*	**IN THE HIGH COURT OF DELHI AT NEW DELHI**

\+	**<u>LPA No.31/2015</u>**

<u>Pronounced on: 22.01.2015</u>

BIOLOGICAL E LTD & ANR ..... Appellant

Through: Mr. Kapil Sibal, Sr. Adv. with Mr. Abdullah Hussain, Mr. Koshy John and Mr. Manav Vohra, Advs.

Versus

NATIONAL PHARAMACEUTICAL PRICING AUTHORITY & ORS ..... Respondents

Through: Mr. Sanjay Jain, ASG with Mr. Anurag Ahluwalia and Mr. Vidur Mohan, Advs.

CORAM:
HON'BLE THE CHIEF JUSTICE
HON'BLE MR. JUSTICE RAJIV SAHAI ENDLAW

<u>J U D G M E N T</u>

**:	<u>MS.G.ROHINI, CHIEF JUSTICE</u>**

1. The appellant herein filed W.P.(C) No.9308 of 2014 aggrieved by the demand raised by the respondent No.1 for a sum of Rs.33,28,03,171/- alleging that the appellants had sold 'Tetanus Toxoid' vaccine (hereinafter referred to as 'the vaccine') for a price more than the ceiling price prescribed vide Notification dated 14.06.2013 as amended by Corrigendum dated 07.02.2014.

2. By the order under appeal, the learned Single Judge while directing to list the petition on 05.03.2014 to enable the parties to complete the pleadings, stayed the impugned demand notice dated 28.11.2014 subject to

the appellants depositing, without prejudice to their rights and contentions, 25% of the demanded amount.

3. The said order is assailed in this appeal contending *inter alia* that as the determination of the ceiling price for 1ml pack of the vaccine in question is beyond the jurisdiction of respondent No.1, the impugned demand notice being contrary to law and therefore, the condition imposed by the learned Single Judge to deposit 25% of the demand, which would be more than Rs.8 Cores, is unjustified and unwarranted.

4. It is submitted by Shri Kapil Sibal, the learned Senior Counsel appearing for the appellants that since the vaccine in question did not have specific dosage under the First Schedule to the Drugs (Price Control) Order (for short 'DPCO'), the ceiling price could only be fixed as per the lowest pack size of that category i.e. 0.5ml and that since the pack size of the vaccine in question has not been prescribed under Rule 105 of the Drugs and Cosmetics Rules, 1945 read with Schedule P-1, the size of the vaccine in question can only be as determined by the licensing authority appointed under Rule 21 in terms of the second proviso to Rule 105(2) read with the Explanation (i) to Rule 122-E. Thus it is contended by the learned Senior Counsel that the fixation of the ceiling price for the vaccine in question by the respondent No.1 by issuing a Corrigendum at Rs.10.29 per '1ml' instead of 'each pack' is without jurisdiction apart from being in total contravention of the provisions of DPCO 2013, Drugs and Cosmetics Act, 1940 and the Rules made thereunder. Thus, according to the learned Senior Counsel, the impugned demand being contrary to law and also without jurisdiction, the learned Single Judge ought to have passed an unconditional order.

5. Shri Sanjay Jain, the learned ASG on the other hand while referring to Explanation (ii) to Rule 122-E of the Drugs and Cosmetics Rules 1945 contended that the vaccine in question cannot be considered as a new drug and therefore, the contention of the appellants that the impugned demand is without jurisdiction and contrary to law is untenable. Placing reliance upon ***Union of India and Anr. Vs. Cynamide India Ltd. & Anr.*****(1987) 2 SCC 720**, it is also contended by the learned ASG that the appellant who failed to avail the remedy of Review provided under Para 31 of DPCO 2013 cannot be granted any relief under Article 226 of the Constitution of India. The learned ASG also relied upon ***Secretary, Ministry of Chemicals & Fertilizers, Government of India vs. CIPLA Ltd. & Ors.*** **(2003) 7 SCC 1** to substantiate his submission that the leaned Single Judge is fully justified in directing stay of recovery of overcharged amounts subject to condition of depositing of 25%. The learned ASG has also placed before this Court a statement of the prices fixed for the vaccine in question i.e. Tetanus Toxoid manufactured by different companies which shows that so far as one company viz. Bengal Immunity, the pack size is shown as 1ml.

6. However, the learned Senior Counsel appearing for the appellants has disputed the same and reiterated the plea that the standard size of the vaccine in question has always been 0.5ml in the ampoule form and that it is being produced by all companies only in the same size.

7. Having given our thoughtful consideration to the rival submissions noticed above, it appears to us that the matter involves contentious issues and substantial questions of law. In the light of the above-noticed provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder, it appears to us that a *prima facie* case is made out by the

appellants/writ petitioners that the fixation of the price for the vaccine in question can only be on the basis of each pack as initially ordered by the respondent No.1 by Notification dated 14.06.2013. The record does not disclose the basis for issuing the Corrigendum dated 17.02.2014. It also appears to us that the said issue in the first instance requires consideration by the authority empowered to exercise the power of Review under Para 31 of DPCO, 2013.

8. For the aforesaid reasons, we deem it appropriate to dispose of the appeal with the following directions:

(i) The appellants shall apply for a Review of the price determined vide Notification dated 14.06.2013 read with Corrigendum dated 17.02.2014 in terms of Para 31 of DPCO 2013 on or before 30.01.2015. If the Review is filed within the time fixed above, the same shall be considered by the Government of India and an appropriate order shall be passed on or before 04.03.2015 following due process of law.

(ii) The appellants shall furnish security to the sum of 25% of the amount demanded under the impugned Notice dated 28.11.2014 to the satisfaction of the Registrar General of this Court within two weeks from today apart from filing an undertaking before this Court by way of affidavits of two directors of the appellant No.1 to the effect that in the event of dismissal of the writ petition and subject to further orders in the appeal, they would pay the said sum of 25% of the demand under the impugned notice dated 28.11.2014 to the respondent No.1 within one month.

9. The order under appeal shall accordingly stand modified and subject to the compliance with the above directions, the demand notice dated 28.11.2014 shall remain stayed. The writ petition be listed before the learned Single Judge as per the date fixed i.e. 05.03.2015.

10. Appeal is accordingly disposed of.

CHIEF JUSTICE

RAJIV SAHAI ENDLAW, J.

JANUARY 22, 2015
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