

(2010) 11 DEL CK 0217

In the Delhi High Court

Case No : Writ Petition (C) No. 3099 and C.M. No. 5963 of 2008

Ranbaxy Laboratories Limited

APPELLANT

Vs

Union of India (UOI) and Another

RESPONDENT

Date of Decision : 22-11-2010

Acts Referred:

Citation : (2011) 176 DLT 47 : (2011) 121 DRJ 552

Hon'ble Judges : Dr. S. Muralidhar, J

Bench : Single Bench

Advocate : Deepak Khurana and Shobhit Chandra, for the Appellant; A.S. Chandhiok, ASG and Akshay Chandra, for the Respondent

Final Decision : Disposed Off

Judgement

S. Muralidhar, J.—The present case concerns the interpretation of Para 22 of the Drugs (Prices Control) Order, 1995 ("DPCO 1995") which sets out the powers of the Central Government to review a Notification or Order made under the DPCO, 1995. The question that arises is whether rejection of the Petitioner's review petitions by the Central Government in the instant case by the impugned order dated 26th February 2008 was proper.

2. By price fixation Notifications dated 13th and 27th June 2007, the National Pharmaceuticals Pricing Authority ("NPPA"), Respondent No. 2 herein, which is functioning under the Union of India, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilisers, Respondent No. 1 herein, fixed the ceiling price of Roscillin 500 mg and 250 mg under paras 10 and 11 of the DPCO, 1995. Aggrieved by the said Notifications the Petitioner, which is a manufacturer of the above tablets filed review petitions on 27th June 2007 and 10th July 2007 under para 22 of the DPCO, 1995.

3. It is stated that the review petitions were not disposed of for more than six months thereafter. An order dated 10th December 2007 was passed by the Respondent No. 1 calling upon the Petitioner to comply with the price fixation

Notifications dated 13th and 27th June 2007. Aggrieved by the said order dated 10th December 2007, the Petitioner filed Writ Petition (Civil) No. 371/2008 in this Court. The following order was passed by this Court while disposing of the said writ petition on 16th January 2008:

2. In view of the facts which have been noticed herein above in my view this Writ Petition can appropriately be disposed of at this stage with a direction to the respondents to decide the review petition which is pending for over six months without delay.

The respondents are accordingly directed to dispose of the review petition which has been filed by the Petitioner under para 22 of DPCO 1995 within a period of four weeks from today in accordance with prescribed procedure and principles laid down by the Apex Court in Union of India (UOI) and Another Vs. Cynamide India Ltd. and Another etc., . The Respondents shall accord full opportunity to the Petitioner to make their representations including oral hearing and pass a reasoned order thereon. The order which is passed by the Respondents shall be communicated to the Petitioner....

4. A hearing was fixed for the review petitions on 4th February 2008. The Petitioner also filed its written submissions. Thereafter on 26th February 2008, the Petitioner's review petitions were dismissed by Respondent No. 1 by passing an order, the relevant portion of which reads as under:

4. The review petitions as also the direction of the Hon"ble High Court have been considered. It is observed from the records available with the Department of NPPA that the review applications filed under Para 22 of the DPCO do not appear to be maintainable since the compliance of the price notification of NPPA vide S.O. 954(E) dated June 13, 2007 and S.O. 1043(E) dated June 27, 2007 fixing the MRP of Roscillin 500 caps at Rs. 66.77 (8"s pack size) and in respect of Roscillin 250 mg caps (8"s pack size) fixing the MRP at Rs. 36.23 respectively have not been made within the stipulated period. However, the petitioner is free to file a price revision application on NPPA which shall consider and dispose it of as per the prescribed provisions.

5. The grievance of the Petitioner is that the review petitions were rejected on a ground that was not available to the Respondents. The review petitions ought to have been disposed of on merits irrespective of whether the Petitioner had complied with the price fixation Notifications dated 13th and 27th June 2007. It is submitted that in any event for non-compliance of the said notifications a demand can be raised under para 13 of the DPCO, 1995. It is further pointed out that in fact the Petitioner had implemented the price fixation Notifications dated 13th and 27th June 2007. By an affidavit filed on 15th September 2009 the Petitioner has sought to explain that it implemented the said price fixation Notifications in the following manner:

A) So far as Roscillin 250 mg capsules are concerned, the notification dated 27.6.2007 was displayed on the NPPA's website on 28.6.2007 and, accordingly,

the period of 15 days allowed by para 14(2) of the DPCO, 1995 for implementing and giving effect to that notification expired on 13.7.2007. It is necessary to note that the last batch of Roscillin 250 mg capsules which was manufactured immediately before the issuance of the said notification dated 27.6.2007 was Batch No. 9090838, the manufacture of which completed on 05.06.2007, as can be seen from the table annexed hereto and marked as Annexure A. After 05.06.2007, there was no manufacture of Roscillin 250 mg capsules throughout the balance period of June, 2007, nor was there any manufacture of this product anytime during July, 2007. The Batch of Roscillin 250 mg capsules which were manufactured after the issuance of the said notification dated 27.6.2007 was Batch No. 9091109, the manufacture of which was completed on 8.9.2007. The Petitioner Company complied fully with the said Notification dated 27.6.2007 in respect of this batch, and the MRP of the same was Rs. 36.23, as fixed by the impugned Notification. This is also clear from the Annexure A hereto.

B) So far as Roscillin 500 mg capsules are concerned, the impugned Notification dated 13.6.2007 was displayed on NPPA's website on 14.6.2007, accordingly, 15 days period allowed by para 14(2) of the DPCO, 1995 for implementing and giving effect to this Notification expired on 29.6.2007. Before the expiry of the said 15 days period on 29.6.2007, the Petitioner manufactured five batches of Roscillin 500 mg capsules, being Batch Nos. 9090894, 9090895, 9090897, 9090898 and 9090899 as can be seen from the statement, which is annexed hereto and marked as Annexure B. The last of these batches were manufactured on 28.6.2007 i.e. before the expiry of the said 15 days period allowed by para 14(2) of the DPCO, 1995. Accordingly, the pre-notification MRP was applied in respect of these batches. The first batch of Roscillin 500 mg capsule which was manufactured by the Petitioner after the expiry of the said 15 days" period allowed by para 14(2) of the DPCO was Batch No. 9090987, the manufacture of which was completed on 16.7.2007. The Petitioner duly complied with the impugned Notification dated 27.6.2007, as required by para 14(2) of the DPCO, 1995 and the MRP applied in respect of this batch was Rs. 66.77, being the reduced MRP fixed by the said Notification dated 27.6.2007.

6. On its part, the Respondent No. 1 has not denied the above assertions. It has, however, filed an additional affidavit on 6th January 2010 stating that three other review petitions in respect of certain other price notifications, two of which review petitions were filed by the Petitioner and one filed by Novartis India Ltd., had been dismissed by the Respondents on the same ground on which the review petitions of the Petitioner were dismissed in the instant case.

7. This Court has heard the submission of Mr. S. Ganesh, learned Senior counsel for the Petitioner and Mr. A.S. Chandhiok, learned Additional Solicitor General appearing for the Respondents. The respective written notes of arguments filed by both sides after the conclusion of the hearing have also been considered.

8. The writ petition challenges not only the order passed by the Respondent rejecting the review petitions but the price fixation Notifications as well. This

Court proposes to first take up for consideration the point concerning the interpretation of Para 22 of the DPCO, 1995. The said provision reads as under:

22. Power to review - Any person aggrieved by any notification issued or order made under paragraphs 3, 5, 8, 9 or 10 may apply to the Government for a review of the notification or order within fifteen days of the date of publication of the notification in the Official-Gazette or the receipt of the order by him, as the case may be, and the Government may make such order on the application as it may deem proper.

Provided that pending a decision by the Government on the application submitted under the above paragraph, no manufacturer, importer or distributor, as the case may be, shall sell a bulk drug or formulation, as the case may be, at a price exceeding the price fixed by the Government of which a review has been applied for.

9. The proviso to Para 22 empowers the Central Government to insist that pending a decision on the review application, "no manufacturer, importer or distributor, as the case may be, shall sell a bulk drug or formulation, as the case may be, at a price exceeding the price fixed by the Government of which a review has been applied for". However, it is not possible to read the proviso as a pre-condition to the review application being entertained by the Central Government. In other words, there is nothing in Para 22 to indicate that if, for some reason, the proviso to Para 22 is not complied with, the review petition is liable to be dismissed. In other words, it is not possible to read the proviso to Para 22 as empowering the Central Government to reject the review petition, if it forms the opinion that the Petitioner has not complied with the price fixation Notifications of which the Petitioner is seeking review.

10. It appears that the manufacturer, importer or distributor, as the case may be, has been given a right to seek the review of a price fixation Notification under Para 22 and that right is hedged with the conditionality that such manufacturer, importer or distributor, as the case may be, in the meanwhile shall implement the price fixation Notification. However, in the absence of any express provision to that effect, the right to seek review cannot be taken away in the event such manufacturer, importer or distributor does not implement the price fixation Notification of which the review is sought. It is not as if the Central Government is remediless if a manufacturer, importer or distributor fails to comply with the directions contained in proviso to Para 22 to implement the price fixation Notification. The powers in the DPCO, 1995 can be invoked to recover from the manufacturer, importer or distributor what the Central Government perceives to be the amount charged by him over and above what is permissible under the price fixation Notification and require him to deposit such differential amount into the Drug Prices Equalisation Account ("DPEA"). The proviso to Para 22 only underscores the need for a manufacturer to immediately implement the price fixation Notification failing which the amount overcharged would be recoverable in terms of the DPCO 1995. It does nothing more. Therefore the ground on which

the Central Government has, by its impugned order dated 26th February 2008, rejected the Petitioner's review petitions is untenable in law.

11. A reading of the impugned order dated 26th February 2008 shows that the Central Government has not explained the reasons for concluding that the Petitioner failed to implement the price fixation Notifications dated 13th and 27th June 2007. It is not known whether any query was raised by the Central Government in this regard. The Central Government has also not countered the assertion by the Petitioner in the additional affidavit dated 15th September 2009 regarding compliance with the price fixation notifications. In any event, whether the Petitioner's interpretation of the price fixation Notifications is correct and whether the 15 days' period as allowed by para 14(2) of the DPCO, 1995 can be granted or not, is something for the Central Government to consider and decide. For instance, the Petitioner placed reliance upon the judgment of the Division Bench of this Court in Glaxo Smithkline Pharmaceuticals India Limited Vs. Union of India (UOI) and Others, . However, the Central Government points out that on 20th September 2010, the Supreme Court, has by entertaining the SLP (Civil) No. 8475-76/2010 stayed the operation of the above judgment of this Court. Reliance has also been placed by the Respondents on the judgment of the Karnataka High Court in Smithkline Beecham Pharmaceuticals (India) Ltd. v. Union of India Writ Petition (Civil) No. 38973/1998 dated 12th November, 2002 regarding the mandatory nature of compliance with price fixation Notification. Be that as it may, this Court is not called upon to actually examine if the Petitioner has complied with the price fixation Notifications in the manner required by the law. It is only required to examine if the review petitions filed by the Petitioner could have been rejected on the ground on which they have, by the Central Government by the impugned order dated 26th February 2008. For the reasons already explained, this Court answers the said question in the negative. Consequently the other question raised in the writ petition concerning the validity of the price fixation Notifications is not decided reserving to the Petitioner the right to raise it, if the need arises, in other appropriate proceedings at a later stage.

12. Consequently, this Court sets aside the impugned order dated 26th February 2008 passed by the Respondent No. 1 rejecting the Petitioner's two review petitions. The said review petitions are restored to the file of the Respondent No. 1 for a fresh consideration on merits in accordance with law. The Petitioner will be given a hearing, the date of which will be communicated to it by Respondent No. 1 within the next four weeks and at least ten days in advance. After hearing the Petitioner, a reasoned order on the Petitioner's review petitions will be passed by Respondent No. 1 within a period of four weeks and communicated to the Petitioner within two weeks thereafter. It will be open to the Petitioner, if still aggrieved by the decision of Respondent No. 1 on its two review petitions, to seek such appropriate remedies that may be available to it in law. The writ petition is disposed of in the above terms. The pending application is also disposed of.