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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**
+ **W.P.(C) 9985/2018 and CM APPL. 38932/2018**
SEAGULL LABORATORIES (I) P. LTD. Petitioner

Through: Ms Kunal Anand, Advocate.

Versus

UNION OF INDIA AND ANR. Respondents

Through: Mr Kirtiman Singh, CGSC with
Mr Waize Ali Noor and Ms
Shruti Dutt, Advocates.

WITH

55.

+ **W.P.(C) 12543/2018 and CM APPL. 48671/2018**
J K REMEDIES Petitioner

Through: Mr Udit Chauhan, Advocate.

versus

UNION OF INDIA & ANR Respondents

Through: Mr Sanjeev Sabharwal, Senior
Govt. Counsel with Mr Hem
Kumar, Advocate for UOI.
Mr Kirtiman Singh, CGSC with
Mr Waize Ali Noor and Ms
Shruti Dutt, Advocates.

AND

56.

+ **W.P.(C) 12607/2018 and 48977/2018**
M/S NAVA HEALTHCARE PVT. LTD. Petitioner

Through: None.

versus

UNION OF INDIA AND ANR. Respondents

Through: Mr Ripu Daman Bhardwaj,
CGSC with Mr T.P. Singh,
Advocate.
Mr Kirtiman Singh, CGSC with
Mr Waize Ali Noor and Ms

Shruti Dutt, Advocates.

CORAM:

HON'BLE MR. JUSTICE VIBHU BAKHRU

ORDER

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24.04.2019

1. The petitioners impugn a notification – S.O. 4411 (E) dated 07.09.2018 – issued by the Central Government under Section 26A of the Drugs & Cosmetics Act, 1940.
2. In terms of the said notification the manufacture and sale of the drug – Fixed Dose Combination (FDC) of ammonium chloride + sodium citrate + chlorpheniramine maleate + menthol – under the brand name of ‘Capex Expectorant’, is proscribed.
3. Mr Kirtiman Singh, learned counsel appearing for the respondent states that the impugned notification has been rendered ineffective by the order dated 14.02.2019 passed by the Supreme Court in applications filed in ***Union of India and Ors. v M/s Biological E Ltd. & Ors.: Civil Appeal Nos. 23405-23472/2017***. The relevant extract of the said order is set out below:-

“Insofar as the above applications are concerned, the drugs in question i.e. Paracetamol + Propyphenazone + Caffeine/Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol/ Salbutamol+ Hydroxyethyltheophylline (Etofylline) + Bromhexine/ Chlorpheniramine Maleate + Ammonium Chloride + Sodium Citrate claim to be manufactured pre-1988. Hence, they would be at par with the list of 15 drugs that were referred to in our judgment in *Union of India & Anr. vs. Pfizer Limited & Ors.* (2018) 2 SCC 39.

Insofar as these drugs are concerned, they may be continued to be manufactured/distributed and sold

notwithstanding any notifications that may have been issued, and will be subject to the same directions as that contained for the 15 drugs that are pre-1988 in para 36 of our judgment.”

4. It is noticed that the Supreme Court in ***Union of India & Ors. v. Pfizer Limited & Ors.: (2018) 2 SCC 39*** had set aside the notifications issued in respect of 15 drugs that were manufactured pre 21.09.1988. However, the Court had also clarified that the same would not preclude the Central Government to carry out a *de novo* enquiry for issuing a notification under Section 26A of the Drugs and Cosmetics Act, 1940. Paragraph 36 of the said decision is set out below:-

“36. Insofar as the drugs that have been banned and which were manufactured pre-21-9-1988, a list of 15 such drugs has been given to us by Mr Kapil Sibal, learned Senior Counsel for the respondents. We set aside the Central Government notifications banning them as these cases were never meant to be referred to the Kokate Committee. It will be open, however, for the Central Government, if it so chooses, *de novo*, to carry out an inquiry as to whether such drugs should be the subject-matter of a notification under Section 26-A of the Drugs Act.”

5. In view of the above, no further orders are required to be passed in these petitions as the impugned notification dated 07.09.2018, would not come in the way of the petitioners in carrying out their activity. In terms of the directions issued in ***Pfizer Limited & Ors. (supra)*** the Central Government is not precluded carrying out a fresh enquiry for determining whether the manufacture and sale of the FDC in question is required to be restricted or proscribed in terms of Section 26A of the Drugs and Cosmetics Act, 1940.

6. The petitions are disposed of with the aforesaid observations.
The pending applications are also disposed of.

VIBHU BAKHRU, J

APRIL 24, 2019

pkv