

(2019) 05 DEL CK 0404

In the Delhi High Court

Case No : Civil Writ Petition No. 3912 Of 2018, Civil Miscellaneous Application
No. 15431, 15433, 28990 Of 2018

Lupin Limited

APPELLANT

Vs

Union Of India & Ors

RESPONDENT

Date of Decision : 10-05-2019

Acts Referred:

Drugs (Prices Control) Order, 2013 — Section 2(1)(zb), 4, 16, 31

Citation : (2019) 261 DLT 158

Hon'ble Judges : Vibhu Bakhru, J

Bench : Single Bench

Advocate : Amit Sibal, Archana Sahadeva, Namita Kochhar, Surbhi Singh, Luv
Virmani, Ripu Daman Bhardwaj, Mohit Bhardwaj, Sabhya Jain

Final Decision : Allowed

Judgement

Sl. No., "N a m e 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,Budesonide200mcg/Dose,Each Metered Dose,1.50,,

48.,"B u d e s o n i d e +

Formoterol Inhalation", "Budesonide-400

mcg+Formoterol -6

mcg/Dose",Each/Metered Dose,2.74,,

49,"B u d e s o n i d e +

Formoterol Inhalation", "Budesonide-200 mcg +

Formoterol-6 mcg/Dose",Each/Metered Dose,2.19,,

50.,"B u d e s o n i d e +

Formoterol Inhalation", "Budesonide-100 mcg +

Formoterol-6 mcg/Dose",Each/Metered Dose,1.74,,

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",1ML,10.13,1560(E),27.04.2016

86,Budesonide,"Respiratory

Solution for use in

Nebulizer

1mg/ML",1ML,12.22,1560(E),27.04.2016

87,"Budesonide (A)

+Formoterol (B)","Inhalation

(MDI/DPI) 40

mcg (A) + 6 mcg

(B)","1 Dose

0",2.79,1560(E),27.4.2016

88., "Budesonide (A) +

Formoterol (B)","Inhalation

(MDI/DPI) 20

mcg (A) + 6 mcg

(B)","1 Dose

0",2.23,1560(E),27.4.2016

89., "Budesonide (A) +

Formoterol (B)","Inhalation

(MDI/DPI) 10

mcg (A) + 6 mcg

(B)","1 Dose

0",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

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:-",,,,,,

â??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: $P(c) = P(s) \cdot (1 + M/100)$, 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.â??",,,,,,

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:-,,,,,

â??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 â??MDI/DPIâ??. 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 they should be clubbed together for the" ,,,,,,

purpose of price fixation.â?? ,,,,,,

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 Tiotropium 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. Government Decision:,,,,,,

â??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).â??,,,,,,

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 ceiling 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 â?" which merely revised the ceiling prices on the basis of,

annual WPI and implementation of GST â?" 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 petitionerâ?'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 â??in respect of" ,,,,,,
 things done or omitted to be done before such supersessionâ?. 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. ,,,,,,