabular statement included in the impugned price notification dated April 01, 2017, are set out below:-

"**Table: Price Revision as per Annual Wholesale Price Index (WPI) @ 1.97186% increase**.

S. No.	Medicines	Dosage form and Strength	Unit	Ceiling price (wef 01.04.2017 with WPI @ 1.97186%	Existing S.O. No. & Existing Date	
83.	Budesonide	Inhalation (MDI/DPI)100 mcg/dose	1 Dose	1.24	1560(E)	27.04.2016
84.	Budesonide	Inhalation (MDI/DPI)200 mcg/dose	1 Dose	1.53	1560(E)	27.04.2016
85.	Budesonide	Respiratory Solution for use in Nebulizer 0.5mg/ML	1 ML	10.13	1560(E)	27.4.2016
86	Budesonide	Respiratory Solution for use in Nebulizer 1mg/ML	1ML	12.22	1560(E)	27.4.2016
87	Budesonide (A) +Formoterol (B)	Inhalation (MDI/DPI) 400 mcg (A) + 6 mcg (B)	1 Dose	2.79	1560(E)	27.4.2016
88.	Budesonide (A) + Formoterol (B)	Inhalation (MDI/DPI) 200 mcg (A) + 6 mcg (B)	1 Dose	2.23	1560(E)	27.4.2016
89.	Budesonide (A) + Formoterol (B)	Inhalation (MDI/DPI) 100 mcg (A) + 6 mcg (B)	1 Dose	1.77	1560(E)	27.4.2016
xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
629	Tiotropium	Inhalation (DPI) 18 mcg/dose	1 Dose	2.34	1687 (E)	9.5.2016

630	Tiotropium	Inhalation (MDI) 9 mcg/dose	1 Dose	2.20	1687 (E)	9.5.2016

12. The impugned notification dated April 01, 2017, was subsequently superseded by the impugned notification dated June 30, 2017, which was issued to revise the prices consequent to implementation of the Goods and Services Tax (GST) with effect from July 01, 2017. The said impugned notification was, thereafter, superseded by the impugned notification dated April 02, 2018, whereby the ceiling prices were revised as per the annual WPI in terms of Section 16 of the DPCO.

Discussions and Conclusion

13. It is contended on behalf of the petitioner that only the MDI dosage form of the subject formulations was included in the notifications dated April 27, 2016 and May 09, 2016, therefore, the ceiling prices of the said formulations fixed therein were wholly inapplicable to the to the DPI dosage forms of the subject formulations. It is further contended that since the notifications dated April 27, 2016 and May 09, 2016, did not include the DPI dosage forms, the subsequent notifications revising the ceiling price in terms of Section 16 of the DPCO (being impugned notifications April 01, 2017 and April 02, 2018) and on account of implementation of GST (impugned notification dated June 30, 2017) are also inapplicable to the DPI dosage forms of the subject formulations.

14. NPPA contests the above and claims that different dosage forms have no bearing on the ceiling price fixed for the subject formulation and,

therefore, the ceiling prices as notified under the notifications dated April 27, 2016 and May 09, 2016 are applicable to the DPI dosage forms as well, notwithstanding that the same was not specifically mentioned.

15. There is no doubt that the impugned notifications merely revised the ceiling price on the basis of the annual WPI and on account of implementation of GST. No separate exercise to fix the ceiling price of the subject formulations was carried out, as required under Section 4 of the DPCO. Thus, concededly, if the price notifications dated April 27, 2016 and May 09, 2016 are held to be inapplicable to the DPI dosage forms of the subject formulation, the impugned notifications would also be wholly inapplicable to the DPI dosage form for the subject formulations. In view of the above, the central controversy to be addressed is whether the price notification dated April 27, 2016 was applicable to the formulation Budesonide (A) + Formoterol (B) in the DPI Dosage Form and whether the price notification dated May 09, 2016 was applicable to the Tiotropium Inhalation in the DPI dosage form.

16. As noticed above, the notification dated April 27, 2016 and May 09, 2016 do not specifically mention the DPI dosage form. Thus, it is difficult to accept that the ceiling prices fixed under the said notifications for the subject formulations in MDI form could also be imputed to the subject formulations in DPI form. Moreover, considering that MDI and DPI dosage forms are specifically mentioned in Schedule 1 to the DPCO, thus, it cannot be readily accepted that the respondents were not conscious of the difference between them.

17. The contention that there is no material difference between the MDI and DPI dosage forms is unmerited, as there is significant difference between the two dosage forms as noticed hereinbefore. Indisputably, the technology involved in manufacturing such dosage forms is also materially different. It is not disputed that DPI delivery system is easier to use as the user is not required to co-ordinate inhalation with the release of the medication as is required for the MDI delivery system. Further, as explained by the petitioner, MDI uses propellants for delivery of the medication which is not so in the DPI delivery system.

18. At this stage it is also relevant to examine whether NPPA had in fact fixed the ceiling price for DPI Dosage form, as required under Section 4 of the DPCO, which prescribes the manner for calculation of the ceiling price of a scheduled formulation. Section 4 of the DPCO is set out below:-

> "**4. Calculation of ceiling price of a scheduled formulation.**-
>
> (1) The ceiling price of a scheduled formulation of specified strengths and dosage as specified under the first schedule shall be calculated as under
>
> **Step 1**. First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:-
>
> Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic version of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

Step 2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below:
P(c) = P(s).(1+M/100), where
P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step 1 above.
M = % Margin to retailer and its value = 16

(2) The ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also."

19. It is apparent from the above that the ceiling prices are fixed by averaging the Price to Retailer (PTR) of brands and generic versions of the medicine. Therefore, the key question is whether NPPA had included the prices of DPI dosage forms of the subject formulation while calculating the average price for determining the ceiling prices as notified under the notifications dated April 27, 2016 and May 09, 2016.

20. This aforesaid question has been answered by the Central Government (respondent no.2) in an order dated October 30, 2017 passed by it in a review application preferred by M/s Glenmark Pharmaceuticals Limited (GPL), under Section 31 of the DPCO. GPL had assailed the impugned notification dated April 01, 2017 in a review petition filed before respondent no.2, *inter alia*, contending that the notifications dated April 27, 2016 and May 09, 2016 did not fix the ceiling prices for the DPI dosage forms of the subject formulations. Respondent no.2 accepted the aforesaid contention and directed NPPA to re-fix the ceiling price of the said formulations by considering the PTR of both types of inhalers, that is, MDI and DPI. The relevant extract of the said decision is set out below:-

"**5. Examination** :

The company submitted that NPPA, while fixing the ceiling prices of subject formulations, considered the data of only MDI formulations, and while revising the ceiling prices of 660 formulations, including these formulations, treated the formulations as "MDI/DPI". The company's submission is that there is basic difference in both the formulations, MDI comes in AEROSOL form whereas DPI comes in the form of CAPSULES. For administration, AEROSOL is actuated directly in the patient's mouth for inhalation, whereas in the case of DPI, the capsules are broken and put into a special device, which needs to be kept in mouth and inhaled by the patient. Hence, separate ceiling prices should be fixed for both types of formulations.

The issue of considering separate price fixation for metered dose counter/digital inhaler and autohaler was discussed in the Expert Committee of NPPA on 8.5.2017. The Committee observed that Budesonide is a respiratory medicine. The conventional dosage is 100mcg, 200mcg & 400mcg. This is often given in combination with Formeterol in dose of 6 mcg. There are different delivery systems available for inhalations ranging from simple/conventional inhalation device to metered dose inhaler/digital inhaler and autohaler. There may be other different variants/drug dispensing mechanisms available in the market. Although they offer technological advantage/ease of administration say in old age/children or patients with poor coordination ability, there is no significant difference in clinical efficiency and therapeutic outcome once an adequate dose is administered/delivered. Hence, separate price for metered dose counter/digital inhaler and autohaler may not be considered, rather <u>they should be clubbed together for the purpose of price fixation</u>."

The Committee also observed that the inhalational drugs used for bronchial asthma are given by different methods like

MDI, DPI, Soft-mist inhaler and Nebulizer. The DPI can be given as single dose, multi-dose and powder assisted system. This has advantage of portability, does not require much coordination and no spacer is required whereas MDI requires Aerosol which is also portable and independent, reproducing doses & has relatively low cost. In India, the Physician's feedback is that DPI is relatively less used as compared to MDI. Thus, there is not much significant clinical advantage in terms of therapeutic outcome by using DPI over MDI.

On going through the calculation sheets of earlier notifications, i.e. SO 1560(E) dated 27.4.2016 fixing the ceiling price for Budesonide (A) + Formoterol (B) [Inhalation (MDI/DPI) 400 MCG(A)+6MCG(B); 200MCG(A)+6MCG(B) and 100MCG(A)+6MCG(B)], it is noticed that PTR of only MDI formulations were considered. Similarly, the ceiling price of Tiotroplum Inhalation (DPI) 18Mcg/Dose was fixed vide SO 1687(E), dated 9.5.2016 by considering PTR of only MDI Formulations.

As regards NPPA's submission about violating the provisions of DPCO, 2013 for non-implementation of ceiling price of DPI range of formulations by the company, the same cannot be accepted as NPPA has never fixed the ceiling price for Dry Powder Inhalers. Vide SO 1039(E), dated 1.4.2017, NPPA has only revised the CP of the formulations and not fixed the CP. Unless any ceiling price is notified, the company cannot be expected to follow the ceiling price. Therefore, there is no violation of the provisions of DPCO, 2013 on the part of the company.

In view of the above, it is proposed that NPPA may be directed to re-fix the ceiling prices of Budesonide (A) + Formoterol (B) [Inhalation (MDI/DPI) 400 MCG(A)+6MCG(B); 200MCG(A)+6MCG(B) and 100MCG(A)+6MCG(B)] and Tiotropium Inhalation (DPI) 18Mcg/Dose by considering PTR of both types of Inhalers, i.e. Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI).

6. <u>Government Decision</u>:

> "NPPA is hereby directed to re-fix the ceiling price of Budesonide (A) + Formoterol (B) [Inhalation (MDI/DPI) 400 MCG(A)+6MCG(B); 200MCG(A)+6MCG(B) and 100MCG(A)+6MCG(B)] and Tiotropium Inhalation (DPI) 18Mcg/Dose by considering PTR of both types of Inhalers, i.e. Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI)."

21. Given the difference between the two delivery systems, namely, MDI delivery system and DPI delivery system, the question whether the subject formulations in the two dosage forms can be clubbed together for determining the ceiling price of the said formulations is a contentious issue. According to the petitioner the two dosage form cannot be clubbed together for determining a single ceiling price as there is a material difference between the two dosage forms, including the price points at which they are sold. However, it is not necessary to examine this controversy in this petition. This is because there can be no dispute that the PTR of the DPI dosage forms of the subject formulations were not considered while fixing the celing prices of the subject formulations and, therefore, the same cannot be applied to the DPI dosage forms of the formulations in question. Consequently, the ceiling prices of the subject formulations as notified on April 27, 2016 and May 09, 2016 were wholly inapplicable to subject formulations in the DPI dosage form. As noticed earlier, the said notifications specifically mentioned MDI dosage forms and not the DPI dosage forms of the subject formulations. It obviously follows that the impugned notifications – which merely revised the ceiling prices on the basis of annual WPI and implementation of GST – are also wholly inapplicable to the DPI dosage form of the subject formulations.

22. It is relevant to note that in compliance with the directions issued by respondent no.2 in its order dated October 30, 2017 passed in the review petition preferred by GPL, NPPA issued another price notification dated February 26, 2019, fixing a separate ceiling price for the subject formulations in DPI dosage forms. Thus, the petitioner's grievance with regard to applicability of the impugned notifications to the DPI dosage forms has been addressed. However, Mr Sibal, learned senior counsel appearing for the petitioner, contended that there is still some scope for controversy because although the notification dated February 26, 2019 supersedes the impugned notifications, nonetheless, it carves out an exception *"in respect of things done or omitted to be done before such supersession"*. He contends that in view of the said exception, NPPA may still seek to implement the impugned notifications, insofar as the petitioner is concerned.

23. The said apprehension is clearly unfounded as respondent no.2 has accepted in its order dated October 30, 2017 that the ceiling price fixed under the notifications dated April 27, 2016 and May 09, 2016 were not in respect of DPI dosage forms of the subject formulations. This is obvious from the fact that (a) the said notifications mentioned only the MDI dosage form of the subject formulation; and (b) that the ceiling price fixed under the notifications did not take into account the PTR of the DPI dosage forms.

24. In view of the above, the petitions are allowed. The ceiling prices fixed under the impugned notifications are not applicable to the said formulations in the DPI dosage forms. Any demands raised by NPPA or other respondents in respect of the subject formulations in the DPI dosage

forms, on the basis of the impugned notifications, are unsustainable. The impugned notifications to the extent they purport to fix the ceiling prices of the said formulation in the DPI dosage forms are set aside.

25. The pending applications stand disposed of.

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

VIBHU BAKHRU, J

MAY 10, 2019
pkv