**IN THE HIGH COURT OF JUDICATURE AT BOMBAY
ORDINARY ORIGINAL CIVIL JURISDICTION
WRIT PETITION NO. 595 OF 2017
WITH
CHAMBER SUMMONS NO. 135 OF 2017
IN
WRIT PETITION NO. 595 OF 2017**

M/s. Pharmed Limited & Anr. ... Petitioners
Versus
Union of India & Ors. ... Respondents

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Mr. Navroz Seervai, Senior Counsel a/w Mr. Akash Rebello, Mr. Abhay Jadeja and Ms. Urvi Gulechha i/by Jadejas & Partners for Petitioners.
Mr. R. V. Govilkar, Senior Counsel a/w Dr. G. R. Sharma, Mr. D. P. Singh and Ms. Apurva Gupta for Respondent Nos.1 to 3.
Ms. Anupamaa Pawar, AGP for Respondent No. 4-State.

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CORAM : MANISH PITALE AND SHREERAM V. SHIRSAT, JJ.
RESERVED ON : 3rd SEPTEMBER 2026
PRONOUNCED ON : 22nd SEPTEMBER 2026

Judgment (Per Manish Pitale, J.) :

. The petitioners are aggrieved by notifications and notices of demand issued by the respondents for recovery of amounts on the ground that the petitioners sold certain medicinal formulation beyond the ceiling price allegedly fixed by the respondent Nos.1 and 2 under the Drugs (Price Control) Order, 1995 (hereinafter referred to as 'DPCO 1995'). The petitioner No.1 is a company engaged in manufacturing and marketing of pharmaceutical formulations and petitioner No.2 is a shareholder and director of petitioner No.1 company.

2. The respondent No.1-Union of India (Central Government) issued DPCO 1995 as per notification dated 06.01.1995 by exercising power conferred by Section 3 of the Essential

Commodities Act, 1995. DPCO 1995 provided for power in the respondent No.1-Central Government to fix maximum sale price for bulk drugs, power to fix retail price of scheduled formulations and also power to fix ceiling price of scheduled formulations. In the present case, we are concerned with the power exercised by the Central Government under paragraph 9 of DPCO 1995 for fixing ceiling price for scheduled formulations. DPCO 1995 provided a whole scheme and mechanism for exercising such power and also defined key terms such as bulk drug, formulation, scheduled bulk drug and scheduled formulation. The Central Government issued notifications/orders from time to time for fixing ceiling price for various scheduled formulations. It is the case of the petitioners that in the present case, the impugned notifications were issued by respondent No.2 i.e. National Pharmaceuticals Pricing Authority (NPPA), while the power to issue such notifications should have been exercised by the respondent No.1-Central Government under DPCO 1995.

3. The present case concerns a medicinal/pharmaceutical formulation manufactured by the petitioner No.1 called ‘Cartigen Forte Tablets’, a drug for treatment of osteoarthritis. The petitioners have placed on record the ingredients of the said formulation manufactured by them prior to January 2010 and also the ingredients of the formulation manufactured from January 2010 onwards. The petitioners contend that the respondent No.1-Central Government never fixed the ceiling price for the aforesaid formulation manufactured either prior to January 2010 or from

January 2010 onwards and therefore, the impugned demands are wholly unjustified. The petitioners emphasized that the impugned notifications/orders dated 27.09.2007 and 30.01.2009 deserve to be quashed and set aside, insofar as their application to the formulation of the petitioners is concerned, for the reason that the notification dated 27.09.2007 pertains to multivitamin and mineral tablets/capsules, which have nothing to do with the subject formulation of the petitioners. It is further contended that the subsequent notification dated 30.01.2009 is extremely broad-based and it is in the teeth of the paragraphs of DPCO 1995 itself, thereby indicating that it deserves to be quashed and set aside on the said ground. The petitioners contend that the impugned notifications and the consequent demands made by the respondents deserve to be quashed and set aside on this short ground itself. The petitioners have also raised various other grounds to indicate why the writ petition deserves to be allowed.

4. On 04.09.1997, the Central Government through Ministry of Chemicals and Fertilizers issued a notification under paragraph 20 of DPCO 1995, directing the respondent No.2-NPPA to exercise the functions of the Central Government in respect of paragraphs 3 to 5, 7 to 11 and 13 to 21 of DPCO 1995. On 27.09.2007, the respondent No.2-NPPA issued the impugned notification, fixing the ceiling price for multivitamin and mineral tablets, as also multivitamin and mineral capsules. Thereafter, on 30.01.2009, the respondent No.2-NPPA issued another notification stating that any formulation/ composition not covered

in the table of standing orders, that has any scheduled drug as one of its ingredients, shall be subject to price ceiling mentioned at the respective serial number of the respective notification, unless the manufacturer subsequently gets a specific price fixed by the NPPA for that formulation/composition. The language used in the said notification demonstrates that it is extremely widely worded and purports to take within its fold, formulations for which no ceiling price has been fixed.

5. After issuing notices to the contract manufacturer of petitioner No.1 to give details of production of the subject formulation, on 13.10.2010, respondent No.2-NPPA issued show cause notice to the petitioner No.1, alleging that its sale price was higher than the ceiling price and on that basis, called upon the petitioner No.1 explain as to why an amount of Rs.10,97,86,227/- should not be recovered towards estimated overcharged amount. On 31.01.2011, the petitioner No.1 sent reply to the said show cause notice, *inter alia*, stating that the subject formulation had undergone change since January 2010 and that in any case, the subject formulation was not a multivitamin, for which ceiling price had been fixed. It was further stated that NPPA could not issue such a blanket order as the power to do so vests only with the Central Government. The petitioner No.1 also demanded personal hearing in the matter. It is to be noted that on 15.03.2013, DPCO 2013 came into effect and DPCO 1995 was repealed.

6. On 09.09.2014, after more than 3 years and 6 months of the reply to the show cause notice being submitted by the petitioner

No.1, *inter alia*, demanding personal hearing, respondent No.2-NPPA issued a letter fixing the date for final hearing as 22.09.2014. The NPPA also recalculated the overcharged amount as Rs.6,33,62,316/- and further added interest of Rs.4,90,71,525/-, taking the total amount to Rs.11,24,33,841/-.

7. On 22.09.2014, hearing was conducted in the chamber of Member Secretary of the respondent No.2-NPPA and the minutes thereof were circulated along with letter dated 20.10.2014. At the time of hearing, the said Member Secretary of NPPA claimed that it had not received the aforesaid reply to the show cause notice submitted by the petitioner No.1 on 31.01.2011 and hence, an acknowledged copy was handed over. Thereafter, on 27.11.2014, the petitioner No.1 filed its written submissions, stating as to why no amount towards overcharging could be levied upon the petitioner No.1. But, on 26.11.2014, the Deputy Director of respondent No.2-NPPA issued a demand notice, calling upon the petitioner No.1 to deposit the alleged overcharged amount of Rs.11,42,82,631/-. The petitioner No.1 received it in December 2014 and on 23.01.2015, the petitioner No.1 sent a letter in response, pointing out various Infirmities. It was also highlighted that the said notice did not make any reference to the personal hearing and that no speaking order was passed in pursuance of the said personal hearing conducted on 20.10.2014. It was further stated that while the hearing was conducted by the Member Secretary of the NPPA, the order was passed by the Deputy Director, thereby vitiating the order/demand notice. It was also

submitted that such demand notice was prior to placing of the written submission of the petitioner No.1 on record, in pursuance of the personal hearing. On this basis, the petitioner No.1 called upon respondent No.2-NPPA to withdraw the demand notice dated 26.11.2014. Certain communications were exchanged between the parties and eventually, on 09.07.2015, the petitioner No.1 received the impugned notice of demand to defaulter issued by the Tehsildar from the office of the respondent-Collector under Section 267 of the Maharashtra Land Revenue Code, 1966 (MLRC) for depositing an amount of Rs.12,05,92,401/- within a period of 20 days, failing which attachment proceedings would be initiated.

8. On 20.07.2015, the petitioner No.1 filed Writ Petition No. 2804 of 2015, challenging the said demand notices issued by the respondents. On 03.02.2016, a Division Bench of this Court disposed of the writ petition on a statement made on behalf of respondent-NPPA that the petitioners would be heard again and a speaking order would be passed in the matter. It is to be noted that in the said writ petition, ad-interim order was granted. Hence, while disposing of the writ petition by order dated 03.02.2016, this Court directed that the ad-interim order would continue to operate till a fresh order was passed in the matter and for a period of four weeks, the said order would not be acted, if it was adverse to the petitioners. It was further clarified that since the matter was sent back to the NPPA, none of the demand notices that were impugned in the writ petition, could be enforced.

9. In pursuance of the said order passed by this Court, on 01.03.2016, hearing was conducted, wherein the petitioners reiterated their contentions raised in Writ Petition No. 2804 of 2015 and they sought disclosure with respect to material costs to be taken into consideration, as per paragraph 7 of DPCO 1995 for arriving at ceiling price. On 07.03.2016, the respondent No.2-NPPA again issued demand notice, which is impugned in this writ petition, to the petitioner No.1 to deposit amount of Rs.12,73,36,583/- towards overcharged amount and interest thereon, calculated upto 15.03.2016. On 29.03.2016, the petitioner No.1 sent a letter in response, again stating that the demand notice was not preceded by a speaking order, no disclosures were given as demanded by the petitioners, the specific submissions of the petitioner No.1 were not considered and that the demand notice dated 07.03.2016 violated the directions contained in the order dated 03.02.2016 passed by this Court in Writ Petition No. 2804 of 2015. Despite the said response sent by the petitioner No.1, on 12.05.2016, respondent No.2-NPPA issued the second impugned demand notice/letter calling upon the petitioner No.1 to make payment of alleged overcharged amount of Rs.12,93,41,609/-. On 21.11.2016, the respondent No.4 i.e. the office of the Collector through the Tehsildar, issued another notice under Section 267 of the MLRC, for recovery of amount of Rs.13,41,06,802/- in the form of a notice of demand to defaulter.

10. It is in this backdrop that the present petition was filed in December 2016, which was subsequently amended upon

permission granted by this Court. On 05.12.2016, a Division Bench of this Court granted ad-interim relief in favour of the petitioners by directing that no further steps would be taken by the Tehsildar, Mumbai City, on the basis of the impugned demand notice, subject to the condition that the petitioner No.1 would not create any third party rights in respect of the immovable properties held by it and it shall not part with possession thereof. The ad-interim order was continued by subsequent orders. Respondent No.4 filed reply affidavit in January 2017 to which the petitioners filed their rejoinder affidavit. In February 2017, respondent Nos.2 and 3 filed their reply affidavit, in response to which the petitioners filed a further rejoinder affidavit. Subsequently, respondent No.2 filed an additional affidavit in reply to the amended writ petition. On 25.02.2020, this Court directed that the ad-interim order granted on 05.12.2016 as interim relief, would continue until further orders. The writ petition was taken up for hearing.

11. Mr. Seervai, learned Senior Counsel appearing for the petitioners submitted that the impugned notifications dated 27.09.2007 and 30.01.2009 deserve to be quashed and set aside. As regards notification dated 27.09.2007 issued by the respondent No.2-NPPA, it was submitted that the same pertained to multivitamin and mineral tablets/capsules and by no stretch of imagination, could the said notification apply to the subject formulation of the petitioners i.e. Cartigen Forte, used for the treatment of osteoarthritis. It was submitted that prior to January

2010, the subject formulation contained certain vitamins, which formed part of bulk drugs, identified in First Schedule to DPCO 1995, but the active pharmaceutical ingredients of the subject formulation were never made subject matter of fixing ceiling price by the respondents. Even the two vitamins in the pre January 2010 version of the subject formulation, which were included in the bulk drugs in the First Schedule to DPCO 1995, were in minuscule quantity, even less than the quantities specific in the impugned notification dated 27.09.2007, thereby indicating that the said notification could never apply to the subject formulation. In any case, if the said notification was sought to be applied as it is to the subject formulation, it deserves to be quashed and set aside.

12. As regards the impugned notification dated 30.01.2009, it was submitted that the same was *ultra vires* with DPCO 1995. It was submitted that in the first place, the Central Government could not have delegated power to respondent No.2-NPPA to issue such a blanket and broad-based notification. It was specifically submitted that the said impugned notification dated 30.01.2009 was sought to be used by respondent Nos.2 and 3 to cover the subject formulation, despite the fact that ceiling price was not fixed for the subject formulation under paragraph 9 of DPCO 1995, based upon the formula for calculation specified in paragraph 7 thereof. The respondent No.2-NPPA cannot be permitted to escape its responsibility of fixing ceiling price for a particular formulation, in this case the subject formulation, applying the mechanism of paragraphs 7 and 9 of DPCO 1995, by

taking recourse to the aforesaid broad-based and blanket notification dated 30.01.2009. It was submitted that the aforesaid notification deserves to be quashed and set aside, on this ground alone.

13. Thereupon, the learned Senior Counsel appearing for the petitioners invited attention of this Court to various paragraphs of DPCO 1995, to contend that if the stand taken by the respondents was to be accepted, paragraph 7 of DPCO 1995, pertaining to calculation of retail price of a formulation, would be rendered unworkable. Attention of this Court was specifically invited to the various factors included in the formula, as per paragraph 7 of DPCO 1995, including retail price, material costs, conversion cost, cost of packaging material, packing charges and maximum allowable post manufacturing expenses, as also excise duty, to contend that none of these factors were applied in the facts of the present case, to arrive at any fixed price for the subject formulation. According to the petitioners, this is a fundamental and fatal flaw, which renders the impugned notifications, as also the consequential notices of demand, wholly illegal and unsustainable.

14. It was further submitted that the consideration of the case of the petitioners at the hands of the respondents was wholly arbitrary and basic principles of natural justice were violated. Even after the earlier Writ Petition No. 2804 of 2015 filed by the petitioners was partly allowed and the matter was remanded to the respondent No.2-NPPA, the specific issues raised on behalf of the

petitioners in the personal hearing and in the written submissions, were not considered at all. No speaking order was passed and instead, impugned demand notice dated 29.03.2016 was issued, contrary to the specific observations made by this Court in the order dated 03.02.2016 passed in Writ Petition No. 2804 of 2015. It was further submitted that the impugned demand notice dated 07.03.2016 verbatim reproduced the contents of the affidavit in reply filed in Writ Petition No. 2804 of 2015, thereby demonstrating total non-application of mind on behalf of respondent No.2-NPPA while calling upon the petitioner No.1 to deposit huge amount towards alleged overcharging for the subject formulation.

15. It was further submitted that the impugned demand notice issued by respondent No.4 under the provisions of the MLRC is unsustainable because the same has been issued on the basis of the demand notice dated 20.03.2015, which was already set aside by this Court while disposing of Writ Petition No. 2804 of 2015. As per the petitioners, before this Court in the present writ petition, the respondents have sought to justify issuance of the demand notices on the basis of communications and documents which cannot substitute a valid certificate for recovery and therefore, on this ground also, the writ petition deserves to be allowed. It was also submitted that the respondents cannot claim interest for the entire period of alleged delayed payment of the amount towards overcharging from the time it allegedly became due, because major part of the delay was on the part of the respondents in taking

forward the proceedings and thereafter, the earlier Writ Petition No. 2804 of 2015 stood allowed, thereby indicating that the respondents cannot be allowed to take advantage of the time consumed in the process. This would amount to the petitioners being punished for the fault of the respondents in failing to sustain the earlier notices of demand. By placing reliance on judgment of this Court in the case of *Franco Indian Remedies Private Limited & Anr. vs. Union of India & Anr.,* **2016 SCC OnLine Bom 16344**, it was contended that, at best, the respondents could claim interest from the date of the order or notice impugned in the present writ petition till the actual date of payment.

16. It was further submitted that the eligibility of the petitioner No.1 and its contract manufacturer for exemption, on the ground of being small scale industrial unit, was not considered by the respondents. A proper application for the said exemption would show that paragraph 8 of DPCO 1995 regarding fixing of retail price itself would not apply. It was further submitted that the respondents did not consider the entitlement of petitioner No.1 to deduction of trade margin while computing the interest on the alleged overcharged amounts. On the basis of the aforesaid submissions, it was asserted that the writ petition deserves to be allowed.

17. Mr. Govilkar, learned Senior Counsel appearing for respondent Nos.1 to 3 submitted that the contentions raised on behalf of the petitioners are unsustainable on a proper reading of DPCO 1995. By inviting attention of this Court to the definition

of the terms Formulation, Scheduled Formulation and paragraphs 8 to 11 read with First Schedule of DPCO 1995, it was submitted that so long as any of the bulk drugs stated in the First Schedule formed ingredients of the subject formulation, the respondents were entitled to impose ceiling price fixed for such ingredients. It was submitted that the moment any of the bulk drugs mentioned in the First Schedule to DPCO 1995 was found in the formulation, it became a scheduled formulation, for which the respondents were entitled to fix ceiling price and on the basis of the same, recover overcharged amounts. It was submitted that the petitioners had failed to demonstrate lack of power in the respondent No.2-NPPA to issue the impugned notifications. It was submitted that the impugned notifications read in the correct perspective clearly demonstrate that the petitioner No.1 had violated the ceiling price fixed by the respondent No.2-NPPA and that recovery of overcharged amounts was clearly warranted in the facts and circumstances of the present case.

18. The learned Senior Counsel appearing for the said respondents also placed reliance on paragraph 11 of DPCO 1995 to contend that since the petitioner No.1 failed to submit an application for price fixation of the subject formulation, the respondent No.2-NPPA was entitled to fix the same. Accordingly, the respondent No.2-NPPA had exercised power under paragraph 9 of DPCO 1995 to fix ceiling price and since the petitioner No.1 sold the subject formulation above the ceiling price, recovery of overcharged amounts was clearly warranted. On this basis, it was

submitted that the writ petition deserves to be dismissed and the interim order ought to be vacated.

19. It was further submitted that the contentions raised with regard to the principles of natural justice are also unsustainable, for the reason that after the matter was remanded by this Court and ample opportunity of hearing was given to the petitioners, the contentions of the petitioners were considered and thereupon, the revised demand notice was issued. By referring to the contents of the reply affidavit filed on behalf of the said respondents, it was submitted that all the contentions raised on behalf of the petitioners were answered and therefore, the writ petition ought to be dismissed.

20. Ms. Pawar, learned AGP appearing on behalf of respondent No.4 submitted that since the impugned demand notices were issued by the said respondent under the provisions of the MLRC, on the basis of the demand notices issued by respondent No.2-NPPA for overcharged amount, no fault could be found with the impugned demand notice issued by the said respondent. It was submitted that the demand notice issued by respondent No.4 was consequential in nature and therefore, the same does not deserve any interference.

21. Having heard the learned counsel for the rival parties, in order to consider the rival submissions, it is necessary to first refer to the relevant portions of DPCO 2015, which read as follows :

> *"**2. Definitions.**–In this order, unless the context otherwise requires,–*

(h) "formulation" means a medicine processed out of, or containing without the use of any one or more bulk drug or drugs with or pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or and, but shall not include –

(i) any medicine included in any bona fide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;

(ii) any medicine included in the Homeopathic system of medicine; and

(iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply;

(u) "Scheduled bulk drug" means a bulk drug specified in the First Schedule;

(v) "Scheduled formulation" means a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs, including one or more than one drug or drugs not specified in the First Schedule except single ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name;

4. Information to be furnished by the manufacturer in relation to the Scheduled bulk drugs.*–Every manufacturer, producing a Scheduled bulk drug shall furnish to the Government,–*

(a) a list of all Scheduled bulk drugs produced by him within days of the commencement of this Order and indicate the details of the cost of each of such bulk drug in Form I;

(b) the details of the cost of each Scheduled bulk drug produced by him, including such bulk drug which has been produced after the commencement of this Order, in Form I by the 30th September, every year.

7. Calculation of retail price of formulation.*–The retail price of a formulation shall be calculated by the Government in accordance with the following formula namely,–*

R.P.= (M.C.+ C.C. + P.M. + P.C.) x (1 + MAPE/100) + ED.

where–

"R.P." means retail price;

"M.C." means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss thereon specified as a norm from time to time by notification in the Official Gazette in this behalf;

"C.C." means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;

"P.M." means cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by, notification in the Official Gazette in this behalf;

"P.C." means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;

"MAPE" (Maximum Allowable Post-manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations;

"E.D." means excise duty:

Provided that in the case of an imported formulation, the landed cost shall form the basis for fixing its price alongwith such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed fifty percent of the landed cost.

Explanation.–For the purpose of this proviso, "landed cost" means the cost of import of formulation inclusive of customs duty and clearing charges.

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 utilises 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 maybe, 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) Not with standing 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 a new 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.

11. Fixation of price under certain circumstances.–*Where any manufacturer, importer of a bulk drug or formulation falls to submit the application for price fixation or revision, as the case, may be, or to furnish information as required under this Order, within the time specified therein, the Government may, on the basis of such information as may be available with it, by order fix a price in respect of such bulk drug or formulation as the case may be."*

22. In the present case, the subject formulation of the petitioners

is 'Cartigen Forte' used for treatment of osteoarthritis. It is the case of the petitioners that the said formulation is not a multivitamin or mineral tablet. The original composition of the subject formulation was as follows :

Each Film Coated Tablet Contains	
Glucosamine Sulfate Potassium Chloride USP	750 mg
Chondroitin Sulfate Sodium USP	100 mg
Methyl Sulfonyl Methane	250 mg
Vitamin D3 IP	200 IU
Vitamin E Acetate IP	12.5 mg
Vitamin C IP	37.5 mg
Sodium Selenite BP equivalent to elemental Selenium	70 mcg
Zinc Sulphate Monohydrate USP equivalent to elemental zinc	4 mg
Manganese Sulphate USP equivalent to elemental Manganese	3 mg
Chromium Picolinate USP equivalent to elemental Chromium	50 mcg
Copper Sulphate Pentahydrate BP equivalent to elemental Copper	0.5 mg
Sodium Borate BP equivalent to elemental Boron	0.5 mg
Colloidal Silicon Dioxide IP equivalent to elemental Silicon	2 mg
Colour: Red Iron Oxide, Black Iron Oxide and Titanium Dioxide IP	
Appropriate overages of vitamin added	

23. It is undisputed that from January 2010, the composition of the subject formulation was as follows :

Each Film Coated Tablet Contains	
Glucosamine Sulfate Potassium Chloride USP	750 mg
Chondroitin Sulfate Sodium USP	100 mg
Methyl Sulfonyl Methane USP	250 mg
Vitamin D3 IP	200 IU
Calcium Ascorbate USP	50 mg
Sodium Selenite Pentahydrate BP equivalent to elemental Selenium	70 mcg

Zinc Sulphate Monohydrate USP equivalent to elemental zinc	4 mg
Manganese Sulphate USP equivalent to elemental Manganese	3 mg
Chromium Picolinate USP equivalent to elemental Chromium	50 mcg
Copper Sulphate Pentahydrate BP equivalent to elemental Copper	0.5 mg
Sodium Borate BP equivalent to elemental Boron	0.5 mg
Colloidal Silicon Dioxide IP equivalent to elemental Silicon	2 mg
Colour: Red Iron Oxide, Black Iron Oxide and Titanium Dioxide IP	
Appropriate overages of vitamin added	

24. A perusal of the above quoted composition of the subject formulation shows that prior to January 2010, the ingredients of the subject formulation included vitamin C and vitamin E that are bulk drugs specifically included in the First Schedule of DPCO 1995. The composition of the subject formulation w.e.f. January 2010 does not include said vitamin C and vitamin E. It is the specific case of the petitioners that the active pharmaceutical ingredients of the subject formulation used for the treatment of osteoarthritis are Glucosamine Sulfate Potassium Chloride, Chondroitin Sulfate Sodium and Methyl Sulfonyl Methane. Having perused the aforesaid composition of the subject formulation, which is not disputed by the respondents, we are in agreement with the petitioners that the subject formulation is neither a multivitamin nor a mineral tablet/capsule. But, the respondents claim that inclusion of vitamin C and vitamin E in the subject formulation, even if in very small quantities, shows the existence of multivitamins, which are included in the list of bulk drugs in the First Schedule to DPCO 1995. Much emphasis is placed on the definition of Scheduled Formulation in paragraph

2(v) of DPCO 1995 to claim that the moment any of the bulk drugs in the First Schedule either individually or in combination of other drugs are found, ceiling price can be imposed. It is on the basis of the aforesaid stand that the impugned notification dated 27.09.2007 is sought to be justified. At this stage, it would be appropriate to reproduce the relevant portions of the impugned notification dated 27.09.2007, which read as follows :

"ORDER

S.O. 1665(E)- In exercise of the powers, conferred by sub-paragraphs (1) and (2) of paragraph 9 and paragraph 11 of the Drugs (Prices Control) Order, 1995, read with No. S.O. 637 (E) dated the 4th September, 1997 issued by the Government of India in the Ministry of Chemicals and Fertilizers and in supersession of the Order of the Government of India in the Ministry of Chemicals and Fertilizers, (National Pharmaceutical Pricing Authority) No. S.O. 1064(E), dated 11th July, 2006, the National Pharmaceutical Pricing Authority, hereby fixes the prices as specified in column (5) of the table below as ceiling prices exclusive of excise duty and local tax, if any, and in column (6) of the table below as Equivalent MRP inclusive of excise duty and education cess, sales tax/VAT of each of the Scheduled formulations specified in the corresponding entry in column (2) of the said Table with the strength and pack size specified respectively in the corresponding entries in columns (3) and (4) thereof:

Table

Sl. No	Name of the Formulation	Strength	Pack Size	Ceiling Price (Rs.)	Equivalent MRP*(inclusive of all taxes) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)

		Each coated tab contains			
1	Multivitamins and Mineral Tablets	Vitamin A Acetate-5000iu Vitamin D3 -400 iu Vitamin E -15iu / mg, Thiamine Mononitrate-10mg Riboflavine-10mg, Pyridoxine HCl-2mg Cyanocobalamine-7.5mcg, Niacinamide-50mg Calcium Panthothenate-10mg, Ascorbic Acid-75mg Heavy Magnesium Oxide-30mg, Maganese Sulphate Monohydrate-2.8mg Copper Sulphate-2.0mg, Zinc Sulphate Monohydrate-63mg Selenium Di-oxide-70mcg	10's Strip/ Blister	7.32	8.44
		Each hard/soft gelatin capsules contains			
2	Multivitamins and Mineral Capsules	Vitamin A Acetate-5000iu Vitamin B1 Mononitrate-10mg Vitamin B2 (Riboflavine) -10mg, Vitamin B6 (Pyriboxine HCl) -2mg, Vitamin B12 (Cyanocobalamine) -7.5mcg, Vitamin C-75mg, Vitamin D3 -400iu Vitamin E Acetate-15 i.u / mg Calcium Pantothenate-10mg, Folic Acid-1mg, Niacinamide-50mg, Biotin D-150mcg, Zinc Sulphate monohydrate – 63mg Potassium Iodide eq. to Iodine-150mcg, Magnesium Oxide heavy -30mg, Copper Sulphate – 2mg, Chromium picolinate eq. to Chromium-25mcg Selenium Dioxide Monohydrate eq. to Selenium-70mcg	10's Strip/ Blister	8.80	10.15

Sodium Molybdate Dihyderate
eq. to Molybdenum-25mcg
Colloidal Silicon Dioxide eq. to
Silicon-1mg
Sodium Borate eq. to Boron-
150mcg
Magnase Sulphate – 2.8mg

**Subject to actual payment of Government levies/taxes, as applicable.*

Note :

I. For all the other Vitamin formulations having composition within the prescribed range in Schedule-V under Drugs and Cosmetics Act, 1940. The Following adjustment shall be made by a manufacturer to work out the ceiling price (column no.5) for a product under the said order for formulation(s) in column No.2, when there is a change in the composition and the following factors (which are inclusive of admissible MAPE) shall be added/subtracted as the case may be to the notified ceiling price given in column No.5 of the table on the following basis.

II. to V. x x x

VI. For different packing material used or any special feature claimed, companies are required to approach NPPA for approval/fixation of specific prices.

VII. The manufacturer and marketing company for the above said formulation shall be required to take the requisite prior approval from the competent Authority for any change in the composition of the above said formulation with written prior intimation to the National Pharmaceutical Pricing Authority."

25. According to the respondents, inclusion of vitamin C and vitamin E in the impugned notification dated 27.09.2007 is sufficient for the respondent No.2-NPPA insisting that the petitioners should have sold their formulation as per the ceiling price indicated in the said notification. In this context, much emphasis is placed on paragraphs 4 and 11 of DPCO 1995 read

with Notes VI and VII appended to the impugned notification dated 27.09.2007, quoted hereinabove.

26. We have carefully considered the said contention raised on behalf of the respondents. We find that the respondents would certainly have power to fix the price of a formulation on the basis of information available with it when the manufacturer or importer of a bulk drug or formulation fails to submit an application for price fixation and also fails to furnish information as required under DPCO 1995. Such power is indeed found in paragraph 11 of DPCO 1995 read with the obligation on the manufacturer to furnish such information to the respondents under paragraph 4 thereof. The respondents are also justified in contending that the scheduled formulation indeed means a formulation containing a bulk drug specified in the first schedule to DPCO 1995, either individually or in combination with other drugs. But, even if the aforesaid contentions raised on behalf of the respondents are found to be in line with DPCO 1995, what is most crucial is that the respondent No.1 and/or respondent No.2 are required to pass an order for fixing the ceiling price of the scheduled formulation. In order to pass an order for fixing the ceiling price of the scheduled formulation under paragraph 9 of DPCO 1995, the said respondents are required to do so in accordance with the formula laid down in paragraph 7 of DPCO 1995.

27. The subject formulation in the present case is Cartigen Forte used for treatment of osteoarthritis and since its ingredients

included vitamin C and vitamin E prior to January 2010, it could be covered under the definition of Scheduled Formulation, as per paragraph 2(v) of DPCO 1995. But, respondent No.1 and/or respondent No.2 i.e. the Central Government and the NPPA were required to pass an order by notification in the official gazette under paragraph 9 of DPCO 1995 to fix the ceiling price of the subject formulation. In order to do so, the formula for calculation under paragraph 7 of DPCO 1995 was required to be applied. This is evident from clause (1) of paragraph 9 of DPCO 1995 itself, as it specifically lays down that the ceiling price would be fixed from time to time in accordance with the formula laid down in paragraph 7 thereof. A perusal of the above quoted paragraph 7 of DPCO 1995 shows that the price would have to be calculated on the basis of the following formula :

R.P.= (M.C. + C.C. + P.M. + P.C.) x (1 + MAPE/100) + ED.

28. Thus, the calculation of the ceiling price would be determined and arrived at by applying the said formula, which would necessarily entail incorporating all the relevant factors i.e. material cost, conversion cost, cost of packaging material, packaging charges, maximum allowable post manufacturing expenses (MAPE) and excise duty and that too in terms of the mechanism specifically provided in paragraph 7 of DPCO 1995. Therefore, the said respondents were required to pass an order by notification in the official gazette after calculating the ceiling price on the basis of the aforesaid formula specified in paragraph 7 of DPCO 1995. No such exercise was ever undertaken by the said

respondents in respect of the subject formulation. In such a situation, the respondents were not entitled to apply impugned notification dated 27.09.2007 to claim that the ceiling price specified therein stood applied to the subject formulation of the petitioners. A perusal of the above quoted portion of the said notification shows that the formulations for which ceiling price had been fixed were 'multivitamin and mineral tablets' and 'multivitamin and mineral capsules'. No doubt, vitamin C and vitamin E were ingredients recorded in the said formulations when ceiling price was fixed under the said notification dated 27.09.2007, but the ceiling price was arrived at after applying the formula specified in paragraph 7 of DPCO 1995. In other words, the said respondents took into consideration the aforementioned factors and then arrived at the ceiling price.

29. A perusal of Note I, VI and VII appended to the said notification dated 27.09.2007 shows the manner in which the ceiling price is to be applied, if there is a change in composition. In the said notes, there is a reference to MAPE and other such factors. Even otherwise, a perusal of the said notification dated 27.09.2007 shows that vitamin C in the formulation 'multivitamin and mineral capsules' is shown to the extent 75 mg and vitamin E in the 'multivitamin and mineral tablets' at 15 iu/mg. The said weightage of vitamin C and vitamin E, which are indeed bulk drugs included in the First Schedule to DPCO 1995, is shown in combination with other vitamins and minerals. In the subject formulation, prior to January 2010, vitamin C was only 37.5 mg

and vitamin E was only 12.5 mg. The weight of both these scheduled bulk drugs was much less than what was specified in the impugned notification dated 27.09.2007, while shown in combination with other vitamins and minerals for the formulation 'multivitamin and mineral tablets' and 'multivitamin and mineral capsules'. It is also an admitted position that from January 2010 vitamin C and vitamin E were not even ingredients in the subject formulation, thereby showing that the respondents cannot rely upon the impugned notification dated 27.09.2007 to justify their stand.

30. It is also found that the impugned notification dated 27.09.2007 specifically showing ceiling price fixed for the formulations 'multivitamin and mineral tablets' and 'multivitamin and mineral capsules' cannot be applied to the subject formulation, in which the active pharmaceutical ingredients are Glucosamine Sulfate Potassium Chloride, Chondroitin Sulfate Sodium and Methyl Sulfonyl Methane. It is also found that the ceiling price as per the aforesaid impugned notification dated 27.09.2007 is fixed for the entire formulation, the composition of which includes various vitamins and minerals, after applying the specific formula under paragraph 7 of DPCO 1995. On pointed queries put to the respondents, as to how only vitamin C from the formulation of multivitamin and mineral capsules and vitamin E from the formulation of multivitamin and mineral tablets could be segregated for ascertaining the ceiling price to then apply it to the subject formulation, there was no satisfactory response. The

reason for the same is that if the contentions raised on behalf of the respondents on the basis of the impugned notification dated 27.09.2007 are accepted and sought to be applied to the subject formulation, the specific formula contained in paragraph 7 of DPCO 1995 is rendered wholly unworkable. Even if the stand of the respondents is taken into consideration, it is an admitted position that fixing of ceiling price under paragraph 9 of DPCO 1995 for the subject formulation has not been undertaken because the specific formula under paragraph 7 thereof has not been applied for calculation and determination of the ceiling price. The aforementioned factors applied in the said formula have not been considered and determined by the respondents to undertake the exercise of calculation of ceiling price of the subject formulation and therefore, the contentions raised on behalf of the respondents in that regard are rendered wholly unsustainable.

31. There can be no doubt about the fact that reading paragraphs 4 and 11 of DPCO 1995 reserves power in the respondents to fix price of the subject formulation on the basis of the information available to them, in the absence of information being furnished by the manufacturer for fixing of price. But, the procedure prescribed under paragraph 9 read with paragraph 7 of DPCO 1995 has to be followed and a specific order by way of notification in the official gazette has to be issued in respect of the subject formulation to claim that ceiling price is applicable in a given case. No such exercise was undertaken in the context of the subject formulation of the petitioners and therefore, the very basis

of claiming that the petitioners had overcharged, is taken away. Therefore, the impugned notification dated 27.09.2007 to the extent that it is sought to be applied to the subject formulation, deserves to be set aside.

32. In the face of such a situation, the respondents seek to rely upon impugned notification dated 30.01.2009. The said notification reads as follows :

> ***"ORDER***
>
> *S.O.372(E). - In exercise of the powers, conferred by paragraphs 9 and 11 of the Drugs (Prices Control) Order, 1995 read with S.O. 637(E) dated the 4th September 1997 issued by the Government of India, Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority hereby notifies that any formulation/composition not covered in the table of standing orders issued by the NPPA that has any scheduled drug as one of its ingredients, shall be subject to the price ceiling mentioned at the respective serial number of the respective notification, as the case may be, unless the manufacturer has subsequently got a specific price fixed by the NPPA for that formulation/composition.*
>
> *The manufacturer or marketing company not complying with the ceiling prices and the condition specified in the respective notification shall be liable to deposit the overcharged amount along with interest under the provision of Drug Price Control Order, 1995 read with the Essential Commodities Act, 1995."*

33. A perusal of the above quoted notification shows that it is extremely widely worded and it violates DPCO 1995 itself. Although, it has been issued purportedly by exercising power under paragraphs 9 and 11 of DPCO 1995, the crucial part of calculation of ceiling price as per formula under paragraph 7 of DPCO 1995 has been lost sight of. In fact, the impugned

notification dated 30.01.2009 has the effect of completely doing away with the formula specified in paragraph 7 of DPCO 1995. The moment the very formula for calculation of ceiling price as per paragraph 7 read with paragraph 9 is taken away, it becomes clear that the impugned notification dated 30.01.2009 is rendered *ultra vires* DPCO 1995 itself. We find that when ceiling price is not fixed by the respondents as per the mechanism under paragraphs 7, 9 and 11 of DPCO 1995 and it is deemed that the ceiling price is fixed when the same is ascertained as regards any of the ingredients in the formulation, the very basis of calculation and obligation upon the respondents to fix the price of scheduled formulation in terms of DPCO 1995 is taken away.

34. The impugned notification dated 30.01.2009 is clearly over broad, expansive and it operates in the teeth of the paragraphs of DPCO 1995 itself. In other words, it is beyond the power vested in respondent No.2-NPPA to issue such kind of notification. As a matter of fact, it indicates abdication of the responsibilities and obligations cast upon the Central Government and the NPPA to specifically fix ceiling price under paragraph 9 of DPCO 1995 read with the rigorous formula specified in paragraph 7 thereof. We find substance in the contentions raised on behalf of the petitioners in this regard to hold that the impugned notification dated 30.1.2009 is indeed *ultra vires* DPCO 1995.

35. We also find that the exercise of power by respondent No.2-NPPA purportedly under paragraphs 9 and 11 of DPCO 1995 for issuing impugned notification dated 30.01.2009, is wholly

arbitrary and hence, unsustainable. In fact, the manner in which impugned notification dated 27.09.2007 is sought to be applied to the subject formulation and the arbitrary nature of impugned notification dated 30.01.2009, show that the very basis of alleging that the petitioners overcharged in respect of the subject formulation is taken away, rendering the demand notices issued by the respondent No.2-NPPA as well as respondent No.4-Collector, as unsustainable and liable to be quashed and set aside.

36. The moment the impugned notifications dated 27.09.2007 and 30.01.2009 are found unsustainable and liable to be quashed and set aside, the impugned demand notices issued by respondents, including those issued by exercising power under MLRC, also deserve to be quashed and set aside. There is no independent basis for respondent No.4 to have exercised power under MLRC to issue demand notice for recovery of specific amounts and therefore, if the very basis of raising such demands by the respondent No.2-NPPA is found to be unsustainable, the action sought to be undertaken by respondent No.4 under MLRC is also rendered unsustainable.

37. Apart from this, there is substance in the contention raised on behalf of the petitioners that huge amount towards interest could not have been calculated on the basis of the date of basic demand notices issued by respondent No.2-NPPA, for the reason that considerable period of time was consumed due to delay on the part of respondent No.2-NPPA itself in granting hearing to the petitioners and the earlier demand notices being set aside on the

ground of violation of principles of natural justice on the part of the respondent No.2-NPPA. The time consumed in the interregnum, due to the fault of the said respondent, cannot inure to its benefit and to the detriment of the petitioners, insofar as the calculation of the interest is concerned. Thus, in terms of the law laid down by this Court in the case of **Franco Indian Remedies Private Limited & Anr. vs. Union of India & Anr.** (*supra*), at worst, the interest amount could have been calculated from the notice of demand issued after the proceedings were remanded by this Court while allowing earlier Writ Petition No. 2804 of 2015.

38. We also find substance in the contention raised on behalf of the petitioners that the impugned demand notice issued by the respondent No.4-Collector, on the basis of earlier demand notice issued by the respondent No.2-NPPA, that had been already set aside, is wholly unsustainable and deserves to be quashed on the said additional ground also.

39. But, we are of the opinion that since the impugned notifications dated 27.09.2007 and 30.01.2009 themselves are found liable to be set aside, the very basis for claiming that the petitioners had overcharged regarding the subject formulation is taken away and the writ petition deserves to be allowed on that ground alone. Therefore, there is no necessity to go into the question of violation of principles of natural justice, even after remand of the proceedings, as the subsequent demand notice simply reproduced the grounds taken in the reply affidavit filed in the earlier Writ Petition No. 2804 of 2015, and other such

grounds. The question concerning exemption available to petitioner No.1 and its contract manufacturer, as small scale industrial unit, is also not required to be gone into, in the light of the findings rendered hereinabove, in favour of the petitioners in the context of the impugned notifications dated 27.09.2007 and 30.01.2009.

40. In view of the above, the writ petition is allowed in terms of prayer clauses (a), (b), (c), (d) and (e).

41. It is made clear that impugned notification dated 27.09.2007 is quashed to the extent of its applicability to the subject formulation of the petitioners, while impugned notification dated 30.01.2009 is quashed and set aside in its entirety.

42. As a consequence of the writ petition being allowed in terms of prayer clauses (a) to (e), the respondents shall not act upon the impugned demand notices against the petitioners.

43. Pending applications and Chamber Summons, if any, also stand disposed of.

(SHREERAM V. SHIRSAT, J.) **(MANISH PITALE, J.)**

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