

IN THE HIGH COURT AT CALCUTTA
Constitutional Writ Jurisdiction
Appellate Side

Present: - Hon'ble Mr. Justice Subhendu Samanta.

IN THE MATTER OF
WP 20797 (W) of 2015
Palsons Derma Pvt. Ltd. & Anr.
Vs.
Union of India & Ors.

For the Petitioners : **Mr. Samir Chakraborty, Sr Adv.,**
Mr. Soumabho Ghosh, Adv.,
Mr. Sachin Shukla, Adv.,
Mr. Mchul Bachhawat Adv

For the
Union of India : **Mr. Tarunjyoti Tewari, Adv.,**
Mr. Bikramjit Dutta Adv,
Ms. Kausiki Bose Adv.

Reserved on : **05.03.2025**

Judgment on : **17.07.2025**

Subhendu Samanta, J.

1. Petitioner No. 1 is a company incorporated under Companies Act, 1956, carries on business of manufacture and sale of various pharmaceutical products including manufacture of medicines of dermatological elements from the year 1985. Respondent No. 1 & 2 are the Officers of National Pharmaceutical

Pricing Authority (NPPA), a statutory body authorised under Essential Commodities Act, 1995 and Drug Pricing Control Order 1995 [(DPCO)] 1995 to implement and enforces the selling price of identified scheduled Drugs and Scheduled Formulations.

2. (DPCO) 1995 seeks to control and restrict maximum selling price of scheduled bulk drugs enumerated in the scheduled attached to DPCO 1995. One of such drug included in the scheduled DPCO 1995 is “Betamethasone Dipropionate”. By such order NPPA fixed the upper selling price at which the formulations containing scheduled bulk drug can be sold. Accordingly on December 14, 2007 NPPA issued a notification being Standing Order 226 (F) enumerating the maximum selling price of formulations of the scheduled bulk drug “Betamethasone Dipropionate”.

3. In 1997 petitioner No. 1 had started manufacturing a product called “Kancel-B gel” a gel formulation of “Betamethasone Dipropionate”. The standing order specifically covered only the cream, ointment and lotion format of the said scheduled drug but did not include gel formulation. Therefore,

petitioner No. 1 continue manufacturing “Kancel-B gel” without adhering to any price restrictions provided in the standing order.

4. The petitioner No. 1 served with a letter dated 14.01.2010 containing inter alia that it was illegally retailing “Kancel-B gel” without adhering to the selling price restriction imposed in the standing order. Similar letters were sent by NPPA on 06.12.2012 and 01.08.2013. Petitioner replied to the aforesaid letter and informed NPPA that the standing order included only “Betamethasone Dipropionate” in its cream and ointment and not the gel formulation manufactured by the petitioner. It has been further contended by the petitioner that “Kancel-B gel” was distinctly different from ointment and cream and therefore, Standing Order could not anyway applicable to “Kancel-B gel”. NPPA only denied the reasons provided by the petitioner, and on 02.02.2015 raised a demand of Rs. 1,15,61,016/- as the overcharge amount and interest therein. Against the said demand letter, this petitioner approached this court in a writ petitioner being WP 11039 (W) of 2015. A Co-ordinate Bench vide its order dated 08.06.2015 disposed of the writ petition and directed Directors NPPA to examine the issued deeper and passed a

reasoned order after granting reasonable opportunity of hearing to the petitioner thereby the impugned order dated 2nd February 2015 and 17th March 2015 along with of a consequential orders thereto are kept in abeyance. In terms of such direction, the concerned NPPA allowed the petitioner to submit a written representation and allowed the petitioner for hearing thereafter passed the impugned order whereby, respondent authority found representation of petitioner to be devoid of merit and directed petitioner to pay Rs.1,19,62,329/- as demand for price overcharge amount along with interest therein.

5. Issue involved **First:-** whether “Betamethasone Dipropionate” in gel formulation is included in the standing order dated February 14, 2007.

6. **Second:-** whether petitioner entitled to trade discount of 60% as deduction from amount claimed.

7. **Third:-** whether in such a case interests should be calculated from the expiry of the period mentioned in the demand notice or from the date of the over charge.

8. **Petitioner's Submission**

Learned Counsel for the petitioner submits that there are distinction between, cream, ointment and gel formulation. The properties of ointment, cream and gel formulation are distinctly unique. Application of the above named dosage forms is different and heavily dependant on the desired consequences. While ointment/cream is prescribed mostly for case where “occlusion” is the desired effect, gel is prescribed in cases where “absorption”, is the desired fact. It has been stated in various scientific studies that the difference in vehicle that gel provides greater dissolution of drugs, permits easier migration of drug and faster drug release as compared ointment or cream of the same composition. Thus, they are superior in terms of use and patient acceptability. Learned Counsel for the petitioner further argued that “Kancel-B gel” is an entirely different medicine with compared to the ointment or cream formulation of the said bulk drug “Betamethasone Dipropionate”. He further submits gel formulation has been noted to be more efficacious in certain cases where the cream/ ointment formulation are not very effective. Various

scientific studies have unequivocally concluded that correct choosing amount dosage forms gel ointment or cream formulation is critical for effective treating a particular element.

9. Learned Counsel submits that it is to be noted that various scientific studies unequivocally state the characteristics of the vehicle, in this case gel as opposed to cream/ointment can profoundly module the local and systematic safety as well as potency corticosteroid teroid like “Betamethasone Dipropionate” in patients.

10. Learned Counsel further contends that gel is noted to have distinct property faster drug relief when compared other two dosage forms. Petitioner further submits NPPA itself under various notifications identified gel cream and ointment as distinct product. He further submits, it indeed “Kancel-B gel” was envisaged to be included in standing order dated 14.02.2007, there would be an explicit provision stating that “Betamethasone Dipropionate” combination would be included in its gel form.

11. Respondent's contention

Learned Counsel appearing on behalf of the respondents submits that gel formulation is to be considered a special feature, or a different packaging materials and thus forms part of Standing Order and hence it is only remedy for the petitioners to approach NPPA in Form III prescribed in Paragraph-9 (2) of DRCO 1995 for obtaining specific price for “Kancel-B gel”.

Decision on

Issue No. 1

Having heard the Learned Counsels for the parties and considering the rival submissions it is admitted fact and that “Kancel-B gel” is a formulation of “Betamethasone Dipropionate”. It is also admitted that “Kancel-B gel”(gel formulation of Bulk Drug) was not mention in Standing Order dated 14.02.2007. It is also admitted that formulations contained “Betamethasone Dipropionate” is listed as a scheduled Bulk Drug under DRCO 1995 whereas though the gel formulation of particular scheduled drug is completely different from its ointment and cream

formulation but as the formulation is contained “Betamethasone Dipropionate” a scheduled drug, as such the gel formulation is subject to price control regulation to regularise of the drug delivery system

12. For better appreciation of issue involved in this matter, clause 9 of Drug Price Control Order, 1995 is required to be set out as follows-

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.

13. On the above clause it appears that manufacturer has the opportunity to file an application before the appropriate authority for fixing revised selling price for the scheduled formulation. As "Betamethasone Dipropionate" is a scheduled drug as it is listed in item 44 in the first scheduled DRCO 1995 the authority concern is empowered to fix and notified maximum sell price of the scheduled bulk drug of the related formulation under the provisions of DRCO 1995. It further appears that as per clause "C" under "note" of order dated 14.02.2007 of NPPA, petitioner has the opportunity to approach the NPPA for approval/fixation of specific price; but the petitioner have not adopted the said procedure and to proceeded to sale out the 'Kancel-B gel' Thus, the concern authority has correctly demanded the

amount of over charge for selling of “Betamethasone Dipropionate” gel formulation in the market. I have also perused the impugned order passed by the concerned authority, the petitioner was heard and also allowed to place his statements. The authority concerned has considered the submission of petitioner has passed the reasoned order. In my opinion the reasoned order passed by the concerned authority is not appears to be illegal, mala fide or arbitrary. Thus the instant issue decided against the petitioner.

Issue No. 2 Paragraph 19 DPCO provides only 16% mergin for retailers the paying company manufacturer of the drug cannot claimed the same relief which is provided for the retailers. Moreover the petitioner has fixed the selling price which includes 16% mergins for the retails. Thus the claim of the petitioner regarding 16% of mergin money given as a trade discount to the retailer is not tenable in the eye of law.

This issue also decided against the petitioner.

Issue 3

It is the contention of the petitioner that issue of claiming interest has already been decided by the Hon'ble other High Courts, though against such orders the respondent authority has approached to the Hon'ble Supreme Court. This is the contention of the respondent authority that Hon'ble Supreme Court has not decided the issues yet.

14. Learned Counsel for the petitioner submits that Section 7 A of EC Act 1955, provides that interest is payable only if a person liable to pay any amount in pursuance of an order u/s 3, makes any default in paying such amount. Such interest is payable @ 15% from the date of default till of date of recovery as arrear land revenue or public demand. He submits that in the present case earlier demand notice dated 02.02.2015 was kept in abeyance and /or set aside by this court by virtue of an order dated 8.06.2015 and respondent authority was directed to pass a fresh reasoned order. Petitioner further submits that under the circulation of coordinate bench of this court, impugned order was passed on 03.08.2015 and it gave petitioner 15 days time from the date of order to pay the demand. Hence, in the

present case interest, if at all can be levied only from 18.08.2015 accordingly. The interest from 18.01.2015 till January 31, 2025 on the principal over charge amount or Rs 43lakh 36thousand 858 @ of 15% amount to RS 61 lakh 55 thousand 963 as against the interest 64 lakh 13 thousand 871 demanded in the impugned order.

In support of his contention he cited several decisions as follows –

27) The Petitioners rely upon the following judgments in support of their submissions on the issue of levy of interest:

a) T. C. Health Care Pvt. Ltd. vs. Union of India 2010 SCC Online All 834 (Para 21-22)

b) Best Laboratories Pvt. Ltd. vs. Union of India (2012 187 DLT 434) (Pg. 12) ("Best Laboratories")

c) Shimal Investment & Trading Co. vs. Union of India & Ors. 2013 SCC Online Del. 4165 (Para 11) ("Shimal Investment")

d) Franco Indian Remedies Private Limited & Ors. vs. Union of India & Ors. MANU/MH/2923/2016 (Paras 60 to 63) ("Franco Indian")

e) Unreported judgment dated 02.11.2018 of this Hon'ble Court in WP (C) 3335/2015 in Hesa Pharmaceutica vs NPPA & Anr (Paras 5 to 9) ("Hesa Pharmaceutica")

f) Astalife Vs. MANU/TN/6786/2022 (Para 9 to 12) ("Astalife")

It appears from the status report annexed with the written notes of argument of the petitioner that **Franco India (supra)** the division Bench of Bombay High court has ordered that the interest was to be levied on the date of impugned order. It is the further contention of the petitioner that against the order in Jet Enterprices Ltd. Vs. NPPA passed by Hon'ble Bombay High Court, Union of India has approached before the Hon'ble Supreme Court. Petitioner

submits that the said appeal was withdrawn; accordingly, Supreme Court had no occasion to go into the correctness of the law laid down **Jet Enterprises (Supra)**. The petitioner also submits that three appeals filed against the judgment dated 20nd April 2010 of Allahabad High Court in **TC Health Care (supra)** were filed by the Union of India. The appeal of Union of India based on issues of trade discount and interest. All three appeals were dismissed by a common judgment of the Hon'ble Supreme Court on 15th November 2019. The Hon'ble Apex Court has not decided anything on merit but has dismissed appeal of Union of India. Thus the finding of Hon'ble Allahabad High court. Now ruling the field.

15. Having heard the Learned Counsel for the petitioner it appears that there are pronouncement of judgment by the different High courts in respect of the issue of interest. In this case a Coordinate Bench of this court has disposed of the earlier writ petition thereby demand notice dated 02.02.2015 was kept in abeyance. The order of kept in abeyance not means that the same has been set aside.

16. Under the above observation I find no merit to entertain the writ petition accordingly the instant writ petition is dismissed and disposed of.

17. However, co-ordinate Bench of this court has directed the authority concerned to take a fresh decision. In pursuance to such direction impugned order was passed on 03.08.2015. this impugned order directed the petitioner to pay the amount within 15 days from the date of the order. Thus, interest has to be calculated from the date of default of fresh decision (impugned) i.e. from 18.08.2015 till its realisation

18. Parties to act upon the server copy and urgent certified copy of the judgment be received from the concerned Dept. on usual terms and conditions.

(Subhendu Samanta, J.)

Later:-

After the judgment is pronounced in open court Learned Counsel for the petitioner seeks an order of stay of operation of the order passed by this court today.

Strong objection raised by Learned Counsel for the respondent.

Considering the submissions, the prayer for stay is considered and rejected.

(Subhendu Samanta, J.)