



WEB COPY

IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 16.11.2021

CORAM

THE HONOURABLE MR.JUSTICE S.M.SUBRAMANIAM

W.P.NO.10979 OF 2011

AND

M.P.NO.2 OF 2011

Lupin Limited,
No.508/3A, 1st Floor,
Inner Ring Road,
Madhavaram, Chennai - 600 040,
Rep. by its General Manager-Legal

... Petitioner

.Vs.

1. The Union of India,
Through Secretary,
Ministry of Health and Family Welfare,
FDA Bhavan, ITO Kotla Road,
New Delhi - 110 002.

2. The Drug Controller General of India,
FDA Bhavan, ITO Kotla Road,
New Delhi - 110 002.

... Respondents

PRAYER:-

Writ Petition filed Under Article 226 of the Constitution of India, to issue a Writ of Certiorarified Mandamus, calling for the entire records in connection with the impugned notification issued by the 1st Respondent in GSR No.82 (E) published in Gazette of India Extraordinary Part II - Section 3 - Sub section (i), dated 10.02.2011 and quash the same in so far as it relates to item Nos.1 and 3 viz., Nimesulide and Phenylpropanolamine and direct the respondents to review the issue after giving an opportunity to the Petitioner.

For Petitioner : Mr.T.D.Selvan Babu

For Respondents : Mr.A.Kumaraguru
SCGSC



O R D E R

The lis on hand has been instituted questioning the validity of the notification published by the respondents in the Gazette of India on 10.02.2011 prohibiting manufacture, sale and distribution of certain drugs with immediate effect. As per the notification issued by invoking Section 26A of the Drugs and Cosmetics Act, 1940, six drugs were prohibited. Out of the six drugs, the petitioner is confining the challenge only in respect of Serial No.1, which is 'Nimesulide formulations for human use in children below 12 years of age.'

2. The learned counsel for the petitioner relying on the sworn affidavit filed by the petitioner submitted that the petitioner company is not at all manufacturing or supplying the said Nimesulide in respect of the children below 12 years of age. It is specifically stated in paragraph-11 of the affidavit filed in support of the writ petition that 'the concerned authorities have abused the notification by harassing all concerned by asking them to withdraw all products bearing Nimesulide whether or not meant for use by children upto 12 years of age, with immediate effect. In so far as Nimesulide is concerned, there cannot be total ban on manufacture, sale and distribution when the intention is to prohibit sale for pediatric used for children below 12 years. Such an aspect rests with the medical practitioners.'

3. The learned counsel for the petitioner reiterated that the petitioner is not manufacturing the said drugs for the children below 12 years and they have manufacturing the drugs only for adults, which is not prohibited under the impugned notification.

4. The counter affidavit filed on behalf of the respondents unambiguously specifies that the prohibition is imposed only for manufacturing and supply of the said drug and administer the same for the children below 12 years. The said position is clarified in paragraph-9 of the counter, which reads as under:-

'9. That in reply to the contents of paragraph No.11, it is denied that the Notification with respect to Nimesulide formulations is vague. The Notification clearly and unambiguously specifies that Nimesulide formulations for human use in children below 12 years of age are hereby prohibited for manufacture, sale and distribution with immediate effect. It is apparent from the language of the Notification that all formulations containing Nimesulide meant for use in children below twelve years of age stands prohibited. The



WEB COPY

intent of the Notification is that there shall be an absolute prohibition for manufacture, sale and distribution of any formulation of Nimesulide, whether liquid or solid, meant for children below 12 years of age. It may be added that the other formulations containing Nimesulide for adult use will continue to remain available in the market. The petitioner is trying to mislead the Hon'ble Court by stating that the State Licensing Authorities are abusing the notification and harassing all concerned by asking them to withdraw all the formulations containing Nimesulide. That the submission relating to the harassment of the petitioner is denied for want of knowledge. It is denied that there is complete ban for manufacture, sale and distribution of Nimesulide. It is reiterated that as per the Notification, Nimesulide preparations for human use for patients of 12 years and above are not prohibited for manufacture, sale and distribution in the country.'

5. The power under Section 26(A) of the Drugs and Cosmetics Act was invoked by the Government of India based on the recommendations of the expert committee, which also clarified in paragraph-15 of the counter, which reads as under:-

15. That in reply to the contents of paragraph Nos. 20 to 22, the submissions made herein above are reiterated. It is submitted that the section 26A does not mandate consultation with Drug Technical Advisory Board (DTAB) before invoking the provisions of this section unlike provisions elsewhere in the Drugs and Cosmetics Act, 1940 where consultation with DTAB is necessary. It is however submitted that the drug has been prohibited on the basis of the recommendations of the Expert Committee. It is denied that there is no DTAB in existence as on date. The Central Government had vide Notification S.O. 722(E) has reconstituted the DTAB with effect from 08.04.2011.'

6. In respect of other drug in Serial No. 3 i.e. Phenylpropanolamine and its formulations for human use is concerned, this Court has already quashed the said notification in the case of Cipla Ltd., Regional Office, 106/A, Allapakkam Main Road, Allapakkam, Chennai-600 116, rep. by Depot Manager vs. 1. Union of India, through Secretary, Ministry of Health and Family Welfare, FDA Bhavan, ITO Kotla Road, New Delhi-110 002



and another reported in 2011 (5) CTC 640 and therefore, no further consideration is required in respect of the drug prohibited in serial No.3 of the impugned notification dated 10.02.2011.

WEB COPY

7. In view of the fact that the petitioner admittedly has not manufacturing the prohibited drug and supplying the said Nimesulide only for the adults, there is no necessity to interfere with the order impugned, as the order impugned is not prohibiting the petitioner from supplying the drugs to the adults and therefore, the cause for filing of the writ petition is clarified by the respondents in their counter affidavit and thus, no further adjudication is required and accordingly, the writ petition stands disposed of. No costs. Consequently, connected miscellaneous petition is closed.

Sd/-
Assistant Registrar (CS V)

//True Copy//

Sub Assistant Registrar

vs

To

1. The Secretary,
The Union of India,
Ministry of Health and Family Welfare,
FDA Bhavan, ITO Kotla Road,
New Delhi - 110 002.
2. The Drug Controller General of India,
FDA Bhavan, ITO Kotla Road,
New Delhi - 110 002.

+1cc to Mr.T.D.Selvan Babu, Advocate, S.R.No.58910

W.P.NO.10979 OF 2011 AND
M.P.NO.2 OF 2011

PMK (CO)
PBS/02/12/2021