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

\+ WP (C) 39/2005

GLAXO SMITHKLINE PHARMA. LTD. ..... Petitioner
Through: Mr. U.A. Rana and Mr. Himanshu Mehta, Advs.

versus

UOI & ANR. ....Respondents
Through: Mr. Bhagvan Swarup Shukla, CGSC for UOI

\+ WP (C) 1527/2005

KEMWELL BIOPHARMA PVT. LTD. & ANR ..... Petitioners
Through: Mr. U.A. Rana and Mr. Himanshu Mehta, Advs.

versus

UOI & ANR ....Respondents
Through: Mr. Bhagvan Swarup Shukla, CGSC for UOI
Ms. Pragya Barsaiyan, Adv. for Mr. Gautam Narayan, ASC for GNCTD

CORAM:
HON'BLE MR. JUSTICE C. HARI SHANKAR

J U D G M E N T

% **26.12.2023**

WP (C) 39/2005

1. This writ petition, instituted under Article 226 of the Constitution of India by GlaxoSmithKline Pharmaceuticals Ltd,

assails communications dated 5 October 2004 and 17 December 2004, issued to the petitioner by the National Pharmaceutical Pricing Authority (NPPA) (impleaded as Respondent 2) in exercise of the powers conferred by Para 13[1] of the Drug (Price Control) Order 1995 ("the DPCO 1995").

2. The communication dated 5 October 2004 directed the petitioner to deposit ₹ 54,844,247/– with the Department of Chemicals & Petrochemicals (Respondent 1). The subsequent order dated 17 December 2004 rejected the petitioner's representation against the order dated 5 October 2004 and reiterated the demand of ₹ 5,59,32,906/–.

3. The demand of ₹ 5,59,32,906/- consists of a principal amount of ₹ 4,35,46,347/- and ₹ 1,23,86,559/– towards interest. By orders passed by this Court in the present proceedings, enforcement of the demand was stayed, conditional on the petitioner depositing the principal amount with this Court and furnishing bank guarantee for the interest.

4. The writ petition has been heard finally. Mr. U.A. Rana appeared for the petitioner and Mr. Bhagwan Swarup Shukla, Ld. Central Government Standing Counsel (CGSC) represented the respondents.

[1] **13. Power to recover overcharged amount –** Notwithstanding anything contained in this order, the Government shall by notice, require the manufacturers, importers or distributors, as the case may be, to deposit the amount accrued due to the charging of prices higher than those fixed or notified by the Government under the provisions of Drugs (Prices Control) Order, 1987 and under the provisions of this Order.

5. The said petition was heard along with W.P. (C) 1527/2005 (***Kemwell Biopharma Pvt. Ltd. v. U.O.I.***). As the issue in controversy in both the petitions is the same, a substantive judgement is being passed in this petition, which would be applied, *mutatis mutandis*, to WP (C) 1527/2005 by way of a separate order.

Facts

6. In exercise of the powers conferred by Para 9(1)[2] of the DPCO, the NPPA, by Notification dated 16 November 1999, fixed a price of ₹ 68.50 as the price at which – inhalers containing Salbutamol - as one of the scheduled formulations which found place in the First Schedule to the Notification – could be sold.

7. The petitioner asserts that they never overcharged for Salbutamol, and abided by the Notification dated 16 November 1999.

8. Certain other manufacturers challenged the inclusion of seven bulk drugs, including Salbutamol, in the First Schedule to the DPCO 1995 in a batch of writ petitions before the High Court of Bombay. By judgement dated 31 August 2001[3], the High Court held that the drugs in question, including salbutamol, did not fall within the purview of the DPCO and that, therefore, the NPPA could not have

[2] **9. Power to fix ceiling price of Scheduled formulations.–**
(1) Notwithstanding anything contained in this Order, the Government may, from time to time, by notification in the Official Gazette, fix a ceiling price of a Scheduled formulation in accordance with the formula laid down in para 7, keeping in view the cost of efficiency, or both, of major manufacturers of such formulations and such price shall operate as the ceiling sale price for all such facts including those sold under generic name and for every manufacturer of such formulations.

[3] **Cipla Ltd v. U.O.I., (2002) 2 Mah LJ 631**

fixed any price for sale of the drugs under the DPCO. As such, all the writ petitions were allowed to the extent of the challenge to the inclusion of the said seven drugs, including salbutamol, in the first Schedule to the DPCO. The notices issued to the petitioners before the High Court, demanding overcharged amounts from them were also, therefore, quashed and set aside.

9. The impugned communication dated 5 October 2004 alleged that the petitioner had violated the provisions of the DPCO 1995 by charging a higher price, for sale of Ventorlin inhaler (Salbutamol 100 mcg) ("Ventorlin"), than the price fixed by the NPPA on 16 November 1999. The petitioner, as per the communication, was charging ₹ 86.36 and ₹ 94.89, as against the price fixed by the DPCO 1995 which was ₹ 68.50. Thus, during the period March 2002 to August 2003, it was alleged that the petitioner had overcharged consumers by an amount of ₹ 4,35,46,347/–. The communication, therefore, called upon the petitioner to deposit the said amount along with interest of ₹ 1,12,97,900/– on or before 5 November 2004. The demand, it was clarified, was only provisional and subject to enhancement, if any further amount was found due from the petitioner.

Rival Contentions

10. Mr. Rana, learned Counsel for the petitioner, submits that, by its judgment in ***Cipla v. UOI***[4], the Division Bench of the High Court of Bombay clearly struck down the DPCO 1995 to the extent it included the seven drugs forming subject matter of consideration before the

[4] **2001 SCC OnLine Bom 683**

Court, including Salbutamol, in the First Schedule to the DPCO 1995. Resultantly, held the High Court, the price of Salbutamol could not be subjected to control under the DPCO 1995. The decision was challenged by the Union of India by way of SLP. Leave was granted by the Supreme Court on 3 May 2002, without staying the operation of the judgment of the High Court. Subsequently, by judgment dated 1 August 2003 in ***Secretary, Ministry of Chemical & Fertilizers v. CIPLA Ltd.***[5], the Supreme Court set aside the judgment of the High Court and remanded the matter for *de novo* consideration. The period of dispute, for which the demand has been raised by the respondent, is March 2002 to August 2003. This was the period during which the judgment of the High Court of Bombay remained in operation. It was only for this period that the petitioner has increased the price of its Salbutamol. Consequent on the Supreme Court setting aside the judgment of the High Court on 1 August 2003, the petitioner once again reduced the price of Salbutamol to bring it in accordance with the DPCO 1995.

11. Mr. Rana submitted that it could not, therefore, be said that the Petitioner had acted in violation of the DPCO as, during the period of demand, the inclusion of Salbutamol under the First Schedule to the DPCO stood set aside by the High Court of Bombay.

12. Mr. Rana has relied, in this context, on Section 7-A(1)[6] of the Essential Commodities Act 1955 (the ECA). He submits that any

[5] **(2003) 7 SCC 1**

[6] **7-A. Power of Central Government to recover certain amounts as arrears of land revenue**. –
(1) Where any person, liable to –

recovery on the basis of the DPCO 1995 has to abide by the provisions of the ECA. Inasmuch as, during the period of demand, no amount was payable by the Petitioner under the DPCO 1995, it could not be said that the petitioner was in default of payment as would justify recovery from it. In the absence of a sustainable demand, there could be no question of recovery of interest under Section 7-A either.

13. Moreover, submits Mr. Rana, the default, if any, would arise only on the failure of the petitioner to deposit the amount claimed by the NPPA on the expiry of the period allowed for such deposit in the impugned communications. He relies, for this purpose, on the judgment of the Division Bench of High Court of Allahabad in ***T.C. Healthcare Pvt. Ltd. v. U.O.I***[7].

14. ***T.C. Healthcare*** is also cited by Mr. Rana for the proposition that, as Para 19[8] of the DPCO 1995 obliges a manufacturer to sell scheduled formulations to retailers at the notified retail price less 16% thereof in case of scheduled drugs, the said 16%, which constitutes

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(a) pay any amount in pursuance of any order made under Section 3, or
(b) deposit any amount to the credit of any Account or Fund constituted by or in pursuance of any order made under that section,
makes any default in paying or depositing the whole or any part of such amount, the amount in respect of which such default has been made shall whether such order was made before or after the commencement of the Essential Commodities (Amendment) Act, 1984, and whether the liability of such person to pay or deposit such amount arose before or after such commencement] be recoverable by Government together with simple interest due thereon computed at the rate of fifteen per cent per annum from the date of such default to the date of recovery of such amount, as an arrear of land revenue or as a public demand.

[7] **2010 SCC OnLine All 834(DB)**

[8] **19. Price of formulations sold to the dealer, -**
(1) A manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of this Order or any order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen per cent thereof in the case of Scheduled drugs.

trade margin, cannot be said to have accrued to the manufacturer and, therefore, could not be included in the alleged over-charged amount.

15. Mr. Rana submits that the decision in ***T.C. Healthcare*** was challenged by the Union of India before the Supreme Court which dismissed the SLP on merits *vide* judgment dated 15 November 2019[9], against which a review petition and a curative petition were preferred, which were both dismissed.

16. Mr. Rana points out that, in para 20 of its judgment, the Supreme Court held that the amount over-charged would have to be decided by taking into account the price charged by the manufacturer to the next dealer.

17. Responding to the submissions of Mr. Rana, Mr. Bhagwan Swarup Shukla, learned CGSC, submits that the judgment of the Supreme Court in ***Cipla*** operated retrospectively and not prospectively**.** He invites attention to para 11 of the decision of the judgment which allowed the appeal of the Union of India and granted liberty to the statutory authorities to recover 50% of the over-charged amounts pending fresh determination by the High Court. Thus, he submits, the petitioner cannot entirely escape liability by relying on the judgment of the High Court of Bombay. He also relies on the judgment of the Supreme Court in ***Kunhayammed v. the State of Kerala***[10] to contend that the judgment of the High Court of Bombay

[9] **T.C. Healthcare v. U.O.I, (2020) 15 SCC 117**
[10] **(2000) 6 SCC 359**

has merged in the judgment of the Supreme Court and could not, therefore, be relied upon.

18. Incidentally, Mr. Shukla has also sought to advance the somewhat extreme contention that, even if the Supreme Court did not stay the judgment of the High Court of Bombay the petitioner was not within its rights in increasing the price of Ventorlin inhaler, was it was aware that the Union of India was in appeal before the Supreme Court against the judgment of the High Court.

19. Arguing in rejoinder, Mr. Rana submits that the reliance, by Mr. Shukla on para 11 of the judgment of the Supreme Court in ***Cipla*** is completely misplaced. He submits that, in so asserting, Mr. Shukla has overlooked the fact that there was a fundamental difference between the petitioners before the High Court in ***Cipla*** and the present petitioner. The petitioners before the High Court in ***Cipla*** were in clear defiance of the DPCO 1995, as they had increased the price of the Scheduled formulations in violation of the DPCO 1995 *even while the DPCO 1995 was in operation and the inclusion of the seven drugs in dispute in that case in the First Schedule to the DPCO 1995 was yet to be stayed*. The demand against the petitioner, on the other hand, relates entirely to a period during which, by virtue of the judgment of the High Court of Bombay, the operation of the DPCO 1995, insofar as it included Salbutamol as a Scheduled drug, stood stayed. The decision of the Supreme Court to direct Cipla and other respondents before it to deposit 50% of the over-charged amount could not, therefore, be applied to the present petitioner. He reiterates that there

was no point of time when the present petitioner recovered, for the Salbutamol manufactured and sold by it, any amount in excess of that fixed by the DPCO.

20. Mr. Rana also disputes Mr. Shukla's contention that the judgment of the High Court of Bombay had merged in the judgment of the Supreme Court. He submits that, as no *lis* was determined by the Supreme Court in its judgment, there could be no question of merger.

21. Mr. Rana, in conclusion, relies, on the Circular dated 9 January 2002 issued by the NPPA, directing State Drug Controllers not to take any coercive action against manufactures, importers or distributors in respect of any of the seven drugs which formed subject matter of dispute in ***Cipla***, for having sold the said seven drugs at prices higher than those fixed by the DPCO 1995, though the judgment of the High Court was in appeal before the Supreme Court.

Analysis

Re: The impact of judgment of High Court of Bombay and the Supreme Court in ***Cipla***

22. Mr. Rana submits that during the entire period in respect of which the impugned demand has been raised, the judgment of the High Court of Bombay in ***Cipla*** was in operation, as no stay had been granted by the Supreme Court. It was for this reason, he submits, that the NPPA had, in its circular dated 9 January 2002 addressed to all

State Drug Controllers, restrained any coercive action being taken against manufacturers who had charged, for one or more of the seven drugs which formed subject matter of controversy in ***Cipla*** – which included Salbutamol – any amount in excess of that fixed by the DPCO 1995.

23. Inasmuch there was no over-charging by the Petitioner in respect of its Ventorlin inhaler, no demand under Para 3 of the DPCO 1995 could be raised.

24. Mr. Rana is correct.

25. Till the date of the judgment of the High Court of Bombay in ***Cipla***, the price charged by the petitioner for its Ventorlin inhaler was, in fact, in accordance with the DPCO 1995. The inclusion of Salbutamol in the First Schedule to the DPCO 1995 was *struck down* by the High Court in its decision in ***Cipla***, which was rendered on 31 August 2001. With effect from 31 August 2001, therefore, *Salbutamol was no longer included in the First Schedule to the DPCO 1995.* The period of demand in the present case is March 2002 to August 2003. The judgment of the Supreme Court in Cipla was rendered on 1 August 2003. As soon as the judgment was rendered, the Petitioner reduced the prices of its Ventorlin inhaler and brought it in accordance with the DPCO 1995. It is clear, therefore, that the Petitioner was in in compliance with the DPCO as it was in existence and operation at all points of time.

26. The court has, however, to address the implication of the judgment of the Supreme Court in ***Cipla***, rendered by it on 1 August 2003, on demands pertaining to the period 31 August 2001 to 1 August 2003. In the present case, the demand which relates to the period March 2002 to 31 August 2003, relates to the said period.

27. The pivotal issue is whether, in view of the judgment of the Supreme Court, it is open to the respondents to enforce the impugned communications dated 5 October 2004 and 17 December 2004 against the petitioner.

28. This has to be examined in the background of Para 13 of DPCO 1995, seen in the light of the judgment of the Supreme Court in ***Cipla***.

29. Para 13 empowers the government to require manufacturers who charge prices higher than the prices fixed or notified under the DPCO 1995, to deposit the amount that accrued to the manufacturers as a result of such over-charging. During the period of demand in the present case, *there was in fact no price fixed by the DPCO in respect of Salbutamol in force*. It was not as though the Bombay High Court had merely stayed the inclusion of Salbutamol in the First Schedule to the DPCO 1995 by its judgment dated 31 August 2001, in which case it might have been possible to contend that the inclusion of Salbutamol in the First Schedule merely stood eclipsed during the period the judgement of the High Court remained in operation, and that the shadow was removed with the judgement of the Supreme Court. Where the inclusion of Salbutamol in the First Schedule was

struck down by the High Court, the doctrine of eclipse has no application. The judgment set aside the inclusion of the seven drugs which formed subject matter of controversy in the First Schedule to the DPCO 1995. The Supreme Court has not dismissed the writ petitions filed by Cipla and others before the High Court of Bombay. The writ petitions have been remanded for *de novo* consideration. Unless the Supreme Court were to explicitly so state, or the writ petitions filed by Cipla and others before the High Court were to fail, there could be no question of treating Salbutamol as included in the First Schedule to the DPCO 1995 during the period 31 August 2001 to 1 August 2003.

30. Mr. Shukla's contention that, on par with the respondents before the Supreme Court in ***Cipla***, the present petitioner should also be directed to deposit 50% of the impugned demand, fails to notice a fundamental difference between the petitioners before the Bombay High Court in ***Cipla*** and the present petitioner. The petitioners before the High Court were manufacturers who, *during the time the seven drugs in question were part of the First Schedule to the DPCO 1995*, charged in excess of the price fixed by the DPCO in respect of those drugs. In stark contrast, *the price fixed by the Petitioner in respect of its Ventorlin inhaler during that period was in accordance with the DPCO 1995*. The Petitioner increased its price only after the Bombay High Court by its judgment dated 31 August 2001, set aside the inclusion of Salbutamol (and six other drugs) in the First Schedule to DPCO 1995. *Unlike the Petitioner before the High Court of Bombay, therefore, the present Petitioner never charged, for Salbutamol, in*

derogation of the DPCO 1995 or the price fixed by it. Absent overcharging, it is obvious that there can be no sustainable demand under para 13 of the DPCO 1995.

31. The Supreme Court was, therefore, concerned with manufacturers who had charged in excess of the prices fixed by the DPCO 1995 even while the DPCO was in operation. Having charged in excess of the price fixed by the DPCO 1995, the said manufacturers – who were the respondents before the Supreme Court – sought to challenge the inclusion of their drugs in the First Schedule of 1995 itself.

32. That challenge was accepted by the High Court of Bombay. The Supreme Court reversed the judgment of the High Court of Bombay and remanded the matter for *de novo* consideration. The decision of the Supreme Court to subject the respondents before it to a condition of deposit of 50% of the demand against them cannot, therefore, apply to the present petitioner, as the situation of the petitioner is fundamentally different from that of the respondents before the Supreme Court. The respondents before the Supreme Court had consciously charged, for the products manufactured by them, prices which were in excess of those fixed by the DPCO 1995, before proceeding to launch a challenge to the DPCO. It was 50% of such over-charged amounts which the Supreme Court directed the said companies to deposit.

33. As against this, the Petitioner never charged any amount in excess of the price fixed by the DPCO 1995 at any point of time.

34. During the period of demand in the present case, Salbutamol was not a scheduled drug under the DPCO 1995. It has not become a scheduled drug under the DPCO 1995 by virtue of the judgment of the Supreme Court either.

35. I do not see, therefore, how Mr. Shukla seeks to rely on the judgment of the Supreme Court in ***Kunhayammed***. To reiterate, this is not a case in which Salbutamol was actually in the First Schedule to the DPCO 1995 during the period of demand, and its inclusion stood stayed by the High Court of Bombay. Had that been the situation, perhaps the reliance on ***Kunhayammed*** might have been justified.

36. This is a case in which, during the period of demand, Salbutamol *was not* part of the First Schedule to the DPCO 1995.

37. The very basis of the impugned demand, therefore, is fundamentally misplaced. Rule 13 applies only where a manufacturer charges for its drug, a price which is in excess of that fixed by the DPCO 1995. For that, the drug has, in the first instance, to be included in the First Schedule to the DPCO 1995. During the period of dispute, was not a Scheduled drug under the DPCO 1995.

38. Where the respondent appears to have erred is in assuming that the sequitur of the judgment of the Supreme Court in Cipla was to include, in the First Schedule to the DPCO 1995, the seven drugs

which were subject matter of controversy before the Supreme Court. That, however, is not the effect of the judgment of the Supreme Court. The Supreme Court has not dismissed the challenged of Cipla and other petitioners before the High Court of Bombay. It has remanded the challenge for *de novo* consideration. The judgment does not, therefore, undo the effect of the High Court of Bombay and bring Salbutamol, and the other six drugs, within the fold of the First Schedule to the DPCO 1995. The High Court has been directed to re-examine the matter. In fact, after having referred to the aspects which, according to it, escaped the attention of the High Court while rendering its decision, the Supreme Court, in para 8.6 of its judgment, observed thus:

> "8.6. We have broadly indicated the aspects on which the High Court could have focused its attention before reaching the conclusion it did. *Nothing precludes the High Court from having regard to other aspects or material which it considers relevant to test the correctness of the writ petitioners' claims*. However, we would like to clarify one thing. If, on reconsideration, the turnover of any drug is found to be very close to the figure — ₹ 400 or 100 lakhs, as the case may be, the relevant criterion must be deemed to have been satisfied. As we said earlier, mathematical accuracy is not what is required."
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> (Emphasis supplied)

39. Thus, it cannot be said, in law, that, by operation of the judgment of the Supreme Court, Salbutamol *ipso facto* stood included in the First Schedule of the DPCO 1995 during the period to which demand in the present case relates. I have not been informed of any further developments in the High Court of Bombay consequent to the remand by the Supreme Court. The website of High Court of Bombay seems to indicate that the writ petitions are still pending.

40. The outcome of the proceedings in the High Court of Bombay is still in the realm of speculation.

41. As of today, the position is that, during the period of demand in the present case, Salbutamol was not in the First Schedule to the DPCO 1995 and, therefore, there could be no demand for overcharging of Salbutamol predicated on Para 13 of the DPCO 1995.

42. Even for this reason, therefore, the impugned communications, and the demand envisaged therein, have necessarily to be set aside.

43. In that view of the matter, the necessity of examining the alternate submission of Mr. Rana, predicated on the judgement of the High Court of Allahabad in ***T.C. Healthcare***, stands obviated.

Conclusion

44. In view of the aforesaid, the impugned communications dated 5 October 2004 and 17 December 2004, and the demand envisaged therein cannot sustain on facts or in law.

45. The demand is accordingly quashed and set aside. The writ petition stands allowed, with no order as to costs.

46. The petitioner would be entitled to the refund of amount deposited with this Registry consequent to the impugned orders along

with any interest that may have been accrued thereon. The petitioner shall also be entitled to be returned to the bank guarantee furnished by it as per the interim orders passed by this Court.

WP (C) 1527/2005

47. The facts of this case are identical to those in WP (C) 39/2005. The period of demand is also the same vis-à-vis March 2002 to August 2003. The dates of the impugned communications are, however, different, as they are dated 14 October 2004 and the 19 January 2005.

48. The impugned communications dated 14 October 2004 and the 19 January 2005 are therefore quashed and set aside.

49. The petitioners would be entitled to the refund of amount deposited with this Registry consequent to the impugned orders along with any interest that may have been accrued thereon. The petitioners shall also be entitled to be returned to the bank guarantee furnished by it as per the interim orders passed by this Court.

C. HARI SHANKAR, J.

DECEMBER 26, 2023
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