A M/S T.C. HEALTHCARE P. LTD. & ANR.

v.

UNION OF INDIA & ANR.

(Civil Appeal No. 4687 of 2010)

B NOVEMBER 15, 2019

[ARUN MISHRA, VINEET SARAN AND S. RAVINDRA BHAT, JJ.]

Drugs (Price Control) Order, 1995: Paras 3, 7, 8 and 9 Fixation of ceiling price of drug, Scheduled formulations – C *Notifications dated 11th July, 2006 and 30th April, 2009 imposing ceiling prices on a drug formulation, Frusemide, Potassium and Theophylline – Challenged to, by the drug manufacturers as ultra vires Para 7 of the DPCO – High Court dismissed the writ petitions – Interference with – Held: Not called for – Modifications in drug* D *release are often desirable to increase the stability, safety and efficacy of the drug, to improve the therapeutic outcome of the drug treatment and/or to increase patient compliance and convenience of administration – Use of the term "sustained release" denotes the systems that maintain the rate of drug release over a sustained* E *period – Controlled release systems are drug delivery systems in which the drug is released in a predetermined pattern over a fixed period of time – Materials on the record show that the DPCO was aware of the existence of different systems of drug delivery and of sustained release – Manufacturers ought to have demonstrated that the systems used by them were unique or different – In absence* F *thereof, they were obliged to follow the pricing norms and ceiling prices fixed by the impugned notifications.*

Dismissing the appeals, the Court

HELD: 1.1 The High Court, took note of the notification dated 13th August, 2008, which fixed conversion costs for plain G **tablets, coated tablets, dispersible tablets, gelatin coated tablets, bi layered tablets, *sustained release* tablets, chewable tablets, effervescent tablets, inlay tablets, capsules and other drugs. The appellants had not urged that different conversion costs were fixed for controlled release system, or the continuous release** H **systems, anytime. In these circumstances, it was held that the**

pricing norms were applicable. Note (d) to the notification of 30th April, 2009, stated that f*or different packing materials used or different drug delivery systems or any other special features/forms claimed, the ceiling prices, as specified in Column 5 shall be applicable unless the companies approach NPPA for specific price approvals for its formulations".* In the instant case, the appellants did not approach NPPA for specific price, or contend before it that their products contained special features. On the other hand, the allusion to "sustained release" and drug delivery systems (in Note (d)) clearly contemplated that unless otherwise specifically sought– in regard to particular drugs, the price fixation norms applied to all. [Para 10, 11] [626-C-G]

1.2 According to pharmacopedias and the US Food and Drug Administration's definitions, modifications in drug release are often desirable to increase the stability, safety and efficacy of the drug, to improve the therapeutic outcome of the drug treatment and/or to increase patient compliance and convenience of administration. In that context, the use of the term "sustained release" denotes the systems that maintain the rate of drug release over a sustained period. For example, if the release of the drug from the dosage form is sustained such that the release takes place throughout the entire gastrointestinal tract, one could prolong the time interval of drug concentration in the therapeutic range. This in turn may reduce the frequency of dosing, for example from three times a day to once a day. Sustained–release dosage forms achieve this mostly by the use of suitable polymers, used either to coat granules or tablets (reservoir systems) or to form a matrix in which the drug is dissolved or dispersed (matrix systems). Controlled release systems are drug delivery systems in which the drug is released in a predetermined pattern over a fixed period of time. Therefore, the materials on the record show that the DPCO was aware of the existence of different systems of drug delivery; it specifically talked of sustained release. If the appellants wished to say that the systems used by them were unique or different, it was open for them to have so demonstrated. Their omission to do so, did not in any way affect their obligation to follow the pricing norms and ceiling prices fixed by the impugned notifications. Therefore, there is no reason to differ from the

conclusions and findings of the High Court. [Para 12] [626-G-H; 627-A-D]

Union of India v. Cynamide India Ltd. **(1987) 2 SCC 720 – referred to.**

Case Law Reference

(1987) 2 SCC 720	**referred to**	**Para 6**

CIVIL APPELLATE JURISDICTION : Civil Appeal No. 4687 of 2010.

From the Judgment and Order dated 20.04.2010 of the High Court of Judicature at Allahabad in Writ Petition No. 33753 of 2009.

With

C.A. No. 4679/2010 and 10687/2011.

Maninder Singh, Sr. Adv., N.S. Ahluwalia, Salil Seth, Neeraj Malik, Umesh Kumar Khaitan, Somiran Sharma, A.P. Mayee, Gurmeet Singh Makker, Advs. for the appearing parties.

The Judgment of the Court was delivered by

S. RAVINDRA BHAT, J.

1. This appeal by special leave questions a decision of the Allahabad High Court rejecting a writ petition. In those proceedings, the appellant had challenged the *vires* of notifications dated 11th July, 2006 and 30th April, 2009, which imposed ceiling prices on a drug formulation, Frusemide.

2. The facts necessary for deciding this appeal are that the appellants, i.e. TC Healthcare and Modi Mundipharma Pvt. Ltd. (hereafter "TCH" and "Modi" respectively and "the appellants" collectively), at the relevant time, manufactured drugs. By reason of a notification dated 2nd March, 1995, the appellants were exempted from the regime of price fixation, under the Drugs (Price Control) Order, 1995 (hereafter "DPCO") as they were small scale units. Para 8 of the DPCO prescribed that if the Central Government were to fix the price of any bulk drug under Para 3, and such bulk drug is used by a manufacturer to prepare a formulation, the manufacturer must apply under Form III for price revision of such formulation, upon which the Central Government may fix or revise the price of the formulation.

3. TCH, at the relevant time, was manufacturing several drug formulations. It was registered as a small-scale unit (SSU) and therefore, exempt, by reason of Para 8 of the DPCO, from the drug price control regime. Likewise, Modi too was, at the relevant time, exempt, as an SSU, from drug price control. TCH produces and distributes several formulations, including Diucontin K (20mg and 40mg) prepared from the bulk drug Frusemide. Modi on the other hand, manufactures Unicontin (400 mg and 600 mg) derived from the bulk drug Theophylline. For this formulation, (i.e in the 400 mg and 600 mg tablets) drug ceiling prices were fixed by a notification dated 11th July, 2006. Initially, Modi filed an injunction suit; however, that was dismissed for non-prosecution. Upon receiving demand notices, it sought for quashing of the said notification (dated 11th July, 2006) and the consequent notifications/ demands, in writ proceedings before the Allahabad High Court. Similarly, TCH's writ petition challenged the notification dated 30th April, 2009, whereby the ceiling price of formulations containing Frusemide and Potassium were fixed; it also questioned the consequent demands by the Central Government.

4. Before the High Court, it was contended by the present appellants that the price fixation exercise was undertaken arbitrarily and was the result of non-application of mind. It was urged that the notification overlooked the cost and efficiency of major manufacturers. It was also urged that the price fixation through the impugned notifications was *ultra vires* Para 7 of the DPCO, as there were no price norms in respect of formulations that used the sustained release technology or method in the final product for effective dose delivery. It was further urged that the respondents had no figures or details with respect to cost or efficiency of major manufacturers and that consequently, they were obliged to call for such particulars. Similarly, in respect of Unicontin, it was urged by Modi that there were no norms in respect of the continuous release technology used for effective and efficacious drug delivery.

5. In the impugned judgment, the High Court negatived the challenge to the notifications on the ground that they were *ultra vires* Para 7 of the DPCO, observing that the material brought on record by the Central Government and other respondents revealed that a set of questionnaires were designed by the Cost Audit Branch of the Ministry of Finance to elicit information for various costs for CC, PC and PL

A norms, which were sent to 470 pharmaceutical producers across the country, covering a diverse range of products. Further, a press release was issued and published in newspapers, informing the manufacturers about the move to revise the norms, and further seeking data and information. Such data and information was furnished by
B pharmaceutical manufacturers and companies, and was considered. The norms were notified on 13th August, 2008. In that, the conversion cost, packing charges, process loss of raw materials and other norms were fixed.

6. The High Court refuted the charge by the appellants that the
C absence of any notice, permitting their participation- in the drug price fixation process, vitiated it. The court relied on the judgment of this court in *Union of India v. Cynamide India Ltd.* (1987) 2 SCC 720, to the effect that price fixation is essentially a legislative exercise. The High Court also rejected the argument that the technology used by TCH and Modi, i.e. sustained release (SR) and continuous release of dosage
D through the products could not be subjected to price fixation as those methods or technologies were not contemplated by the DPCO, 1995.

7. The relevant provisions of DPCO, 1995, are extracted below:

E *"2 (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*
F *under the generic name."*

8. Paragraph 7 of DCPO, 1995, (which replaced DCPO, 1987) and other relevant provisions are extracted below:

"7. CALCULATION OF RETAIL PRICE OF FORMULATION—The retail price of a formulation shall be
G *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) + E.D.

H *"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, and process loss there on in accordance with such norms as may be specified by the government 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 the cost of packing material used in the packing of a 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 along with such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed fifty per cent 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.

The relevant provision in DCPO 1987, i.e. Para 10, significantly, provided that retail cost had to be calculated in the following manner:

A *"R.P. = (M.C. + C.C. + P.M. + P.C.) x (1 + M.U./100) + E.D.*

"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, and process loss there on in accordance with such norms as may be specified by the government from time to time by notification in the official gazette in this behalf.

"C.C" means conversion cost worked out in accordance with such norms as may be specified by the government from time to time by notification in the official gazette in this behalf.

"P.M." means the cost of packing material including process loss thereon worked out in accordance with such norms as may be specified by the government from time to time by notification in the official gazette in this behalf.

"P.C." means packing charges worked out in accordance with such norms as may be specified by the government from time to time by notification in the official gazette in this behalf.

"M.U." means mark-up referred to in para 11.

"E.D." means excise duty.

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8(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.

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8(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.

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.

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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 maybe, to deposit the amount accrued due to 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."

9. The appellants argue before this court, that the High Court erred in overlooking that the "sustained release" and "continuous release" technologies used in their products had not been made the subject of any price fixation norm. Therefore, the price fixation resorted to in their case was contrary to law. The learned senior counsel appearing on their behalf submitted that the High Court had fallen into error in this regard, and consequently, its decision requires to be set aside.

10. The High Court, in the impugned judgment, we notice, had taken note of the notification dated 13th August, 2008, which fixed conversion costs for plain tablets, coated tablets, dispersible tablets, gelatin coated tablets, bi layered tablets, *sustained release* tablets, chewable tablets, effervescent tablets, inlay tablets, capsules and other drugs. The appellants had not urged that different conversion costs were fixed for controlled release system, or the continuous release systems, anytime. In these circumstances, it was held that the pricing norms were applicable. The court also extracted Note (d) to the notification of 30th April, 2009, which pertinently stated that:

"(d) For different packing materials used or different drug delivery systems or any other special features/forms claimed, the ceiling prices, as specified in Column 5 above, shall be applicable unless the companies approach NPPA for specific price approvals for its formulations"

11. In this case, the appellants did not approach NPPA for specific price, or contend before it that their products contained special features. On the other hand, the allusion to "sustained release" and drug delivery systems (in Note (d)) clearly contemplated that unless otherwise specifically sought- in regard to particular drugs, the price fixation norms applied to all.

12. According to pharmacopedias and the US Food and Drug Administration's definitions, modifications in drug release are often desirable to increase the stability, safety and efficacy of the drug, to improve the therapeutic outcome of the drug treatment and/or to increase patient compliance and convenience of administration. In that context, the use of the term "sustained release" denotes the systems that

maintain the rate of drug release over a sustained period. For example, if the release of the drug from the dosage form is sustained such that the release takes place throughout the entire gastrointestinal tract, one could prolong the time interval of drug concentration in the therapeutic range. This in turn may reduce the frequency of dosing, for example from three times a day to once a day. Sustained-release dosage forms achieve this mostly by the use of suitable polymers, used either to coat granules or tablets (reservoir systems) or to form a matrix in which the drug is dissolved or dispersed (matrix systems). Controlled release systems are drug delivery systems in which the drug is released in a predetermined pattern over a fixed period of time. Therefore, the materials on the record show that the DPCO was aware of the existence of different systems of drug delivery; it specifically talked of sustained release. If the appellants wished to say that the systems used by them were unique or different, it was open for them to have so demonstrated. Their omission to do so, did not in any way affect their obligation to follow the pricing norms and ceiling prices fixed by the impugned notifications. This court, therefore, sees no reason to differ from the conclusions and findings of the High Court.

13. In view of the above analysis, these appeals have to fail. They are accordingly dismissed, without order on costs.

Nidhi Jain Appeals dismissed.