SUPREME COURT OF INDIA

Union of India

Vs.

Swiss Garnier Life Sciences

C.A.No.5117 of 2013

(G.S.Singhvi and Sudhansu Jyoti Mukhopadhaya JJ.)

04.07.2013

JUDGMENT

SUDHANSU JYOTI MUKHOPADHAYA, J.

1. Leave granted. These appeals are preferred by the Union of India and others against the common judgment dated 15th March, 2011 passed by the Division Bench of the Delhi High Court in LPA No. 634 of 2010 with LPA No.790 of 2010. By the impugned judgment the Division Bench affirmed the order dated 19th May, 2010 passed by the learned Single Judge of the Delhi High Court in W.P.(C)No.10277 with W.P.(C)No.12958 of 2009 and dismissed the appeals preferred by the appellants.

2. The respondents filed the aforesaid two writ petitions challenging the price fixation Notifications dated 30th April, 2009 and 17th November, 2009 whereby the Government had fixed the prices of "Doxofylline formulations" in exercise of power conferred under paras 9 and 11 of the Drugs (Prices Control) Order, 1995 (hereinafter referred to as 'DPCO, 1995' for short). Learned Single Judge set aside the Notifications aforesaid and held that 'Doxofylline' is not a bulk drug within the meaning ascribed to it under para 2(a) of the DPCO, 1995.

3. The factual matrix of the case is as follows: On 14th May, 2008 an article appeared in the Newspaper 'THE HINDU', regarding the sale of 'Doxofylline formulations' as a part of tactics to replace less profitable price controlled products i.e. 'Theophylline' with huge profitable alternatives of the same class. The article captioned – 'Drug companies chasing profits, cheating patients; Costlier asthma drugs duck curb, hit market' wherein the Editor of the Medical Journal, Monthly

Index of Medical Specialties, Dr. C.M. Gulati, while giving various reasons for the real reason for 'Doxofylline' entry into the country, stated that 'Doxofylline' was being offered as a more profitable alternative to Theophylline. Further, by successive orders in 2006, all loopholes to sell Theophylline products at high profit margins have been closed by the National Pharmaceutical Pricing Authority (NPPA), the body that monitors medicine prices in India. Therefore, nearly all companies selling Theophylline formulations have been scouting for similar molecules outside the price control system irrespective of whether they are similar, better or even worse than their current brands. It was alleged that the core issue is profits, not patients.

4. In the light of aforesaid newspaper report and complex of consideration implied in the DPCO, 1995, on 22nd July, 2008, the appellants wrote to all the Doxofylline formulation manufactures asking them to provide reasons as to why 'Doxofylline' should not be classified as derivative of Theophylline. Since the requisite information was not furnished by the manufacturers /formulators, including the respondents herein, and Industry Associations even after a lapse of substantial time, and the matter being significant, they were once again reminded by the appellants vide letter dated 16th September, 2008 to furnish the reply latest by 30th September, 2008.

5. The matter was then considered by Technical Committee of the NPPA(2nd appellant). The Technical Committee decided to seek the experts opinion of the Indian Institute of Science, Bangalore (IISc for short) on whether 'Doxofylline' is a derivative of 'scheduled bulk drug' Theophylline. The IISc, Bangalore, vide their letter dated 23rd January, 2009, informed the appellants that 'Doxofylline', is in fact, a derivative of scheduled bulk drug - Theophylline.

6. On the advice of the IISc, Bangalore, it was decided by the 2nd appellant to fix the price of 'Doxofylline formulations'. A letter dated 17th February, 2009 was addressed by 2nd appellant to all known manufacturers of the Doxyfylline formulations seeking details of the purchase price of the bulk drug 'Doxofylline' necessitated for fixation of price of the 'Doxofylline formulation'.

> As per provisions and paras 4 and 5 of the DPCO, 1995, all the manufacturers of the bulk drugs are required to furnish details of manufacture, sales and cost of different bulk drugs including non-scheduled bulk drugs to the NPPA. However, none of the manufacturers of the bulk drug 'Doxofylline' complied with the mandatory requirement of DPCO provisions. In absence of the required information from the manufacturers of

bulk drug 'Doxofylline', 2nd appellant considered the price of the 'Doxofylline', based on best available information in terms of para 11 of the DPCO, 1995. Accordingly, the prices of the 'Doxofylline formulations' were fixed by 2nd appellant vide Notification Nos.S.O.1124(E) and S.O.1084(E), both dated 30th April, 2009, as per the provisions of paras 9 and 11 of the DPCO, 1995.

7. The 2nd Appellant, vide their letter dated 14th May, 2009 requested the IISc, Bangalore for specific views of IISc on the issue as to whether 'Doxofylline' is a salt or ester or stereo-isomer or derivative of the bulk drug Theophylline.

8. In the meantime, the respondents, who are manufacturers of 'scheduled formulations' of 'Doxofylline', filed applications for review, both dated 19th May, 2009 under para 22 of DPCO, 1995 against the notifications aforesaid. Therefore, the appellants, vide their letter dated 25th May, 2009 addressed to the Director, National Institute of Pharmaceutical Education and Research (NIPER), SAS Nagar, Punjab, requested them to give expert advice as to whether the drug 'Doxofylline' was a new chemical entity/new drug or a derivative of Theophylline. The respondents were also given opportunity of hearing on 9th June, 2009 to discuss the said review applications.

9. During the pendency of the review applications aforesaid, by letter dated 28th May, 2009, the IISc clearly opined that 'Doxofylline' is a 'derivative' of Theophylline.

The Director, NIPER, Professor P. Rama Rao, vide his letter dated 1st June, 2009 also opined that:

"1. Drug Doxofylline is a new chemical entity/new drug.

2. Drug Doxofylline is a derivative of Theophylline." Going through the review applications filed by the respondents- companies and after giving them hearing, 1st appellant passed an order on 2nd July, 2009 directing 2nd appellant to consider the cost of raw material Doxofylline used in the formulations whose prices have been fixed by Notifications dated 30th April, 2009 in respect of the Doxofylline formulations either by obtaining the cost of Doxofylline from the respondents or by fixing the cost of Doxofylline by the authority.

10. Aggrieved by the review order dated 2nd July, 2009 passed in review applications, the respondents approached the Delhi High Court by filing writ petitions. During the pendency of the writ petitions, 2nd appellant requested the Pharma Industry Associations, i.e., Indian Drug Manufacturers' Association (IDMA), Organisation of Pharmaceutical Producers of India (OPPI) and the Indian Pharmaceutical Association and 8 known bulk drug manufacturers to send the cost details of Doxofylline bulk drug, within a stipulated period. A reminder was also issued on 31st August, 2009. Twelve known manufacturers including M/s Lupin Ltd. were requested on 11th August, 2009 to furnish the data I Form-III for the fixation of price of Doxofylline. Appellant No.2 also requested the manufacturers on 9th October, 2009 to furnish the detailed information in Form-III of the DPCO, 1995 in respect of the revision in the price fixation of the Doxofylline based formulation.

11. In line with the review order of the Department of Pharmaceuticals and in view of the fact that the prices of Doxofylline formulation were very high in the market, 2nd appellant decided that the prices of bulk drug Doxofylline may be fixed on the basis of available information under para 3 and para 11 of DPCO, 1995 to bring down the prevailing market price of Doxofylline based products for consumers/patients and also to provide a reasonable incentive to the manufacturers by giving a better price than that of Theophylline. Vide Notification dated 17th November, 2009 upward price revision had been carried out, based on maximum sale price of Rs.1487/kg for the Doxofylline bulk drug (as against the earlier adopted price of Rs.512/kg based on notified price of bulk drug Theophylline) in respect of Doxofylline formulations including those which were fixed/notified on 30th April, 2009.

12. Subsequent notification was also challenged by the respondents before the High Court and the learned Single Judge by judgment dated 19th May, 2010 allowed the writ petitions with cost of Rs.5,000/- in favour of the respondents which has been affirmed by the Division Bench of the High Court.

13. Ms. Indira Jaising, learned Additional Solicitor General, appearing for the appellants submitted as follows:

> (a) Doxofylline is a bulk drug within the meaning of para 2(a) of DPCO, 1995, therefore, maximum sale price of such bulk drug can be notified under para 3 and sale price of formulations based on such bulk drug can be notified under para 9 of DPCO, 1995.

(b) Doxofylline is a derivative of Theophylline, it comes within the meaning of bulk drug. The salts, esters, stereo- isomers and derivatives of any bulk drug also come within the meaning of para 2(a) of DPCO, 1995.

(c) If the pharmaceutical, chemical, biological or plant product conforms the requirement of Second Schedule of the Drugs and Cosmetics Act, 1940, it also applies to every salts, esters, stereo-isomers and derivatives of pharmaceutical, chemical, biological or plant product. But salts, esters, stereo-isomers and derivatives of bulk drug need not require to be listed separately in First Schedule of DPCO, 1995, if the pharmaceutical, chemical, biological or plant product is listed in the First Schedule.

14. On behalf of the respondents the following broad contentions were advanced:

(1) Doxofylline is a new drug, and has been considered as a new drug by the authority under Rule 122B of the D & C Rules. Doxofylline was previously a patented drug (for which patent has now expired), and therefore clearly meets the test of novelty etc. It cannot, therefore, be considered a derivative of Theophylline;

(2) Even if Doxofylline is considered to be a derivative, it is not a bulk drug as it is not mentioned in any official Pharmacopoeia. Under para 2(a) of DPCO, even salts, esters, stereo-isomers and derivatives must conform to the standards laid down in Second Schedule of the Drugs and Cosmetics Act, (i.e., being listed in pharmacopoeia);

(3) Even if Doxofylline is considered as a bulk drug it is not a 'scheduled bulk drug' within the meaning of para 2(u) as it is not specified in the First Schedule of DPCO. As such it is not amenable to price control; and

(4) Doxofylline can only be tamenable to price control if it meets the price criteria set out in para 22.7-2. "Span of Control" in the New Drug Policy of 1994.

15. The contentions which found favour with the High Court are:

(i) Doxofylline does not conform the pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940. Therefore, Doxofylline could not be regarded as a 'bulk drug' on the dates on which the impugned judgment/notifications were issued.

(ii) The definition of 'scheduled formulation' [para 2(v) of the DPCO, 1995] indicates that the expression - 'scheduled formation' refers to a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs etc. As Doxofylline is not specified in the First Schedule of DPCO, 1995, the Doxofylline formulation cannot be regarded as scheduled formulation and consequently would not be covered under para 9 of the DPCO, 1995 for fixing the ceiling price for such formulation.

(iii) Theophylline is not contained in the Doxofylline formulation either independently or in combination with other drugs. Therefore, Doxofylline formulation contains Doxofylline and not Theophylline and for that Doxofylline formulations are not covered under the expression scheduled formulation appearing in para 2(v) of DPCO, 1995.

16. The High Court did not feel it necessary to go into the issue whether the impugned Notifications were issued after satisfaction of the criteria specified in para 22.7-2 of the New Drug Policy.

17. The questions involved in these cases are:

a) Whether 'Doxofylline' is a bulk drug within the meaning of para 2(a) of DPCO, 1995;

b) Whether 'Doxofylline' is a 'schedule bulk drug' within the meaning of para 2(u) of DPCO, 1995 ; and

c) Whether 'Doxofylline' is a "scheduled formulation" within the meaning of para 2(v) of DPCO, 1995; and

d) Whether the appellant has power to fix the ceiling price or revise the price of Doxofylline under paras 9 and 10 of DPCO, 1995 ?

18. For determination of the above stated issues it is necessary at this stage to notice the broad features of the DPCO, 1995, as discussed below: In exercise of powers conferred under Section 3 of the Essential Commodities Act, 1955, the Central Government made order, namely, the Drugs (Prices Control) Order, 1995. It repealed the earlier the Drugs (Prices Control) Order, 1987. It was so issued to

control the prices of the essential drugs including life saving drugs. Para 2 is the definition clause. Bulk drug is defined in para 2(a) as under:

> "2(a). 'bulk drug' means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo- isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation;"

Whereas para 2(f) defines "drug", In this case, we are concerned with para 2(f)(iii) which indicates "drug" includes "bulk drugs and formulations". The same is quoted hereunder:

"2(f)(iii). "bulk drugs and formulations"

Then comes to what is defined as "formulation" in para 2(h) and reads as follows:

"2(h).'formulation' means a medicine processed out of, or containing one or more bulk drug or drugs with or without the use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, 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 Homoeopathic system of medicine; and

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

Para 2(u) defines 'scheduled bulk drug" in the following manner:

"2(u) 'scheduled bulk drug' means a bulk drug specified in the First Schedule;"

Whereas "scheduled formation" is defined in para 2(v) as follows:

"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 under the generic name;"

19. From the aforesaid definitions, we find that for the purpose of coming within the meaning of bulk drug, pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives should conform to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940, while for the purpose of coming within the purview of "scheduled bulk drug" within the meaning of para 2(u) or "scheduled formulation" within the meaning of para 2(v), it is not necessary to refer to the Second Schedule of the Drugs and Cosmetics Act, 1940, the bulk drug is specified in the First Schedule of DPCO, 1995.

20. We will now move into para 3 which relates to power to fix the maximum sale prices of bulk drugs specified in the First Schedule, which reads as follows:

"3. Power to fix the maximum sale prices of bulk drugs specified in the First Schedule.-(1)The Government may, with a view to regulate the equitable distribution and increasing supplies of a bulk drug specified in the First Schedule and making it available at a fair price, from different manufacturers, after making such inquiry as it deems fit, fix from time to time, by notification in the Official Gazette, a maximum sale price at which such bulk drug shall be sold:

Provided that for the purpose of enquiry, in addition to the information required to be furnished by the manufacturers under this Order, the manufacturers shall provide any such additional information as may be required by the Government, and shall allow for inspection of their manufacturing premises for verification through on the spot study of manufacturing processes and faculties and records thereof, by the Government.

| (2)While fixing the maximum sale price of a bulk drug under | |sub-paragraph (3), the Government shall take into consideration a | |post-tax return of fourteen per cent on net worth or a return of | |twenty-two percent on capital employed or in respect, of a new plant | |an internal rate of return of twelve per cent based on long term | |marginal costing depending upon the option for any of the specified | |rates of return that may be exercised by the manufacturer of a bulk | |drug: | |Provided that where the production is from

basic stage, the | |Government shall take into consideration a post-tax return of | |eighteen percent on net worth or a return of twenty-six percent on | |capital employed : | |Provided further that the option with regard to the rate of return | |once exercised by a manufacturer shall be final and no change of | |rates shall be made without the prior approval of the Government. | |(3)No person shall sell a bulk drug at a price exceeding the maximum | |sale price fixed under sub-paragraph (1) plus local taxes, if any: | |Provided that until the price of a bulk drug is fixed, by the | |Government under sub-paragraph (1), the price of such bulk drug shall| |be the price which prevailed immediately before the commencement of | |this Order and the manufacturer of such bulk drug shall not sell the | |bulk drug at a price exceeding the price prevailing immediately | |before the commencement of this Order. | |(4)Where, after the commencement of this Order, any manufacturer | |commences Production of any bulk drug specified in the First | |Schedule, he shall within fifteen days of the commencement of | |production of such bulk drug, furnish the details to the Government | |in Form I, and any such additional information as may be required by | |the Government and the Government may after receipt of the | |information and after making such inquiry as it may deem fit, may fix| |the maximum sale price of bulk drug by notification in the Official | |Gazette. | |(5)Any manufacturer, who desires revision of the maximum sale price | |of a bulk drug fixed under sub-paragraph (1) or (4) or as permissible| |under sub-paragraph (3), as the case may be, shall make an | |application to the Government in Form 1, and the Government shall | |after making such inquiry, as it deems fit within a period of four | |months from the date of receipt of the complete information, fix a | |revised price for such bulk drug or reject the application for | |revision for reasons to be recorded in writing." | | |

In the present case, it is not necessary for us to go into the details of para 4 and para 5 except to state that the manufacturers producing "scheduled bulk drugs" are required to furnish details under para 4 as per the said order to the Central Government. Similarly, manufacturers of "non-scheduled bulk drugs" are also required to furnish details as per para 5 to the Central Government.

We will now deal with the special provisions relating to "fixation of price" as provided under para 9 and 11, which read 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 formulation 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 or importer of bulk drug or formulation fails 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."

21. First Schedule of the DPCO, 1995 indicates the 'bulk drugs' recognised by the Government. There are 75 Bulk Drugs shown therein. At Serial No.34

“Theophylline” has been shown as one of the bulk drugs for the purpose of para 2 and 3. ‘Doxofylline’ as such has not been shown as one of the bulk drugs in the First Schedule of the DPCO, 1995.

22. The Second Schedule of the Drugs and Cosmetics Act, 1940 provides “Standards to be complied with by imported drugs and by drugs manufactured for sale, stocked or exhibited for sale or distributed”. The class of drugs and the standards to be complied with has been shown therein. For the purpose of the present case, we would refer Item Nos.1 and 5 of the class of drug and standards to be complied with, which read as under:

“THE SECOND SCHEDULE

(See sections 8 and 16)

STANDARDS TO BE COMPLIED WITH BY IMPORTED DRUGS AND BY DRUGS MANUFACTURED FOR SALE, STOCKED OR EXHIBITED FOR SALE OR DISTRIBUTED

| | | |Class of drug | | |Standard to be complied with | | |1. Patent or proprietary |The formula of list of ingredients | |medicines |displayed in the prescribed manner | |[other than Homoeopathic |on the label or container and such | |medicines] |other standards as may be | | |prescribed. | | | | | | | |Standards of identity, purity and | |5. Other drugs- |strength specified in the edition of| | |the Indian Pharmacopoeia for the | |(a) Drugs included in the |time being in force and such other | |Indian Pharmacopoeia |standards as may be prescribed. | | |In case the standards of identity, | | |purity and strength for drugs are | | |not specified in the edition of the | | |Indian Pharmacopoeia for the time | | |being in force but are specified in | | |the edition of the Indian | | |Pharmacopoeia immediately preceding | | |the standards of identity, purity | | |and strength shall be those | | |occurring in such immediately | | |preceding edition of the Indian | | |Pharmacopoeia and such other | | |standards as may be prescribed. | | | | | |Standards of identity, purity and | |(b) Drugs not included in |strength specified for drugs in the | |the Indian Pharmacopoeia but |edition of such official | |which are included in the |Pharmacopoeia of any other country | |official Pharmacopoeia of |for the time being in force and such| |any other country. |other standards as may be | | |prescribed. In case the standards of| | |identity, purity and strength for | | |drugs are not specified in the | | |edition of such official | | |Pharmacopoeia for the time being in| | |force, but are specified in the | | |edition immediately preceding

the | | |standards of identity, purity and | | |strength shall be those occurring in| | |such immediately preceding edition | | |of such official Pharmacopoeia and | | |such other standards as may be | | |prescribed. |

23. According to the respondents 'Doxofylline' is a new drug; it is not a 'bulk drug' as 'Doxofylline' is not mentioned in the official pharmacopeia. Even salts, ester, stereo-isomers and derivatives of Doxofylline do not conform to the standards laid down in the Second Schedule to the Drugs and Cosmetics Act, 1940. 'Doxofylline' cannot be considered as a derivative of 'Theophylline'.

24. In answer to this, the stand of the appellants is that 'Doxofylline' is derivative of Theophylline, therefore, by virtue of being a derivative, ipso facto, is itself a bulk drug.

25. In view of such stand taken by the parties, it is necessary to decide on the question whether the 'Doxofylline' is a derivative of 'Theophylline'.

In reply to a letter written by the Department of Chemical and Petro-Chemicals, Ministry of Chemical and Fertilizer, New Delhi dated 5th December, 2008 in connection with Doxofylline as a derivative of Theophylline, Indian Institute of Science, Bangalore vide letter dated 23rd January, 2009 informed that Doxofylline, was in fact, a derivative of scheduled drug Theophylline. The said letter is quoted herein: "Dear Mr. Jagdish Kumar

Thank you for your letter of December 5, 2008 in connection of Doxophylline as a derivative of Theophylline a scheduled bulk drug under DPCO 1995.

I have gone through the structures of both the compounds and the methods of preparation of Doxophylline from Theophylline. My recommendation is as follows.

While Doxophylline is a new compound it is prepared by N- alkylation of Theophylline by treatment with 2-boromethy -13- dioxalane. Instead of replacement of hydrogen with methyl or ethyl or propyl group it is being replaced by 1.3 dixalan 2-yl methyl group. Therefore it should be considered as an N-alkyl derivative of Theophylline.

My recommendation is that Doxophylline is a derivative of scheduled drug Theophylline. If you need any others clarification feel free to in tough with me.

With kind regards (SD)

S. Chandrasekartan."

26. The National Institute of Pharmaceutical Education and Research (NIPER) by its letter dated 1st June, 2009 informed as follows: "After going through your letter and the information as provided by Prof. A.K. Chakraborti, I am of the opinion that:

1. Drug Doxofylline is a new chemical entity/new drug.

2. Drug Doxofylline is a derivative of Theophylline."

27. The aforesaid opinions of the experts of Indian Institute of Science (IISc), Bangalore, and Director, National Institute of Pharmaceutical Education and Research (NIPER) have not been disputed by the respondents.

28. In the present case, what we find is that the present stand taken by the respondents is contrary to their stand taken before the authorities while they applied for grant of registration of Doxofylline 400 mg. tablets. The record as enclosed by the respondent-Mars Therapeutics Ltd. reveals the following facts:

(i) Application for grant of registration of Doxofylline 400 mg. tabs. formulation was filed on 3rd October, 2003. Therein the respondents enclosed a number of documents including reports in its support. Item No.3 is "a copy of the letter from M/s. Suven Pharmaceuticals Ltd., Hyderabad relating to supply of 'Bulk Drug Doxofylline'. This shows that the respondents had knowledge that Doxofylline is a bulk drug.

(ii) In Form-44 the composition of the formulation of Doxofylline 400 mg. as shown at Serial No.8 the active ingredients and inactive ingredients as Annexure I and II and which is specification and standard test procedures over 'active and inactive ingredients'. The analytical control schedule shows that Doxofylline is the ingredient of Theophyllin and the relevant portion of the same is extracted below:

"7-Theophyllin acetaldehyde <0.2%

Theophylline 2.91- 0.5%

Theophyllinemethyl – 1.3-dioxolane"

(iii) Under the heading denomination while common denomination has been shown "Doxofylline" , which has been mentioned as follows: "Denomination

Common denomination Doxofylline

Systematic demonation : 2-7' – Theophyllinemethyl-1,3-dioxolane"

(iv) In Annexure II attached with Form 44 Chemical Pharmaceutical information has been supplied therein. Chemical information has been shown as follows:

"Name of the material/Code:Doxofylline Category:Finished Formulation

Chemical Information

General Name Doxofylline

Chemical Name (s) 2-7' –Theophyllinemethyl-1.3- dioxolane"

(v) On the Toxicological and Pharmacological (Pre-Clinical) documentation of 'Doxofylline' has been shown in the expert report enclosed with Form 44, relevant portion of which reads as follows:

"1. INTRODUCTION

Doxofylline or 2(7'-theophyllinmethyl)-1.3"dioxolane is a theophylline derivative with the following structural formula:

Doxofylline was synthesized with the aim of reducing the typical theophylline side effects, without affecting antibronchospastic and bronchodilator effects that are the main pharmacological activities of methylxanthines useful for the therapy of asthma."

From the expert opinion of IISc and NIPER which has been submitted by the appellants, details enclosed by the respondent- Mars Therapeutics Ltd. with their Form 44, and the stand taken in their application for registration, we find and hold that Doxofylline is a derivative of Theophylline.

29. The difference between 'bulk drug' [para 2(a)], 'scheduled bulk drug' [para 2(u)] and 'scheduled formulation' [para 2(v)] has already been noticed in the preceding paragraphs. As per definition the bulk drug should conform to the pharmacopoeial or other standards specified in Second Schedule to the Drugs and Cosmetics Act, 1940. On the other hand, to find out whether a drug is a 'scheduled bulk drug' within the meaning of para 2(u) or 'scheduled formulation' within the meaning of para 2(v), one has to find out whether the bulk drug is specified in the First Schedule of DPCO, 1995, individually or in combination with other drugs.

30. Theophylline is a 'bulk drug' shown at Serial No.34 of the First Schedule of DPCO, 1995. It is also not in dispute that Theophylline is shown in the Indian pharmacopeia and conforms to the standard as per Second Schedule to the Drugs and Cosmetics Act, 1940. Therefore, Theophylline comes within the meaning of bulk drug as defined in para 2(a) and also comes within meaning of 'scheduled bulk drug' [para 2(u)] and 'scheduled formulation' [para 2(v)].

31. From the experts opinion of IISc, Bangalore and NIPER, Punjab and opinion enclosed with the Form 44 submitted by the respondent-Mars Therapeutics Ltd., we have noticed and held that Doxofylline is a derivative of Theophylline. In the preceding paragraph we have noticed that Theophyline is a bulk drug, therefore, and by virtue of being derivative of Theophylline, Doxofylline, ipso facto, is itself a bulk drug. Where a certain "pharmaceutical, chemical, biological or plant product", i.e. the "base drug" satisfies the test laid down under para 2(a), its "salts, esters, stereo-isomers and derivatives" are also automatically included and to be treated as bulk drug in terms of para 2(a). Therefore, if the "base drug" conforms the requirement of Second Schedule to the Drugs and Cosmetics Act, 1940, it automatically applies to every salts, esters, stereo-isomers and derivatives of such "base drug".

32. As per Para 2(a) 'bulk drug' means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 , and which is used as such or as an ingredient in any formulation. The words "includes also" in the context of definition of lease was considered by this Court in State of Uttarakhand and others vs. Harpal Singh

Rawat, (2011) 4 SCC 575. If the ratio of the said case is followed, we find and hold that the definition of "bulk drug" contained in para 2(a) consists of two parts. The first part is applicable to "base drug" i.e. any pharmaceutical, chemicals, biological or plant product. The second part, which is inclusive, applies to salts, esters, stereo-isomers and derivatives of such "base drugs". The use of the word "includes" implies that the definition of bulk drug contained in para 2(a) is very wide and it not only applies to the base drug but also ipso facto applies to its salts, esters, stereo-isomers and derivatives.

33. In view of the definition of 'bulk drug' [para 2(a)] and our finding as recorded above, we hold that if any pharmaceutical, chemical, biological or plant product conforms to pharmacopeial or other standards accepted under the Drugs and Cosmetics Act, 1940, and thus comes within the meaning of bulk drug, as defined in para 2(a), all salts, esters, stereo-isomers and derivatives of such bulk drug are, ipso facto, deemed to be conforming to the pharmacopoeial or other standards accepted under the Drugs and Cosmetics Act and are deemed to be bulk drug within the meaning of para 2(a) of DPCO, 1995.

34. We have already held that Doxofylline is a derivative of Theophylline and admittedly, Theophylline is a bulk drug shown in First Schedule (Item No.34) of DPCO, 1995 and is conforming to pharmacopoeial and other standards specified in the Drugs and Cosmetics Act. We hold that Doxofylline is deemed to be a bulk drug within the meaning of para 2(a) conforming to pharmacopoeial and other standards specified in the Second Schedule to the Drugs and Cosmetics Act. Further, in view of the definition of bulk drug [para 2(a)], Theophylline if used as such (i.e. Theophylline) or as an ingredient (i.e. Doxofylline) in any formulation, it will deem to be a bulk drug within the meaning under para 2(a).

35. 'Scheduled bulk drug' means a bulk drug specified in the First Schedule of DPCO, 1995 [Para 2(u)]. Theophylline has been shown as one of the scheduled drug at Serial No.34 of the First Schedule. In view of our finding that Doxofylline is a derivative of Theophylline, we hold that Doxofylline comes within the meaning of bulk drug as defined in para 2(a) and also within the meaning of 'scheduled bulk drug' as defined in para 2(u).

36. 'Scheduled formulation' is defined in para 2(v), 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. In view of the finding recorded above, Doxofylline being the derivative of Theophylline, a bulk drug, and Doxofylline in any formulation having held to be a bulk drug within the meaning of para 2(a), we hold

that Doxofylline also comes within the definition of scheduled formulation under para 2(v).

37. Under sub-para (1) of para 9, notwithstanding anything contained in DPCO, 1995, the Government is empowered to fix the ceiling price of a scheduled formulation. In view of our finding that Doxofylline formulation is a scheduled formulation as defined under para 2(v), we hold that the Government was very well within its jurisdiction to fix the ceiling price of Doxofylline formulation.

> It is not the case of the respondents that ceiling price has not been fixed as per formula laid down in para 7 keeping in view the cost or efficiency or both of the major manufacturers of such formulation as laid down in sub-para (1) of para 9. For the reason aforesaid, there was no occasion for the High Court to interfere with the impugned Notification Nos.S.O.1124(E) and S.O.1084(E), both dated 30th April, 2009 or Notification dated 17th November, 2009.

38. In the present case we have noticed that though the appellants called for details from manufacturers of Doxofylline formulations by letters dated 22nd July, 2008, 16th September, 2008, they failed to furnish information as required under DPCO, 1995, within the time specified therein. In view of such refusal to furnish the detailed information, it was well within the jurisdiction of the Government to fix price under para 11 on the basis of information as available with it, by order fixing a price in respect of Doxofylline or its formulation.

39. In this case, we have noticed the news appeared in the newspaper insinuating that drug companies were cheating patients, by following a strategy by way of which, they would stop selling less profitable, price controlled products and replacing them with highly profitable alternatives of the same class. The article captioned – 'Drug companies chasing profits, cheating patients; Costlier asthma drugs duck curb, hit market'. Dr. C.M. Gulati have given various reasons for Doxofylline entry into the country, stated that " 'Doxofylline' has been offered as a more profitable alternative to Theophylline. Further, by successive orders in 2006, all loopholes to sell Theophylline products at high profit margins have been closed by the National Pharmaceutical Pricing Authority (NPPA), the body that monitors medicine prices in India. Therefore, nearly all companies selling Theophylline formulations have been scouting for similar molecules outside the price control system irrespective of whether they are similar, better or even worse than their current brands" adds Dr. Gulati. On the basis of such report, the Government suo

moto took the matter under para 11 of the DPCO, 1995, called for reports and opinion of experts and then fixed the price.

40. In this view of the matter and having regard to the facts that we have held that Doxofylline is derivative of Theophylline, a bulk drug, and Doxofylline in any formulation comes within the definition of scheduled formulation, we hold that it is well within the jurisdiction of the Government to fix the ceiling price of Doxofylline formulation under para 9 or para 11 of DPCO, 1995. Therefore, interference with Notification (s) both dated 30th April, 2009 and 17th November, 2009 is uncalled for.

41. Consequently, the appeals are allowed; the judgments and orders dated 19th May, 2010 and 15th March, 2011 passed respectively by the Single Judge and the Division Bench of the Delhi High Court are set aside. The writ petitions preferred by the respondents in the High Court are dismissed. The parties shall bear their own cost.