IN THE HIGH COURT OF DELHI AT NEW DELHI

% Judgment delivered on: 12.10.2018

+ **W.P.(C) 12351/2009**

AMKAY LABORATORIES PVT LTD ..... Petitioner

versus

UNION OF INDIA AND ORS ..... Respondents

Advocates who appeared in this case:

For the Petitioner : Mr Piyush Sharma and Mr K. G. Mishra, : Advocates.

For the Respondent : Mr Kirtiman Singh, CGSC, Mr Manish : Mohan, CGSC with Ms Manisha Saroha, : Mr Waize Ali Noor, Mr Prateek Dhanka, : Ms Shruti Dutt and Mr Vikramaditya : Singh, Advocates.

CORAM
HON'BLE MR JUSTICE VIBHU BAKHRU

JUDGMENT

VIBHU BAKHRU, J

1. The petitioner has filed the present petition, *inter alia*, impugning a notification – S.O. 1022(E) dated 1st December, 1998 – issued by respondent no.2 (hereafter 'NPPA') fixing the ceiling price of Gentamycin Sulphate Eye/Ear Drops. The petitioner also impugns an order dated 20.01.2009, *inter alia*, demanding a sum of ₹8,98,946/- from the petitioner on account of charging a price in excess of the ceiling price fixed for the formulation in question. In addition, the petitioner is also called upon to pay interest quantified at ₹2,82,853/-

on the aforesaid amount up to January, 2009 and further interest at the rate of 15% p.a. on the amount so demanded.

2. The petitioner owns a Small Scale Industrial Unit located in the State of Uttar Pradesh. In 1994, the petitioner was granted the license by the Drug Controller State of Uttar Pradesh for manufacture of Gentamycin Sulphate with 2% base.

3. On 01.12.1998, the NPPA issued a price fixation order modifying an earlier order dated 31st January, 1995 whereby, the price for formulations containing Gentamycin was fixed. The relevant extract of the revised prices so fixed are reflected in the tabular statement set out below:-

5.	Gentamycin Sulphate E/E Drop	Each ml contains Gentamycin Sulphate eq to 0.3% of Gentamycin Base	5 ml Vial Droper & Carbon	6.68
7.	Gentamycin Sulphate & Hydrocortisone Acetate E/E/ Drop	Gentamycin Sulphate eq. to 0.3% of Gentamycin Base + Hydrocortisone Acetate 1%	5 ml Vial Droper & Carton	11 20"

4. It is the petitioner's case that since it is a Small Scale Industry, it is exempt from the rigors of the Drugs(Price Control) Order, 1995 (hereafter 'the DPCO') issued in exercise of powers under the Essential Commodities Act, 1955.

5. In addition, the petitioner contends that the formulation manufactures by it – "Gentamycin Sulphate 0.3% w/v Benzalkonium

Chloride Solution (as preservative) 0.02% v/v Sterile Istonic Aqucous base Gentamycin Sulphate" (hereafter 'the Product') – is not covered under the impugned notification issued by the NPPA.

6. It is the petitioner's case that there is a vast difference between the Product (formulation manufactured by the petitioner) and the formulation for which ceiling price has been fixed in terms of the impugned notification. The petitioner has set out a tabular statement in the petition, indicating the differences between the Product and the formulation as specified in the impugned notification. The said statement is set out below:-

Head	**As per SO-1022 (E) dated 01.12.1998**	**As per petitioner approved formulation**
Name of Product	Gentamycin Sulphate E/E Drop	Gentocin Eye/Ear Drops
Composition (each ml. contains)	Gentamycin Sulphate eg. To 0.3% of Gentamycin Base	Gentamicin Sulphate 0.3% w/v Benzalkonium Chloride Solution (As preservative) 0.02% v/v Sterile Istonic Aqucous base
Packing Detail	5 ml Vial Droper & Carton	5 ml ETO Sterlised Plastic Bottle & Carton
Definition	It is complex Mixture of Gentamicin C1C2C1a produced by fermentation of Micromonospora purpurea	It is complex mixture of sulphate salt of Gentamicin C1C2C1a produced by fermentation of Micromonospora purpurea
Description	White amorphous powder, melting	White hygroscopic powder melting point

	point 1020C-1080C, Freely soluble in water	2180C-2370C, soluble in ethylene glycol and water
Actual composition	Gentamicin sulphate eg. To Gentamycin base 0.3% which is equivalent to 0.396% of Gentamicin Sulphate	Gentamycin Sulphate 0.3% which is equivalent to 0.227% of Gentamycin base
Calculateion	If 100 mg. Of Gentamycin is = 132 mg. Of Gentamycin Sulphate Then 0.3 mg. Of Gentamycin is = 132x0.3/100=0.396 mg. Gentamycin Sulphate	If 132 mg. Of Gentamycin Sulphate is = 100 mg. Of Gentamycin Then 0.3 mg. Of Gentamycin Sulphate is = 100x0.3/132=0.227 mg. of Gentamycin
Note	As per Indian Pharmacopoeia 2007 Gentamycin Sulphate contains 32=35% of Sulphate. Above calculation is based considering sulphate contents at 32%	As per Indian Pharmacopoeia 2007 Gentamycin Sulphate contains 32-35% of SSulphate. Above calculation is based considering sulphate contents at 32%
Potency	0.3 mg of Gentamycin base contains 0.396 mg of Gentamycin Sulphate77	0.3 mg. Of Gentamycin Sulphate Contains .227 mg. Of Gentamycin base

7. The petitioner also impugns the ceiling price fixed under Paragraph 7 of the DPCO on the ground that the Central Government had not specified the norms for costs as required in terms of Paragraph 7 of the DPCO.

8. It is seen that the issues raised by the petitioner are squarely covered by various decisions of the Supreme Court.

9. In ***M/s Swiss Garnier Life Sciences and another v. Unionof India and another*** :***(2013) 8 SCC 615***, the Supreme Court had authoritatively held that if the bulk drug as included in the Schedule to the DPCO was used in a formulation, the same would fall within the definition of the term "scheduled formulation" as defined in Paragraph 2 (v) of the DPCO. In this view, the product manufactured by the petitioner falls within the scope of the term 'scheduled formulation', and is subject to the rigors of the DPCO.

10. The issue whether the Small Scale Industrial Units are excluded from the scope of DPCO is also not *res integra.* The Supreme Court, in the case of ***Union of India & Ors. v. Cipla Ltd. &Anr.: (2017) 5 SCC 262***, had held that "*there is nothing in the DPCO 1995 to suggest that a small-scale industry is kept out of the rigor of the DPCO 1995. It is equally bound by any retail price or ceiling price fixation by the Central Government*".

11. In view of the above, the contention that the DPCO is inapplicable to the petitioner is erroneous and is, accordingly, rejected.

12. The petitioner's challenge to the impugned notification on the ground that the Central Government had not fixed the norms for costs, is also unsustainable. Concededly, the said issue is also covered against the petitioner in terms of the decision of the Supreme Court in ***Union of India &Ors. v. Cipla Ltd. & Anr.*** (*supra*).

13. In view of the above, the learned counsel appearing for the petitioner earnestly contended that since the Product is considered to be a scheduled formulation, which is covered under the impugned notification, the petitioner must have an opportunity to approach the NPPA for determining the ceiling price, as the petitioner's cost of packaging is higher than the packaging considered by NPPA. He contended that NPPA has fixed the ceiling price of the formulation packaged in a vial dropper and carton; however, the petitioner packages the formulation in a plastic bottle, which entails significantly higher costs. He further submitted that the petitioner had made a representation to the Central Government on 15.09.2009 but had received no response thereto. He submitted that the said representation was pending and was required to be considered for factoring in the higher cost of the packaging used by the petitioner. He also referred to Paragraph 22 of the DPCO and contended that the petitioner was entitled seek a review of any order made under the specified provisions (Paragraphs 3,5,8,9 or10) of the DPCO.

14. It is relevant to note that the impugned notification was issued on 01.12.1998 (almost 20 years ago). If the petitioner was aggrieved by the same, the petitioner had an option to seek revision of the retail price or the ceiling price fixed for the formulation in question. This option was available to the petitioner in terms of Paragraphs 8 and 9 of the DPCO. However, the petitioner had filed to avail of the said option.

15. Paragraphs 8 and 9 of the DPCO are set out below:-

"**8. Power to fix retail price of Scheduled Formulations**:

1. The Government may, from time to time, by order, fix the retail price of a Scheduled formulation in accordance with the formula laid down in paragraph 7.
2. Where the Government fixes or revises the price of any bulk drug under the provisions of this Order and a manufacturer utilizes such bulk drug in his Scheduled formulations he shall, within thirty days of such fixation or revision, make an application to the Government, in Form-III for price revision of all such formulations and the Government may, if it considers necessary, fix or revise the price of such formulation.
3. The retail price of a formulation once fixed by the Government under (1) and (2) shall not be increased by any manufacturer the- prior approval of the Government.
4. Any manufacturer, who desires revision of the retail price of a formulation fixed, under sub paragraph (1), shall make an application to the Government in Form III or Form IV, as the case may be, and the Government shall after making such enquiry, as it deems fit within a period of two months from the date of receipt of the complete information, fix a revised price for such formulation or reject the application for revision for reasons to be recorded in writing.
5. Notwithstanding anything contained in the foregoing sub-paragraphs, the retail price of a Scheduled formulation, of a manufacturer shall until the retail price thereof is fixed under the provisions of this Order, be the price which prevailed immediately before the commencement of this Order, and the manufacturer of such formulation shall not sell the formulation at a price exceeding the price prevailing immediately before the commencement of this Order.

6. No manufacturer or importer shall market anew pack, if not covered under sub-paragraph 3 of para 9, or a new formulation or a new dosage form of his existing Scheduled formulation without obtaining the prior approval of its price from the Government.

7. No person shall sell or dispose of any imported Scheduled formulation without obtaining the prior approval of its price from the Government.

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 the ceiling price of a Scheduled formulation in accordance with the formula laid down in paragraph 7, keeping in view the cost or efficiency, or both, of major manufacturers of such formulations and such price shall operate as the ceiling sale price for all such packs including those sold under generic name and for every manufacturer of such formulations.

2. The Government may, either on its own motion or on application made to it in this behalf by a manufacturer in Form III or Form IV, as the case may be, after calling for such information as it may consider necessary, by notification in the Official Gazette, fix a revised ceiling price for a Scheduled formulation.

3. With a view to enabling the manufacturers of similar formulations to sell those formulations in pack size different to the pack size for which ceiling price has been notified under the sub-paragraphs (1) and(2), manufacturers shall work out the price for their respective formulation packs in accordance with such norms, as may be notified by the Government from time to time, and he shall intimate the price of formulation pack, so worked out, to the Government

> and such formulation packs shall be released for sale only after the expiry of sixty days after such intimation:
>
> Provided that the Government may, if it considers necessary, by order revise the price so intimated by the manufacturer and upon such revision, the manufacturer shall not sell such formulation at a price exceeding the price so revised.
>
> **Explanation -** For the purpose of this paragraph the "Scheduled formulation" includes single ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name."

16. It is also relevant to note that if the petitioner had applied for revision of the retail price or the ceiling price at the material time and the same was accepted, it would be operative only after the revised price had been fixed. Thus, at this stage, the request of the petitioner that it be permitted to apply for factoring in its costs in the price fixed in terms of the impugned notification, cannot be accepted.

17. The contention that the petitioner had made a representation with regard to the costs to the Central Government, which is required to be considered, is also not persuasive. A plain reading of the representation dated 15.09.2009 submitted by the petitioner indicates that the same was bereft of any particulars as to the additional costs, which the petitioner now requests should be factored in the ceiling price for the Product.

18. The contention, that the representation ought to have been considered as review under Paragraph 22 of the DPCO, is equally

unmerited. A plain reading of paragraph no.2 of the said representation indicates that the petitioner has expressly asserted that its case could not be covered under the provisions of Paragraph 22 of the DPCO. Thus, the petitioner's representation could not be considered as an application for review under Paragraph 22 of the DPCO. Since, there was no other provision for considering the petitioner's representation, the same was not responded to. Therefore, the petitioner's grievance in this regard is also unjustified.

19. The learned counsel for the petitioner further relied on the decision of the Allahabad High Court in ***TC Healthcare Pvt. Ltd. v. Union of India*** : ***ADJ 2010 5 401***; the decision of the High Court of Rajasthan in ***M/s Lark Laboratoris (India) Limited &Anr. v. Union of India &Ors.: (D.B.) Civil Writ Petition No. 7198/2017, decided on 13.10.2017***; and the decision of Himachal Pradesh High Court in ***M/s Swiss Garnier Life Sciences and Anr. V. Union of India and Anr.*** : ***CWP 4128/2009, decided on 30.07.2018*** in support of his contention that the matter should be remanded to NPPA to consider afresh.

20. The said decisions are wholly inapplicable in the facts of the present case. In ***Swiss Garnier Life Sciences and Anr. V. Union of India and Anr.*** : ***CWP 4128/2009*** (*supra*), the High Court of Himachal Pradesh was concerned with an order passed by the Director (Legal) rejecting the petitioner's claim for exemption and further imposing a monetary penalty. The Court found that there was nothing on record which could lead to the inference that Director (Legal) had the authority to adjudicate the issue of imposition of penalty and,

accordingly, the matter was remanded to the Competent Authority under the DPCO to decide the matter afresh. This is clearly not the issue involved in the present case.

21. In the case of ***M/s Lark Laboratoris (India) Limited &Anr.*** (*supra*), the Court had not remanded the matter but permitted the petitioner to file a review petition under paragraph 22 of the DPCO. In the facts of the present case, this Court does not consider it apposite to grant any such liberty. The DPCO is no longer applicable and has been replaced by the Drugs (Price Control) Order, 2013. It would not be apposite to permit the petitioner to seek review of the cost structure that was considered by the NPPA in 1998.

22. The decision of the case of ***TC Healthcare Pvt. Ltd.*** (*supra*) is also of little assistance to the petitioner in this regard. The said decision was rendered in petitions filed to challenge the notification dated 30.04.2009. The said petitions were disposed of on 20.04.2010 and, in the facts of that case, the Court granted (in Writ Petition No. 3375/2009) liberty to the petitioner to move an application for review under Paragraph 22 of the DPCO. However, no such liberty was granted to the writ petitioner in W.P. (C) 7400/2009 wherein notices for overcharging were raised.

23. Thus, the contention of the petitioner that the formulation manufactured by it is not a "scheduled formulation" or is not subject to the ceiling price notified in terms of the DPCO, is unmerited and is rejected as such.

24. Insofar as the demand for the overcharged amount computed at ₹8,98,946/- is concerned, this Court also finds no infirmity with the order dated 20.01.2009. However, the demand for interest (quantified at ₹2,82,853/-) relating to the period prior to the said order is unsustainable.

25. A Coordinate Bench of this Court in ***Best Laboratories Pvt. Ltd. v. Union of India and Ors.: 2011 (124) DRJ 390*** had observed that the liability to pay interest would arise only once a default is committed in making a payment of the demanded amount within the time stipulated therein. The Court also referred to a similar view expressed by the Division Bench of the Allahabad High Court in ***T. C. Healthcare Pvt. Ltd. v. Union of India*** (*supra*). The Court had also referred to Section 7A of the Essential Commodities Act, 1955 and observed that the said provision made it explicit that interest would be payable in the event of default was committed in not paying the amount demanded within time.

26. In the present case, the demand was raised for the first time by the impugned order dated 20.01.2009 and the petitioner was called upon to pay the amount demanded within a period of fifteen days from the date of the said letter. Thus, the liability to pay interest would only arise with effect from 04.02.2009 (that is, on expiry of fifteen days after the date of the impugned letter).

27. In ***Shimal Investment and Trading Co. v. Union of India and Ors.: W.P.(C) 3125/2001, decided on 21.10.2013***, another Coordinate

bench of this Court had followed the earlier decision in ***Best Laboratories*** (*supra*)**,** and directed that the interest would be payable only from the date the excess amount was demanded for the first time.

28. In view of the above, the impugned order to the extent it seeks recovery of interest for the period prior to the date of the order, is set aside.

29. The petition is disposed of in the above terms.

VIBHU BAKHRU, J

OCTOBER 12, 2018
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