

**IN THE HIGH COURT OF JUDICATURE AT BOMBAY
CIVIL APPELLATE JURISDICTION
WRIT PETITION NO. 4949 OF 2016**

Adonis Laboratories Pvt. Ltd.
versus
Union of India and anr.

.....Petitioner
.....Respondents

Mr. Shyam Kapadia along with Mr. Omkar Bade i/b. Desai and Diwanji,
advocates for the petitioner.
Mrs. S. V. Bharucha along with Mohamedali M. Chunawala and Mr.A. A.
Ansari, advocates for the respondents.

**CORAM : RANJIT MORE &
SMT.SADHANA JADHAV, JJ.**

DATE : 25th APRIL, 2018.

P. C. :

Heard the learned counsel appearing for the petitioner and
respondents respectively.

2. The petitioner is a pharmaceutical company engaged in the
business of manufacturing and selling of drugs and pharmaceutical
products. By this petition under Article 226 of the Constitution of India,
the petitioner is challenging the notification dated 10th March, 2016,
issued by the Central Government in exercise of powers conferred by
Section 26A of the Drugs and Cosmetics Act, 1940, prohibiting the
petitioner from manufacture for sale, sale and distribution for human
use of drug **“fixed dose combination of Caffeine + Paracetamol +**

Phenylephrine + Chlorpheniramine". By similar notification, the Central Government prohibited the manufacture for sale, sale and distribution for human consumption total 344 fixed dose combinations (for short "FDCs"). Some of the pharmaceutical companies approached various High Courts and during the pendency of this petition, the High Courts protected those petitioners by order of status-quo. Various High Courts set-aside those notifications on the basis that the principles of nature justice are not followed.

3. The Central Government approached the Apex Court by filing civil appeal No.22972 of 2017. The Apex Court upheld the contention of the Central Government that hearing to pharmaceutical companies before issuance of the notification, though advisable, was not mandatory. The Apex Court, however, felt necessary that before banning 344 FDCs, the cases of the said FDCs should go to the DTAB and/or a Sub-Committee formed by the DTAB for the purpose of having a relook into the cases. The Apex Court also observed that the DTAB/Sub-Committee appointed for that purpose will not only hear the petitioners before them but they will also hear submissions from the All India Drugs Action Network. The Apex Court further held that the DTAB/Sub-Committee set up for the said purpose will deliberate on the parameters set out in Section 26A of the Drugs Act.

4. The learned counsel for the respondents placed on record a letter dated 24th April, 2018 of Dr. K. Bangarurajan, Joint Drugs Controller (India) addressed to the Deputy Drugs Controller (India). The letter reveals that the issue with regard to 344 FDCs was deliberated in DTAB meeting held on 12th February, 2018 and as per the recommendations of DTAB, a sub-committee constituted under the Chairmanship of Dr. Nilima Kshirsagar to review the banned 344 FDC plus 5 FDCs.

5. Admittedly, the drug which was manufactured by the petitioner was banned under the impugned notification is amongst this 344 FDCs. In the light of the discussion made hereinabove, it is clear that the petitioner's drug would also be reviewed by the sub-committee constituted under the Chairmanship of Dr. Nilima Kshirsagar. In that view of the matter, both learned counsel appearing for the respective parties fairly concedes that, the grievance raised in the petition, no more survives. The writ petition is, accordingly, disposed of.

6. The Apex Court in the above referred civil appeal protected the pharmaceutical companies before it by continuing the status-quo granted earlier. In the present case also, this Court by its order dated 3rd May, 2016, has granted status-quo qua the petitioner in respect of the impugned notification with further direction that no coercive steps shall

be taken against the petitioner, their stockist and/or agents. In the light of the order passed by the Apex Court, we continue the status-quo granted in favour of the petitioner by this Court under order dated 3rd May, 2016 till the review is undertaken by the said sub-committee and fresh notification is issued.

(SMT. SADHANA JADHAV, J.)

[RANJIT MORE, J.]