

IN THE HIGH COURT OF DELHI AT NEW DELHI

W.P. (C) 10277/2009 & CM APPL 8853/2009

MARS THERAPEUTICS & CHEMICALS LTD. Petitioner
Through Mr. S. Ganesh, Senior Advocate with
Ms. Malini Sud, Mr. Deepak Khurana and
Ms. Tania Sharma, Advocates

versus

THE UNION OF INDIA AND ANR Respondents
Through Mr. Atul Nanda with
Mr. Gaurav Gupta, Advocate for UOI.

and

W.P. (C) 12958/2009 & CM APPL Nos. 13834-35/2009, 2209/2010

SWISS GARNIER LIFE SCIENCES AND ORS Petitioners
Through Mr. S. Ganesh, Senior Advocate with
Ms. Malini Sud, Mr. Deepak Khurana and
Ms. Tania Sharma, Advocates

versus

THE UNION OF INDIA AND ANR Respondent
Through Mr. Gaurav Duggal, Advocate

CORAM: JUSTICE S. MURALIDHAR

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| 1. Whether reporters of local paper may be allowed to see the order? | No |
| 2. To be referred to the reporter or not? | Yes |
| 3. Whether the order should be referred in the digest? | Yes |

ORDER
19.05.2010

1. The facts and issues in both these petitions are more or less similar and they are, accordingly, being disposed of by this common order.

2. The question that arises for consideration in both these cases is whether Doxofylline is itself a “bulk drug” in terms of Para 2(a) of the Drugs (Prices Control) Order 1995 (‘DPCO 1995’).

3. The above question first arose in the context of Notification Nos. 1084 (E) and 1124 (E) dated 30th April 2009 issued by the National Pharmaceuticals Pricing Authority (‘NPPA’), Department of Chemicals & Petrochemicals, Government of India fixing the ceiling prices of ‘scheduled formulations’ Doxofylline Tab 400 mg and Doxofylline Syrup. M/s. Mars Therapeutics and Chemicals Limited (‘MTCL’) the Petitioner in Writ Petition (Civil) No. 10277 of 2009, earlier filed Writ Petition (Civil) No. 9019 of 2009 in this Court challenging the aforesaid notifications. The said writ petition was disposed of by this Court on 18th May 2009 directing the Petitioner MTCL to file a review application under Para 22 of the DPCO 1995. Consequently, the MTCL filed on 21st May 2009 a detailed review application challenging the said notifications. M/s. Swiss Garnier Life Sciences (‘SGLS’), the Petitioner in Writ Petition (Civil) No. 12958 of 2009 also filed a review application on 19th May 2009 under Para 22 of the DPCO 1995 against the aforesaid notifications. Both the Petitioners state that they had raised the question that Doxofylline was not a “bulk drug” within the meaning of Para 2(a) of the DPCO 1995; that it was not a derivation of ‘Theophylline’ as projected by the NPPA and that in any event without fixing the price of the bulk drug Doxofylline, the prices of the formulations could not be fixed. The Petitioners filed documents showing the break-up of the actual cost of production and the prevailing prices of the bulk drugs

Doxofylline. The point urged by both Petitioners was that paras 9 and 11 of the DPCO 1995 under which the notifications were issued applied only to ‘Scheduled formulations’ which were defined in clause (v) of sub para 2 of the DPCO 1995. It was also pointed out that the bulk drug Doxofylline and the formulations using it as raw material were introduced in India in 2006 for the first time as approved by the Drugs Controller General India (‘DCGI’) under the Drugs and Cosmetics Act, 1940 (‘DCA’) and Rule 122B of the Drugs and Cosmetics Rules, 1945 (‘DCR’) read with Schedule ‘Y’ thereof. Hearing was granted to MTCL on 25th May 2009 and to SGLS on 9th June 2009.

4. On 2nd July 2009 the review application filed by MTCL was disposed of by the Deputy Secretary to the Government of India, Ministry of Chemicals and Petrochemicals, Department of Pharmaceuticals (‘DOP’) observing that:

“It has been observed from the facts available on records that NPPA has fixed the price of Doxofylline formulations considering the cost of Theophylline which is not used in the manufacture of these formulations. The provisions of para 11 of the DPCO 1995 can also not be applied for fixation of the price because the communications issued by NPPA to the formulators does not stipulate any period for furnishing the requisite information. The representations made by various Associations to the NPPA have also not been considered properly.”

5. By the above order, NPPA was directed “to consider the cost of the raw material Doxofylline used in the formulations whose prices have been fixed by NPPA vide notifications Nos. S.O. 1124 (E) and S.O. 1084 (E) both

dated 30th April 2009 in respect of the Doxofylline formulations, either by obtaining the cost of Doxofylline from the formulators or by fixing the cost of Doxofylline by the Authority.”

6. Aggrieved by the above order, the MTCL has filed Writ Petition (Civil) No. 10277 of 2009.

7. As regards the SGLS, when its review application was not being disposed of, it had filed Writ Petition (Civil) No. 11794 of 2009 in this Court. By an order dated 18th September 2009 this Court directed the review application to be disposed of. Thereafter an order was passed by the Under Secretary to the Government of India, Department of Pharmaceuticals on 30th September 2009 on the same lines as the order dated 2nd July 2009 in the case of MTCL. The said order dated 30th September 2009 has been challenged by SGLS in W.P.(C) No. 12958 of 2009.

8. Meanwhile, pursuant to the order in review dated 30th September 2009, the NPPA issued the Notification on 17th November 2009 fixing the ceiling prices in respect of Doxofylline formulations, viz., Doxofylline Tablet 400 mg and Doxofylline Syrup. The Petitioner’s application for amendment of the W.P.(C)No. 12958 of 2009 to challenge the said two notifications dated 17th November 2009 was allowed by this Court by an order dated 18th February 2010.

9. By an order dated 3rd December 2009 the learned Single Judge of this

Court declined the stay of the impugned notifications dated 17th November 2009. Aggrieved by the refusal of the stay SGLS filed LPA No. 6 of 2010 which was disposed of by the Division Bench of this Court on 15th January 2010 staying the operation and implementation of the Doxofylline price fixation notifications dated 17th November 2009.

10. This Court has heard the submissions of Mr. S. Ganesh, learned Senior counsel appearing for the petitioners and Mr. Gaurav Duggal as well as Mr. Atul Nanda, learned counsel for the Respondents.

11. It is first submitted on behalf of the petitioners that the impugned notifications dated 17th November 2009 proceed on the footing that Doxofylline is a bulk drug and that Doxofylline formulations are “Scheduled Formulations” within the meaning of the DPCO 1995. It is submitted that a ‘bulk drug’ under para 2 (a) of the DPCO 1995 should be either a pharmaceutical drug or a derivative “conforming to pharmacopeia or other standards specified in the Second Schedule to the Drugs and Cosmetics Act and which is used as such or as an ingredient in any formulation.” It is submitted that unless Doxofylline or its salts, esters or derivative is included in the Second Schedule to the DCA, it cannot fall within the definition of ‘bulk drug’ under para 2(a) DPCO 1995. It is next submitted that the ‘scheduled formulation’ within the meaning of para 2 (v) DPCO 1995 has to mean 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.” It is pointed out that in the Schedule to the DPCO 1995, the bulk drugs mentioned therein include at Serial No. 34 ‘Theophylline’. However, both the order dated 30th September 2009 passed by Respondent No. 1 in the review application filed by SGLS and the order dated 2nd July 2009 in the review application filed by MTCL, acknowledge that “Theophylline” is not used in the manufacture of these formulations. It is pointed out that while disposing of the review applications in both cases the Respondent No. 1 has not dealt with the principal submission of the Petitioners that Doxofylline itself is not a ‘bulk drug’. It is also not a derivative of Theophylline. It is a new drug in terms of the DCA and therefore, falls out the scope of the DPCO 1995. Reliance has been placed upon the judgment of the Supreme Court in *Secretary, Ministry of Chemicals & Fertilizers, Government of India v. Cipla Limited (2003) 7 SCC 1* in which it was, inter alia, held that only those drugs and formulations which are specifically mentioned in DPCO can be subject to a ceiling price notification.

12. It is submitted that Doxofylline does not satisfy the criteria set out in the New Drug Policy announced by the Government in 1994 based on which DPCO 1995 was issued. It is submitted that under para 22.7.2 of the New Drugs Policy 1994, one criterion of bringing a drug under price control would be the minimum annual turnover of Rs. 400 lakhs; The second criterion is that it should be a drug of popular use. For this purpose, it will have to be first established that the bulk drug in question has an annual

turnover of Rs. 100 lakhs or more and that for such bulk drug there is a single formulator having 90% or more market share in the retail trade as per the Operation Research Group ('ORG'). A third criterion is that a drug in which there is sufficient market competition, i.e., there are at least five bulk drugs producers and at least 10 formulators and none has more than 40% market share in the retail trade as per the ORG, it will not be subject to price control.

13. It is submitted that none of the above criteria are fulfilled by Doxofylline. It is further submitted that without fixing the price of the bulk drug Doxofylline, the Respondents have gone ahead and fixed the prices of Doxofylline formulations which is not permissible in law.

14. It is submitted that Doxofylline and Theophylline are distinct and different drugs. According to the report prepared by the National Institute of Pharmaceutical Education & Research Institute ('NIPER'), Doxofylline formulations can be prepared by "reacting Theophylline with 2-(halomethyl)-1, 3-dioxolane in a polar solvent containing a base (as an acid scavenger) in one step. The other method of preparation is "by converting theocin or anhydride theocin with a base at 50-150° for 2-4 hours into its salt, dissolving the salt and halo-substituted acetaldehyde cyclic ethylene acetal at molar ratio..." Therefore, it is not true that Doxyfylline is always a 'derivative' of Theophylline. Lastly, it is submitted that the submissions made in the review application concerning the actual cost of production have not been considered by the authorities.

15. Mr. Gaurav Duggal, learned counsel for the Respondent submits that Doxofylline is a derivative of Theophylline in terms of the report of the NIPER. Theophylline finds mention in the First Schedule to the DPCO 1995. After the review order was passed, the Respondent No. 2 on 14th July 2009 requested the Pharma Industry Associations i.e. IDMA, BDMA, OPPI and eight known bulk drug manufacturers including Ranbaxy Labs Ltd; Dr. Reddy's Labs Ltd, MTCL, Suven Lifesciences Ltd, to send the cost details in respect of Doxofylline bulk drug within three weeks. A reminder was sent on 31st August 2009. Only one manufacturer of Doxofylline bulk drug namely M/s. Cadila Health Care Limited (CHCL) submitted their data for the year 2008-09. It is submitted that available data/information in respect of Doxofylline bulk drug was duly considered by the NPPA at the 112th Authority meeting held on 13th November 2009 and in accordance with paras 3 and 11 of the DPCO 1995, the maximum sale price was fixed for Doxofylline bulk drug by notification dated 13th November 2009.

16. As far as the price fixation/revision of Doxofylline formulations was concerned, on 11th August 2009, 12 known manufacturers including the Petitioner No. 2 in Writ Petition (Civil) No. 12958 of 2009 i.e. M/s. Lupin Limited were requested to furnish the data. A Reminder letter was also issued on 25th September 2009. By letter dated 1st September 2009 the Petitioner No. 2 informed that they did not manufacture Doxofylline formulations but only distributed and sold the same after buying it from the manufacturer i.e. SGLS on 'principal to principal basis'. However the Petitioner No. 1 SGLS by its letter dated 12th November 2009 did not furnish

the cost details stating that “the request for seeking details in Form No. III of the DPCO 1995 ought to be kept in abeyance in any event till the next date of hearing.” Based on the availability of the data, NPPA fixed the prices of Doxofylline formulations and the notification dated 17th November 2009 was issued.

17. It is submitted that after the judgment of the Supreme Court in *Union of India v. Cynamide India Private Limited (1987) 2 SCC 720*, it is imperative that each manufacturer is under a legal obligation to strictly adhere to the ceiling prices fixed for the formulations and drugs. It is further submitted that against the notification dated 17th November 2009, it is open to the manufacturers to file a review application for revision of ceiling prices in accordance with para 22 of the DPCO 1995.

18. It is submitted that the primary consideration is the interest of the consumers who are affected by asthma, chronic bronchitis and other lung ailments. Doxofylline bulk drug and its other formulations are used in the treatment of such ailments. Therefore, it was the concern of the Respondent that the required medicines based on Doxofylline are to be made available at fair and reasonable prices.

19. The above submissions have been considered by this Court.

20. One of the questions that arise for consideration is whether Doxofylline

is a 'bulk drug' within the meaning of Para 2(a) DPCO 1995, which reads as under:

““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.”

21. A careful reading of the above definition shows that a bulk drug should be:

- (i) any pharmaceutical, chemical, biological or plant product.
- (ii) Such product could include salts, esters, stereo isomers and derivatives of such product.
- (iii) Both the product and its salts, esters, stereo-isomers and derivatives have to conform to pharmacopoeial or other standards specified in the Second Schedule to the DCA.
- (iv) The product or its derivatives should be used as such or as an ingredient in any formulation.

22. The stand of the Respondents is that as long as Theophylline is a bulk drug included at Serial No. 34 of the Schedule to the DPCO 1995, its derivative Doxofylline would also come under the definition of 'bulk drug'. The above submission is inconsistent with the observations of the Respondent No.1 itself in two orders passed in the review applications of the petitioners. It is clear from the order dated 2nd July 2009 passed by Respondent No. 1 in the review application of MTCL that “NPPA has fixed

the price of Doxofylline formulations **considering the cost of Theophylline which is not used in the manufacture of these formulations.”**

23. The Petitioner’s contention that Doxofylline and Theophylline are distinct and different bulk drugs and that for the manufacture of the formulations in question, SGLS did not use Theophylline has not been countered by the Respondents. From the report of the NIPER, a copy of which is on record, it appears that Doxofylline can be prepared through two distinct methods, as noticed. The conclusion in the NIPER report is that Doxofylline is a new chemical entity/drug and Doxofylline is a derivative of Theophylline. However, if one goes by the views expressed by the Respondent in the review orders in these cases as regards Doxofylline formulations prepared by these Petitioners, it is plain that these formulations do not contain any Theophylline at all. It also appears that Doxofylline is indeed a new chemical entity/new drug.

24. It is an admitted position that Doxofylline does not find mention in the Second Schedule to the DCA. It was introduced in 2006 for the first time as a new drug and approved by the DCGI under Rule 122B of the DCR read with Schedule ‘Y’ thereof.

25. It must be mentioned that Doxofylline is not listed in any of the pharmacopeia as required by the Second Schedule to the DCA. Consequently, the essential requirement of Para 2 (a) of the DPCO 1995 is not fulfilled, inasmuch as Doxofylline find no mention in the Second

Schedule to the DCA. This is assuming that Doxofylline is a derivative of Theophylline which is in fact contradicted in the review order as far as the Doxofylline formulations manufactured by the Petitioners are concerned.

26. It must be mentioned that both the impugned notifications dated 17th November 2009 clearly state that the price being fixed by the notification are “ceiling prices” as well as the equivalent market retail prices of the ‘Scheduled formulations’ specified in the corresponding entry in the column (2) of the said table. Therefore, it is very clear that the impugned notifications treated the Doxofylline formulation whose prices are fixed as ‘Scheduled formulation’, that is the reason why the notification cited para 9 of the DPCO 1995. The explanation to para 9 states that “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.” The definition of ‘Scheduled formulation’ under para 2 (v) also requires it be a formulation containing any bulk drug specified in the First Schedule. In view of the earlier para, it is plain that Doxofylline formulations cannot be considered as ‘scheduled formulations’ for the simple reason that they do not contain a bulk drug specified in the First Schedule.

27. Mr. Duggal, learned counsel relied upon the para 11 to justify the impugned notification. Para 11 reads as under:

“11. **Fixation of price under certain circumstances** – Where any manufacturer, importer of a 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.”

28. It was submitted that even if Doxofylline formulations are not considered to be ‘Scheduled formulations’ they should be considered to be ‘formulations’ simpliciter and therefore, on the strength of para 11, prices can be fixed for such formulations.

29. The above contention ignores the scheme of the DPCO 1995. The power under the DPCO 1995 is to fix the maximum sale prices of bulk drugs specified in the First Schedule (Para 3), the retail price of Scheduled Formulations (Part 8), the ceiling price of Scheduled formulations (Para 9), revision of price of bulk drugs and formulations (Para 10) and so on. Para 11 also only states that where any manufacturer, importer of a bulk drug or formulations fails to submit an application for price fixation or revision or fails to furnish information as required under the DPCO, within the time specified therein, the Government may “on the basis of such information as may be available with it, fix a price in respect of such bulk drug or formulation as the case may be.” In other words, for the purpose of exercise of fixing the ceiling price of a bulk drug or a scheduled formulation, if the Government is not furnished with the necessary information by the manufacturer of such bulk drug or scheduled formulations within the time, it

may proceed on the basis of whatever information is available. In other words, Para 11 itself is not a source of independent power to fix the ceiling price of a scheduled formulation. Therefore, the reference to para 11 in the impugned notification is only to indicate that as regards Doxofylline formulations, the government has relied on whatever information was available with it for fixing the ceiling price. That information was provided by CHCL, since neither of these Petitioners furnished the requisite information to the Government.

30. The result of the above discussion is that the Petitioners are right in their contentions that Doxofylline is not a bulk drug within the meaning of para 2 (a) of the DPCO 1995.

31. In that view of the matter, the writ petitions are, accordingly, allowed and the impugned notifications dated 17th November 2009 are held to be unsustainable in law and are hereby quashed.

32. The writ petitions and the pending applications are disposed of with costs of Rs. 5,000/- in each petition which will be paid to each of the Petitioners by the Respondents within four weeks.

S. MURALIDHAR, J.

MAY 19, 2010
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