* **HIGH COURT OF DELHI : NEW DELHI**

Judgment delivered on: 15.03.2011

\+ LPA. 634/2010

UNION OF INDIA & ORS. .....Appellants

Versus

M/S. SWISS GARNIER LIFE SCIENCES & ORS. ……Respondents

AND

\+ LPA. 790/2010

UNION OF INDIA & ANR. .....Appellants

Versus

M/s MARS THERAPUTICS AND CHEMICALS LIMITED.
……Respondents

Advocates who appeared in this case :-

For the Appellants:	Mr Mukesh Kumar Tiwari with Mr Sanjiv Kumar Saxena for Mr Ruchir Mishra, Advocate for UOI.
For the Respondents:	Mr S. Ganesh, Sr. Advocate with Mr Varun Singh, Advocate in LPA 634/2010. Mr S. Ganesh, Sr. Advocate with Mr Deepak Khurana & Mr Shobhit Chandra, Advocates in LPA 790/2010.

Coram:
HON'BLE MR. JUSTICE BADAR DURREZ AHMED
HON'BLE MR. JUSTICE MANMOHAN SINGH

1. Whether the Reporters of local papers may be allowed to see the judgment? Yes.

2. To be referred to Reporter or not? Yes.

3. Whether the judgment should be reported in the Digest? Yes.

BADAR DURREZ AHMED, J. (ORAL)

1. These appeals arise out of the common judgment dated 19.05.2010 passed by a learned Single Judge of this Court in W.P.(C)

Nos. 10277/2009 and 12958/2009. The said writ petitions had been filed challenging the price fixation notifications dated 30.04.2009 and 17.11.2009 whereby the government had fixed the prices of Doxofylline formulations. By virtue of the impugned judgment it has been held that Doxofylline is not a bulk drug within the meaning ascribed to it under paragraph 2(a) of the Drugs (Prices Control) Order 1995 (hereinafter referred to as 'the DPCO, 1995'). The contention of the appellant before us and the respondent before the learned Single Judge was that Doxofylline was a bulk drug under the said paragraph 2(a) and, therefore, the government was entitled to fix the price of its formulations under paragraph 9 of the DPCO, 1995 and it is pursuant to that power that the said notifications dated 30.04.2009 and 17.11.2009 were issued, fixing the prices of Doxofylline formulations.

2. On the other hand, it was contended on behalf of the respondents herein and the petitioners before the learned Single Judge that Doxofylline was not a bulk drug within the meaning of paragraph 2(a) of the DPCO, 1995. Mr Ganesh, the learned Senior Counsel appearing on behalf of the respondents further submitted that even if it were to be assumed, without admitting, that Doxofylline was a bulk drug, as defined in paragraph 2(a) of the DPCO, 1995, the prices of Doxofylline formulations could not be fixed under paragraph 9 or 11 of the DPCO, 1995 because paragraph 9 and consequently paragraph 11 only relates to scheduled formulations. He submitted that Doxofylline formulations in respect of which the said notifications were issued were

not scheduled formulations and, therefore, on this ground also the notifications were liable to be struck down. It was further contended by Mr Ganesh that even if we ignore the first two points, the issue of satisfaction of the criteria specified under paragraph 22.7-2 of the new drugs policy would still have to be considered. He submitted that the criteria which are set out in the said paragraph are not at all satisfied in the present cases. He further submitted that though this point was noted by the learned Single Judge in paragraphs 12 and 13 of the impugned judgment, he did not think it necessary to deal with the same because of the view, that he took, that Doxofylline was not a bulk drug.

3. Mr Ganesh further pointed out that the learned Single Judge took note of the review orders passed in the case of both the writ petitioners wherein the Reviewing Authority namely the Under Secretary to the Government of India, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals observed as under:

> "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 learned Single Judge relied on this observation and finding to hold against the appellants that Doxofylline could not be considered to be a derivative of Theophylline in the facts of the present cases.

4. We shall take up the first point and that is whether Doxofylline is a bulk drug within the meaning of paragraph 2(a) of the DPCO, 1995.

Bulk drug has been defined in the said paragraph 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."

5. According to the learned counsel for the appellants, the said definition implies that once a pharmaceutical, chemical or biological or plant product has been established to be a bulk drug, its derivative would automatically be covered under the definition of bulk drug also. On the other hand Mr Ganesh appearing on behalf of the respondents submitted that the second part of the definition which relates to the product or its derivatives conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Chemicals Act, 1994 would equally apply to the product and its derivatives. We find that the definition of bulk drug has been analyzed by the learned Single Judge in the following manner:

> "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."

6. There is no dispute with regard to the conditions (i), (ii) and (iv). The learned counsel for the appellants submitted that the interpretation given by the learned Single Judge, as it appears in (iii) above, is not the correct interpretation. However, we are of the view that the learned Single Judge has correctly analyzed the said definition and has broken it up into constituent components. It is also clear that both, the product and its salts, esters, stereo-isomers and derivatives are qualified by the expression "conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940". Therefore, it would not be sufficient if a bulk drug by itself conforms to the pharmacopoeial or other standards specified in the Second Schedule to the said Act, the derivative would also have to conform to such standards before it can be included in the definition of bulk drug.

7. In this context, it is clear that even if we assume that Doxofylline is a derivative of Theophylline, it must further be established that Doxofylline conforms to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940. Serial No. 5 of the Second Schedule to the Drugs and Cosmetics Act, 1940 is relevant for our purposes and the same reads as under:

[5. Other drugs — (a) Drugs included in the Indian Pharmacopoeia	Standards of identity, purity and strength specified in the edition of the Indian Pharmacopoeia for the time being in force and such other 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 strength specified for drugs in the edition of such official Pharmacopoeia of any other country for the time being in force and such other standards as may be prescribed.
(b) Drugs not included in the Indian Pharmacopoeia but which are included in the official Pharmacopoeia of any other country.	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.]

8. From the said entry it is apparent that before a drug qualifies to be one which is specified in the Second Schedule, it must either be included in the Indian pharmacopoeia or in the official pharmacopoeia of any other country. For the first time, by way of a notification dated 23.08.2010 (w.e.f. 01.12.2010), Doxofylline has been listed in the Indian Pharmacopoeia. But, at the point of time when the impugned notifications fixing the prices of Doxofylline formulations were issued, Doxofylline was not mentioned in the Indian pharmacopoeia. We had

granted time on previous occasions to the appellants to point out as to whether Doxofylline was included in any official pharmacopoeia of any other country. They have not been able to point out any official pharmacopoeia of any other country which included Doxofylline at the time the impugned notifications were issued.

9. The learned counsel for the appellants also made a submission that there are several opinions available with them from experts to indicate that Doxofylline was a derivative of Theophylline. However, we find that in the review orders the government itself has given a finding that Theophylline is not used in the manufacture of Doxofylline in the present cases. This is factual finding from which the appellants cannot shy away.

10. However, even if we were to consider Doxofylline to be a derivative of Theophylline, it does not conform to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940. Therefore, we are in complete agreement with the conclusion arrived at by the learned Single Judge that Doxofylline could not be regarded as a bulk drug on the dates on which the impugned notifications were issued.

11. The second aspect of the matter is that the power to fix the ceiling price of formulations, which is given under paragraph 9 of the DPCO, 1995 is limited to scheduled formulations only. Paragraph 9 of the DPCO, 1995 reads as under:

> "**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 paragraph7, 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 manufacture 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 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."

12. It is obvious that the government has the power to fix the ceiling price of scheduled formulations. Now, scheduled formulations are defined in paragraph 2(v) of the DPCO, 1995 as under:

> "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;"

13. The said definition indicates that the expression "scheduled formulation" refers to a formulation containing any bulk drug specified in the First Schedule either independently or in combination with other drugs etc. What this means is that, the formulation in question must contain a bulk drug which is specified in the First Schedule. Even if we were to assume that Doxofylline was a bulk drug, Doxofylline formulations could be regarded as scheduled formulations only if Doxofylline was specified in the First Schedule to the DPCO, 1995. We find that Doxofylline is not so specified in the First Schedule to the DPCO, 1995. Thus Doxofylline formulations cannot be regarded as scheduled formulations and consequently would not be covered under paragraph 9 of the DPCO, 1995. The result of this is that even if we were to assume that Doxofylline was a bulk drug, its formulations could not be regarded as scheduled formulations, inasmuch as, Doxofylline was not specified in the First Schedule to the DPCO, 1995 and, therefore, the government

could not invoke paragraph 9 for fixing the ceiling price for such formulations.

14. It was contended on behalf of the appellants that although Doxofylline is not listed in the First Schedule to the DPCO, 1995, Theophylline is mentioned at Serial No. 34 and since Doxofylline, according to them, is a derivative of Theophylline, therefore, indirectly Doxofylline formulations can be regarded as scheduled formulations. We are unable to accept this contention because a plain reading of paragraph 2(v), which defines scheduled formulations, indicates that the formulations containing a bulk drug must be one where the bulk drug is itself specified in the First Schedule, either independently or in combination with other drugs. It is an admitted position that Theophylline is not contained in the Doxofylline formulations either independently or in combination with other drugs. Doxofylline formulations contain Doxofylline and not Theophylline. The Doxofylline formulations also do not contain any combination of Theophylline. Therefore, we are of the clear view that the Doxofylline formulations are not covered in the expression "Scheduled formulation" as appearing in paragraph 2(v) of the DPCO, 1995.

15. It was also contended on behalf of the appellants that apart from paragraph 9 of the DPCO, 1995, the government had independent power under paragraph 10 to fix and revise the price of bulk drugs and formulations including non-scheduled formulations and, therefore, notifications which are impugned were not beyond the power of the

government. We find that the notifications themselves have been issued in exercise of the powers under paragraphs 9 and 11 of the DPCO, 1995 and there is no reference to paragraph 10. Therefore, the argument raised by the learned counsel for the appellants is without any factual basis. Furthermore, the power under paragraph 10 is different and distinct from the power under paragraph 9. Whereas, under paragraph 10 the government has the power to fix the retail price, under paragraph 9 the power is in respect of fixing of the ceiling price of scheduled formulations. The notifications purport to fix the ceiling price of formulations and, even if it were assumed that paragraph 9 and 11 have been wrongly mentioned, the notifications themselves do not even purport to have been issued under paragraph 10 of the DPCO, 1995.

16. The final aspect of the matter is with regard to the satisfaction of the criteria specified in paragraph 22.7-2 of the New Drugs Policy. Just as the learned Single Judge did not feel it necessary to go into this issue in view of the conclusion arrived at on other two aspects, we also think that it would not be necessary to deal with this aspect of the matter.

17. We entirely agree with the reasoning as well as the conclusions arrived at by the learned Single Judge and find no infirmity in the impugned judgment. However, we may observe that the fact that Doxofylline was not included in the Indian pharmacopoeia at the point of time when the said notifications were issued would not come in the way of the government in issuing fresh notifications, now that Doxofylline has been included in the Indian pharmacopoeia, provided, they comply with

all the other requirements of law including the DPCO, 1995. With these observations, the appeals are dismissed.

18. No orders as to costs.

BADAR DURREZ AHMED, J

MANMOHAN SINGH, J

MARCH 15, 2011
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