SC Fr No. 2214/2017 T.P.NO 1176-1182/17

Diary No. 21401/2017

Date of submission. 19-07-2017

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

TRANSFER PETITION[C]NO._____OF 2017

[UNDER ARTICLE 139 A OF THE CONSTITUTION OF INDIA R/W ORDER XL SUPREME COURT RULES, 2013 against the **W.P.[C]No.5336 of 2017** [Mankind Pharma Limited V/s Union of India & Anr], **W.P.[C]No.5340 of 2017** [Akums Drugs & Pharmaceuticals Ltd V/s Union of India & Anr], **W.P.[C]No.5345 of 2017** [J.B. Chemicals & Pharmaceuticals Limited & Ors V/s Union of India & Anr], **W.P.[C]No.5391 of 2017** [M/s IPCA Laboratories Limited & Anr V/s Union of India & Anr], **W.P.[C]No.5397 of 2017** [Ahlcon Parenterals India Ltd. V/s Union of India & Anr], **W.P.[C]No.5398 of 2017** [J.K. Printpacks V/s Union of India & Anr] and **W.P.[C]No.5399 of 2017** [Windlas Biotech Pvt. Ltd. V/s Union of India & Anr, pending before the **High Court of Delhi at New Delhi**],

IN THE MATTER OF:

Union of India & Anr. ...Petitioners

Versus

Mankind Pharma Limited ...Respondents

WITH

I.A.NO._____OF 2017

AN APPLICATION FOR STAY

VOLUME-I

PAPER BOOK

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ADVOCATE FOR THE PETITIONERS: **G.S.MAKKER**

F.NO.2214/17/CAS

HRS

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LISTING PROFORMA

IN THE SUPREME COURT OF INDIA

The case pertains to (Please tick/check the correct box):	
Central Act: (Title)	The Drugs and Cosmetics Rules, 1945
Section:	
Central Rule: (Title)	NA
Rule No.(s):	NA
State Act: (Title)	NA
Section :	NA
State Rule: (Title)	NA
Rule No.(s):	NA
Impugned Interim Order : (Date)	NA
Impugned Final Order/Decree; (Date)	NA
High Court: (Name)	NA
Names of Judges:	NA
Tribunal/Authority: (Name)	
1. Nature of Matter:	ORIGINAL
2. (a) Petitioner/appellant No.1:	UNION OF INDIA & ANR
(b) e-mail ID:	NA
(c) Mobile Phone number:	NA
3. (a) Respondent No.1:	MANKIND PHARMA LIMITED & ORS
(b) E-mail ID:	NA
(c) Mobile phone number:	NA
4. (a) Main category classification:	NA
(b) sub classification:	NA
5. Not to be listed before:	NA
6. Similar/Pending matter:	

A-2

7. Criminal Matters:	NA
(a) Whether accused/convict has surrendered:	No
(b) FIR No.	N.A.
(c) Police Station:	N.A.
(d) Sentence Awarded:	N.A.
(e) Sentence Undergone:	N.A.
8. Land Acquisition Matters:	N.A.
(a) Date of Section 4 notification:	N.A.
(b) Date of Section 6 notification:	N.A.
(c) Date of Section 17 notification:	N.A.
9. Tax Matters: State the tax effect:	NA
10. Special Category (first petitioner/appellant only):	N.A.
Senior Citizen > 65 years	N.A.
SC/ST	N.A.
Woman/Child	N.A.
Disabled	N.A.
Legal Aid Case	N.A.
In custody	N.A.
11. Vehicle Number (in case of Motor Accident Claim Matters):	N.A.
12. Decided cases with citation:	N.A.

Date: .7.2017

[G.S.MAKKER]
Advocate for the Petitioners

SYNOPSIS

The petitioner herein is preferring present Transfer Petition under Article 139-A [1] of the Constitution of India read with Order XL, Rule-1 of the Supreme Court Rules 2013 for transfer/withdrawal to this Hon'ble Court, the W.P.[C]No.5336 of 2017 [Mankind Pharma Limited V/s Union of India & Anr], W.P.[C]No.5340 of 2017 [Akums Drugs & Pharmaceuticals Ltd V/s Union of India & Anr], W.P.[C]No.5345 of 2017 [J.B. Chemicals & Pharmaceuticals Limited & Ors V/s Union of India & Anr], W.P.[C]No.5391 of 2017 [M/s IPCA Laboratories Limited & Anr V/s Union of India & Anr], W.P.[C]No.5397 of 2017 [Ahlcon Parenterals India Ltd. V/s Union of India & Anr], W.P.[C]No.5398 of 2017 [J.K. Printpacks V/s Union of India & Anr] and W.P.[C]No.5399

of 2017 [Windlas Biotech Pvt. Ltd. V/s Union of India & Anr], pending before Hon'ble High Court of Delhi at New Delhi, for hearing along with the S.L.P [C] No.7061 of 2017, SLP [C] No.10170-10178 of 2017 and Transfer Petitions Nos. 1729-37 of 2016, wherein the constitutional validity of Notifications issued by Central Government under section 26-A of the Drugs and Cosmetics-1940, banning the manufacture for sale, sale and distribution for human consumption of certain fixed doze combination medicines, is under consideration.

In present case the Drug Manufacturers have challenged the impugned Notifications S.O.1852 [E] & 1855 [E] both dated 08.06.2017 issued by the Central Government under section 26-A of the Drugs and Cosmetics-1940, Before the Hon'ble High Court of Delhi, by contending that said Notification

has been issued in contravention of Section 5,6,7 & 26A of the Cosmetics Act1940. They have relied on the decision of the same High Court in Pfizer Ltd case, wherein 344 notifications have been quashed against, which the above mentioned SLP & TPs are pending before this Hon'ble Court.

In view of this the writ petitions pending before Hon'ble High Court of Delhi may be transferred to this Hon'ble Court for hearing along with the S.L.P [C] No.7061 of 2017, SLP [C] No.10170-10178 of 2017 and Transfer Petitions Nos.1729-37 of 2016, so as to maintain consistency.

CHRONOLOGY OF EVENTS

10.04.1940: The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as

"Rules"), made there under is a legislation with an objective to regulate the import, manufacture, distribution and sale of drugs and cosmetics while preventing the spurious, adulterated and substandard drugs to be imported, manufactured, distributed and sold in the country. The avowed objective of the Act is to ensure the safety, efficacy and the quality of the drugs being imported, manufactured, distributed and sold in the country. It is further stated that while granting or renewing the permission for a drug, the emphasis is on the quality, safety and efficacy of the drug.

21.09.1988: That the combination of two or more drugs i.e. FDC combined for the first

time fall under the definition of a New Drug. The requirements for import, manufacture of New drugs including FDCs was introduced in Drugs and Cosmetics Rules, 1945 vide GSR No. 944E dated 21.9.1988 by introducing Rule 122A, 122B, 122D, 122E and Schedule Y which required that the manufacturers of FDCs falling under the definition of new drug shall require the permission from DCG(I). It is submitted that Fixed Dose Combination (FDC) is a 'New Drug' as defined under Rule 122E of the Drugs and Cosmetics Rules, 1945 and it specifies procedures to be followed by the manufacturers to obtain manufacturing permission/ marketing authorization. Further this Rule clearly specifies that any manufacturer

interested in marketing any new drug including Fixed Dose Combination is required to apply to the Licensing Authority notified under Rule 21 i.e. the Drugs Controller General (India). The procedure specified under Schedule-Y involves examination and experimentation, which includes clinical and non-clinical studies of the molecules or fixed dose combination of molecules. It is further submitted that in case of the FDCs, the applicant has to establish by experimentation and through clinical and non-clinical studies, the rationality, safety and efficacy by evaluating the critical parameters like pharmacological compatibility, pharmacokinetic compatibility, dose placing, dose spacing, cumulative toxicity, etc.

While granting a manufacturing license, the Licensing Authority has to satisfy itself about the rationality, safety and efficacy of the drug. Schedule Y of Drugs and Cosmetics Rules clearly specifies that the data submitted should be based on experimentation carried out to establish the rationality, safety and efficacy of such combinations.

01.02.1983: With effect from 01.02.1983 major changes were brought in the Act 1940 and the scope of the Act was widened.

17.08.2009: The FDC of Ofloxacin + Ornidazole injection was approved on 17.8.2009 for the treatment of Diarrhoea of mixed infection in adult patients initially for the first time (i.e.

Innovator Company) in favour of M/s Venus Remedies.

20.10.2009: That the Fixed Dose Combination of Etodolac + Paracetamol was approved by CDSCO on 20.10.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis initially for the first time (i.e. innovator company) in favour of M/s IPCA Laboratories.

31.03.2011: That Ministry of Health & family Welfare vide its order No. X.19029/5/2011-DFQC dated 31.03.2011 constituted New Drug Advisory Committee (NDAC) in various therapeutic categories to advise Drugs Controller General (India) in matters for review of

Applications of New Drugs & Clinical Trials.

08.05.2012: Parliamentary Standing Committee (PSC) on Health & Family Welfare in its 59th Report has considered the issue regarding the prevalence of many Fixed Dose Combinations (FDC) in the Indian market that had not been tested for efficacy or safety.

PSC observed that some of the State Licensing Authorities (SLAs) have issued manufacturing licenses for a very large number of FDCs without prior clearance from Central Drugs Standard Control Organization (CDSCO). This resulted in the availability of many FDCs in the market which have not been tested for efficacy and safety. This can put

patients at risk. The PSC expressed its view that those unauthorized FDCs that pose risk to patients and communities such as a combination of two antibacterials need to be withdrawn immediately due to danger of developing resistance that affects the entire population. PSC in their report had also recommended to invoke sec. 26 A of the Drugs and Cosmetics Act, 1940 which, in its opinion was adequate to deal with the problem of irrational and/or FDC's not cleared by CDSCO. It is submit that Of the cases scrutinized, there were 13 drugs (33%) which did not have permission for sale in any of the major developed countries (United States, Canada, Britain, European Union nations and Australia). None of

these drugs have any special or specific relevance to the medical needs of India. These drugs are: (i) Buclizine for appetite stimulation (UCB); ii. Nimesulide injection (Panacea); (iii) Doxofylline (Mars) (iv) FDC of Nimesulide with Levocetirizine (Panacea); (v) FDC of Pregabalin with other agents (Theon); (vi) FDC of Tolperisone with Paracetamol (Themis); (vii) FDC of Etodolac with Paracetamol (FDC); (viii) FDC of Aceclofenac with Thiocolchicoside (Ravenbhel); (ix) FDC of Ofloxacin with Ornidazole (Venus), (x) FDC of Aceclofenac with Drotaverine (Themis); (xi) FDC of Glucosamine with Ibuprofen (Centaur); (xii) FDC of Diclofenac with Serratiopeptidase

(Emcure) and (xiii) FDC of Gemifloxacin with Ambroxol (Hetero).

The Parliamentary Standing Committee (PSC) also stated that Section 26A of the Drugs and Cosmetics Act, 1940 is adequate to deal with the problem of irrational FDCs. There is a need to make the process of approving and banning FDCs more transparent and fair. In general, if an FDC is not approved anywhere in the world, it may not be cleared for use in India unless there is a specific disease or disorder prevalent in India, or a very specific reason backed by scientific evidence and irrefutable data applicable specifically to India that justifies the approval of a particular FDC. The

Parliamentary Standing Committee strongly recommended that a clear, transparent policy may be framed for approving FDCs based on scientific principles.

The recommendations of Parliamentary Standing Committee were considered by the Government. As per decision taken by the Government of India and conveyed through the Action Taken Note on the 59th report to the PSC, the PSC in its 66th Report recommended that these FDCs be referred to the New Drug Advisory Committee (NDAC) for examination and review to decide on the continued marketing of these drugs and updating of their product monographs in light of recent

knowledge and regulatory changes overseas.

10.03.2016: In another set matters pursuant to the acceptance of the report of the Kokate Committee, the Petitioner [UOI] prohibited the manufacture, sale and distribution of 344 FDCs in exercise of powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940.

14.03.2016: Being aggrieved of the Notifications dated 10.03.2016 issued by the Petitioner u/s. 26A, approximately 453 writ petitions were filed on 14.03.2016 before the Hon'ble High Court of Delhi at New Delhi challenging the validity and correctness of the Notifications dated 10.03.2016.

17.03.2016: Further aggrieved by the said Notifications dated 10.03.2016 issued by the Petitioner u/s. 26A, various Writ Petitions were filed before High Court of Delhi, Madras, Karnataka, Bombay, Rajasthan, Jammu & Kashmir between the period from 17.3.2016 to 07.09.2016.

01.12.2016: That by its common impugned Judgment dated 01.12.2016 the Hon'ble High Court of Delhi dispose of the Writ Petition No.2212/2016 along with the batch of 453 Writ Petitions thereby quashed the notifications issued on 10.03.2016 without appreciating the express and unambiguous language used in the different provision of the Act.

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10.03.2016: As per recommendation of the "New Drug Advisory Committee" (NDAC) the FDC in question were recommended to be banned. As the above sequence of events brings out, the Government has made elaborate attempts to ensure that all facets of the matter get duly examined and no injustice is done to anyone and more importantly the safety of patients is not compromised. In the process sufficient notice and opportunity had been given to all concerned to the innovators companies who were granted approval by CDSCO for the first time while approving the new drug at that point of time in the year 2009. The Government had prohibited these FDCs to safeguard public interest and hence these were

prohibited under section 26A in order to safeguard public health from such irrational FDCs irrespective of the manufacturer. This was done in the larger public interest and it cannot be anyone's case that he should be given a differential treatment in the face of such facts in public interest as there was no therapeutic justification for such FDCs.

It is respectfully submitted that even if an approval to the said FDC was granted in the year 2009, it was done on the basis of the available literature and knowledge at that point of time which does not bar the Government to re-examine the FDC in the current scenario in the light of latest scientific knowledge and

information. As such the said FDC was examined by the New Drug Advisory Committee, and it was found that the FDCs are irrational and was accordingly recommended by the New Drug Advisory Committee.

31.03.2017: Aggrieved by the Judgment dated 01.12.2016 the petitioners herein filed the S.L.P. [C] No.7061 of 2017, [U.O.I V/s Pfizer Pvt. Ltd] before this Hon'ble Court. Further the All India Drug Action Network also file SLP against the judgment dated 01.12.2016 being SLP [C] No.10170-10178 of 2017. After hearing their Lordships were pleased to issue notice on 31.03.2017.

15.06.2017: Aggrieved by the Notification dated 10.03.2017 the respondents herein

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filed writ Petition before the Hon'ble High Court of Delhi being W.P.[C]No.5336 of 2017 [Mankind Pharma Limited V/s Union of India & Anr], W.P.[C]No.5340 of 2017 [Akums Drugs & Pharmaceuticals Ltd V/s Union of India & Anr], W.P.[C]No.5345 of 2017 [J.B. Chemicals & Pharmaceuticals Limited & Ors V/s Union of India & Anr], W.P.[C]No.5391 of 2017 [M/s IPCA Laboratories Limited & Anr V/s Union of India & Anr], W.P.[C]No.5397 of 2017 [Ahlcon Parenterals India Ltd. V/s Union of India & Anr], W.P.[C]No.5398 of 2017 [J.K. Printpacks V/s Union of India & Anr] and W.P.[C]No.5399 of 2017 [Windlas Biotech Pvt. Ltd. V/s Union of India & Anr].

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12.07.2017: That the S.L.P. [C] No.7061 of 2017, [U.O.I V/s Pfizer Pvt. Ltd] along with other batch matter was listed before this Hon'ble Court and after hearing their lordships were pleased give liberty to file present transfer petition and adjourned the matter for hearing of all the cases on 29.07.2017.

13.07.2017: Hence the present Transfer Petition.

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

1. TRANSFER PETITION (C) NO. __ OF 2017

POSITION OF PARTIES

BEFORE THE HIGH COURT	IN THIS HON'BLE COURT

IN THE MATTER OF :

1. Union of India
   Through Secretary
   Department of Health and Family Welfare,
   Ministry of Health and Family Welfare,
   Nirman Bhawan,
   New Delhi-110 001 ...Respondent No.1 ...Petitioner No.1

2. The Drug Controller General of India
   Through its Director General
   FDA Bhawan
   ITO, Kotla Road
   New Delhi-110 002. ...Respondent No.2 ...Petitioner No.2

VERSUS

Mankind Pharma Limited.
A company existing under the
Companies Act, 2013
Having its registered office at:
208, Okhla Industrial Estate
Phase-III, New Delhi-110 020
Through its Authorized Signatory
Mr.Prateush Manmohan Sharma.

..... Petitioner.... Respondent

(In W.P.[C]No.5336 of 2017 pending before Hon'ble High Court of Delhi at New Delhi)

2. TRANSFER PETITION (C) NO. ___ OF 2017

IN THE MATTER OF :

1. Union of India
Through Secretary
Department of Health and Family Welfare,
Ministry of Health and Family Welfare,
Nirman Bhawan,
New Delhi-110 001 ...Respondent ...Petitioner
No.1 No.1

2. The Drug Controller General of India
Through its Director General
FDA Bhawan
ITO, Kotla Road
New Delhi-110 002.

...Respondent No.2 ...Petitioner No.2

VERSUS

Akums Drugs & Pharmaceuticals Limited
A company existing under the Companies Act, 2013
Having its registered office at:
304, Mohan Place, L.S.C., Block-C
Saraswati Vihar,New Delhi-110 034
Through its Authorized Signatory
Mr.Devendra KLurnar Joshi.

..... Petitioner.... Respondent

(W.P.[C]No.5340 of 2017 pending before High Court of Delhi At New Delhi)

3. TRANSFER PETITION (C) NO. ___ OF 2017

IN THE MATTER OF :

1. Union of India
   Through Secretary
   Department of Health and Family Welfare,
   Ministry of Health and Family Welfare,
   Nirman Bhawan,
   New Delhi-110 001

   ...Respondent No.1 ...Petitioner No.1

2. The Drug Controller General of India
   Through its Director General
   FDA Bhawan
   ITO, Kotla Road
   New Delhi-110 002.

   ...Respondent No.2 ...Petitioner No.2

VERSUS

1. J.B. CHEMICALS & PHARMACEUTICALS LIMITED
   HAVING ITS REGISTERED OFFICE AT
   NEELAM CENTRE, 4TH FLOOR,
   B WING, HIND CYCLE ROAD,
   WORLI, MUMBAI - 400 030

   AND ITS CORPORATE OFFICE AT:

CNERGY IT PARK, UNIT A2,
3RD FLOOR, UNIT A, 8TH FLOOR,
APPA SAHEB MARATHE MARG,
PRABHADEVI,
MUMBAI 400 025

..Petitioner....Respondent
No.1 No.1

2. MS. RITU YADAV
W/O- SHRI, RAJESH YADAV
HAVING RESIDENCE AT:
B-408, MIRA-JAI ARIHANT TOWER,
SAIBABA NAGAR, MIRA ROAD (E),
DIST-THANE, 401 107

..Petitioner....Respondent
No.2 No.2

(W.P.[C]No.5345 of 2017 pending before High Court of Delhi At New Delhi)

4. TRANSFER PETITION (C) NO.____OF 2017

IN THE MATTER OF :

1. Union of India
Through Secretary
Department of Health and Family Welfare,
Ministry of Health and Family Welfare,

Nirman Bhawan,
New Delhi-110 001

...Respondent No.1 ...Petitioner No.1

2. The Drug Controller General of India
Through its Director General
FDA Bhawan
ITO, Kotla Road
New Delhi-110 002.

...Respondent No.2 ...Petitioner No.2

VERSUS

1. M/s IPCA Laboratories Limited
Having its Registered Office at
48, Kandivli Industrial Estate
Kandivli [West]
Mumbai -400 067,
Maharashtra.

AND ITS CORPORATE OFFICE AT:
142, AB, KANDIVLI INDUSTRIAL ESTATE
KANDIVLI [WEST]
MUMBAI-400 067,
MAHARASHTRA

...Petitioner... .. Respondent No.1 No.1

2. Mr. Harish Kamath
Having Residence at:
Flat 2-D-602, 6th Floor,
D Wing, Ashok Nagar `B' Complex,
Vazira Naka, L T oad,
Borivali [W],
Mumbai-400 091.

...Petitioner... .. Respondent
No.2 No.2

(W.P.[C]No.5391 of 2017 pending before High Court of Delhi At New Delhi)

5. TRANSFER PETITION (C) NO.____ OF 2017

IN THE MATTER OF :

1. Union of India
Through Secretary
Department of Health and Family Welfare,
Ministry of Health and Family Welfare,
Nirman Bhawan,
New Delhi-110 001

...Respondent ...Petitioner
No.1 No.1

2. The Drug Controller General of India
Through its Director General
FDA Bhawan
ITO, Kotla Road
New Delhi-110 002....Respondent ...Petitioner
No.2 No.2

VERSUS

Ahlcon Parenterals India Ltd.
A company existing under the
Companies Act, 2013
Having its registered office at:
Plot No.30 & 30E, 2nd Floor
Shivaji Marg, Najafgarh Road
Industrial Area, New Delhi-110 015
Through its Authorized Signatory
Mr.Ranjan Kumar Sahu.
.....Petitioner ... .. Respondent

(W.P.[C]No.5397 of 2017 pending before High Court of Delhi At New Delhi).

6. TRANSFER PETITION (C) NO. ____ OF 2017

IN THE MATTER OF :

1. Union of India
   Through Secretary
   Department of Health and Family Welfare,
   Ministry of Health and Family Welfare,
   Nirman Bhawan,
   New Delhi-110 001 ...Respondent ...Petitioner
   No.1 No.1

2. The Drug Controller General of India
   Through its Director General
   FDA Bhawan
   ITO, Kotla Road
   New Delhi-110 002. ...Respondent ...Petitioner
   No.2 No.2

VERSUS

J.K. Printpacks
A partnership Firm
Having its office at:
C-14 to C-17,
Sara Industrial Estate Ltd.
VPO, Rampur, Dehradun-248 110.

Through its Partner
Mr.Veerpal Singh. ....Petitioner. ... Respondent

(W.P.[C]No.5398 of 2017 pending before High Court of Delhi At New Delhi).

7. TRANSFER PETITION (C NO. ____ OF 2017

IN THE MATTER OF :

1. Union of India
   Through Secretary
   Department of Health and Family Welfare,
   Ministry of Health and Family Welfare,
   Nirman Bhawan,
   New Delhi-110 001

   ...Respondent No.1 ...Petitioner No.1

2. The Drug Controller General of India
   Through its Director General
   FDA Bhawan
   ITO, Kotla Road
   New Delhi-110 002.

   ...Respondent No.2 ...Petitioner No.2

Versus

Windlas Biotech Pvt. Ltd.
A company existing under the
Companies Act, 2013

Having its office at:
Khasra No.141 to 143 & 145
Mohabewala Industrial Area,
Dehradun-248 110
Through its Managing Director
Mr.Ashok Kumar Windlas

...Petitioner... Respondent

(W.P.[C]No.5399 of 2017 pending before High Court of Delhi At New Delhi).

TRANSFER PETITION UNDER ARTICLE 139 A OF THE CONSTITUTION OF INDIA R/W ORDER XL SUPREME COURT RULES, 2013 FOR WITHDRAWAL AND TRANSFER OF W.P.[C]No.5336 of 2017 [Mankind Pharma Limited V/s Union of India & Anr], W.P.[C]No.5340 of 2017 [Akums Drugs & Pharmaceuticals Ltd V/s Union of India & Anr], W.P.[C]No.5345 of 2017 [J.B. Chemicals & Pharmaceuticals Limited & Ors V/s Union of India & Anr],

W.P.[C]No.5391 of 2017 [M/s IPCA Laboratories Limited & Anr V/s Union of India & Anr], W.P.[C]No.5397 of 2017 [Ahlcon Parenterals India Ltd. V/s Union of India & Anr], W.P.[C]No.5398 of 2017 [J.K. Printpacks V/s Union of India & Anr] and W.P.[C]No.5399 of 2017 [Windlas Biotech Pvt. Ltd. V/s Union of India & Anr], PENDING BEFORE THE HON'BLE HIGH COURT OF DELHI AT NEW DELHI TO THIS HON'BLE COURT FOR HEARING ALONG-WITH S.L.P. [C] NO.7061 OF 2017, [U.O.I V/S PFIZER PVT. LTD] AND SLP [C] NO. SLP [C] No.10170-10178 of 2017 [ALL INDIA DRUG ACTION NETWORK V/S PFIZER PVT LTD]

TO

HON'BLE THE CHIEF JUSTICE OF INDIA AND HIS COMPANION JUDGES OF THE SUPREME COURT OF INDIA.

The humble application of the applicant-petitioners abovenamed,

MOST RESPECTFULLY SHOWETH:

1. That the petitioner is filing present transfer petition under Article 139-A of the Constitution of India read with Order XL Rule 1 of Supreme Court Rules-2013 for withdrawal and transfer of W.P.[C]No.5336 of 2017 [Mankind Pharma Limited V/s Union of India & Anr], W.P.[C]No.5340 of 2017 [Akums Drugs & Pharmaceuticals Ltd V/s Union of India & Anr], W.P.[C]No.5345 of 2017 [J.B. Chemicals & Pharmaceuticals Limited & Ors V/s Union of India & Anr], W.P.[C]No.5391 of 2017 [M/s IPCA Laboratories Limited & Anr V/s Union of India & Anr], W.P.[C]No.5397 of 2017 [Ahlcon Parenterals India Ltd. V/s Union of India & Anr], W.P.[C]No.5398 of 2017 [J.K. Printpacks V/s Union of India & Anr] and W.P.[C]No.5399

of 2017 [Windlas Biotech Pvt. Ltd. V/s Union of India & Anr], W.P.[C]No.5336 of 2017 [Mankind Pharma Limited V/s Union of India & Anr], W.P.[C]No.5340 of 2017 [Akums Drugs & Pharmaceuticals Ltd V/s Union of India & Anr], W.P.[C]No.5345 of 2017 [J.B. Chemicals & Pharmaceuticals Limited & Ors V/s Union of India & Anr], W.P.[C]No.5391 of 2017 [M/s IPCA Laboratories Limited & Anr V/s Union of India & Anr], W.P.[C]No.5397 of 2017 [Ahlcon Parenterals India Ltd. V/s Union of India & Anr], W.P.[C]No.5398 of 2017 [J.K. Printpacks V/s Union of India & Anr] and W.P.[C]No.5399 of 2017 [Windlas Biotech Pvt. Ltd. V/s Union of India & Anr], pending before the Hon'ble High Court of Delhi At New Delhi for hearing by this Hon'ble Court along with S.L.P. [C] No.7061 of 2017, [U.O.I V/s Pfizer Pvt. Ltd] and the All India Drug Action Network v/s Pfizer SLP [C] No. SLP [C] No.10170-10178 of 2017.

2. That the petitioners have not filed another Petition or similar Transfer Petition for transfer and withdrawal of above mentioned Writ Petition before this Hon'ble Court earlier to the present petition.

3. That all the parties arrayed before this Hon'ble Court, were party before the High Court and their addresses given in this petition are complete and correct as per record of the Writ Petition.

4. That in the Writ Petition sought to be transferred and the SLP/TP pending before this Hon'ble Court, a common question of law as to the constitutional validity of Notifications issued by Central Government under section 26-A of the Drugs and Cosmetics-1940, banning the manufacture sale and distribution of fixed doze combination medicines.

5. Briefly stated the facts leading to filing of present Transfer Petition are as under:-

[A]. The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as "Rules"), made there under is a legislation with an objective to regulate the import, manufacture, distribution and sale of drugs and cosmetics while preventing the spurious, adulterated and substandard drugs to be imported, manufactured, distributed and sold in the country. The avowed objective of the Act is to ensure the safety, efficacy and the quality of the drugs being imported, manufactured, distributed and sold in the country. It is further stated that while granting or renewing the permission for a drug, the emphasis is on the quality, safety and efficacy of the drug.

[B]. That the combination of two or more drugs i.e. FDC combined for the first time fall under the definition of a New Drug. The requirements for import, manufacture of New drugs including FDCs was introduced in Drugs and Cosmetics Rules, 1945 vide GSR No. 944E dated 21.9.1988 by introducing Rule 122A, 122B, 122D, 122E and Schedule Y which required that the manufacturers of FDCs falling under the definition of new drug shall require the permission from DCG(I). It is submitted that Fixed Dose Combination (FDC) is a 'New Drug' as defined under Rule 122E of the Drugs and Cosmetics Rules, 1945 and it specifies procedures to be followed by the manufacturers to obtain manufacturing permission/marketing authorization. Further this Rule clearly specifies that any manufacturer interested in marketing any new drug including Fixed Dose Combination is

required to apply to the Licensing Authority notified under Rule 21 i.e. the Drugs Controller General (India). The procedure specified under Schedule-Y involves examination and experimentation, which includes clinical and non-clinical studies of the molecules or fixed dose combination of molecules. It is further submitted that in case of the FDCs, the applicant has to establish by experimentation and through clinical and non-clinical studies, the rationality, safety and efficacy by evaluating the critical parameters like pharmacological compatibility, pharmacokinetic compatibility, dose placing, dose spacing, cumulative toxicity, etc. While granting a manufacturing license, the Licensing Authority has to satisfy itself about the rationality, safety and efficacy of the drug. Schedule Y of Drugs and Cosmetics Rules clearly specifies that the data submitted should be based on

experimentation carried out to establish the rationality, safety and efficacy of such combinations. Further with effect from 01.02.1983 major changes were brought in the Act 1940 and the scope of the Act was widened.

[C]. The FDC of Ofloxacin + Ornidazole injection was approved on 17.8.2009 for the treatment of Diarrhoea of mixed infection in adult patients initially for the first time (i.e. Innovator Company) in favour of M/s Venus Remedies. Further the Fixed Dose Combination of Etodolac + Paracetamol was approved by CDSCO on 20.10.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis initially for the first time (i.e. innovator company) in favour of M/s IPCA Laboratories.

[D]. That Ministry of Health & family Welfare vide its order No. X.19029/5/2011-DFQC dated 31.03.2011 constituted New Drug Advisory Committee (NDAC) in various therapeutic categories to advise Drugs Controller General (India) in matters for review of Applications of New Drugs & Clinical Trials.

[E]. Parliamentary Standing Committee (PSC) on Health & Family Welfare in its 59th Report has considered the issue regarding the prevalence of many Fixed Dose Combinations (FDC) in the Indian market that had not been tested for efficacy or safety.

PSC observed that some of the State Licensing Authorities (SLAs) have issued manufacturing licenses for a very large number of FDCs without prior clearance from Central Drugs Standard Control Organization (CDSCO). This

resulted in the availability of many FDCs in the market which have not been tested for efficacy and safety. This can put patients at risk. The PSC expressed its view that those unauthorized FDCs that pose risk to patients and communities such as a combination of two antibacterials need to be withdrawn immediately due to danger of developing resistance that affects the entire population. PSC in their report had also recommended to invoke sec. 26 A of the Drugs and Cosmetics Act, 1940 which, in its opinion was adequate to deal with the problem of irrational and/or FDC's not cleared by CDSCO. It is submit that Of the cases scrutinized, there were 13 drugs (33%) which did not have permission for sale in any of the major developed countries (United States, Canada, Britain, European Union nations and Australia). None of these drugs have any special or specific relevance to

the medical needs of India. These drugs are: (i) Buclizine for appetite stimulation (UCB); ii. Nimesulide injection (Panacea); (iii) Doxofylline (Mars) (iv) FDC of Nimesulide with Levocetirizine (Panacea); (v) FDC of Pregabalin with other agents (Theon); (vi) FDC of Tolperisone with Paracetamol (Themis); (vii) FDC of Etodolac with Paracetamol (FDC); (viii) FDC of Aceclofenac with Thiocolchicoside (Ravenbhel); (ix) FDC of Ofloxacin with Ornidazole (Venus), (x) FDC of Aceclofenac with Drotaverine (Themis); (xi) FDC of Glucosamine with Ibuprofen (Centaur); (xii) FDC of Diclofenac with Serratiopeptidase (Emcure) and (xiii) FDC of Gemifloxacin with Ambroxol (Hetero).

The Parliamentary Standing Committee (PSC) also stated that Section 26A of the Drugs and Cosmetics Act, 1940 is adequate to deal with

the problem of irrational FDCs. There is a need to make the process of approving and banning FDCs more transparent and fair. In general, if an FDC is not approved anywhere in the world, it may not be cleared for use in India unless there is a specific disease or disorder prevalent in India, or a very specific reason backed by scientific evidence and irrefutable data applicable specifically to India that justifies the approval of a particular FDC. The Parliamentary Standing Committee strongly recommended that a clear, transparent policy may be framed for approving FDCs based on scientific principles.

The recommendations of Parliamentary Standing Committee were considered by the Government. As per decision taken by the Government of India and conveyed through the Action Taken Note on the 59th report to the

PSC, the PSC in its 66th Report recommended that these FDCs be referred to the New Drug Advisory Committee (NDAC) for examination and review to decide on the continued marketing of these drugs and updating of their product monographs in light of recent knowledge and regulatory changes overseas.

[F]. 10.03.2016:In another set matters pursuant to the acceptance of the report of the Kokate Committee, the Petitioner [UOI] vide notification dated 10.03.2017 prohibited the manufacture, sale and distribution of 344 FDCs in exercise of powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940.

[G]. Being aggrieved of the Notifications dated 10.03.2016 issued by the Petitioner u/s. 26A, approximately 453 writ petitions were filed on 14.03.2016 before the Hon'ble High Court of

Delhi at New Delhi challenging the validity and correctness of the Notifications dated 10.03.2016. Further aggrieved by the said Notifications dated 10.03.2016 issued by the Petitioner u/s. 26A, various Writ Petitions were filed before High Court of Delhi, Madras, Karnataka, Bombay, Rajasthan, Jammu & Kashmir between the period from 17.3.2016 to 07.09.2016.

[H]. That by its common impugned Judgment dated 01.12.2016 the Hon'ble High Court of Delhi dispose of the Writ Petition No.2212/2016 along with the batch of 453 Writ Petitions thereby quashed the notifications issued on 10.03.2016 without appreciating the express and unambiguous language used in the different provision of the Act.

[I]. 10.03.2016: As per recommendation of the "New Drug Advisory Committee" (NDAC) the FDC in question were recommended to be banned. As the above sequence of events brings out, the Government has made elaborate attempts to ensure that all facets of the matter get duly examined and no injustice is done to anyone and more importantly the safety of patients is not compromised. In the process sufficient notice and opportunity had been given to all concerned to the innovators companies who were granted approval by CDSCO for the first time while approving the new drug at that point of time in the year 2009. The Government had prohibited these FDCs to safeguard public interest and hence these were prohibited under section 26A in order to safeguard public health from such irrational FDCs irrespective of the manufacturer. This was done in the larger

public interest and it cannot be anyone's case that he should be given a differential treatment in the face of such facts in public interest as there was no therapeutic justification for such FDCs.

It is respectfully submitted that even if an approval to the said FDC was granted in the year 2009, it was done on the basis of the available literature and knowledge at that point of time which does not bar the Government to re-examine the FDC in the current scenario in the light of latest scientific knowledge and information. As such the said FDC was examined by the New Drug Advisory Committee, and it was found that the FDCs are irrational and was accordingly recommended by the New Drug Advisory Committee. True and correct copy of the Notifications S.O.1852 [E] & 1855 [E] both dated 08.06.2017 issued

by the Central Government under section 26-A of the Drugs and Cosmetics-1940 are enclosed herewith and marked as **ANNEXURE P-1 (Page_42-46)**

[J]. Aggrieved by the Judgment dated 01.12.2016 the petitioners herein filed the S.L.P. [C] No.7061 of 2017, [U.O.I V/s Pfizer Pvt. Ltd] before this Hon'ble Court. Further the All India Drug Action Network also file SLP against the judgment dated 01.12.2016 being SLP [C] No.10170-10178 of 2017. After hearing their Lordships were pleased to issue notice on 31.03.2017.

[K]. Aggrieved by the Notification dated 10.03.2017 the respondents herein filed writ Petition before the Hon'ble High Court of Delhi being W.P.[C]No.5336 of 2017 [Mankind Pharma Limited V/s Union of India & Anr],

W.P.[C]No.5340 of 2017 [Akums Drugs & Pharmaceuticals Ltd V/s Union of India & Anr], W.P.[C]No.5345 of 2017 [J.B. Chemicals & Pharmaceuticals Limited & Ors V/s Union of India & Anr], W.P.[C]No.5391 of 2017 [M/s IPCA Laboratories Limited & Anr V/s Union of India & Anr], W.P.[C]No.5397 of 2017 [Ahlcon Parenterals India Ltd. V/s Union of India & Anr], W.P.[C]No.5398 of 2017 [J.K. Printpacks V/s Union of India & Anr] and W.P.[C]No.5399 of 2017 [Windlas Biotech Pvt. Ltd. V/s Union of India & Anr].

True and correct copy of the memo of W.P. [C] No. 5336 of 2017, dated 15.06.2017 filed before the High Court of Delhi at New Delhi is annexed and marked as **ANNEXURE P-2 (Page.47-110).**

True and correct copy of the memo of W.P.[C]No.5340 of 2017, dated 16.06.2017 filed before the High Court of Delhi at New Delhi is annexed and marked as **ANNEXURE P-3 (Page- 111-179),**

True and correct copy of the memo of W.P.[C]No.5345 of 2017 dated 19.06.2017 filed before the High Court of Delhi at New Delhi is annexed and marked as **ANNEXURE P-4 (Page 180-245).**

True and correct copy of the memo of W.P.[C]No.5391 of 2017 dated 27.06.2017 filed before the High Court of Delhi at New Delhi is annexed and marked as **ANNEXURE P-5 (Page.246-320).**

True and correct copy of the memo of W.P.[C]No.5397 of 2017 dated 29.06.2017 filed before the High Court of Delhi at New

Delhi is annexed and marked as **ANNEXURE P-6 (Page.321-391).**

True and correct copy of the memo of W.P.[C]No.5398 of 2017 dated 29.06.2017 filed before the High Court of Delhi at New Delhi is annexed and marked as **ANNEXURE P-7 (Page.392-460).**

True and correct copy of the memo of W.P.[C]No.5399 of 2017 dated 29.06.2017 filed before the High Court of Delhi at New Delhi is annexed and marked as **ANNEXURE P-8 (Page.461-535).**

[L]. That the S.L.P. [C] No.7061 of 2017, [U.O.I V/s Pfizer Pvt. Ltd] along with other batch matter was listed before this Hon'ble Court on 12.07.2017 and after hearing their lordships were pleased give liberty to file present

transfer petition and adjourned the matter for hearing of al the cases on 29.07.2017.

True and correct copy of the order dated 12.07.2017 passed by this Hon'ble Court in SLP [C] No.7061 of 2017 is enclosed herewith and marked as **ANNEXURE P-9 (Page.536-540)**

6. The petitioners herein prefer the present transfer petition on following amongst other grounds:

GROUNDS

I. Because in the Writ Petition, sought to be transferred before this Hon'ble Court, a common question of law as to the interpretation of Notifications dated 10.03.2017 issued by the Central Government

under section 26-A of the Drugs and Cosmetics-1940, has been raised.

II. Because in all the writ petitions it has been contended that said Notifications have been issued in violation of principle of natural justice and without following due process of law and are illogical and violative of the provisions of Article 14, 19 [1] [g] and 21 of the Constitution of India.

III. Because the Respondents/Writ Petitioners have challenged the impugned Notifications dated 10.03.2017 issued by the Central Government under section 26-A of the Drugs and Cosmetics-1940, by contending that said Notifications have been issued in violation of principle of natural justice and without following due process of law and are illogical

and violative of the provisions of Article 14, 19 [1] [g] and 21 of the Constitution of India.

IV. Because, the identical issues were raised in different High Courts, therefore transfer petitions were filed which are pending consideration of this Hon'ble Court, being Transfer Petitions Nos. 1729-37 of 2016 bearing the identical and similar issue i.e. challenge to Notifications issued by Central Government under section 26-A of the Drugs and Cosmetics-1940, banning the manufacture sale and distribution of fixed doze combination medicines, are pending before this Hon'ble Court. Further S.L.P. [C] No.7061 of 2017, [U.O.I V/s Pfizer Pvt. Ltd] is pending before this Hon'ble Court. Further the All India Drug Action Network also file SLP against the judgment dated 01.12.2016 being SLP [C] No.10170-10178 of 2017.

V. Because in the writ petitions which are sought to be transferred and withdrawn to this Hon'ble Court, substantially the same, common and identical questions of law is involved i.e. constitutional validity of Notifications issued by Central Government under section 26-A of the Drugs and Cosmetics-1940, banning the manufacture sale and distribution of fixed doze combination medicines.

VI. Because in case of conflicting decision on the issue will ultimately lead to filing of petitions before this Hon'ble court and thus it will unnecessary cost burden on the govt. exchequer. It is submitted that if this Hon'ble Court pleases to withdraw the said writ petitions and decide the same, it will avoid the unnecessary expenditure and reduced the litigation.

PRAYER

In these premises, the Petitioner most respectfully pray that this Hon'ble Court may graciously be pleased to:-

[a] allow the present Transfer petition by withdrawing the W.P.[C]No.5336 of 2017 [Mankind Pharma Limited V/s Union of India & Anr], W.P.[C]No.5340 of 2017 [Akums Drugs & Pharmaceuticals Ltd V/s Union of India & Anr], W.P.[C]No.5345 of 2017 [J.B. Chemicals & Pharmaceuticals Limited & Ors V/s Union of India & Anr], W.P.[C]No.5391 of 2017 [M/s IPCA Laboratories Limited & Anr V/s Union of India & Anr], W.P.[C]No.5397 of 2017 [Ahlcon Parenterals India Ltd. V/s Union of India & Anr], W.P.[C]No.5398 of 2017 [J.K. Printpacks V/s Union of India & Anr] and W.P.[C]No.5399 of 2017 [Windlas Biotech Pvt. Ltd. V/s Union of

India & Anr], pending before the Hon'ble High Court of Delhi At New Delhi for hearing along with S.L.P. [C] No.7061 of 2017, [U.O.I V/s Pfizer Pvt. Ltd] and SLP [C] No.10170-10178 of 2017 [All India Drug Action Network V/s Pfizer pending before this Hon'ble Court; AND/OR

[b]. pass such order or further order as may deem fit and proper under the facts and circumstances of the case.

FOR THIS ACT OF KINDNESS THE PETITIONER AS IN DUTY BOUND SHALL EVER PRAY.

DRAWN BY: FILED BY:

S.WASIM A. QADRI
Advocate
Supreme Court, New Delhi.

(G. S. MAKKER)
Advocate-on-Record
for the Petitioner

Drawn On: 12.07.2017

NEW DELHI:
Filed on: .07.2017

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

TRANSFER PETITION[C]NO._____OF 2017

IN THE MATTER OF:

Union of India & Anr. ...Petitioners

Versus

Mankind Pharma Limited ...Respondents

CERTIFICATE:

Certified that [1] W.P.[C]No.5336 of 2017 [Mankind Pharma Limited V/s Union of India & Anr], [2] W.P.[C]No.5340 of 2017 [Akums Drugs & Pharmaceuticals Ltd V/s Union of India & Anr], [3] W.P.[C]No.5345 of 2017 [J.B. Chemicals & Pharmaceuticals Limited & Ors V/s Union of India & Anr], [4] W.P.[C]No.5391 of 2017 [M/s IPCA Laboratories Limited & Anr V/s Union of India & Anr], [5] W.P.[C]No.5397 of 2017 [Ahlcon Parenterals India Ltd. V/s Union of India & Anr], [6]

W.P.[C]No.5398 of 2017 [J.K. Printpacks V/s Union of India & Anr] and [7] W.P.[C]No.5399 of 2017 [Windlas Biotech Pvt. Ltd. V/s Union of India & Anr], are involve similar questions of law. The said questions are substantial questions of general importance in terms of Clause [1] of Article 139A of the Constitution of India.

[G.S.MAKKER]
Advocate for the petitioners

NEW DELHI :

DATED : 07.2017

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

TRANSFER PETITION[C]NO._____OF 2017

IN THE MATTER OF:

Union of India & Anr. ...Petitioners

Versus

Mankind Pharma Limited ...Respondents

AFFIDAVIT

I, Debananda Sahoo s/o Late Shri H.N.Sahoo, aged about 57 years, presently working as Deputy Secretary to the Govt. of India, Drugs Division, Ministry of Health and Family Welfare, New Delhi, do hereby state and declare as solemn affirmation as under:

1. That I am the Deputy Secretary to the Govt. of India, Drugs Division, Ministry of Health and Family Welfare and as such am well conversant with the facts and circumstances of the case and thus competent to swear this affidavit.

2. That I have read and understood the contents of the accompanying Transfer Petition [Para 1-8],

[Pg. No._____] and Synopsis and List of Dates [B to], I.As. and having understood the contents thereof, I say that the facts stated therein are true to my knowledge.

3. That the annexures are true copies to their respective originals.

4. That the facts stated in the above affidavit are true to my knowledge and belief. No part of the above affidavit is false and nothing material has been concealed therefrom.

PRABHA JAIN OATH COMMISSIONER APPOINTED BY THE GOVT. OF DELHI

DEPONENT
(देवानन्द साहू)
(D. N. SAHOO)
उप सचिव/Deputy Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & F.W.
भारत सरकार/Govt. of India
नई दिल्ली/New Delhi

VERIFICATION:

I identify the Executant Shri who has signed in my presence.

I, the abovenamed deponent do hereby verify that the facts stated therein are true to my knowledge and belief. No part of the above affidavit is false and nothing material has been concealed therefrom.

Verify at New Delhi on this 18th day of July, 2017.

Identified that the contents
Shri Debanand Sahoo H.N.Sahoo
s/o Ministry of Health
identified by Rishi Kant Shukla Adv
solemnly at me at New Delhi
that the contents of affidavit which has been
readover & explained are true & correct

Oath Commissioner New Delhi 18.7.17

DEPONENT
(देवानन्द साहू)
(D. N. SAHOO)
उप सचिव/Deputy Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & F.W.
भारत सरकार/Govt. of India
नई दिल्ली/New Delhi

ANNEXURE-P-1

THE GAZETTE OF INDIA

EXTRA ORDINARY

(PART II—SEC. 3(ii)]

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 8th June, 2017

S.O.1852(E).—Whereas it had been brought to the notice of the Central Government that the use of the drug fixed dose combination of Ofloxacin+ Ornidazole injection is not rational;

And, whereas, the matter has beer, examined by the New Drugs Advisory

Committee constituted by the Central Government and the said Committee has recommended to the Central Government that the said fixed dose combination is not rational and there is no specific advantage an administering both drags together in parental form and as such there is no therapeutic justification for the continued marketing of this drug;

And, whereas, after examination of the recommendations of the aforesaid Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition, the manufacture for sale, sale and distribution for- human use of the said drug in the country;

Now, therefore, in exercise of the powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, hereby prohibits the manufacture for sale, sale and distribution for human use of the drug fixed dose combination of Ofloxacin + Qrnidazole injection with immediate effect,

[F.No.X.11014/12/2017-DRS]
K.L.SHARMA, Jt Secy.

/TRUE COPY/

NOTIFICATION

New Delhi, the 8th June, 2017

S.O. 1855(E) .—Whereas it had been brought to the notice of the Central Government that the use of the drag fixed dose combination of Etodolac + Paracetamol is not rational;

And, whereas, the matter has been examined by the New Drugs Advisory Committee constituted by the Central Government that the said fixed dose combination drug does not have therapeutic justification and the two drugs are best administered separately on as required basis;

And, whereas, after examination of the recommendations of the aforesaid Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition, the

manufacture for sale, sale and distribution for human use of the said drug in the country;

Now, therefore, in exercise of the power? conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, hereby prohibits the manufacture for sale, sale and distribution for human use of the drug fixed dose combination of Etodolac + Paracetamol with immediate effect.

[F. No. X.11014/12/2017-DRS]
K. L. SHARMA, Jt Secy.

/TRUE COPY/

ANNEXURE-P-2

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY ORIGINAL WRIT JURISDICTION

WRIT PETITION (C) N0.5336 0F 2017

IN THE MATTER OF:

Mankind Pharma Limited ..... Petitioner

Versus

Union of India & Anr. .....Respondents

MEMO OF PARTIES

Mankind Pharma Limited
a company existing under the
Companies Act, 2013
having its registered office at:
208, Okhla Industrial Estate
Phase III, New Delhi-110020
through its Authorized Signatory
Mr. Prateush Manmohan Sharma .....Petitioner

-VERSUS

-

1. Union of India
   through Secretary
   Department of Health and Family
   Welfare, Ministry of Health and
   Family Welfare
   Nirman Bhawan,
   New Delhi-110001

2. The Drug Controller General of India,
   FDA Bhawan
   ITO, Kotla Road
   New Delhi-11002 .....Respondents

PETITIONER

THROUGH:

PRA LAW OFFICES
R. JAWAHAR LAL
ADVOCATE FOR THE PETITIONER
ENR. NO. D-933/1992
W-126, GREATER KAILASH PART II
NEW DELHI 110048
PH# 01140676767, 9958996312 (M)

PLACE: NEW DELHI
DATE: 15.06.2017

SYNOPSIS

The Petitioner is invoking the extraordinary writ jurisdiction of this Hon'ble Court under Article 226 of the Constitution of India challenging Notifications S.O. No. 1852 (E) and 1855(E) both dated 08.06.2017, whereby the Respondent No. 1, in purported exercise of its powers under Section 26A of the Drugs and Cosmetics Act, 1940 ("D&C Act") prohibited the manufacture for sale, sale and distribution for human use of the fixed dose combination (drug with more than one active ingredient, in short referred to as "FDC") of (a) Ofloxacin + Ornidazole injection and (b) Etodolac + Paracetamol, with immediate effect on the purported ground that the same there is no rational or therapeutic justification. The decision to prohibit manufacture for sale, sale and distribution of the two FDC by the Impugned Notifications is based on the

recommendation of the New Drugs Advisory Committee constituted by Respondent No. 1. The Petitioner submits that the New Advisory Committee is not a statutory body, contemplated under the D&C Act. The Petitioner submits that the Impugned Notifications dated 08.06.2017 is ex-facie illegal, arbitrary and irrational and is therefore likely to be quashed by this Hon'ble Court as:

1. The Impugned Notifications has been issued by the Respondent No.1 in contravention of Sections 5, 6, 7 and 26A of the D&C Act. This Hon'ble Court considered 344 Notifications issued by Respondent No.1 banning a large number of FDC in its Judgment in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) dated 01.12.2016. After hearing detailed arguments,

this Hon'ble Court held that any exercise of powers by the Respondent No. 1 under Section 26A of the D&C Act has to be preceded by consultation and ought to be based on the advice, of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act viz. Drugs Technical Advisory Board ("DTAB"), Central Drugs Laboratory ("CDL") and Drugs Consultative Committee ("DCC"). Since, earlier Respondent No.1 had unilaterally and without seeking advice of the aforesaid statutory bodies, all 344 notifications were quashed by this Hon'ble Court. In the present case also, prior to issue of the Impugned Notifications, the Respondent No.1 did not consult or sought the advice and recommendation of the aforesaid statutory bodies. The Respondent No.1 prohibiting the FDC in question had acted unilaterally on the basis of recommendation of New Drugs Advisory Committee (a non-

statutory Committee appointed by the Respondent No. 1), which is impermissible under the statutory regime of D&C Act and in particular Sections 5, 6, 7 and 26A thereof.

2. The Petitioner submits that Sections 5, 6 and 7 of the D&C Act are mandatory in nature and cannot be in any manner ignored or by-passed by the Respondent No.1. Sections 5 & 7 of the D&C Act provide that the purpose of constitution of DTAB is to advice the Respondent No.1 on technical matters arising out of administration of the Act and to carry out other functions assigned to the Respondent No.1 under the D&C Act and that the purpose of constitution of the DCC is to advice the Respondent No.1 and the DTAB on any matter tending to secure uniformity throughout India in the administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C

Act provide that the Respondent No.1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and hold consultation with DTAB and DCC. Moreover the functions of DTAB under Section 5 of the D&C Act, is not only to advice on technical matters but also to carry out "other functions assigned' to the Respondent No.1 under the D&C Act.

3. Irrefutably, the New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act, as the D&C Act does not provide constitution of such' a Committee. The New Drugs Advisory Committee is a committee functioning under the Central Drugs Standard Control Organization ("CDSCO"), which itself not a statutory body under the D&C Act. This fact has been held by this Hon'ble Court in Pfizer Ltd. & Anr. (supra) and forms part of the

rationale of this Hon'ble Court to set aside the 344 Notifications, challenged in the batch of writ petitions filed before this Hon'ble Court. Thus, the very act of the Respondent No.1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go-by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notification and renders it unsustainable in the eyes of law.

4. The Respondent No.1 in exercise Of powers vested under the D&C Act, cannot circumvent the statutory provisions of the D&C Act, take away the statutory powers vested in DTAB, DCC and vest them in a Committee unilaterally formed by the Respondent No.1.

5. In addition, to being in consonance with Sections 5, 6 and 7 of D&C Act, any action

under Section 26A of the D&C Act, has to be preceded by hearing all stake holders (manufacturers etc.), unless there is grave urgency, for which reasons should be recorded, as held by this Hon'ble Court in Pfizer Judgment. It is submitted that prior to issue of the Impugned Notifications, no such notice or opportunity of hearing was afforded to the Petitioner, who manufacturers the FDC through contract manufacturers, in its brand name (Zenflox-OZ Infusion and Orthokind-P 400) and markets the same across India.

6. The Petitioner submits that the fact that there was no grave urgency warranting exercise of powers under Section 26A of D&C Act is also evident from the fact that the Impugned Notifications themselves mention that the prohibition is premised on the fact that the use of FDCs in question is not rational as the FDCs

does not have any therapeutic justification and the two drugs which are the constituents of FDCs are best administered separately. The prohibition is not premised on any adverse health consequences or risk to human beings and therefore it can be safely said that there were no compelling circumstances in giving a go-by to the requirement of issuance of notice and opportunity of hearing to manufacturers before prohibiting the FDCs. Thus, the Impugned Notifications dated 08.06.2017 are violative of Article 14 of the Constitution of India as it is arbitrary and unreasonable.

7. It is pertinent to mention here that the said FDCs have been approved by the Respondent No.2, Drug Controller General of India on 17.08.2009 and 01.10.2010, respectively and the Petitioner has been marketing the same from 01.03.2010 and 01.11.2010 under its

well-known brand name, viz. Zenflox-OZ infusion and Orthokind-P 400. After having approved the two FDCs, there is no justification whatsoever to ban the FDCs, even without following the mandatory procedure specified under the D&C Act. Also, the Petitioner and other manufacturers were not even given an opportunity of hearing. Thus, the Impugned Notifications dated 08.06.2017 is contrary to the principles of natural justice.

LIST OF DATES & EVENTS

17.08.2009	The Respondent No.2 approved the FDC Ofloxacin 2 mg per ml + Ornidazole 5 mg per ml Infusion
01.10.2010	The Respondent No.2

	approved the FDC Etodolac 400 mg+ Paracetamol 500 mg
01.03.2010	The Petitioner amongst the top five pharmaceutical companies in India started marketing Ofloxacin 2 mg per ml + Ornidazole 5 mg per ml Infusion under the brand name, Zenflox-OZ Infusion
01.11.2010	The Petitioner started marketing Etadolac 400 mg + Paracetamol 500 mg under the brand name, Orthokind-P 400
10.03.2016	The Respondent No.1

	issued 344 Notifications prohibiting manufacture for sale, sale and distribution of FDCs
01.12.2016	This Hon'ble Court vide Judgment in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) quashed the 344 Notifications on the ground that the Respondent No.1 while issuing the notification has acted in contravention of the statutory regime under

	D&C Act, including Section 5,6,7 & 26A thereof
08.06.2017	The Respondent No.1 has issued the Impugned Notifications S.O. No. 1852 (E) and 1855 (E) prohibit manufacture for sale, sale and distribution of the two FDC, viz. (a) Ofloxacin + Ornidazole injection and (b) Etadolac + Paracetamol
15.06.2017	Hence the present Writ Petition

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY ORIGINAL WRIT JURISDICTION

WRIT PETITION (C) NO.5336 OF 2017

IN THE MATTER OF:

Mankind Pharma Limited

a company existing under the Companies Act, 2013

having its registered office at:

208, Okhla Industrial Estate

Phase III, New Delhi-110 020

through its Authorized Signatory

Mr. Prateush Manmohan Sharma .....Petitioner

-Versus-

1. Union of India

through Secretary

Department of Health and Family Welfare

Ministry of Health and Family Welfare

Nirman Bhawan, New Delhi-110 001

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

AND IN THE MATTER OF:

WRIT PETITION UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA, 1950 SEEKING A WRIT OF CERTIORARI OR ANY OTHER WRIT, ORDER OR DIRECTION IN THE NATURE OF CERTIORARI CALLING FOR THE RECORDS AND QUASHING NOTIFICATIONS BEARING S.O. NO. 1852 (E) AND S.O. NO. 1855 (E) BOTH DATED 08.06.2017 (ANNEXURK P- I (COLLY) ISSUED BY RESPONDENT NO. 1, IN PURPORTED EXERCISE OF POWERS UNDER

SECTION 26A OF THE DRUGS AND COSMETICS ACT, 1940; IMPUGNED NOTIFICATIONS ARE ARBITRARY, ILLEGAL AND IRRATIONAL AND ISSUED IN VIOLATION OF SECTIONS 5, 6, 7 AND 26A OF THE DRUGS AND COSMETICS ACT, 1940

TO

THE HON'BLE ACTING CHIEF JUSTICE AND HER COMPANION JUSTICES OF THE HON'BLE HIGH COURT OF DELHI AT NEW DELHI

THE HUMBLE PETITION OF THE PETITIONER NAMED ABOVE:

MOST RESPECTFULLY SHOWETH:

1. The Petitioner is invoking the extraordinary writ jurisdiction of this Hon'ble Court under Article 226 of the Constitution of India challenging Notifications S.O. No. 1852 (E) and

1855(E) both dated 08.06.2017 (in short the "Impugned Notifications"), whereby the Respondent No. 1, in purported exercise of its powers under Section 26A of the Drugs and Cosmetics Act, 1940 (in short the "D&C Act") prohibited the manufacture for sale, sale and distribution for human use of the fixed dose combination (drug with more than one active ingredient, in short referred to as "FDC") of (a) Ofloxacin + Ornidazole injection (under SO No. 1852 (E) and (b) Etodolac and Paracetamol (under SO No. 1855 (E), with immediate effect on the purported ground that there is no rational or therapeutic justification for the two FDCs. The decision to prohibit manufacture for sale, sale and distribution of the two FDC by the Impugned Notifications is based on the recommendation of the New Drugs Advisory Committee constituted by Respondent No. 1. In this context, it is relevant to submit that the

New Advisory Committee is not a statutory body, contemplated under the D&C Act. True typed copy of the Notifications S.O. Nos. 1852 (E) and SO No. 1855(E) both dated 08.06.2017 issued by the Respondent No.1 are annexed and marked as Annexure P-I (Colly).

2. The Petitioner submits that the Impugned Notifications dated 08.06.2017 is ex-facie illegal, arbitrary and irrational and is therefore likely to be quashed by this Hon'ble Court as:

2.1 The Impugned Notifications has been issued by the Respondent No.1 in contravention of Sections 5, 6, 7 and 26A of the D&C Act, in as much exercise of powers under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers of the concerned FDCs and ought to be based on the advice of

statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act viz. Drugs Technical Advisory Board, Central Drugs Laboratory and Drugs Consultative Committee. In this context, it is respectfully submitted that on 10.03.2016, the Respondent No.1 had issued 344 Notifications, banning a large number of FDC. While considering the challenge to 344 Notifications, the Hon'ble Court in its Judgment (in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) dated 01.12.2016, held that any exercise of powers by the Respondent No.1 under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers and ought to be based on the advice of statutory bodies constituted

under Sections 5, 6 and 7 of the D&C Act. In the present case also, prior to issue of the Impugned Notifications, the Respondent No.1 did not consult the manufacturers or sought the advice anti recommendation of the aforesaid statutory bodies. The Respondent No.1 had acted unilaterally on the basis of recommendation of New Drugs Advisory Committee (a non-statutory Committee appointed by the Respondent No.1), which is impermissible under the statutory regime of D&C Act and in particular Sections 5, 6, 7 and 26A thereof.

2.2 In the present case, the two FDCs were approved by the Respondent No.2 on 17.08.2009 and 01.10.2010; therefore by virtue of Explanation (ii) to Rule 122E they cease to be a New Drug by

17.08.2013 and 01.11.2014 (i.e. upon expiry of 4 years from the date of approval by DCGI (Respondent No.2). Therefore, even assuming without admitting that the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to "new drugs" (as defined in Rule 122E of the D&C Rules), such Committee cannot consider ban of existing FDCs, especially when the FDCs, in the present case, cease to be New Drugs, as defined in Rule 122E of the D&C Rules (per Explanation (ii) to Rule 122E of the D&C Rules).

2.3 The Petitioner respectfully submits that Sections 5, 6 and 7 of the D&C Act are mandatory in nature and cannot be in any manner ignored or by-passed by the

Respondent No.1, as held by this Hon'ble Court in Pfizer Limited. The purpose of constitution of Drugs Technical Advisory Board is to advice the Respondent No. \ on technical matters arising out of administration of the Act and to carry out other functions assigned to the Respondent No.1 under the D&C Act and the purpose of constitution of the Drugs Consultative Committee is to advice the Respondent No.1 and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C Act provide that the Respondent No.1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and hold consultation with Drugs Technical Advisory Board and Drugs

Consultative Committee. Moreover the functions of Drugs Technical Advisory Board under Section 5 of the D&C Act, is not only to advice on technical matters but also to carry out "other functions assigned" to the Respondent No.1 under the D&C Act.

2.4 Indisputably, the New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act, as the D&C Act does not provide for constitution of such a Committee. The New Drugs Advisory Committee is a committee functioning under the Central Drugs Standard Control Organization (in short "CDSCO"), which itself is not a statutory body under the D&C Act. Thus, the very act of the Respondent No.1 in acting on the purported recommendation

of New Drugs Advisory Committee and giving a go-by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notification and renders it unsustainable in the eyes of law, as the Respondent No.1 in exercise of powers vested under the D&C Act, cannot take away the statutory powers vested in DTAB, DCC arid vest them in a Committee unilaterally formed by the Respondent No.1.

2.5 In addition, for any action under Section 26A of the D&C Act, has to be preceded by hearing all stake holders (manufacturers etc.), unless there is grave urgency, for which reasons should be recorded, as held by this Hon'ble Court in Pfizer Judgment. It is submitted that prior to issue of the Impugned

Notifications, no such notice or opportunity of hearing was afforded to the Petitioner, who manufacturers the FDC through contract manufacturers, in its brand name (Zenflox-OZ Infusion and Orthokind-P 400) and markets the same across India.

2.6 The Petitioner submits that the fact that there was no grave urgency warranting exercise of powers under Section 26A of D&C Act is evident from the fact that the Impugned Notifications themselves mention that the prohibition is premised on the fact that the use of FDC in question is not rational as the FDC floes not have any therapeutic justification and the two drugs which are the constituents of FDC are best administered separately. The prohibition is not premised on any adverse

health consequences or risk to human beings and therefore it can be safely said that there were no compelling circumstances in giving a go-by to the requirement of issuance of notice and opportunity of hearing to manufacturers before prohibiting the FDC. Thus, the Impugned Notifications dated 08.06.2017 is violative of Article 14 of the Constitution of India as it is arbitrary and unreasonable and violative of principles of natural justice.

2.7 It is pertinent to mention here that the said FDCs have been approved by the Respondent-No.2, Drug Controller General of India on 17.08.2009 and 01.10.2010, respectively and the Petitioner has been marketing the same from 01.03.2010 and 01.11.2010 under its well-known brand

name, viz. Zenflox-OZ Infusion and Orthokind-P 400. After having approved the two FDCs, there is no justification whatsoever to ban the FDCs, that too without following the mandatory procedure specified under the D&C Act.

3. The brief facts giving rise to the filing of the present Writ Petition before this Hon'ble Court are as under;

3.1 The Petitioner is amongst the top five pharmaceutical companies in India, having a turnover of more than Rs. 4,000 Crore. The Petitioner employs nearly 12,000 employees and has 4 own factories and in addition, its products are manufactured by more than 50 contract manufactures. The products of the Petitioner are marketed across India

through a vast network of 50 C&F Agents and over 7,500 stockists. The Petitioner manufactures a wide range of pharma products including Antibiotics, Antifungal, NSAIDs, Gastrointestinal, Anthelmintic, Cardiovascular, Dermal, Erectile Dysfunction, and several other categories of pharma products. In addition to India, the Petitioner operates in 11 countries across Asia, Africa and SE Asia countries. The Petitioner aspires to aid the community in leading a healthy life through two parallel objectives: formulating, developing and commercializing medicines, and delivering affordable and accessible medication that satisfies urgent medical needs.

3.2 Fixed Dose Combinations (FDC) refer to products containing two or more active

ingredients used for particular indication(s). This term is used generically to mean a particular combination of actives irrespective of the formulation or brand. It may be administered as single entity products given concurrently or as a finished pharmaceutical product. The development of FDCs is becoming increasingly important from a public health perspective. The basic rationale of making "fixed dose combination" medicinal products is either to improve adherence or to benefit from the added effects of the two medicinal products given together. FDCs have shown to be particularly useful in the treatment of diseases like HIV, malaria and tuberculosis and also in cardiology, diabetes and cancer conditions, based on international guidelines recommended by expert

bodies, where giving multiple drugs for the management of a given condition is an accepted medical norm and practice. FDCs are also of use in chronic conditions especially when multiple disorders often co-exist. FDCs are known to offer' specific advantages over the single entity preparations, such, as increased efficacy, and/or better patient compliance dosage, possibly reduced cost and simpler logistics of distribution relevant to situations of limited resources.

3.3 Amongst other pharmaceutical products, the Petitioner markets a Fixed Dose Combination of Ofloxacin 2 mg per ml and Ornidazole 5 mg per ml Infusion under the brand name Zenflox-OZ Infusion. Zenflox-OZ Infusion is manufactured by the contract manufacturer of the Petitioner

viz. Ahlcon Parenterals (I) Ltd. under licenses issued by the State Licensing Authority, under the D&C Act. Similarly, the Petitioner markets a Fixed Dose Combination of Etodolac 400 mg and Paracetamol 500 mg, under the brand name Orthokind-P 400 Tablets. Orthokind-P 400 Tablets are manufactured by the contract manufacturers of the Petitioner viz. Windlas Biotech Ltd. and J.K. Printpacks (Pharma Division) under licenses issued by the State Licensing Authority under the D&C Act. True copy of the licenses issued by the State Licensing Authority under the D&C Act granting approval for manufacture of Orthokind-P 400 Tablets and Zenflox-OZ Infusion are annexed herewith and marked as Annexure P-2.

3.4 The Impugned Notifications dated 08.06.2017 prohibit manufacture for sale and sale and distribution of FDC in question and therefore the Petitioner is a person aggrieved and has the locus to file the Writ Petition. The Petitioner states that the FDCs in question have been approved by the Respondent No. 2 viz. Drug Controller General of India on 17.08.2009 (01.03.2010) and 01.10.2010 (01.11.2010) and the Petitioner has been marketing since then under the aforesaid brand names. Infact, the Fixed Dose Combination of Ofloxacin 200 mg and Ornidazole 500 mg in Tablet Form, which is also an approved FDC has not been prohibited, however the Impugned Notification (S.O.1852(E) prohibits the same combination in the form of infusion/injection, without any rational.

This itself evidences a total non-application of mind on the part of the Respondent No.1 while issuing the Impugned Notifications. True copy of the relevant extract of the list of approved FDCs by the Respondent No. 2 is annexed its Annexure P-3.

3.5 Zenflox-OZ Infusion is used for effective treatment of diarrhea of mixed infection. The annual turnover of Zenflox-OZ Infusion km for the years, viz. 2014-15, 2015-16, 2016-17 is respectively Rs. 553.01 lakh, Rs. 575.20 lakh and Rs. 620.29 lakh. Orthokind-P 400 Tablets is used for effective treatment of toothache, joint pain, headache, ear pain, etc. The annual turnover of Orthokind-P 400 Tablets for the years, viz. 2014-15, 2015-16, 2016-17 is respectively Rs. 323.40

lakh, Rs. 333.57 lakh and Rs. 333.93 lakh. It is also pertinent to state here that the FDCs in question are marketed in several countries. In fact, large amount of material is available in public domain, including but not limited to medical rationale of FDC sin question, which goes to show that the said FDCs have enormous amount of therapeutic justification and relevance.

3.6 In this context, it is. stated that Section 5 of D&C Act mandates the Central Government to constitute the Drugs Technical Advisory Board (in short "DTAB") consisting of expert members to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions

assigned to it under D&C Act. The term of office of die nominated and elected members of DTAB has also been prescribed as three years or for so long as they hold the appointment of the office by virtue of which they are nominated or elected. DTAB, vide Section 5 (4) has been authorized to frame its bye-laws fixing a quorum and regulating its own procedure and the conduct of all business and vide Section 5 (5) to constitute sub-committees for consideration of particular matters. The Central Government has been mandated by Section 5 (7) to appoint a person to be the Secretary of DTAB and to provide DTAB with clerical and other staff necessary.

3.7 Section 6 of D&C Act mandates the Central Government to establish a Central

Drugs Laboratory (CLS) under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by the Act or by any Rules made thereunder. Section 6 empowers the Central Government to "after consultation with" DTAB make Rules prescribing the functions of the Central Drugs Laboratory and the procedure for analysis or tests of the drugs and for such other matters as may be necessary.

3.8 Section 7 mandates the Central Government to constitute an Advisory Committee to be called the Drugs Consultative Committee (in short "DCC"), to advise the Central Government, the State Governments and DTAB on any other matter tending to secure uniformity throughout India in the administration of

D&C Act. The DCC has been prescribed to consist of two representatives nominated by the Central Government and one representative nominated by each of the State Governments.

3.9 The Petitioner states that under Section 26A of the D&C Act, the Respondent No.1 is vested with the powers to regulate, restrict or prohibit manufacture, sale or distribution of a drug or cosmetic which is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do.

3.10 However, the Respondent No.1 can exercise its powers under Section 26A of the D&C Act only after consultation and on the advice/recommendation of DTAB, DCC etc. under Section 5, 6 and 7 of the D&C Act. This Hon'ble Court in Pfizer Ltd, (supra) had held that the provisions of Sections 5, 6 and 7 of the D&C Act are mandatory and cannot be given a go-by by the Respondent No.1 while passing any Order under Section 26 A of the D&C Act.

3.11 Rule 122E of the Drugs and Cosmetics Rules, 1945 defines New Drug. In terms of Rule 122E of D&C Rules, a FDC of two or move drug, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed

combination is proposed to be changed, with certain claims viz. indications dosage, dosage form and route of administration will be a New Drug. Further, in terms of the Explanation to Rule 122E, a New Drug shall continue to be consider as New Drug for a period of four years from the date of its first approval [Explanation (ii) to Rule 122E].

3.12 The Petitioner states that if is an irrefutable position on record that the Respondent No. 2 had approved the FDCs in question on 17.08.2009 and 01.10.2010; therefore by virtue of Explanation (ii) to Rule 122E, the FDCs in question cease to be a New Drug on or after 17.08.2013 and 01.11.2014. Hence, there is no requirement of obtaining approval from Respondent No. 2 treating

the two FDCs, as "New Drug" within thy meaning of Rule 122E of the D&C Rules.

3.13 Hence, even assuming without admitting that the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to new drugs, such Committee cannot consider banning existing FDCs, especially when the FDCs, in the present case, do not fall within (he definition of New Drugs, under Rule 122E of the D&C Rules, as in terms of Explanation (ii) to Rule 122E of the D&C Rules, any drug which was granted approval four years earlier by the Respondent No.2 ceases to be a new drug, within the meaning of Rule 122E of the D&C Rules.

3.14 However to the utter shock and surprise of the Petitioner, the Respondent No.1 has issued the Impugned Notifications on 08.06.2017 and has prohibited the manufacture for sale, sale and distribution for human use of the, FDC with immediate effect as in its opinion it is not rational. The said decision of Respondent No.1 is based on the recommendation of New Drugs Advisory Committee constituted by Central Government which has come to a conclusion that the FDCs in question does not have therapeutic justification and the two drugs are best administered separately on as required basis. It is evident that the Respondent No.1 while issuing the Impugned Notifications has completely ignored the mandatory consultative process as provided under Sections 5, 6 and 7 of the D&C Act in as

much as the decision of the Respondent No.1 is not based on any advice/recommendation of DTAB, DCC, etc. Further Section 26A of D&C Act, enjoins the 'Respondent No.1 to give an opportunity of hearing to stakeholders, including the manufacturers, marketers, distributors, etc. No notice, in this regard was received by the Petitioner.

3.15 In this context, it is submitted that the National Pharmaceutical Pricing Authority, a body existing under the supervision of Respondent No.1 has created an Integrated Pharmaceutical Data Base Management System (in short "IPDMS"), wherein, all the pharmaceutical companies are required to file extensive details in relation to ail drugs manufactured/ marketed by them. Hence, it is clear that

the Respondents have information about the fact that the FDCs in question are manufactured/marketed by the Petitioner. Hence, the Petitioner ought to have been heard, prior to issue of the Impugned Notifications dated 08.06.2017.

4. The Petitioner submits that the .Impugned Notifications dated 08.06.2017 are illegal and arbitrary as the purported exercise of power by the Respondent No.1 under Section 26 A of D&C Act is de-hors the statutory scheme of D&C Act and in particular the mandatory procedure prescribed under of Section 5, 6, 7. & 26A of D&C Act.

5. Feeling aggrieved, the Petitioner is filing the present Writ Petition on inter-alia following amongst other grounds:

GROUNDS

A. FOR, the Impugned Notifications dated 08.06.2017 suffer from manifest error of law, apparent on the face of record;

B. FOR, the Impugned Notifications are ex-facie illegal, arbitrary, irrational and unreasonable and is therefore violative of Article 14 of the Constitution of India;

C. FOR, the Impugned Notifications have been issued by the Respondent No.1 in contravention of Sections 5, 6, 7 and 26A of the D&C Act. This Hon'ble Court has in Pfizer Ltd. (supra) dated 01.12.2016 has held that any exercise of powers by the Respondent No. 1 under Section 26A of the D&C Act has to be preceded by consultation with the statutory bodies constituted under Sections 5, 6 and 7 of

the D&C Act viz. DTAB, Central Drugs Laboratory and DCC and any action under Section 26A of the D&C Act by the Respondent No.1 is to be based on the advice of the aforesaid statutory bodies constituted under the D&C Act. In case the Respondent No.1 acts unilaterally or does not seek advice of the aforesaid statutory bodies then any action of the Respondent No.1 under Section 26A is unsustainable and shall be struck down/set aside by the Hon'ble Court;

D. FOR, in the present case, it is manifest from the Impugned Notifications that the Respondent No.1 has not consulted or sought the advice and recommendation of the aforesaid statutory bodies while prohibiting the FDC in question and has unilaterally acted on the basis of

recommendation of New Drugs Advisory Committee, which is impermissible under the statutory regime of D&C Act and in particular Sections 5, 6, 7 and 26A thereof;

E. FOR, this Hon'ble Court in Pfizer Ltd. (supra), in identical circumstances (wherein also while issuing 344 Notifications prohibiting FDCs, the Respondent No.1 had failed to consult, seek advice and recommendation of DTAB, Central Drugs Laboratory and DCC), had struck down the Notifications on the ground that it constitutes violation of Sections 5, 6, 7 and 26A of the D&C Act.

F. FOR, Sections 5, 6 and 7 of the D&C Act are mandatory and cannot be in any

Section 5 is not only to advice on technical

manner ignored or by-passed by the Respondent No.1 Sections 5 & 7 of the D&C Act provide that the purpose of constitution of DTAB is to advice the Respondent No.1 on technical matters arising out of administration of the Act and to carry out other functions assigned to the Respondent No.1 under the D&C Act and that the purpose of constitution of the DCC is to advice the Respondent No.1 and DTAB on any matter tending to secure uniformity throughout India in the administration of the D&C Act, Thus, by its very nature Sections 5, 6 and 7 of the D&C Act which provide that the Respondent No.1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and hold consultation with DTAB and DCC, is mandatory. Moreover the functions of DTAB under

not a statutory body under the D&C Act. This has been held by this Hon'ble Court in Pfizer Ltd. (supra). Thus, the very act of the Respondent No. 1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go-by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notifications and renders it unsustainable in the eyes of law;

H. FOR, in addition to being in consonance with Sections 5, 6 and 7 of D&C Act, any action of the Respondent No.1 under Section 26A of the D&C Act, has to be preceded by giving notice and opportunity of hearing to the manufacturers of the FDC unless there is a grave urgency for which reasons should be recorded. In the present case, no such notice or

opportunity of hearing has been afforded to the Petitioner who is one of the leading marketer, of the prohibited FDCs under the brand name Zenflox-OZ Infusion and Orthokind-P 400 Tablets;

I. FOR, the FDCs in question has been approved by the Respondent No.2 and the Petitioner has been marketing the same from 01.03.2010 and 01.11.2010 under the brand names, viz, Zenflox-OZ Infusion and Orthokind-P 400 Tablets. In such circumstances, it is difficult to contemplate that there were any urgency situation warranting the exercise of powers under Section 26A of D&C Act without issuance of notice and affording an opportunity of hearing to the manufacturers including the Petitioner. Thus, the Impugned Notifications is

contrary to the principles o f natural justice;

J. FOR, even assuming without admitting that the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to new drugs such Committee cannot consider banning existing FDCs, especially when the FDCs, in, the present case, do not fall within the definition of New Drugs, under Rule 122E of the D&C Rules, as in terms of Explanation (ii) to Rule 122E of the D&C Rules, any drug which was granted approval four years earlier by the Respondent No.2, ceases to be a new drug, within the meaning of Rule 122E of the D&C Rules.

K. FOR, the fact that there was no grave urgency warranting exercise of powers under Section 26A of D&C Act is also evident from the fact that the Impugned Notifications dated 08.06.2017 itself mention that the prohibition is premised on the fact that the use of FDCs in question Is not rational as the FDCs do not have any therapeutic justification and the two drugs which are the constituents of FDC are best administered separately. The prohibition is not premised on any adverse health consequences or risk to human beings and therefore it can be safely said that there were no compelling circumstances in giving a go-by to the requirement of issuance of notice and opportunity of hearing to manufacturers before prohibiting the FDC. Thus, the Impugned Notification is violative of

Article 14 of the Constitution of India as it is arbitrary and unreasonable;

L. FOR, the Fixed Dose Combination of Ofloxacin 200 mg and Ornidazole 500 mg in Tablet Form, which is also an approved FDC has not been prohibited, however the Impugned Notification (S.O. 1852(E) prohibits the same combination in the form of Infusion/Injection, without any rational. This itself evidences a total non-application of mind on the part of the Respondent No.1 while issuing the Impugned Notifications dated 08.06.2017;

M. FOR, the Respondent No. 1 has issued the Impugned Notifications on 08.06.2017 and has prohibited the manufacture for sale, sale and distribution for human use of the FDC with immediate effect as in its

opinion it is not rational. The said decision of Respondent No.1 is based on the recommendation of New Drugs Advisory Committee constituted by Central Government which has come to a conclusion that the FDCs in question does not have therapeutic justification and the two drugs are best administered separately on as required basis. It is evident that the Respondent No.1 while issuing the Impugned Notifications has completely ignored the mandatory consultative process as provided under Sections 5, 6 and 7 of the D&C Act in as much as the decision of the Respondent No.1 is not based on any advice/recommendation of DTAB, DCC, etc. further Section 26A of D&C Act, enjoins the Respondent No.1 to give an opportunity of hearing to stakeholders,

including the manufacturers, marketers, distributors, etc. No notice, in this regard was received by the Petitioner. In this context, it is submitted that the National Pharmaceutical Pricing Authority, a body existing under the supervision of Respondent No.1 has created an Integrated Pharmaceutical Data Base Management System (in short "IPDMS"), wherein all the pharmaceutical companies are required to file extensive details in relation to ail drugs manufactured/ marketed by them. Hence, it is clear that the Respondents have information about the fact that the FDCs in question are manufactured/ marketed by the Petitioner. Hence, the Petitioner ought to have been heard, prior to issue of the Impugned Notifications dated 08.06.2017;

N. FOR, any pharmaceutical company to make available alternate drugs, minimum time-gap of six months is required considering the time consumed in preparation of new formulations, packaging preparations, approvals by the authorities under the D&C Act, etc. and also the time consumed in development, analysis, stability studies, etc. Thus, the immediate ban is drastic especially when crores of worth formulations are lying distributed in retail drug shops in the country and it is practically very difficult to withdraw the products besides the huge toss that will be caused to manufacturers. It would also result in denial of access to medicines to patients across the country and to consumers who have been using FDCs products regularly;

O. FOR, Rule 74 (b) D&C Rules clearly provides that "the licencee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may he specified in any rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the Rules, these would come into force, four months after publication in the Official Gazette" , especially when violation of the provisions of Section 26A of the D&C Act is punishable under Section 28B of the D&C Act with imprisonment and fine. Considering such scheme of the D&C Act, it is improbable that the Legislature ever intended that a ban can be imposed with immediate effect especially when the decision making process has not been notified to all the stake-holders.

Furthermore, the stocks on hand of the manufacturers can by itself expose the parties to penal actions. It is submitted that it is a statutory obligation of the Respondent No.1 specifically incorporated in the D&C Act itself that while taking a decision in imposing any prohibition/restriction under the D&C Act, the entitlements/ obligations respectively which have come into existence thereby also creating vested rights, should always be suitably provided for in any subsequent policy;

P. FOR, the Petitioner submits that the Impugned Notifications dated 08.06.2017 is in teeth of the Judgment of this Hon'ble Court in Pfizer Ltd. (supra) & Anr.. Though the Respondent No.1 has filed a Special Leave Petition before the Hon'ble Supreme

Court from the judgment, the same pending and there is no stay of the judgment of this Hon'ble Court. The Impugned Notification is therefore likely to be quashed by this Hon'ble Court;

6. The grounds urged above are without prejudice to each other and the Petitioner craves leave to add, alter, amend or modify the same if deemed necessary.

7. The Petitioner has no alternative efficacious remedy other than to invoke the extraordinary jurisdiction of this Hon'ble Court under Article 226 of the Constitution.

8. The Petitioner has not filed any other petition before this Hon'ble Court or before the Hon'ble Supreme Court on the facts and circumstances of the present case and in respect of the

Impugned Notifications which forms the subject matter of the present writ petition.

9. The Petitioner has no alternate efficacious remedy under the D&C Act in respect of the Impugned Notifications which forms the subject matter of the present writ petition.

10. That the present writ petition is filed by the Petitioner through its Authorized Signatory Mr. Prateush Mohan Sharma, who has been duly authorized vide Board Resolution dated 17.06.2016, to file the present writ petition, on its behalf.

PRAYER

In view of the aforesaid facts and circumstances, the Petitioner most respectfully prays that this Hon'ble Court may be graciously pleased to:-

(i) issue a writ of Certiorari or any other writ, order or direction in the nature of Certiorari calling for the records and quashing the Notifications bearing S.O. No.1852(E) and S.O. No.1855(E) both dated 08.06.2017 (Annexure P-1 (Colly) issued by Respondent No.1; and

(ii) award cost(s) of the present petition to the Petitioner; and

(iii) pass any other appropriate order/orders as this Hon'ble court may deem fit and proper in the facts and circumstances of the case.

PETITIONER

THROUGH

R. JAWAHAR LAL

PRA LAW OFFICES
ADVOCATE FOR THE PETITIONER

NEW DELHI
DATE: 15.06.2017

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY ORIGINAL WRIT JURISDICTION

WRIT PETITION (C) N0.5336 0F 2017

IN THE MATTER OF:

Mankind Pharma Limited ..... Petitioner

Versus

Union of India & Anr. .....Respondents

AFFIDAVIT

I, Prateush Manmohan Sharma, aged about 51 years, son of Mr. Manmohan Sharma, having office at 208, Okhla Induistrial Estate, Phase-III, Delhi do solemnly state and affirm as under

1. That I am-the Authorized Signatory of the Petitioner Company in the Writ Petition and as such well conversant with the facts of the case.

2. I have, gone through the accompanying Writ Petition and the contents thereof are true to my knowledge and belief. No part of it is false

and nothing material has been kept concealed therefrom.

3. The annexures annexed with the Writ Petition are true copies of their respective originals.

DEPONENT

VERIFICATION:

Verified at New Delhi on this15th day of June, 2017, that the contents of the foregoing affidavit are true and correct to my knowledge. No part of the affidavit is false and nothing material has been concealed therefrom.

DEPONENT

/TRUE COPY/

ANNEXURE P-3

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRA ORDINARY WRIT JURISDICTION

WRIT PETITION (C) NO.5340 OF 2017

IN THE MATTER OF:

Akums Drugs & Pharmaceuticals Ltd. ....Petitioner

Versus

Union of India & Anr. ....Respondents

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PETITIONER

THROUGH:

Sd/-

PRA LAW OFFICES
R. JAWAHAR LAL
ENR. NO. D-933/1992
ADVOCATE FOR THE PETITIONER
W-126, GROUND FLOOR
GREATER KAILASH PART-II
NEW DELHI-110 048
Ph: 011-40676767
Mob. 9958996312
e-mail: jawahar@pralaw.in

NEW DELHI
DATED: 16.06.2017

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRA ORDINARY WRIT JURISDICTION

WRIT PETITION (C) NO.5340 OF 2017

IN THE MATTER OF:

Akums Drugs & Pharmaceuticals Ltd. ....Petitioner

Versus

Union of India & Anr. ....Respondents

MEMO OF PARTIES

Akums Drugs & Pharmaceuticals Ltd.
Through Mr. Devendra Kumar Joshi
having its registered office at
304, Mohan Place
LSC, Block-C, Saraswati Vihar
New Delhi 110 034 ... Petitioner

Versus

1. Union of India
through Secretary
Department of Health and
Family Welfare Ministry
of Health and Family Welfare

Nirman Bhawan,
New Delhi-110 001

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

PETITIONER

THROUGH:

Sd/-
PRA LAW OFFICES
R. JAWAHAR LAL
ENR. NO. D-933/1992
ADVOCATE FOR THE PETITIONER
W-126, GREATER KAILASH PART-II
NEW DELHI-110 048
Ph: 011-40676767
Mob. 9958996312

NEW DELHI
DATED: 16.06.2017

SYNOPSIS

The Petitioner is invoking the extraordinary writ jurisdiction of this Hon'ble Court under Article 226 of the Constitution of India challenging Notification S.O. No. 1852 (E) dated 08.06.2017, whereby the Respondent No.1, in purported exercise of its powers under Section 26A of the Drugs and Cosmetics Act, 1940 ("D&C Act") prohibited the manufacture for sale, sale and distribution for human use of the fixed dose combination (drug with more than one active ingredient, in short refer reel to as "FDC") of Ofloxacin Ornidazole injection, with immediate effect on the purported ground that the same there is no rational or therapeutic justification. The decision to prohibit manufacture for sale,

sale and distribution of the FDC by the Impugned Notifications is based on the recommendation of the New Drugs Advisory Committee constituted by Respondent No.1. The Petitioner submits that the New Advisory Committee is not a statutory body, contemplated under the 'D&C Act. The Petitioner submits that the Impugned Notifications dated 08.06.2017 is ex-facie illegal, arbitrary and irrational and is therefore likely to be quashed by this Hon'ble Court as:

1. The Impugned Notification has been issued by the Respondent No.1 in contravention of Sections 5, 6, 7 and 26A of the D&C Act, inasmuch exercise of powers under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers of the concerned FDCs

and ought, to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act viz. Drugs Technical Advisory Board, Central Drugs Laboratory and Drugs Consultative Committee. In this context, it is respectfully submitted that on 10.03.2016, the Respondent No. had issued 344 Notifications, the Hon'ble Court in its Judgment, (in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) dated 01.12.2016, held that any exercise of powers by the Respondent No. 1 under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act.

In the present case also, prior to issue of the Impugned Notification, the Respondent No.1 did not consult the manufacturers or sought the advice and recommendation of the aforesaid statutory bodies. The Respondent No.1 had acted unilaterally on the basis of recommendation of New Drugs Advisory Committee (a non-statutory Committee appointed by the Respondent No.1), which is impermissible under the statutory regime of D&C Act and in particular Sections 5, 6, 7 and 26A thereof.

2. In the present case, the FDC was approved by the Respondent No. 2 on 17.08.2009; therefore by virtue of Explanation (ii) to Rule 122E they cease to be a New Drug by 17.08.2013 (i.e. upon expiry of 4 years from the date of

approval by DOGI (Respondent No. 2). therefore, even assuming without admitting' that the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to "new drugs" (as defined in Rule 122 E of the D&C Rules), such Committee cannot consider ban of existing FDC, especially when the EDC, in the present case, ceased to be New Drug, as defined in Rule 122E of the D&C Rules (per Explanation (ii) to Rule 122E of the D&C Rules). Also the Petitioner was granted approval to manufacture the FDC in form 46 by the Respondent No.2 on 24.11.2009 under Rule 122B (2A) of the Drugs and Cosmetics Rules, 1945.

3. The Petitioner respectfully submits that Sections 5, 6 and 7 of the D&C Act arc

mandatory in nature and cannot be in any manner ignored or by passed by the Respondent No.1, as held by this Hon'ble Court in Pfizer Limited. The purpose of constitution of Drugs Technical Advisory Board is to advice (he Respondent No. 1 on technical matters arising out of administration of the Act and to carry out other functions assigned to the Respondent No. 1 under the D&C Act and the purpose of constitution of the Drugs Consultative Committee is to advice the Respondent No. 1 and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C Act provide that the Respondent No. 1 in exercise of powers, technical or otherwise is enjoined to obtain advice

from and hold consultation with Drugs Technical Advisory Board and Drugs Consultative Committee. Moreover the functions of Drugs Technical Advisory Board under Section 5 of the D&C Act, is not only to advice on technical matters but also to carry out "other functions assigned" to the Respondent. No. 1 under the D&C Act.

4. Indisputably, the New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act, as the D&C Act does not provide for constitution of such a Committee. The New Drugs Advisory Committee is a committee functioning under the Central Drugs Standard Control Organization (in short "CDSCO"), which itself is not. a statutory body under the D&C Act. Thus,

the very act of the Respondent No. 1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notification and renders it unsustainable in the eyes of law, as the Respondent No. 1 in exercise of powers vested under the D&C Act, cannot take away the statutory powers vested in DTAB, DCC and vest them in a Committee unilaterally formed by the Respondent No.1.

5. In addition, for any action under Section 26A of the D&C Act, has to be preceded by hearing all stake holders (manufacturers etc.), unless there is grave urgency, for which reasons should be recorded, as held by this Hon'ble Court

in Pfizer Judgment, it is submitted that prior to issue of the impugned "Notifications, no such notice or opportunity of hearing was afforded to the Petitioner, who .manufactures the FDC in question.

6. The Petitioner submits that the fact that there was no grave urgency warranting exercise of powers under-Section 26A of D&C Act is evident from the fact that the Impugned Notifications themselves mention that the prohibition is premised on the fact that the use of FDC in question is .not rational as the FDC does not have any therapeutic justification and the two drugs which are the constituents of FDC are best administered separately. The prohibition is not premised on any adverse health consequences or risk to human

beings and therefore it can be safely said that there were no compelling circumstances in giving a go by to the requirement of issuance of notice and opportunity of hearing to manufacturers before prohibiting the FDC. Thus, the Impugned 'Notification dated 08.06.2017 is violative of Article 14 of the Constitution of India as it is arbitrary and unreasonable and violative of principles of natural justice.

7. It is pertinent to mention here that the said FDC has been approved by the Respondent No.2, Drug Controller General of India on 17.08,2009 and the Petitioner has been manufacturing the same after seeking approval from the Respondent No, 2 on 24,11.2009 and State Licencing Authority, Uttarakhand dated 20.02.2010.

After having approved the FDC, there is no justification whatsoever to ban the FDC, that too without following the mandatory procedure specified under the D&C Act.

LIST OF DATES & EVENTS

17.08.2009	The Respondent No.2 approved the FDC Ofloxacin 2 mg per ml+ Ornidazole 5 mg per ml Infusion
24.11.2009	The Petitioner was granted approval to manufacture the FDC in Form 46 by the Respondent. No. 2 under Rule 122B (2A) of Drugs and Cosmetics Rules, 1945
20.02.2010	The Petitioner was also granted licence to manufacture the FDC in

question by the State Licencing Authority, Uttarakhand and it has been manufacturing the FDC

10.03.2016 The Respondent No.1 issued 344 Notifications prohibiting manufacture for sale, sale and distribution of FDCs

01.12.2016 This Hon'ble Court vide Judgment in Pfizer Ltd. & Anr, Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) quashed the 344 Notifications on the ground that the Respondent No. 1 while issuing the notifications has acted in contravention of the statutory regime under D&C Act, including Section 5,6,7 & 26A thereof

08.06.2017	The Respondent No. 1 has issued the Impugned Notifications 8.0. No. 1852 (E) prohibiting manufacture for sale, sale and distribution of the two FDC, Ofloxacin + Ornidazole injection
16.06.2017	Hence the present Writ Petition

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRA ORDINARY WRIT JURISDICTION

WRIT PETITION (C) NO.5340 OF 2017

IN THE MATTER OF:

Akums Drugs & Pharmaceuticals Ltd.
A company existing under the companies Act, 2013
having its registered office at
304, Mohan Place
LSC, Block-C, Saraswati Vihar
New Delhi 110 034
Through its Authorised signature
Mr. Devendra Kumar Joshi ... Petitioner

Versus

1. Union of India
through Secretary
Department of Health and
Family Welfare Ministry
of Health and Family Welfare
Nirman Bhawan,

New Delhi-110 001

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

AND IN THE MATTER OR

WRIT PETITION UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA, 1950 SEEKING A WRIT OF CERTIORARI OR ANY OTHER WRIT, ORDER OR DIRECTION IN THE NATURE OF CERTIORARI CATLING FOR THE RECORDS AND QUASHING NOTIFICATION BEARING S.O. NO. 1852 (E) DATED 08.06.2017 (ANNEXURE P-1) ISSUED BY RESPONDENT NO.1, IN PURPORTED EXERCISE OF POWERS UNDER SECTION 26A OF THE DRUGS AND

COSMETICS ACT, 1940; IMPUGNED NOTIFICATION ARE ARBITRARY, ILLEGAL AND IRRATIONAL AND ISSUED IN VIOLATION OF SECTIONS 5, 6, 7 AND 26A OF THE DRUGS AND COSMETICS ACT, 1940

To

THE HON'BLE ACTING CHIEF JUSTICE AND HER COMPANION JUSTICES OF THE HON'BLE HIGH COURT OF DELHI AT NEW DELHI

THE HUMBLE PETITION OF THE PETITIONER NAMED ABOVE

MOST RESPECTFULLY SHOWETH:

1. The Petitioner is invoking the extraordinary writ jurisdiction of this Hon'ble Court under Article 226 of the Constitution of India challenging Notification S.O. No. 1852, (E)

dated 08.06.2017 (in short the "Impugned Notification"), whereby the Respondent No.1, in purported exercise of its powers under Section 26A. of the Drugs and Cosmetics Act, 1940 (in short the "D&C Act") prohibited the manufacture for sale, sale and distribution for human use of the fixed dose combination (drug with more than one active ingredient, in short referred to as "FDC") of Ofloxacin + Ornidazole Injection with immediate effect, on the purported ground that there is no rational or therapeutic justification for the two FDCs. The decision to prohibit manufacture for stile, sale and distribution of the FDC by the Impugned Notification is based on the recommendation of the New Drugs Advisory Committee constituted by Respondent No.1. In this context, it is relevant to submit that the New Advisory Committee is not a statutory body, contemplated under the D&C Act. True typed

copy of the Notification S.O. Nos. 1852 (E) dated 08.06.2017 issued by the Respondent No. 1 are annexed and marked as Annex tire P-1.

2. The Petitioner submits that the Impugned Notification dated 08.06.2017 is ex-facie. illegal, arbitrary and irrational and is therefore likely to be quashed by this Hon'ble Court as:

2.1 The impugned Notification has been issued by the Respondent No.1 in contravention of Sections 5, 6, 7 and 26 A of the D&C Act, inasmuch exercise of powers under Section 26 A of the D&C Act has to be preceded by consultation with the manufacturers of the concerned FDCs and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act viz.

Drugs Technical Advisory Board, Central Drugs Laboratory and Drugs Consultative. Committee. In this context, it is respectfully submitted that on 10.03.2016, the Respondent No.1 had issued 344 Notifications, banning a large number of FDC. While considering the challenge to 344 Notifications, the Hon'ble Court in its Judgment (in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions Filed by the Petitioner herein) dated 01.12.2016, held that any exercise of powers by the Respondent No.1 under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act. in the present ease also, prior to issue of

the Impugned Notification, the Respondent No.1 did not consult the manufacturers or sought the advice and recommendation of the aforesaid statutory bodies. The Respondent No.1 had acted unilaterally on the basis of recommendation of New Drugs Advisory Conun.itt.ee (a non-statutory Committee appointed by the Respondent No.1), which is impermissible under the statutory regime of D&C Act and in particular Sections 5, 6, 7 and 26A thereof.

2.2 In the present, case, the FDC was approved by the Respondent No.2 on 17.08.2009; therefore by virtue of Explanation (ii) to Rule 122E, they cease to be a New Drug by 17.08.2013 (i.e. upon expiry of 4 years from the date of approval by DCGI (Respondent No. 2).

Therefore, even assuming without admitting that the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to "new drugs" (as defined in Rule 122 E of the D&C Rules), such Committee cannot consider ban of existing FDC, especially when the FDC, in the present case, ceased to be New Drug, as defined in Rule 122E of the D&C Rules (per Explanation (ii) to Rule I22E of the D&C Rules). Also the Petitioner was granted approval to manufacture the FDC in Form 46 by the Respondent No. 2 on 24.11,2009 under Rule 122B (2A) of the Drugs and Cosmetics Rules, 1945.

2.3 The Petitioner respectfully submits that Sections 5, 6 and 7 of the D&C Act are mandatory in nature and cannot be in any

manner ignored or by passed by the Respondent No. 1, as held by this Hon'ble Court in Pfizer Limited. The purpose of constitution of Drugs Technical Advisory Board is to advice the Respondent No. 1 on technical matters arising out of administration of the Act and to carry out other functions assigned to the Respondent No. 1 under the D&C Act and the purpose of constitution of the Drugs Consultative Committee is to advice the Respondent No. 1 and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C Act provide that the Respondent. No.1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and hold consultation with Drugs

Technical Advisory Board and Drugs Consultative Committee. Moreover the functions of Drugs Technical Advisory Board under Section 5 of the D&C Act, is not only to advice on technical matters but also to carry out "other functions assigned" to the Respondent No.1 under the D&C Act.

2.4 Indisputably, the New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act, as the D&C Act. does not provide for constitution of such a Committee. The New Drugs Advisory Committee is a committee, functioning under the Central Drugs Standard Control Organization (in short "CDSCO") which itself is not a statutory body under the D&C Act. Thus, the very act of the Respondent No. 1 in

acting on the purported recommendation of New Drugs Advisory Committee and giving a go-by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notification and renders it unsustainable in the eyes of law, as the Respondent No.1 in exercise of powers vested under the D&C Act, cannot take away the statutory powers vested in DTAB, DCC and vest them in a Committee unilaterally formed by the Respondent No.1.

2.5 in addition, for any action under Section 26A of the D&C Act, has to be preceded by hearing all stake holders (manufacturers etc.), unless there is grave urgency, for which reasons should be recorded, as held by this Hon'ble Court in Pfizer Judgment. It is submitted that

prior to issue of the Impugned Notifications, no such notice or opportunity of hearing was afforded to the Petitioner, who manufactures the FDC in question.

2.6 The Petitioner submits that the fact that there was no grave urgency warranting exercise of powers under Section 26 A of D&C Act is evident from the fact that the Impugned Notifications themselves mention that the prohibition is premised on the fact that the use of FDC in question is not rational as the FDC does not have any therapeutic justification and the two drugs which are the constituents of FDC are best administered separately. The prohibition is not premised on any adverse health consequences or risk, to human beings and therefore it can be safely said

that there were no compelling circumstances in giving a go-by to the requirement of issuance of notice and opportunity of hearing to manufacturers before prohibiting the FDC. Thus, the Impugned Notification dated 08.06.2017 is violative of Article 14 of the Constitution of India as it is arbitrary and unreasonable and violative of principles of natural justice.

2.7 It is pertinent to mention here that the said FDC has been approved by the Respondent No.2, Drug Controller General of India on 17.08.2009 and the Petitioner has been manufacturing the same after seeking approval from the Respondent No. 2 on 24,11,2009 and State Licencing Authority, Uttarakhand dated 20.02.2010, Alter having approved the FDC, there is no

justification whatsoever to ban the FDC, that too without following the mandatory procedure specified under the D&C Act.

3. The brief facts giving ri.se to the filing of the present Writ Petition before this Hon'ble Court are as under:

3.1 The Petitioner is a pharmaceutical company of repute and is the largest contract manufacturer of pharmaceutical formulations in India. The Petitioner manufactures a wide range of pharma products including Anti-Diabetic, Antibiotics, Anti fungal, NSAIDs, Gastrointestinal, Anthelmintic, Cardiovascular, Dermal, and several other categories of pharma products. The Petitioner is also engaged in formulation developments, technological innovations

conducting stability studies and arranging bio-ecjui valence studies and clinical trials. The Petitioner aspires to aid the community in leading a healthy life through two parallel objectives: formulating, developing and commercializing medicines, and delivering affordable and accessible medication that satisfies urgent medical needs. The Petitioner Company has been manufacturing pharmaceutical products for big Indian and Multinational Pharma Companies.

3.2 The Petitioner Company is having sophisticated Research & Development, and Formulation Development Centres. The Petitioner's Laboratory is fully equipped for Physical and metallurgical testing, Micro-biological testing, Effective

controls of process, Chemical testing, Pharmacological testing, Stability Studies etc. The Petitioner Company has nine plants in Hand war in its own name and in the name of its subsidiaries Pure & Cure Healthcare Pvt. Ltd., Malik Life sciences Pvt. Ltd. & Maxcure Nutravedics Ltd.

3.3 fixed Dose Combinations (FDC) refer to products containing two or more active ingredients used for particular indication(s). This term is used generically to mean a particular combination of actives irrespective of the formulation or brand, it may be administered as single entity products given concurrently or as a finished pharmaceutical product. The development of FDCs is becoming increasingly important from a public health perspective. The basic rationale of

making "fixed dose combination" medicinal products is either to improve adherence or to benefit from the added effects of the two medicinal products given together. FDCs have shown to be particularly useful in the treatment of diseases like HIV, malaria and tuberculosis and also in cardiology, diabetes and cancer conditions, based on international guidelines recommended by expert bodies, where giving multiple drugs for the management of a given condition is an accepted medical norm and practice. FDCs are also of use in chronic conditions especially when multiple disorders often co-exist. FDCs are known to offer specific advantages over the single entity preparations, such as increased efficacy, and/or better patient compliance dosage, possibly reduced cost and simpler logistics

of distribution relevant to situations of limited resources.

3.4 Amongst: of her pharmaceutical products, the Petitioner manufactures for sale a fixed Dose Combination of Ofloxacin 2 mg per ml and Ornidazole 5 mg per ml in fusion. The said FDC is manufactured by The Petitioner in its capacity as a contract manufacturer for various other pharmaceutical companies.

3.5 The Impugned Notification dated 08.06.2017 prohibit manufacture for sale, sale and distribution of FDC in question arid therefore the Petitioner is a person aggrieved and has the locus to file the Writ Petition. The Petitioner states that has been approved by the Respondent No.2 viz. Drug Controller General of India

on 17.08.2009. Infact the fixed Dose Combination of Ofloxacin 200 mg and Ornidazole 500 mg in Tablet Form, which is also an approved FDC has not been prohibited, however the Impugned Notification prohibits the same combination in the form of infusion/injection, without any rational. This itself evidences a total non-application of mind on the part of the Respondent. No.1 while issuing the impugned Notifications, True copy of the relevant extract of the list of approved FDC by the Respondent No. 2 is annexed as Annexure P-2.

3.6 The Petitioner had applied with the Respondent No. 2 for grant of approval to manufacture the FDC and the Petitioner was granted approval to manufacture the

FDC in Form 46 by the Respondent No. 2 on 24.11.2009 under Rule 122B (2A) of the Drugs and Cosmetics Rules, 1945. True typed copy of the approval dated 24.11.2009 granted by the Respondent No. 2 in respect of the FDC is annexed herewith and marked as Annexure P-3.

3.7 The Petitioner was also granted licence to manufacture the FDC in question by the State Licencing Authority, Uttarakhand dated 20.02.2010 and it has been manufacturing the same from the year 2010 onwards. The said licence has been renewed from time to time and the copy of the valid and subsisting licence dated 22.05.2013 issue by the Drug Licencing and Controlling Authority, Uttarakhand is annexed herewith and marked as Annexure P-4.

3.8 The FDC in question, viz. Ofloxacin + Ornidazole Injection is used for effective treatment of diarrhea of mixed infection, is also pertinent to state here that the FDC in question are marketed in several countries. It is submitted that the strength of each composition used in making the FDC, ensures that the said FDC is safe for consumption and is beneficial to the patients to which it is administered. In fact, large amount, of material is available in public domain, including but not limited to medical rationale of FDC in question, which goes to show that the said FDC has enormous amount of therapeutic justifical ion and relevance. True copy of evidence in the form of rationale for Ofloxacin + Ornidazole is annexed herewith and marked as Annexure P-5.

3.9 The Petitioner states that the referenced FDC has been prescribed by doctors to patients of effective treatment, of diarrhea of mixed infection and patients are benefitting from the same. There has been no Adverse Drug Reaction reported to the Petitioner or any serious complaints received by the Petitioner to raise a concern with regard to the safety and efficacy of the said FDC.

3.10 In this context, it is stated that Section 5 of D&C Act mandates the Central Government to constitute the Drugs Technical Advisory Board (in short "DTAB") consisting of expert members to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions

assigneed to it under D&C Act. The term of office of the nominated and elected members of DTAB has also been prescribed as three years or for so long as they hold the appointment of the office by virtue of which they are nominated or elected. DTAB, vide Section 5 (4) has been authorized to frame its bye-laws Fixing a quorum and regulating its own procedure and the conduct of all business and vide Section 5 (5) to constitute sub-committees for consideration of particular matters. The Central Government has been mandated by Section 5 (7) to appoint a person to be the Secretary of DTAB and to provide DTAB with clerical and other staff necessary.

3.11 Section 6 of D&C Act mandates the Central Government to establish a Central

Drugs Laboratory (CLS) under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by the Act or by any Rules made thereunder. Section 6 empowers the Central Government to "after consultation with" DTAB make Rules prescribing the functions of the Central Drug: Laboratory and the procedure for analysis or tests of the drugs and for such other matters as may be necessary.

3.12 Section 7 mandates the Central Government to constitute an Advisory Committee to be called the Drugs Consultative Committee (in short "DCC"), to advise the Central Government, the State Governments and DTAB on any other matter lending to secure uniformity throughout India in the administration of

D&C Act. The DCC has been prescribed to consist of two representatives nominated by the Central Government and one representative nominated by each of the State Governments.

3.13 The Petitioner states that under Section 26 A of the D&C Act, the Respondent No.1 is vested with the powers to regulate, restrict or prohibit manufacture, sale or distribution of a drug or cosmetic which is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do.

3.14 However, the Respondent No.1 can exercise its powers tinder Section 26A of the D&C Act only after consultation and on the advice/recommeudation of DTAB, DCC etc. under Section 5, 6 and 7 of the D&C Act. This Hon'ble Court in Pfizer Ltd. (supra) had held that the provisions of Sections 5, 6 and 7 of the D&C Act are mandatory and cannot be given a go-by by the Respondent No.1 while passing any Order under Section 26 A of the D&C Act.

3.15 Rule 122E of the Drugs and Cosmetics Rules, 1945 defines New Drug. In terms of Rule 122E, of D&C Rules, a FDC of two or more drug, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed

combination is proposed to be changed, with certain claims viz. indications dosage, dosage form and route of administration will be a New Drug. Further, in terms of the Explanation to Rule 122E, a New Drug shall continue to be consider as New Drug for a period of four years from the date of its first approval [Explanation (ii) to Rule 122E].

3.16 The Petitioner states that it is an irrefutable position on record that the Respondent No.2 had approved the FDC in question on 17.08.2009; therefore by virtue of Explanation (ii) to Rule 122E, the FDCs in question cease to be a New Drug on or after 17.08.2013. Hence, there is no requirement of obtaining approval from Respondent No.2 dealing the two FDCB, as "New Drug" within the meaning of Rule

122E of the D&C Rules on or after 17.08.2013.

3.17 Hence, even assuming without admitting that, the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to new drugs, such Committee cannot, consider banning existing FDCs, especially when the FDCs, in the present case, do not fall within the definition of New Drugs, under Rule 122E of the D&C Rules, as the terms of Explanation (ii) to Rule 122E of the D&C Rules, any drug which was granted approval four years earlier by the Respondent No.2, ceases to be a new drug, within the meaning of Rule 122 E of the D&C Rules.

3.18 However to the utter shock and surprise of the Petitioner, the Respondent No.1 has issued the Impugned Notification on 08.06.2017 and has prohibited the manufacture for sale, sale and distribution for human use of the FDC with immediate effect as in its opinion it is not rational. The said decision of Respondent No.1 is based on the recommendation of New Drugs Advisory Committee constituted by Central Government, which has come to a conclusion that the FDCs in question does not have therapeutic justification and the two drugs are best administered separately on as required basis. It is evident that the Respondent No.1 while issuing the Impugned Notifications has completely ignored the mandatory consultative process as provided under Sections 5, 6 and 7 of the D&C Act

inasmuch as the decision of the Respondent. No.1 is not based on any advice/recommendation of DTAB, DCC, etc. Further Section 26A of D&C Act, enjoins the Respondent No.1 to give an opportunity of hearing to stakeholders, including the manufacturers, marketers, distributors, etc. No notice, in this regard was received by the Petitioner.

3.18 In this context, it is submitted that the National Pharmaceutical Pricing Authority, a body existing under the supervision of Respondent No.1, has created an Integrated Pharmaceutical Data Base Management System (in short "IPDMS"), wherein alt the pharmaceutical companies are required to file extensive details in relation to all drugs manufactured/marketed by them. Hence,

it is clear that the Respondents have information about the fact that the FDC in question is manufactured by the Petitioner. Also, the Respondent No.2 had granted approval to manufacture the FDC in Form 46 on 24.11.2009 under Rule 122B (2A) of the Drugs and Cosmetics Rules, 1945. Hence, the Petitioner ought to have been heard, prior to issue of the Impugned Notification dated 08.06.2017.

4. The Petitioner submits that the Impugned Notification dated 08.06.2017 are illegal and arbitrary as the purported exercise of power by the Respondent No. 1 under Section 26A of D&C Act is de hors the statutory scheme of D&C Act and in particular the mandatory procedure prescribed under of Section 5, 6, 7 & 26A of D&C Act.

5. Feeling aggrieved, the Petitioner is filing the present Writ Petition on inter-alia following amongst other grounds:

GROUNDS

A. FOR, the Impugned Notification dated 08.06.2017 suffer from manifest error of law apparent on the face of record;

B. FOR, the Impugned Notifications are ex-facie illegal, arbitrary, irrational and unreasonable and is therefore violative of Article 14 of the Constitution of India;

C. FOR, the Impugned Notification has been issued by the Respondent No.1 in contravention of Sections 5, 6, 7 and 26 A of the D&C Act. This Hon'ble Court has in Pfizer Ltd. (supra) dated 01.12.2016 has held that any exercise of powers by the

Respondent No.1 under Section 26A of the D&C Act has to be preceded by consultation with the statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act viz. DTAB, Central Drugs Laboratory and DCC and any action under Section 26A of the D&C Act by the Respondent No.1 is to be based on the advice of the aforesaid statutory bodies constituted under the D&C Act. The case the Respondent No.1 acts unilaterally or does not seek advice of the aforesaid statutory bodies then any action of the Respondent No.1 under Section 26A is unsustainable and shall be struck down/set aside by the Hon'ble Court;

D. FOR, in the present case, it. is manifest from the Impugned Notifications that the Respondent No.1 has not consulted or

sought the advice and recommendation of the aforesaid statutory bodies while prohibiting the FDC in question and has unilaterally acted on the basis of recommendation of New Drugs Advisory Committee, which is impermissible under the statutory regime of D&C Act in particular Sections 5, 6, 7 and 26A thereof;

E. FOR, this Hon'ble Court in Pfizer Ltd. (supra), in identical circumstances (wherein also while issuing 344 Notifications prohibiting FDCs, the Respondent. No. 1 had failed to consult, seek advice and recommendation of DTAB, Central Drugs Laboratory and DCC), had struck down the Notifications on the ground that it constitutes violation

of Sections 5, 6, 7 and 26A of the D&C Act.

F. FOR, Sections 5, 6 and 7 of the D&C Act are mandatory and cannot be in any manner ignored or by passed by the Respondent No.1 Sections 5 & 7 of the D&C Act provide that the purpose of constitution of DTAB is to advice the Respondent No.1 on technical matters arising out of administration of the Act and to carry out other functions assigned to the Respondent No.1 under the D&C. Act and that the purpose of constitution of the DCC is to advice the Respondent No. 1 and DTAB on any matter tending to secure uniformity throughout India in the administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C Act which provide that the

Respondent No.1 in exercise of powers, technical nr otherwise is enjoined to obtain advice from and hold consultation with DTAB and DCC, it mandatory. Moreover the functions of DTAB under Section 5 is not only to advice on technical matters but also to carry out "other functions assigned" to the Respondent No.1 under the D&C Act. If the Respondent No.1 of its own was found fit to exercise the functions under the D&C Act including of a technical nature and have the wherewithal therefore, there was no need for constituting the DTAB and DCC;

G. FOR, the Petitioner submits that New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act. The D&C Act does not

contemplate creation of the New Drugs Advisory Committee and thus it is not a statutory body under the D&C Act. The New Drugs Advisory Committee is a body functioning under CDSCO which is itself not a Act. This has been held by this Hon'ble Court in Pfizer Ltd. (supra). Thus, the very act of the Respondent No.1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go-by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notifications and renders it unsustainable in the eyes of law;

H. FOR, in addition to being in consonance with Sections 5, 6 and 7 of D&C Act, my action of the Respondent No.1 under Section 26A of the D&C Act, has to be preceded by giving notice and opportunity

of hearing to the manufacturers of the FDC unless there is a grave urgency for which reasons should be recorded. In the present ease, no such notice or opportunity of hearing has been afforded to the Petitioner who is one of the lending manufacturer of the prohibited FDC;

I. FOR, the FDCs in question has been approved by the Respondent No.2 on 17.08.2009. Further, the Petitioner had applied with the Respondent No.2 for grant of approval to manufacture the FDC and the Petitioner was granted approval to manufacture the FDC in Form 46 by the Respondent No.2 on 24.11.2009 under Rule 122B (2A) of the Drugs and Cosmetics Rules, 1945. The Petitioner was also granted licence to manufacture the FDC in question by the State Licencing

Authority, Uttarakhand dated 20.02.2010 and it has been manufacturing the same from the year 2010 onwards. The said licence has been renewed from time to time. In such circumstances, it is difficult to contemplate that there were any urgency situation warranting the exercise of powers under Section 26A of D&C Act without issuance of notice and affording an opportunity of hearing to the manufacturer including the Petitioner. Thus, the Impugned Notifications is contrary to the principles of natural justice;

J. FOR, even assuming without admitting that the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to new drugs, such committee cannot

consider banning existing FDCs, especially when the FDCs, in the present case, do not fall within the definition of New Drugs, under Rule 122E of the D&C Rules, as the terms of Explanation (ii) to Rule 122E of the D&C Rules, any drug which was granted approval four years earlier by the Respondent No.2, ceases to be a new drug, within the meaning of Rule 122 E of the D&C Rules.

k. FOR, the fact that there was no grave urgency warranting exercise of powers under section 26A of D&C Act is also from the fact that the Impugned Notification dated 8.6.2017 itself mention that the prohibition is premised on the fact that the use of FDCs in question is not rational as the FDCs do not have any therapeutic justification and the two drugs which are

the constituents of FDC are best administrated separately. The prohibition is not premised on any adverse health consequences or risk to human beings and therefore it can be safely that there were no compelling circumstances in giving a goby to the requirements of issuance of notice and opportunity of hearing to manufacturers before prohibiting the FDC, thus, the Impugned Notification is violative of Article 14 of the Constitution of India is arbitrary and unreasonable;

L. FOR, THE fixed Dose combination of Ofloxacin 200 mg and Ornidazole 500 mg in Tablet, form, which is also an approved FDC has not been prohibited, however the Impugned Notification prohibits the same combination in the form of

infusion/injections, without any rational. This itself evidences a total non-application of mind on the part of the respondent nO.1 while issuing the Impugned Notification dated 08.06.2017.

M. FOR, the respondent No.1 has issued the Impugned Notification on 08.06.2017 and has prohibited the manufacture for sale, sale and distribution for human use of the FDC with immediate effect as in its opinion it is not rational. The said decision of Respondent No.1 is based on the recommendation of New Drugs Advisory committee constituted by Central Government which has come to a conclusion that the FDCs in question does not have therapeutic justification and the two drugs are best administrated separately on as required basis. It is

evident that the Respondent No.1while issuing the Impugned Notification has completely ignored the mandatory consultative process as provided under section 5,6 and 7 of the D&C Act inasmuch as the decision of the Respondent NO.1 is not based on any advice/recommendation of DTAB, DCC, etc. Further Section 26A of D & C Act, enjoing the Respondent NO.1 to give an opportunity of hearing to stakeholders including the manufacturers, marketers, distributiors, etc. no notice, in this regard was received by the Petitioner. In this context, it is submitted that the National Pharmaceutical Pricing Authority, a body exisiting under the supervision of Respondent No.1 has created and Integrted Pharmaceuticals Data Base Management system (in short "IPDMS")

wherein all the pharmaceuticals companies are required to file extensive details in relation to all drugs manufactured/marketed by them. Also, the respondent NO.2 had granted approval to manufacture the FDC in Form 46 on 24.11.2009 under Rule 122B (2A) of the Drugs and Cosmetics rules, 1945. Hence, it is clear that the respondents have Information about the fact that the FDCs in question are manufactured/ marketed by the Petitioner. Hence, the Petitioner ought to have been heard, prior to issue of the Impugned Notifications dated 08.06.2017;

N. FOR, any pharmaceutical company to make available alternate drugs, minimum time gap of six months is required considering the time consumed in

preparation of new formulations, packaging preparations, approval by the authorities under the D&C Act, etc. and also the time consumed in development, analysis, stability studies etc. thus, the immediate ban is drastic especially when crores of worth formulations are lying distributed in retail drug shops in the country and it is practically very difficult to withdraw the products besides the huge loss that will be caused to manufacturers. It would also result in denial of access to medicines to patients across the country and to consumers who have been using FDCs Products regularly;

O. FOR, Rule 74 (b) D&C Rules clearly provides that "the licencee shall comply with the provisions of the Act and of these rules and with such further requirements,

if any, as may be specified in any rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the rules, these would come into force four months after publication in the "Official Gazette" especially when violation of provisions of section 26A of the D&C act is punishable under section 28B of the D&C act with imprisonment and fine. Considering such scheme of the D&C Act, it is imporable that the Legislature ever intended that a ban can be imposed with immediate effect especially when the decision making process has not been notified to all the stake-holders. Further more, the stocks on hand of the manufacturers can by itself expose the parties to penal actions. It is submitted that it is a statutory obligation of the Respondent No.1 specifically

incorporated in the D&C act itself that while taking a decision in imposing any prohibition/ restriction under the D&C act, the entitlements/obligations respectively which have come into existence thereby also creating vested rights, should always be suitably provided for in any subsequent policy;

P. For, the petitioner company is having huge inventory of the product which becomes a waste immediately after the Impugned Notification as petitioner is a contract manufacturer and is manufacturing several brands under the said composition. Customers and trade associations, retailers and distributions have been writing to petitioner for returning the products and also not lifting the finished products. The manufacturer

and further distributors and stockiest have paid excise and sales tax on the products. Under the circumstances it is bound to happen that there will be shortage of medicine due of this ban and stock lying in the market will become unless and public at large will suffer owing to the lack of the medicines in the market. The petitioner will also lose business.

Q. FOR, the petitioner submits that the Impugned Notifications dated 08.06.2017 is in teeth of the Judgment of this Hon'ble Court in Pfizer Ltd. (Supra)& Anr. Through the Respondent No.1 has filed a special Leave Petition before the Hon'ble Supreme Court from the judgment, the same pending and there is no stay of the judgment of this Hon'ble court. The

impugned Notification is therefore likely to be quashed by this Hon'ble Court;

6. the grounds urged above are without prejudice to each other and the petitioner craves leave to add, alter, amend or modify the same if deemed necessary.

7. The Petitioner has no alternative efficacious remedy other than to invoke the extraordinary jurisdiction of this Hon'ble Court under Article 226 of the Constitution.

8. The Petitioner has not filed any other petition before this Hon'ble Court of before the Hon'ble Supreme Court on the facts and circumstances of the present case and in respect of the Impugned Notifications which forms the subject matter of the present writ petition.

9. The petitioner has no alternate efficacious remedy under the D&C Act in respect of the Impugned Notifications which forms the subject matter of the present writ petition.

10. That the present writ petition is filed by the petitioner through its Authorized signatory Mr. Devendera Kumar Joshi, who has been duly authorized vide Board Resolution dated 26.03.2017, to file the present writ petition, on its behalf.

PRAYER

In view of the aforesaid facts and circumstances, the petitioner most respectfully prays that this Hon'ble Court may be graciously pleased to:-

(a) Issue a writ of Certiorari or any other writ, order or direction in the natures of Certiorari calling for the records and quashing the Notifications bearing S.O.

No. 1852 (E) dated 08.06.2017 (Annexure P-1) issued by Respondent NO.1; and

(b) award cost (s) of the present petition to the Petitioner; and

PRA LAW OFFICES
R. JAWAHAR LAL
ADVOCATE FOR THE PETITIONER
ENR. NO. D-933/1992

PLACE: NEW DELHI
DATE: 15.06.2017

/TRUE COPY/

ANNEXURE-P-4

IN THE HON'BLE HIGH COURT OF DELHI AT

NEW DELHI

(EXTRAORDINARY ORIGINAL CIVIL JURISDICTION)

WRIT PETITION (CIVIL) NO.5345 OF 2017

MEMO OF PARTIES

1. J.B. CHEMICALS & PHARMACEUTICALS LIMITED HAVING ITS REGISTERED OFFICE AT NEELAM CENTRE, 4TH FLOOR,
B WING, HIND CYCLE ROAD,
WORLI, MUMBAI - 400 030

AND ITS CORPORATE OFFICE AT:
CNERGY IT PARK, UNIT A2, 3RD FLOOR,
UNIT A, 8TH FLOOR,
APPA SAHEB MARATHE MARG,
PRABHADEVI, MUMBAI 400 025 ...PETITIONER NO.1

2. MS. RITU YADAV

W/O- SHRI, RAJESH YADAV

HAVING RESIDENCE AT:

B-408, MIRA-JAI ARIHANT TOWER,

SAIBABA NAGAR, MIRA ROAD (E),

DIST-THANE, 401 107 ....PETITIONER NO.2

VERSUS

1. UNION OF INDIA

THROUGH THE SECRETARY

MINISTRY OF HEALTH & FAMILY WELFARE

NIRMAN BHAWAN, MAULANA AZAD ROAD,

NEW DELHI -110011 ...RESPONDENT NO. 1

2. DRUG CONTROLLER GENERAL OF INDIA

DIRECTORATE GENERAL OF HEALTH SERVICES, CENTRAL DRUGS STANDARD

CONTROL ORGANIZATION, MINISTRY OF HEALTH AND FAMILY WELFARE FDA BHAVAN, ITO, KOTLA ROAD,

NEW DELHI - 110002 ...RESPONDENT NO. 2

[AJAY BHARGAVA] / [ARVIND KUMAR RAY]
D/186/1997(R) D /1659 / 2011
KHAITAN & CO
ADVOCATES FOR THE PETITIONERS
12TH FLOOR, ASHOKA ESTATE
24, BARAKHAMBA ROAD
NEW DELHI- 110 001
PHONE NO: + 91 9999389106

PLACE: NEW DELHI
DATED: 19.06.2017

SYNOPSIS & LIST OF DATES

The Petitioners are filing the present Writ Petition to Challenge the Notification No. Notification No. S.O. 1852(E) dated 8 June 2017 ("impugned Notification") issued by the Respondents under Section 26A of the Drugs and Cosmetics Act, 1940 ("Act"), whereby manufacture for sale, sale and distribution of a drug being a fixed dose combination of Ofloxacin + Ornidazole injection ("FDC") has been banned with immediate effect.

That the said Notification is premised on the recommendation of New Drugs Advisory Committee (NDAC). It is submitted that NDAC is not a statutory committee as contemplated under Section 5 and Section 7 of the Act. Without prejudice to the contention of the Petitioner No.1 that the Respondents cannot

act on the recommendation of NDAC while exercising its powers under Section 26A of the Act, the Petitioner No.1 submits that the recommendation of the NDAC as recorded in the minutes of the meeting dated 28 February 2014 ("impugned Recommendation") is also liable to be set aside as the recommendation of NDAC are based on consideration of irrelevant material and is a glaring example of complete non-application of mind. In any event the Petitioner No.1 has not been granted any opportunity being heard by the Respondents before issuing the Impugned Notification and further the NDAC has also not given any opportunity of being heard to the Petitioner No.1 before recommending to the Respondents that the FDC is not rational.

The impugned Notification is in violation of Articles 14 and 19(1) (g) of the Constitution of

India, in as much as the same has been issued in an arbitrary and unreasonable manner, without any justification or rationale being provided and in total disregard of the principles of natural justice.

The said FDC has been in the market for the past several years and the Petitioner No.1 has been manufacturing / marketing the said FDC since the year 2009 itself.

The impugned Notification has been issued:

A. Without affording it any opportunity by means of personal hearing to show cause against the proposed ban;

B. Without putting to the Petitioner No.1 the material that allegedly formed the basis for the alleged satisfaction of the Central Government that the FDC is not rational and there is no specific advantage in

administering Ofloxacin and Ornidazole together in parental form and there is no therapeutic justification for the continued marketing of the FDC.

It is the further submission of the Petitioner No.1 that in total violation of the principles of natural justice and acting wholly arbitrarily and illegally, the Central Government has relied on purported recommendation of NDAC which is not a committee under Section 5 and 7 of the Act; without even putting to the Petitioner No.1 the alleged recommendation as well as the material allegedly considered by NDAC in arriving at its conclusion and affording the Petitioner No.1 an opportunity of meeting the same.

It is submitted that nothing has been put to the Petitioner No.1 to show the basis for the

alleged finding of the expert committee that the said FDC is not rational.

It is submitted that impugned Notification is vitiated for failure of the Central Government to consult the Drugs Technical Advisory Board ("DTAB") or Drugs Consultative Committee ("DCC") constituted under Sections 5 and 7 respectively of the Act, to arrive at its satisfaction under Section 26A of the Act. Such consultation has been held to be mandatory (Re: M/SE. Merck (India) Ltd. v. Union of India, AIR 2001 Delhi 2006; Cipla Ltd. v. Union of India, (2011) 8 MLJ 281). In Pfizer Limited and Anr vs UOI and Anr [2016 SCC OnLine Del 6150), this Hon'ble Court has held as under:

> "No merit is found in the aforesaid contention also. There can be no estoppel against the law. Once it is found that the

law i.e. the Drugs Act requires the Central Government to exercise the power under Section 26A after taking advice from and in consultation with the statutory bodies created thereunder i.e. the DTAB and DCC, the exercise of power without such advice and consultation cannot be upheld even if exercised bona fide and in consultation with and on advice of other experts who may be as competent as the DTAB and DCC. The maxim, what is prescribed to be done in a particular way must be done in that way and no other way, would apply."

1976	That the Petitioner No. 1 was incorporated in the year 1976 and it is one of the oldest

	pharmaceutical companies in India.
17.08.2009	The fixed dose combination of Ofloxacin and Ornidazole injection ("FDC") was approved by the Respondent No. 2.
24.11.2009	Akums Drugs and Pharmaceuticals Limited ("Akums") obtained approval from the Respondent No.2 for manufacturing of the FDC as the said FDC was a new drug within the meaning of Rule 122E of the Drugs and Cosmetics Rules, 1945 ("Rules"). Until August 2013, the

	Petitioner No.1 purchased this FDC from Akums and marketed (in accordance with the licences granted to the Petitioner No.1) and sold in domestic market under its own brand name.
31.03.2011	The Respondents constituted 12 New Drugs Advisory Committee ("NDAC"). It is submitted that NDAC is not a statutory committee as contemplated under Section 5 and Section 7 of the Act. As per the

	terms of reference, it appears that NDAC is only supposed to evaluate applications for new drugs and clinical trials.
August 2013	The FDC ceased to be new drug i.e., after the expiry of a period of four years from the date of its first approval.
19.09.2013	The Petitioner No. 1 obtained a loan licence for manufacture of FDC. The Petitioner No.1's said loan licence has also been approved by the Central Licensing

	Approval Authority. The license of the Petitioner No.1 is valid and subsisting till date.
28.02.2014	NDAC recommended to the Respondents that the FDC is not rational. It is submitted that the recommendation of the NDAC is based on consideration of irrelevant material and is a glaring example of complete non-application of mind.
8.06.2017	Impugned Notification was published. The Respondents have prohibited that the

	manufacture for sale, sale and distribution of the FDC.
.06.2017	Hence, the present Writ Petition.

IN THE HON'BLE HIGH COURT OF DELHI AT

NEW DELHI

(EXTRAORDINARY ORIGINAL CIVIL JURISDICTION)

WRIT PETITION (CIVIL) NO.5345 OF 2017

IN THE MATTER OF:

J.B. CHEMICALS & PHARMACEUTICALS
LIMITED & ANOTHER ...PETITIONERS

VERSUS

UNION OF INDIA AND ANOTHER ...RESPONDENTS

WRIT PETITION UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA PRAYING, INTER ALIA, FOR A WRIT OF CERTIORARI AND/OR ANY OTHER APPROPRIATE WRIT, ORDER OR DIRECTION TO QUASH NOTIFICATION BEARING S.O.1852 (E) DATED 8 JUNE 2017, ISSUED BY THE RESPONDENTS PROHIBITING, WITH

IMMEDIATE EFFECT, THE MANUFACTURE FOR SALE, SALE AND DISTRIBUTION FOR HUMAN USE OF FIXED DOSE COMBINATION OF OFLOXACIN + ORNIDAZOLE INJECTION AND SETTING ASIDE OF THE RECOMMENDATION DATED 28 FEBRUARY, 2014 OF NEW DRUGS ADVISORY COMMITTEE

MOST RESPECTFULLY SHEWETH:

1. The Petitioners are filing the present Writ Petition to challenge the Notification No. S.O. 1852(E) dated 8 June 2017 ("Impugned Notification") issued by the Respondent No.1 under Section 26A of the Drugs and Cosmetics Act, 1940 ("Act"), whereby manufacture for sale, sale and distribution of a drug being a fixed dose combination of Ofloxacin + Ornidazole Injection ("FDC") has been banned with immediate effect. A copy of the Impugned

Notification bearing S.O. 1852(E) dated 8 June 2017 issued by the Respondent No.1 is annexed herewith and marked as ANNEXURE P1.

2. The impugned Notification has been issued by the Respondent No.1 on the recommendation of New Drugs Advisory Committee (NDAC). It is submitted that NDAC is not a statutory committee as contemplated under Section 5 and Section 7 of the Act. Without prejudice to the contention of the Petitioner No.1 that the Respondents cannot act on the recommendation of NDAC while exercising its powers under Section 26A of the Act, the Petitioner submits that the recommendation of the NDAC as recorded in the recommendation of the meeting dated 28 February 2014 ("Impugned Recommendation") is also liable to be set aside as the recommendation of NDAC

are based on consideration of irrelevant material and is a glaring example of complete non-application of mind. In any event the Petitioner No.1 has not been granted any opportunity being heard by the Respondents before issuing the Impugned Notification and further the NDAC has not given any opportunity of being heard to the Petitioner No.1 before recommending to the Respondents that the FDC is not rational. Copy of the recommendation dated 28 February 2014 of the NDAC is annexed herewith as ANNEXURE-P2.

3. That the Respondent No.1 is the Central Government whereas Respondent No.2 is an authority vested with functions under the Act and Rules framed under the Act. Therefore, both the Respondents are 'State', within the meaning of Article 12 of the Constitution of

India and are amenable to the Writ Jurisdiction of this Hon'ble Court.

4. That the relevant facts leading up to the filing of the present Writ Petition are enumerated herein below:

A. That the Petitioner No.1 is a Company incorporated under the laws of India having its registered office at N6eiam Centre, 4th Floor, B Wing, Hind Cycle Road, Worli, Mumbai - 400 030. The Petitioner No.1 is, inter alia, engaged in the business of manufacturing and/ or marketing several drugs, including, amongst others, manufacturing and marketing of Ofloxacin Ornidazole Injection; being a fixed dose combination drug. The Petitioner No.1 has appointed Ms. Bhoomi Desai as an authorised representative of the Petitioner No.1. The copy of the Resolution whereby

Ms. Bhoomi Desai is authorised to represent the Petitioner No.1 and do all necessary acts, deeds and things in the present Petition is being filed along with the present Petition.

B. That the Petitioner No.1 was incorporated in the year 1976 and it is one of the oldest pharmaceutical companies in India. The Petitioner No.1 is one of India's fastest growing pharmaceutical companies. An integrated, research-oriented, public listed organisation with a focus on supplying affordable, quality products both in India and International markets, the Petitioner No.1 is trusted by healthcare professionals globally. Today, the Petitioner No.1 exports to over 30 countries across the world and earns more than half its revenue from its international business.

The Petitioner No.1 is widely committed to manufacturing a range of innovative specialty products that include various pharmaceutical dosage forms like tablets, injectable (vials, ampoules, form fill seal), creams & ointments, lozenges, herbal liquids and capsules. In India and International markets, Petitioner No.1 is also known as Unique Pharmaceutical Laboratories, which is a division of Petitioner No.1.

C. That the Petitioner No.2 is a shareholder of the Petitioner No.1 and is a citizen of India and is therefore vitally interested in the business of the Petitioner No.1.

D. The Respondent No.1 is the Central Nodal Ministry regulating the business in which the Petitioner No.1 is engaged and has issued the Impugned Notification. The

Respondent No.2 is the Authority who has been appointed under the Act and acting in furtherance of the directions issued by the Respondent No.1.

E. That the Petitioner No.1 is, inter-alia, manufacturing and marketing certain Fixed Dose Combinations, one of them being a combination of Oflóxacin + Ornidazole Injection, better described in the table below-

COMPONENT AND STRENGTH	TRADE NAME	PURPOSE	MANUFACTURED / MARKETED SINCE
Ofloxacin 200 mg.+ Ornidazole 500 mg.	OF Plus I.V.	Treatment of Diarrhea of mixed	2010

(100ml.)		infection in adult patients	

F. The said FDC, is sold in India, only on a prescription basis to the end user. The said FDC is a Schedule H Drug and the packaging in which the said FDC is sold contains the following warnings:

> "SCHEDULE H DRUG: Warning: To be sold by retail on the prescription of a Registered Medical Practitioner Only. CAUTION: EVEN INVISIBLE DAMAGE TO BOTTLE CAUSED DURING STORAGE OR TRANSIT MAY RESULT IN CONTAMINATION. DO NOT USE IF LEAK FOUND ON SQUEEZING OR CONTENTS NOT CLEAR AND RETURN FOR REPLACEMENT."

G. It is pertinent to mention that the said FDC, composed of Ofloxacin 200 mg. + Ornidazole 500 mg. (100 ml.) is being sold in the market for over eight years. That on 24 November 2009, Akums Drugs and Pharmaceuticals Limited ("Akums") obtained approval from the Respondent No.2 for manufacturing of the FDC as the said EDC was a new drug within the meaning of Rule 122E of the Drugs and Cosmetics Rules, 1945 ("Rules"). The said FDC was approved for the first time by the Respondent No.2 on 17 August 2009. Until August 2013, the Petitioner No.1 purchased this FDC from Akums and marketed (in accordance with the licences granted to the Petitioner No.1) and sold in domestic market under its own brand name. Copy of the list of approvals to various drugs granted by the Respondent

No.2 in the year 2009 is annexed herewith and marked as ANNEXURE-P3. Copy of the approval dated 24 November 2009 granted to Akums is annexed herewith and marked as ANNEXURE-P-4.

H. That the said FDC ceased to be new drug in August 2013 i.e., after the expiry of a period of four years from the date of its first approval. Hence, the Petitioner No.1 obtained a loan licence dated 19 September, 2013, for manufacture of FDC at the premises of Unique Pharmaceutical Laboratories (A division of the Petitioner No.1).It is pertinent to note that the Petitioner No.1's said loan licence has also been approved by the Central Licensing Approval Authority. The said license of the Petitioner No. 1 is valid and subsisting till date. Copies of the loan license for

manufacture of the FDC and letter dated 25 October, 2013 from DCGI granting approval for manufacture of FDC by petitioner No.1 are annexed herewith as ANNEXURE-P5 (COLLY).

I. The sales figures of the FDC in question since its launch are as under:

Year	Sales (in INR)
2010-2011	94,73,465
2011-2012	57,90,800
2012-2013	78,28,617
2013-2014	1,11,56,920
2014-2015	2,70,75,798
2015-2016	1,40,22,064
2016-2017	1,32,33,847

J. That since the manufacturing and marketing of the said product, composed of the said FDC, the same has been widely

sold and various patients are being benefitted by the same. Till date, there has been no adverse events or any complaints received by the Petitioner No.1 to raise a concern with regard to the safety and efficacy of the said FDC.

K. That there are several ether manufacturers of the said FDC in the country.

L. That the on 8 June 2017, the impugned Notification has been issued without giving any opportunity of personal hearing to the Petitioner No.1; without affording it any opportunity to show cause against the proposed ban; without putting to the Petitioner No.1 the material that allegedly formed the basis for the alleged satisfaction of the Central Government that the said FDC is not rational and there

is no specific Advantage in administering Ofloxacin and Ornidazole together in parental form and there is no therapeutic justification for the continued marketing of the FDC. The Petitioner No.1 should have been given an opportunity of personal hearing before issuing the impugned Notification, particularly when the Respondent No.2 has specifically approved manufacture of the said FDC by the Petitioner No.1.

M. That the alleged satisfaction of the Respondents is based on recommendations of New Drugs Advisory Committee ("NDAC") constituted by the Respondent No.1. It is submitted that the NDAC is not a statutory committee as contemplated under Section 5 and Section 7 of the Act. It is important to note that

NDAC was constituted by the order bearing No.X.19029/5/2011-DFQC of the Respondent No.1. That NDAC is only supposed to evaluate applications for new drugs and clinical trials. The terms of reference of NDAC is reproduced as under:

> "The committee will advise DCO (I) in the following matters:
>
> i. To undertake in-depth evaluation of non-clinical data including pharmacological toxicological data, clinical trial data (Phase I, II, III, and IV) etc. furnished by the applicant for approval of following:
>
> - New drug substance of chemical and biological origin to be introduced for

the first time in the country including vaccines & r-DNA derived products.

- Global clinical trials.
- Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research industry in evolving acceptance criteria for marketing approval of new drugs of different therapeutic categories.

iii. Defining roadmap for research industry for appropriate development of new drugs relevant to Indian population.

While considering cases of new drugs the committee will examine

essentiality and desirability of new drugs in terms of:

- Assessment of Risk versus Benefit to the patient
- Innovation vis-a-vis existing therapeutic option
- Unmet medical need in India"

Copy of the Orders dated 31 March 2011, whereby 12 NDAC(s) have been constituted by the Respondents is annexed herewith and ANNEXURE–P6.

N. Without prejudice to the contention of the Petitioner No. 1 that the Respondents cannot ban the FDC under Section 26A of the Act on the recommendation of NDAC, the Petitioner No.1 submits that NDAC has not considered the relevant material and data while recommending that the said

parenteral form as both can be given individually, if indicated, it is submitted that the impugned Recommendation of the NDAC are illegal and arbitrary.

O. That the Petitioner No.1 has no knowledge or information in relation to any other recommendation of NDAC or any other committee of the Respondents, wherein the said FDC has been considered as irrational. The Petitioner No.1 reasonably and in good faith believes that apart from the above mentioned minutes of the meeting of NDAC, there is no other recommendation by any other committee or Drugs Technical Advisory Board ("DTAB"), wherein the said FDC has been found to be irrational.

P. That the said FDC is more effective than Ofloxacin or Ornidazole alone against susceptible organisms based on Antibiotic Susceptibility Test (AST) and Minimum inhibitory Concentration (MIC). The combination of Ofioxacin with Ornidazoie infusion is found to be significantly effective in controlling diarrhoea & associated symptoms with excellent tolerability. Being marketed since May 2010, till date no side effects have been reported. The FDC is safe, effective and well tolerated in the treatment of diarrhoea of mixed infection in adults. The FDC is safe for use in mixed infection diarrhoea of aerobic bacterial, anaerobic bacteria and pathogenic protozoan's especially in severe infection, and when oral administration is unfeasible. The safety, efficacy, rationality of the said FDC

is well established in, inter alia, the following reported published literature:

a. Faruqui AA, Joshi C. Evaluation of efficacy and tolerability Of fixed dose combination of ofloxacin with ornidazole infusion (infusion O2) in the management of diarrhoea and dysentery. J Indian Med Assoc. 2012 Mar;110(3):1936.

b. Manu Chaudhary, Anupama Tamta and Rajesh Sehgal. Sub-Chronic Toxicity Study of Fixed Dose Combination of Ofloxacin-Ornidazole in Mus Musculus Mice. The Open Toxicology Journal, 2009, 3, 24-29.

c. S.M. Shrivastava. S. Kumar. and M. Chaudhary. Comparative Evaluation of Fixed Dose Combination of

Ofloxacin and Ornidazole Against Some Aerobic Bacteria. Trends in Medical Research 4 (2): 30-34. 2009.

It is submitted that since the Petitioner No. 1 was not given an opportunity of hearing by the Respondents, the above literature have not been brought to the attention of the Respondents which clearly evidences the safety and rationality of the said FDC. Copy of the medical literatures are annexed herewith and marked as ANNEXURE-P7 (COLLY).

5. It is submitted that the Impugned Notification is wholly arbitrary, illegal and in contravention of the provisions of the Act as well as principles of natural justice and liable to be set aside.

6. As submitted above, no show cause notice or personal hearing was given to the Petitioner No. 1 prior to the imposition of the ban by the

Impugned Notification. Without prejudice to the contention of the Petitioner No. 1 that NDAG has no jurisdiction to recommend :to the Respondents to ban the FDC in exercise of powers under Section 26A of the Act it is respectfully submitted that the recommendation of the NDAC was not acted upon by the Respondents for a period more than 3 years. Further, before issuing the Impugned Notification the Respondents did not feel the need of even notifying the affected persons and considering the latest data and material in relation to the safety of the FDC. Hence, the Petitioners have no other alternative remedy but to approach this Hon'ble Court seeking quashing of the Impugned Notification.

7. It is submitted that the Impugned Notification and the minutes of the meeting of NDAC dated

28 February 2014 are liable to be set aside for the following, amongst other, grounds, which are without prejudice to each other:

GROUNDS

A. BECAUSE the impugned Notification and impugned Recommendation have been issued without granting any personal hearing to the Petitioner No.1 to represent against the proposed ban;

B. BECAUSE the Impugned Notification and impugned Recommendation have been issued without specifying as to how the said FDC is not rational and there is no specific advantage in administering Ofloxacin + Ornidazole in parental form.

C. BECAUSE the impugned Notification and impugned Recommendation have been

issued without specifying as to how the said FDC has no therapeutic justification.

D. BECAUSE the Impugned Notification and Impugned Recommendation have been issued without giving to the Petitioner No. 1 the material that allegedly formed the basis for the alleged Satisfaction of the Central Government that the use of the said FDC was likely to involve risk to human beings and enabling Petitioner No.1 to rebut the same;

E. BECAUSE the Impugned Notification and Impugned Recommendation violate the basic principles of natural justice in as much as it has been passed without affording any opportunity of personal hearing to the Petitioner No.1, whatsoever. It is pertinent to note that

the impugned Notification adversely affects the legal rights of the Petitioners and therefore, before passing the same, the Respondents should have ensured a fair and patient hearing to the Petitioner No. 1. There cannot be any dispute to the fact that the legal maxim, audi alteram partem, is an integral part of the Constitutional jurisprudence of our country; and any Notification, such as the Impugned Notification, passed in derogation or violation of the same must be held to be bad in law. It is most humbly submitted that the said Impugned Notification deserves to be quashed on this very ground of violation of the principles of natural justice, alone.

F. BECAUSE the impugned Notification also violates the fundamental right of the

Petitioner No.1 to carry on its business and trade, as provided under Article 1-9(1) (g) of the Constitution of India. Moreover, it will be seen that the fundamental rights of the Petitioner No.1 to carry on the business and trade in question, is not hit by any law in force. In the present facts, it is wholly illegal on the part of the Respondents to encroach upon the said right of the Petitioner No. 1 in flagrantly violating the rights of the Petitioner No. 1 and no justification, whatsoever, under law, can be provided for such violation.

G. BECAUSE the Impugned Notification is further bad in law as the same is in violation of Article 14 of the Constitution of India. It is settled law that an arbitrary or a wholly unreasonable action on part of

the State is a violation of Article 14 and such an action/ Order is not sustainable in the eyes of law, on this ground, alone. As already stated, the said impugned Notification has been passed without affording any opportunity to the Petitioner No. 1 of being heard. In addition to that, it is patently clear that the said impugned Notification is a blatant abuse of authority in as much as it is passed in an absolutely arbitrary manner. Therefore, the impugned Notification is liable to be quashed on this ground alone, as an arbitrary action, affecting substantive and fundamental rights of the Petitioner No. 1, cannot stand in the eyes of law, in any circumstance, whatsoever.

H. BECAUSE the impugned Notification reeks of mala fide intention, biasness and

vindictive attitude of the Respondents towards the Petitioners. It is submitted that such treatment meted out to the Petitioner No. 1 by the Respondents is bad in law and any action taken in furtherance of the same, is liable to be struck dowlas illegal.

I. BECAUSE the Respondents have acted in an arbitrary manner in passing the impugned Notification, in as much as the same is based on misinterpretation of the provisions of the Acts and Rules.

J. BECAUSE the Petitioner No.1 was never given a personal hearing or an opportunity to justify the manufacturing and sale of the FDC. Further, the reasons for prohibiting the FDC, by way of the impugned Notification, were never

conveyed to the Petitioner No.1; thereby, depriving it of an opportunity to explain and prove to the Respondents the efficacy and safety of the FDC. The Petitioner No.1 should have been given an opportunity of personal hearing before issuing the impugned Notification, particularly when the Respondent No.2 has specifically approved manufacture of the said FDC by the Petitioner No. 1.

K. BECAUSE the Impugned notification is further violative of Article 14 in as much as different FDCs with different strengths of various components that they comprise of, have been painted with the same brush, it is submitted that the Impugned Notification goes on to prohibit the FDC, without specifying as to this strength or the quantity in which each component in

tine FDC should have been used to render it unsafe. It is submitted that such a blanket action, without specifying exact strengths or quantities of each component in the FDC, reeks of total non-application of mind and makes it writ large that the impugned Notification have been issued on an absolutely unscientific basis. It is submitted that the strength of each component used in making the FDC by the Petitioner No, i, ensures that the said FDC are safe for consumption and are beneficial to the patients who consume the same.

L. BECAUSE the impugned Notification does not take into consideration the fact that each individual component of the said FDC can still be prescribed/ sold separately, as the same is beyond the ambit of the

prohibition sought to be imposed by the Impugned Notification. The said fact further shows that the Impugned Notification has been issued with complete non-application of mind and an unscientific manner. That the said FDC when taken in the fixed combination has been found to be safe by virtue of its continued use over the past several years, without any adverse incident having been reported. However, the same cannot be said if each of the individual components were to be consumed separately, albeit desiring the same result. Accordingly, the Impugned Notification in fact jeopardies the health and interest of consumers at large.

M. BECAUSE the impugned Notification is bad in law as there is no provision in the Act

or the Rules empowering the Respondents to hold a FDC as 'irrational'. Thus, the Respondents have travelled beyond the scope & powers of the Act and the Rules and hence the actions of the Respondents are arbitrary and without jurisdiction.

N. BECAUSE from a perusal of the Act and the Rules, it is submitted that a very elaborate and stringent procedure has been prescribed for the purposes of ensuring that the powers conferred on Respondent No.1 under the Act and in particular under Section 26A is not misused or exercised in an arbitrary and irrational manner. Act specifically provides for the constitution of the Drugs Technical Advisory Board ("DTAB") under Section 5. The constitution of such an expert body has been provided to enable the Central

Government to receive informed advice so as to warrant the exercise of such drastic powers which is required to be based on relevant consideration and material placed before it. Without prejudice to the aforesaid, it is humbly submitted that the consultation with the duly appointed DTAB is a sine-qua-non before the exercise of power under Section 26A of the Act. In the absence of such consideration/ consultation, the action of Respondent No.1 would be wholly vitiated especially when it is not equipped/ competent in the specialized field of science. The failure and/ or neglect on part of the Respondents to obtain the specific report/ findings of the DTAB in respect of the said FDC establish the mala tides of the Respondents in issuing the impugned Notification. On the aforesaid ground

alone, the impugned Notification deserves to be quashed/ set aside.

O. BECAUSE as per the scheme of the Act, consultation under Section 5 and 7 of the Act, with the duly constituted Drugs Technical Advisory Board ("DTAB") of Drugs Consultative Committee ("DCC") respectively, is a sine qua-non before the exercise of power under Section 26A of the Act. This Hon'ble Court in the case of M/S E. Merck (India) Ltd. v. Union of India, AIR 2001 Delhi 2006, has observed that as per the Scheme of the Act before the Government records its satisfaction to prohibit the manufacture, sale, distribution etc. of a particular drug, the opinion of the DTAB and/or the DCC is to be obtained. This is a position which has also been confirmed by the Hon'ble High

Court of Madras in the case of Cipla Ltd. v. Union of India, (2011) 8 MLJ 281. Admittedly, there has been no such consultation with either the DTAB or the DCC prior to issuing of the impugned Notification. Therefore, in the absence of such consideration/ consultation, the action of the Respondent No. 1 is wholly vitiated illegal and contrary to the judgment of this Hon'ble Court, especially when the Respondent No. 1 has no technical skill and competence within the specialized field of science.

P. BECAUSE the impugned Notification deserves to be struck down also on the ground of the same being in violation of the precious right of the Petitioner No. 1, enshrined under and guaranteed by Article 19(1) (g) Of the Constitution of India. It is

submitted that the impugned Notification strike at the fundamental right of the Petitioner No. 1 to carry on a lawful trade or profession. It must be noted that the Petitioner No. 1 has been manufacturing and marketing the said FDC for the past several years, in total Compliance with the statutory requirements. That for the Respondents to now declare the same as illegal, in an arbitrary and illegal manner, as elaborated above, is an action which is not sustainable in the eyes of law.

Q. BECAUSE the impugned Notification is also liable to be struck down as the same is not in consonance with the scope of Section 26A of the Act, under which, they have been declared to have been issued. That it is pertinent to note that the power und6r Section 26A of the Act can be

exercised only in furtherance of public interest. It is settled law that any action, purporting to further public interest, must be premised on a triggering point or a triggering event that warranted the taking of such an action. In the present case, the Respondents have exhibited no such event or ground, which warranted the taking of the impugned action and that too, making it applicable with immediate effect.

R. BECAUSE contrary to what the Respondents have claimed, the Petitioners humbly submit that the said FDC furthers public interest, in as much as the efficacy, safety and benefits of the same have been empirically verified. The fact that the said FDC has been in the market for several years, in itself admits of the safety of the same as the said fact also naturally admits

of repeated sales, having satisfied patients in previous uses. It is submitted that withdrawing the said FDC, will be to the detriment of the public at large and thus, the Impugned Notification is in fact against the mandate of Section 26A of the Act and accordingly, deserves to be quashed.

S. BECAUSE the FDC is entirely manufactured in India, at a low cost and the benefit of the same is passed on to the patients/consumers in India. Therefore, the said FDC furthers public interest by making itself easily available to the public at large in India, it is humbly submitted that a very large population of patients will be adversely affected if the said FDC is banned.

T. It is submitted that on account of the Impugned Notification directing a ban/ prohibition on the manufacture, distribution and sale of the subject drug, shall result in exposing Petitioner No. 1 to various civil/ criminal prosecution. Petitioner No. 1 has in fact been imposed with such a prohibition in gross violation of the settled principles of law of audi alteram partem by the Respondents. It is nearly impossible to effect such a ban/ prohibition overnight due to the fact that the subject drug is in the hands of several lakh retail outlets across the territory of India, over which Petitioner No. 1 has no control. It is therefore humbly submitted that the enforcement of such ban/ prohibition is beyond the control and capability of Petitioner No. 1.

U. The said FDC is sold to the end user only upon furnishing a prescription for the same. It is, therefore, not sold across the counter and sold only to the users who have been specifically prescribed the said FDC. A drug which is sold under a prescription is to be supervised and administered by a medical practitioner, thereby reducing/ eliminating any risks in relation to the misuse/ abuse/ wrong application of the said drug.

V. Because the Respondents cannot exercise its power under Section 26A of the Act on the recommendation of NDAC.

W. Because NDAC did not have jurisdiction or competence to advise the Respondents to ban the FDC. It is submitted that NDAC is

only mandated to the review the application for clinical trials.

X. Because the Respondents have not considered the latest scientific literature and data before issuing the Impugned Notification.

Y. Because the Respondents did not take any action on the recommendation of the NDAC for a period of almost 3 years.

Z. Without prejudice to the above grounds, the Impugned Notification is also liable to be quashed as the same further reeks of unreasonableness and is excessively harsh in as much as the same has been made applicable with immediate effect, thereby,, requiring the Petitioner No. 1 to immediately stop the manufacturing, distribution and sale of the said FDC. That

without prejudice to the other grounds of challenge to the Impugned Notification, it is humbly submitted that such an action on part of the Respondents is excessively harsh as it does not take into account the fact that stock worth crores of rupees has been sought to be rendered unusable overnight. The present ground of challenge must be considered in the light of the fact that the Respondents have not exhibited any urgency or ground to showcase how the FDC has suddenly become so dangerous for human consumption overnight, so as to warrant such a harsh action against them; that too, when the same has been in active use by the public at large for the past several years, without any adverse incident having been reported in relation to its use.

AA. BECAUSE the Impugned Notification is based on conjectures and surmises which are factually incorrect and hence liable to be quashed.

BB. BECAUSE there is nothing on record to indicate as to how the use of the said FDC would be against public interest. An administrative action banning a drug by invoking public interest is required to satisfy, on a stricter parameter, as to how the continued use would not be, and the ban would be in public interest. There is no material placed in public domain by the Respondents to even prima facie justify the Impugned Notification on the ground of being issued in public interest.

CC. BECAUSE due to the publication of the Impugned Notification, the sales of the

subject drug have come to a grinding halt causing immense loss to the Petitioner No.1 as well as to the consumers/ patients at large. The implementation of the Impugned Notification would severely impact and lead to grave consequences in respect of such medical institutions as well as the millions of the patients all over the country.

DD. For the above mentioned reasons the Impugned Recommendation is also liable to be set aside by this Hon'ble Court.

8. The Petitioners crave leave of this Hon'ble Court to add to, alter, amend, or change, any of the aforesaid grounds, which are without prejudice to each other. The Petitioners crave leave to produce such further documents as may be deemed necessary and are filing the

present Writ Petition in view of grave urgency due to an immediate ban.

9. That the Petitioners are left with no other efficacious alternative remedy but to approach this Hon'ble Court by way of the present Writ Petition.

10. That it is humbly submitted that if the relief(s) prayed for in the present Petition are not granted by this Hon'ble Court, the Petitioners will suffer grave and irreparable loss.

11. That the balance of convenience lies in favour of the Petitioners and against the Respondent.

12. That this Hon'ble Court has the territorial jurisdiction to adjudicate upon the disputes between the parties as the Respondents carries on its activities within the territorial jurisdiction of this Hon'ble Court. Further the Impugned

Notification has been issued within the territorial jurisdiction of this Hon'ble Court.

13. The present Writ Petition has been filed at the earliest and without any delay.

14. That no other same/ similar Petition/ proceeding has been filed by the Petitioners on the cause of action set out in this petition either before the Hon'ble Supreme Court of India or any other High Court in the country.

15. This petition is being made bonafido and in the interest of justice.

PRAYER:

In the facts and circumstances narrated above, it is most humbly prayed that this Hon'ble Court may be pleased to:

a) issue a writ of certiorari, or any other appropriate writ, order or direction quashing the Impugned Notification bearing S.O. No. 1852(E) dated 8 June 2017 issued by the Respondent No.1 ;

b) issue a writ of certiorari, or any other appropriate writ, order or direction quashing the Impugned Recommendation dated 28 February 2014 of the New Drugs Advisory Committee;

c) Issue a writ, order or direction declaring any action taken by the Respondents in furtherance of the Impugned Notification bearing S.O. No. 1852(E) dated 8 June 2017 as null and void;

d) Pass any other Order(s) as this Hon'ble Court may deem fit in the given facts and circumstances of the present case.

J.B. CHEMICAL PHARMACEUTICALS LTD

PETITIONERS

THROUGH:

[AJAY BHARGAVA] / [ARVIND KUMAR RAY]
D/186/1997(R) D /1659 / 2011
KHAITAN & CO
ADVOCATES FOR THE PETITIONERS
12TH FLOOR, ASHOKA ESTATE
24, BARAKHAMBA ROAD
NEW DELHI- 110 001
PHONE NO: +91 9990524846[

PLACE: NEW DELHI
DATED: 19/06/2017

IN THE HON'BLE HIGH COURT OF DELHI AT

NEW DELHI

(EXTRAORDINARY ORIGINAL CIVIL JURISDICTION)

WRIT PETITION (CIVIL) NO.5345 OF 2017

IN THE MATTER OF:

J.B. CHEMICALS & PHARMACEUTICALS LIMITED & ANOTHER .....PETITIONERS

VERSUS

UNION OF INDIA AND ANOTHER ...RESPONDENTS

AFFIDAVIT

I, Bhoomi Desai, daughter of Shri Subodh Desai, aged about 41 years, working for gain at J.B.Chemicals & Pharmaceuticals Ltd. Cnergy IT Park, Unit A2,3rd Floor, Unit A, 8th Floor, Appa Saheb Marathe Marg, Prabhadevi, Mumbai-400 025, do solemnly state and affirm as under

1. That I am-the Authorized Representative of the Petitioner No.1 in the present matter and as such well conversant with the facts of the present case and competent to affirm this affidavit on behalf of the petitioner No.1.

2. I have read and understood the contents of the accompanying Writ Petition, which has been drafted under my instructions and state that the contents of the same are true and correct to my knowledge based on the records maintained by the petitioner.

3. I say that the contents of the para No.1 and 2 of the affidavit are true andcorrect.

4. The annexures annexed with the Writ Petition are true 7 copies of their respective originals.

DEPONENT

VERIFICATION:

Verified at New Delhi on this 16th day of June, 2017, that the contents of the foregoing affidavit are true and correct to my knowledge. No part of the affidavit is false and nothing material has been concealed therefrom.

DEPONENT

/TRUE COPY/

F.NO - 2214/17

Dy No - 21407

19.7.2017.

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

TRANSFER PETITION[C]NO._____OF 2017

[UNDER ARTICLE 139 A OF THE CONSTITUTION OF INDIA R/W ORDER XL SUPREME COURT RULES, 2013 against the **W.P.[C]No.5336 of 2017** [Mankind Pharma Limited V/s Union of India & Anr], **W.P.[C]No.5340 of 2017** [Akums Drugs & Pharmaceuticals Ltd V/s Union of India & Anr], **W.P.[C]No.5345 of 2017** [J.B. Chemicals & Pharmaceuticals Limited & Ors V/s Union of India & Anr], **W.P.[C]No.5391 of 2017** [M/s IPCA Laboratories Limited & Anr V/s Union of India & Anr], **W.P.[C]No.5397 of 2017** [Ahlcon Parenterals India Ltd. V/s Union of India & Anr], **W.P.[C]No.5398 of 2017** [J.K. Printpacks V/s Union of India & Anr] and **W.P.[C]No.5399 of 2017** [Windlas Biotech Pvt. Ltd. V/s Union of India & Anr, pending before the **High Court of Delhi at New Delhi**],

IN THE MATTER OF:

Union of India & Anr. ...Petitioners

Versus

Mankind Pharma Limited ...Respondents

WITH

I.A.NO._____OF 2017

AN APPLICATION FOR STAY

VOLUME-II

PAPER BOOK

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ADVOCATE FOR THE PETITIONERS: **G.S.MAKKER**

F.NO.2214/17/CAS

HRS

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IN THE HON'BLE HIGH COURT OF DELHI

AT NEW DELHI

(EXTRAORDINARY ORIGINAL CIVIL JURISDICTION)

WRIT PETITION (CIVIL) NO._____OF 2017

IN THE MATTER OF:

M/S IPCA LABORATORIES LIMITED & ANOTHER
...PETITIONERS

VERSUS

UNION OF INDIA AND ANOTHER ...RESPONDENTS

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Sd/- Sd/- Sd/-

[AJAY BHARGAVA] /[ARVIND KUMAR RAY]/

[SHREYA AGRAWAL]

D/186/1997(R)
D / 2327 / 2005 D/ 2277/ 2014

KHAITAN & CO

ADVOCATES FOR THE PETITIONERS
12th FLOOR, ASHOKA ESTATE 24,
BARAKHAMBA ROAD NEW DELHI- 110 001
PHONE NO: + 91 9990524846

PLACE: NEW DELHI
DATED:

IN THE HON'BLE HIGH COURT OF DELHI

AT NEW DELHI

(EXTRAORDINARY ORIGINAL CIVIL JURISDICTION)

WRIT PETITION (CIVIL) NO._____OF 2017

MEMO OF PARTIES

1. M/S IPCA LABORATORIES LIMITED
HAVING ITS REGISTERED OFFICE AT
48, KANDIVLI INDUSTRIAL ESTATE
KANDIVLI (WEST)
MUMBAI 400 067, MAHARASHTRA

AND ITS CORPORATE OFFICE AT:
142 AB, KANDIVLI INDUSTRIAL ESTYATE
KANDIVLI (WEST)
MUMBAI 400 067, MAHARASHTRA

...PETITIONER NO. 1

2. MR HARISH KAMATH

HAVING RESIDENCE AT:

FLAT 2-D-602, 6TH FLOOR,

D WING, ASHOK NAGAR 'B' COMPLEX,

VAZIRA NAKA, L T ROAD,

BORIVALI (W), MUMBAI 400 091.

... PETITIONER NO. 2

VERSUS

1. UNION OF INDIA

THROUGH THE SECRETARY

MINISTRY OF HEALTH & FAMILY WELFARE

NIRMAN BHAWAN, MAULANA AZAD ROAD,

NEW DELHI - 110011 ...RESPONDENT NO. 1

2. DRUG CONTROLLER

GENERAL OF INDIA

DIRECTORATE GENERAL OF HEALTH

SERVICES,

CENTRAL DRUGS STANDARD CONTROL

ORGANIZATION, MINISTRY OF HEALTH

AND FAMILY WELFARE

FDA BHAVAN, ITO, KOTLA ROAD,

NEW DELHI- 110002 ...RESPONDENT NO. 2

Sd/- Sd/- Sd/-
[AJAY BHARGAVA] /[ARVIND KUMAR RAY]/
[SHREYA AGRAWAL]
D/186/1997(R) D / 2327 / 2005 D/
2277/ 2014

KHAITAN & CO
ADVOCATES FOR THE PETITIONERS
12th FLOOR, ASHOKA ESTATE 24,
BARAKHAMBA ROAD NEW DELHI- 110 001
PHONE NO: + 91 9990524846

PLACE: NEW DELHI
DATED:

SYNOPSIS & LIST OF DATES

The Petitioners are filing the present Writ Petition to Challenge the Notification No. Notification No. S.O. 1855 (E) dated 8 June 2017 ("impugned Notification") issued by the Respondents under Section 26A of the Drugs and Cosmetics Act, 1940 ("Act"), whereby manufacture for sale, sale and distribution of a drug being a fixed dose combination of Etodolac + Paracetamol ("FDC") has been banned with immediate effect.

That the said Notification is premised on the recommendation of New Drugs Advisory Committee ("NDAC"). It is submitted that NDAC is not a statutory committee as contemplated under Section 5 and Section 7 of the Act, namely Drugs Technical Advisory Board ("DTAB") and Drugs Consultative Committee ("DCC") respectively, consultation

with whom is mandatory. Without prejudice to the contention of the Petitioner No. 1 that the Respondents cannot act on the recommendation of NDAC while exercising its powers under Section 26A of the Act, the Petitioner No.1 submits that the recommendation of the NDAC as recorded in the minutes of the meeting dated 19 February 2014 ("Impugned Recommendation") is also liable to be set aside as the recommendation of NDAC are based on consideration of irrelevant material devoid of any cogent reasons and is a glaring example of complete non-application of mind.

The impugned Notification is in violation of Articles 14 and 19(1)(g) of the Constitution of India, in as much as the same has been issued in an arbitrary and unreasonable manner, without any justification or rationale being

provided and in total disregard of the principles of natural justice since no effective hearing has been accorded to the Petitioner No.1.

The said FDC has been in the market for the past several years and the Petitioner No.1 has been manufacturing / marketing the said FDC since the year 2009 itself. Since then around 4.3 Crores of tablets of Etodolac and Paracetamol combination have been sold and nearly 25 Lakh patients have been exposed to this combination till September 2013. No adverse event reports were received either from the healthcare professionals or from consumers of this combination. The approval granted for manufacture of the subject drug on 20.10.2009 by the Respondent No. 2 was only after the Petitioner submitted the expert's opinions and conducted clinical trials, on the basis of which the licensing authority was

satisfied that the FDC if approved shall be effective and safe for use in the country.

It is submitted that the impugned Notification is bad in law since:

A. No prior notice was issued to the Petitioner to explain the therapeutic rationale of the drug. On 19 February 2014, the Petitioner was asked to make a presentation on the subject FDC and was asked whether expert opinion was obtained before approval was granted for the subject FDC.

B. The Petitioner placed on record the opinion of nine experts including opinion of the experts recommended by the Respondent No. 2 along with the reports of the clinical trials vouching the efficacy and rationale of the FDC which is useful

for faster pain relief and has reduced side effects. However, without putting to the Petitioner No.1 the material that allegedly formed the basis for the alleged satisfaction of the Central Government that the FDC is not rational and that there is no specific advantage in administering Etodolac and Paracetamol together in parental form and there is no therapeutic justification for the continued marketing of the FDC and without referring to the material placed by the Petitioner NDAC made its recommendation that the subject FDC has no therapeutic justification. Thus, no effective opportunity of hearing has been granted to the Petitioner since no opportunity was given for meeting the material relied upon by NDAC.

C. It is the further submission of the Petitioner No. 1 that in total violation of the principles of natural justice and acting wholly arbitrarily and illegally, the Central Government has relied on purported recommendation of NDAC which is not a committee under Section 5 and 7 of the Act and without consulting DTAB and DCC.

It is submitted that nothing has been put to the Petitioner No. 1 to show the basis for the alleged finding of the expert committee that the said FDC is not rational.

It is submitted that impugned Notification is vitiated for failure of the Central Government to consult the Drugs Technical Advisory Board ("DTAB") or Drugs Consultative Committee ("DCC") constituted under Sections 5 and 7

respectively of the Act, to arrive at its satisfaction under Section 26A of the Act. Such consultation has been held to be mandatory (Re: M/S E. Merck (India) Ltd. v. Union of India, AIR 2001 Delhi 2006; Cipla Lid. v. Union of India, (2011) 8 MLJ 281). In Pfizer Limited and Anr vs UOI and Anr [2016 SCO Online Del 6150], this Hon'ble Court has held as under:

"No merit is found in the aforesaid contention also. There can be no estoppel against the law. Once it is found that the law i.e. the Drugs Act requires the Central Government to exercise the power under Section 26A after taking advice from and in consultation with the statutory bodies created thereunder i.e the DTAB and DCC, the exercise of power without such advice and consultation cannot be upheld even if

exercised bona fide and in consultation with and on advice of other experts who may be as competent as the DTAB and DCC. The maxim, what is prescribed to be done in a particular way must be done in that way and no other way, would apply."

1949	That the Petitioner No.1 was incorporated in the year 1949 and it is one of the oldest pharmaceutical companies in India.
27.04.2007	The Petitioner No.1 made an application to the Respondent No. 2 seeking approval for the manufacture of Etodolac and Paracetamol combination ("FDC") under Rule 122B, 122D and 122DA of the Drugs and Cosmetics Rule, 1945.

28.08.2007 Respondent No.2 asked the Petitioner No.1 to submit the opinions of 9 experts on the essentiality and desirability of the FDC, published clinical data on the said FDC and Pharmacokinetic / Pharmacodynamic interaction (if any) between Etodolac + Paracetamol with supportive literature. Out of the nine experts, the Petitioner was asked to obtain opinion of two experts from, institutions recommended by the Respondent No.2.

02.01.2008 The Petitioner No.1 replied to the Respondent No.2 providing the favourable opinion of nine experts, reports of published clinical trials of other pain relieving FDCs with paracetamol and explaining the

rationale behind the combination of the two drugs.

07.05.2008 The Respondent No. 2 granted permission to the Petitioner No. 1 to conduct clinical trials of the said FDC versus Etodolac on 200 patients.'

20.10.2009 The Respondent No.2 granted permission for manufacture of the concerned FDC after being satisfied that the FDC is effective and safe for use in the country.

09.04.2010 Permission was granted in Form 25 for manufacture for sale or distribution.

10.05.2010 The Respondent No.2 asked the Petitioner to submit technical literature in respect of the proposed

FDC for granting permission to market the drug.

03.06.2010 The Petitioner submitted the technical medical literature for the FDC.

31.03.2011 The Respondents constituted 12 New Drugs Advisory Committee ("NDAC"). It is submitted that NDAC is not a statutory committee as contemplated under Section 5 and Section 7 of the Act. As per the terms of reference, it appears that NDAC is only supposed to evaluate applications for new drugs or FDC to be introduced in the country for the first time and its scope cannot be extended for the purpose of Section 26A of the Act.

October 2013 The FDC ceased to be new drug i.e., after the expiry of a period of

four years from the date of its first approval.

11.02.2014 A notice was circulated by the Directorate of Health Services (New Drug Division), for attending the meeting of the NDAC (Analgesics, Anaesthetics & Rheumatology) to be held on 19.02.2014 to examine the matters related to approval of New Drugs, Fixed Dose Combinations, Global Clinical Trials & Biologicals. The Drug Combination of the Petitioner No. 1 was included as Item 10 in the List, under the head of Fixed Dose Combinations Proposals

19.02.2014 . The Petitioner made a representation before the NDAC and furnished the opinion of the experts as called for. However, the NDAC without referring

to the material submitted by the Petitioner recommended to the Respondents that the FDC is not rational. It is submitted that the recommendation of the NDAC is based on consideration of irrelevant material and is a glaring example of complete non-application of mind. Further, the said material was not shared with the Petitioner and no opportunity was given to meet the same.

24.02.2014 The Petitioner No. 1 issued a letter to the Respondent No. 2 stating that while making its representation before the NDAC meeting on 19.02.2014, they were requested to respond to whether expert opinion had been obtained before approval of

the FDC. In connection, thereof, the list of expert opinion letters submitted to the DCGI on 02.01.2008, all of which provided favourable views on the said Combination was described, and the favourable results of clinical trials, and technical literature requested earlier by the DGCI was also highlighted.

08.06.2017 Impugned Notification was published. The Respondents have prohibited the manufacture for sale, sale and distribution of the FDC.

.06.2017 Hence, the present Writ Petition.

IN THE HON'BLE HIGH COURT OF DELHI

AT NEW DELHI

(EXTRAORDINARY ORIGINAL CIVIL JURISDICTION)

WRIT PETITION (CIVIL) NO._____OF 2017

IN THE MATTER OF:

M/S IPCA LABORATORIES LIMITED & ANOTHER
...PETITIONERS

VERSUS

UNION OF INDIA AND ANOTHER ...RESPONDENTS

WRIT PETITION UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA PRAYING, INTER ALIA, FOR A WRIT OF CERTIORARI AND/OR ANY OTHER APPROPRIATE WRIT, ORDER OR DIRECTION TO QUASH NOTIFICATION BEARING S.O. 1855 (E) DATED 8 JUNE 2017, ISSUED BY THE RESPONDENTS PROHIBITING, WITH IMMEDIATE EFFECT, THE MANUFACTURE FOR SALE, SALE AND DISTRIBUTION FOR

HUMAN USE OF FIXED DOSE COMBINATION OF ETODOLAC + PARACETAMOL AND SETTING ASIDE OF THE RECOMMENDATION DATED 19 FEBRUARY 2014 OF NEW DRUGS ADVISORY COMMITTEE

MOST RESPECTFULLY SHEWETH:

1. The Petitioners are filing the present Writ Petition, to challenge the Notification No. S.O. 1855 (E) dated 8 June 2017 ("Impugned Notification") issued by the Respondent No. 1 under Section 26A of the Drugs and Cosmetics Act, 1940 ("Act"), whereby manufacture for sale, sale and distribution of a drug being a fixed dose combination of Etodolac + Paracetamol ("FDC") has been banned with immediate effect. A copy of the impugned Notification bearing S.O. 1855 (E) dated 8 June 2017 issued by the Respondent

No. 1 is annexed herewith and marked as ANNEXURE - P1.

2. The impugned Notification has been issued by the Respondent No. 1 on the recommendation of New Drugs Advisory Committee (NDAC). It is submitted that NDAC is not a statutory committee as contemplated under Section 5 and Section 7 of the Act. Without prejudice to the contention of the Petitioner No. 1 that the Respondents cannot act on the recommendation of NDAC while exercising its powers under Section 26A of the Act, the Petitioner submits that the recommendation of the NDAC dated 19 February 2014 ("Impugned Recommendation") is also liable to be set aside as the recommendation of NDAC is based on consideration of irrelevant material and is a glaring example of complete non-application of mind, in any event the Petitioner No.1 has not

been granted any opportunity of being heard by the Respondents before issuing the Impugned Notification and further the NDAC has not given any effective opportunity of being heard to the Petitioner No.1 before recommending to the Respondents that the FDC is not rational. Copy of the recommendation dated 19 February 2014 of the NDAC is annexed herewith as ANNEXURE - P2.

3. That the Respondent No.1 is the Central Government whereas Respondent No. 2 is an authority vested with functions under the Act and Rules framed under the Act. Therefore, both the Respondents are 'State', within the meaning of Article 12 of the Constitution of India and are amenable to the Writ Jurisdiction of this Hon'ble Court.

4. That the relevant facts leading up to the filing of the present Writ Petition are enumerated herein below:

A. That the Petitioner No.1 is a Company incorporated under the laws of India having its registered office at 48, Kandivli Industrial Estate, Kandivli (West), Mumbai 400 067, Maharashtra. The Petitioner No.1 is, inter alia, engaged in the business of manufacturing and/ or marketing several drugs, including, amongst others, manufacturing and marketing of Etodolac + Paracetamol being a fixed dose combination drug. The Petitioner No.1 has appointed Mr. Harish Kamath as an authorised representative who is also a shareholder and Company secretary of the Petitioner No.1.

B. That the Petitioner No. 1 for more than 60 years, has been partnering healthcare globally in over 110 countries and in markets as diverse as Africa, Asia, Australia, Europe and the US. Petitioner No.1 is a fully-integrated Indian pharmaceutical company manufacturing over 350 formulations and 80 APIs for various therapeutic segments. Petitioner No.1 is one of the world's largest manufacturers and suppliers of over a dozen APIs. These are produced right from the basic stage at manufacturing facilities endorsed by the world's most discerning drug regulatory authorities like US-FDA, UK-MHRA, EDQM- Europe, WHO-Geneva and many more.

C. That the Petitioner No. 2 is a shareholder of the Petitioner No. 1 and is a citizen of

India and is therefore vitally interested in the business of the Petitioner No. 1.

D. The Respondent No. 1 is the Central Nodal Ministry regulating the business in which the Petitioner No. 1 is engaged and has issued the impugned Notification. The Respondent No. 2 is the Authority who has been appointed under the Act and acting in furtherance of the directions issued by the Respondent No. 1.

E. That the Petitioner No. 1 is, inter-alia, manufacturing and marketing certain Fixed Dose Combinations, one of them being a combination of Etodolac + Paracetamol, better described in the table below-

COMPONENT AND	TRADE	PURPOSE	MANUFACTURED/

STRENGTH	NAME		MARKETED SINCE
Etodolac 400 mg + Paracetam o500 mg tablets.	Etova-P	For symptomatic treatment of acute pain and Inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing apondylitis.	2009

F. That the Petitioner No.1 was also granted permission to conduct clinical trials of the said FDC versus only Etodolac on 200 patients. However, it was clarified that

grant of permission to conduct clinical trial could not be equated with grant of permission to market the drug. Copy of the approval dated 07.05.2008 granted by the Directorate General of Health Services, Joint Drugs Controller (India) is annexed herewith and marked as ANNEXURE - P3.

G. It is pertinent to mention that the said FDC, composed of Etodolac 300 mg Paracetamol 500 mg is being sold in the market for many years. That on 20 October 2009, M/S IPCA LABORATORIES LIMITED obtained approval from the Respondent No.2 for manufacturing of the FDC as the said FDC was a new drug within the meaning of Rule 122-B/122-D of the Drugs and Cosmetics Rules, 1945 ("Rules"). The said FDC sold in domestic

market under its own brand name. Copy of the list of approvals to various drugs granted by the Respondent No.2 in the year 2009 is annexed herewith and marked as ANNEXURE - P4. Copy of the various approvals granted to IPCA for manufacture of the FDC is annexed herewith and marked as ANNEXURE - P5 (COLLY).

H. That a Notice was circulated to experts by the Directorate of Health Services (New Drug Division), for attending the meeting of the New Drugs Advisory Committee ("NDAC") (Analgesics, Anaesthetics & Rheumatology) to be held on 19.02.2014 at 11 AM 6 PM, FDA Bhawan, New Delhi, to examine the matters related to approval of New Drugs, Fixed Dose Combinations, Global Clinical Trials &

Biologicals. The Drug Combination of M/s IPCA Labs Ltd. was included as item 10 in the List, under the head of Fixed Dose Combinations Proposals. Copy of the notice dated 11.02.2014 issued by the Directorate of Health Services (New Drug Division) is annexed herewith and marked as ANNEXURE - P6.

I. That the NDAC gave its recommendations on 19.02.2014 pursuant to their meeting regarding the Drug Combination as under, "the committee noted that recommendations of the PSC. The committee evaluated the safety and efficacy reports presented by the firm. The committee obsensed that the product shall not be prescribed more than 10 days as claimed by the firm. The committee opined that FDC is not required for short

term use as paracetamol can be prescribed separately when required and can be tapered off early if need arises. The committee recommended that the FDC is not rationale in the present scenario."

J. That the Petitioner No.1 issued a letter to the Respondent No.2 pursuant to the recommendation of the NDAC stating that while making its representation before the NDAC meeting on 19.02.2014, they were requested to respond to whether expert opinion had been obtained before approval of the Drug Combination. In connection, thereof, the list of expert opinion Setters submitted to the DCGI on 02.01.2008, all of which provided favourable views on the said Combination was described, and the favourable results of clinical trials, and technical literature

requested earlier by the DGCI was also highlighted. The Letter also highlighted how in the Post Marketing Surveillance Study, only non-serious adverse events were observed., and that Periodic Safety Update Reports had been sent as per stipulated timelines. No-spontaneous adverse event reports were received from healthcare professionals or consumers. Further, it was stated that 4.3 crore tablets of the Drug Combination have already been sold, and nearly 25 lakh patients have thus been exposed to the said Drug Combination. Copy of literature on the concerned FDC is annexed herewith and marked as Annexure P-7 (Colly).

K. That the said FDC ceased to be new drug in October 2013 i.e., after the expiry of a

period of four years from the date of its first approval.

L. The sales figures of the FDC in question since its launch are as under:

Year	Sales (in INR)
2010-2011	5,35,00,000
2011-2012	5,64,00,000
2012-2013	7,22,00,000
2013-2014	8,51,00,000
2014-2015	9,86,00,000
2015-2016	11,66,00,000
2016-2017	13,13,00,000

M. That since the manufacturing and marketing of the said product, composed of the said FDC, the same has been widely sold and various patients are being benefited by the same. Till date, there has been no adverse events or any complaints

received by the Petitioner No.1 to raise a concern with regard to the safety and efficacy of the said FDC.

N. That there are several other manufacturers of the said FDC in the country.

O. That the on 8 June 2017, the impugned Notification has been issued without giving any opportunity of personal hearing to the Petitioner No. 1 without affording it any opportunity to show cause against the proposed ban without putting to the Petitioner No. 1 the material that allegedly formed the basis for the alleged 'satisfaction of the Central Government that the said FDC is not rational and there is no specific advantage in administering Etodolac + Paracetamol together in parental form and there is no therapeutic

justification for the continued marketing of the FDC. The Petitioner No.1 should have been given an opportunity of personal hearing before issuing the impugned Notification, particularly when the Respondent No.2 has specifically approved manufacture of the said FDC by the Petitioner No. 1.

P. That the alleged satisfaction of the Respondents is based on recommendations of New Drugs Advisory Committee ("NDAC") constituted by the Respondent No.1. It is submitted that the NDAC is not a statutory committee as contemplated under Section 5 and Section 7 of the Act. It is important to note that NDAC was constituted by the order bearing No.X.19029/5/2011- DFQC of the Respondent No.1. That NDAC is only

supposed to evaluate applications for new drugs and clinical trials. The terms of reference of NDAC is reproduced as under:

"The committee will advise DCG(i) in the following matters:

i) To undertake in-depth evaluation of non-clinical data including pharmacological toxicological data, clinical trial data (Phase I, II, III, and IV) etc. furnished by the applicant for approval of following:

- New drug substance of chemical and biological origin to be introduced for the first time in the country including vaccines & r-DNA derived products.

- Global clinical trials.

- Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research industry in evolving acceptance criteria for marketing approval of new drugs of different therapeutic categories.

iii. Defining roadmap for research Industry for appropriate development of new drugs relevant to Indian population.

While considering cases of new drugs the committee will examine essentiality and desirability of new drugs in terms of:

- Assessment of Risk versus Benefit to the patient

- Innovation vis-a-vis existing therapeutic option

- Unmet medical need in India"

Copy of the Orders dated 31 March 2011, whereby 12 NDAC(s) have been constituted by the Respondents is annexed herewith and ANNEXURE- P8.

Q. Without prejudice to the contention of the Petitioner No.1 that the Respondents cannot ban the FDC under Section 26A of the Act on the recommendation of NDAC, the Petitioner No.1 submits that NDAC has not considered the relevant material and data while recommending that the said FDC is not rational. Pursuant to the Impugned Recommendation, the Petitioner No.1 wrote to the Respondent No.2 stating that while making its

representation before the NDAC meeting on 19.02.2014, they were requested to respond to whether expert opinion had been obtained before approval of the Drug Combination. In connection, thereof, the list of expert opinion letters submitted to the DCGI on 02.01.2008, all of which provided favourable views on the said Combination was described, and the favourable results of clinical trials, and technical literature requested earlier by the DGCI was also highlighted. The said minutes / Impugned Recommendation of the NDAC reflect clear non-application of mind in as much as the said recommendation are not based on any medical/ scientific literature and clinical data. The NDAC without any basis has concluded that the said FDC is not required for short term use as

paracetamol can be prescribed separately when required and can be tapered off early if need arises. It is submitted that the Impugned Recommendation of the NDAC is illegal and arbitrary.

R. That the Petitioner No.1 has no knowledge or information in relation to any other recommendation of NDAC or any other committee of the Respondents, wherein the said FDC has been considered as irrational. The Petitioner No.1 reasonably and in good faith believes that apart from the abovementioned minutes of the meeting of NDAC, there is no other recommendation by any other committee or Drugs Technical Advisory Board ("DTAB"), wherein the said FDC has been found to be irrational.

S. That the said FDC is more effective than Etodolac or Paracetamol alone. The combination of Etodolac and Paracetamol is helpful for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Till date no side effects have been reported.

It is submitted that since the Petitioner No.1 was not given an opportunity of hearing by the Respondents, the medical recommendations given by various medical experts have not been brought to the attention of the Respondents which clearly evidences the safety and rationality of the said FDC. It is pertinent to mention that the said recommendations were considered by the Respondent No.2 while granting approval to the Petitioner No.1

for the said FDC. Copy of the medical recommendations are annexed herewith and marked as ANNEXURE - P9 (COLLY).

5. It is submitted that the Impugned Notification is wholly arbitrary, illegal and in contravention of the provisions of the Act as well as principles of natural justice and liable to be set aside.

6. As submitted above, no show cause notice or personal hearing was given to the Petitioner No.1 prior to the imposition of the ban by the Impugned Notification. Without prejudice to the contention of the Petitioner No.1 that NDAC has no jurisdiction to recommend to the Respondents to ban the FDC in exercise of powers under Section 26A of the Act, it is respectfully submitted that the recommendation of the NDAC was not acted upon by the Respondents for a period more than 3 years. Further, before issuing the

Impugned Notification the Respondents did not feel the need of even notifying the affected persons and considering the latest data and material in relation to the safety of the FDC. Hence, the Petitioners have no other alternative remedy but to approach this Hon'ble Court seeking quashing of the Impugned Notification and the Impugned Recommendation.

7. It is submitted that the impugned Notification and the minutes of the meeting of NDAC dated 19 February 2014 are liable to be set aside for the following, amongst other, grounds, which are without prejudice to each other.

GROUNDS

A. BECAUSE the impugned Notification and the impugned Recommendation have been issued without granting any effective

personal hearing to the Petitioner No.1 to represent against the proposed ban;

B. BECAUSE the Impugned Notification and Impugned Recommendation have been issued without specifying as to how the said FDC is not rational and there is no specific advantage in administering Etodolac + Paracetamol in parental form.

C. BECAUSE the Impugned Notification and impugned Recommendation have been issued without specifying as to how the said FDC has no therapeutic justification.

D. BECAUSE the Impugned Notification and Impugned Recommendation have been issued without giving to the Petitioner No.1 the material that allegedly formed the basis for the alleged satisfaction of the Central Government that the use of the

said FDC was likely to involve risk to human beings and enabling Petitioner No.1 to rebut the same;

E. BECAUSE the Impugned Notification violates the basic principles of natural justice in as much as it has been passed without affording any effective hearing to the Petitioner No.1, whatsoever since the material relied upon by the NDAC to make its recommendation was not shared with the Petitioner. It is pertinent to note that the Impugned Notification adversely affects the legal rights of the Petitioners and therefore, before passing the same, the Respondents should have ensured a fair and patient hearing to the Petitioner No. 1. There cannot be any dispute to the fact that the legal maxim, audi alteram partem, is an integral part of the

Constitutional jurisprudence of our country and any Notification, such as the impugned Notification, passed in derogation or violation of the same must be held to be bad in law. It is most humbly submitted that the said Impugned Notification deserves to be quashed on this very ground of violation of the principles of natural justice, alone.

F. BECAUSE the impugned Notification also violates the fundamental right of the Petitioner No. 1 to carry on its business and trade, as provided under Article 19 (1)(g) of the Constitution of India. Moreover, it will be seen that the fundamental rights of the Petitioner No.1 to carry on the business and trade in question, is not hit by any law in force, in the present facts, it is wholly illegal on the

part of the Respondents to encroach upon the said right of the Petitioner No.1 in flagrantly violating the rights of the Petitioner No.1. and no justification, whatsoever, under law, can be provided for such violation.

G. BECAUSE the impugned Notification is further bad in law as the same is in violation of Article 14 of the Constitution of India, it is settled law that an arbitrary or a wholly unreasonable action on part of the State is a violation of Article 14 and such an action/ Order is not sustainable in the eyes of law, on this ground, alone. As already stated, the said Impugned Notification has been passed without affording any effective opportunity of hearing to the Petitioner No.1. in addition to that, it is patently clear that the said

Impugned Notification is a blatant abuse of authority in as much as it is passed in an absolutely arbitrary manner. Therefore, the impugned Notification is liable to be quashed on this ground alone, as an arbitrary action, affecting substantive and fundamental rights of the Petitioner No.1, cannot stand in the eyes of law, in any circumstance, whatsoever.

H. BECAUSE the Impugned Notification reeks of mala fide intention, biasness and vindictive attitude of the Respondents towards the Petitioners. It is submitted that such treatment meted out to the Petitioner No. 1 by the Respondents is bad in law and any action taken in furtherance of the same, is liable to be struck down as illegal.

I. BECAUSE the Respondents have acted in an arbitrary manner in passing the impugned Notification, in as much as the same is based on misinterpretation of the provisions of the Acts and Rules.

J. BECAUSE the Petitioner No.1 was never given an effective hearing or an effective opportunity to justify the manufacturing and sale of the FDC. The Petitioner No. 1 was asked to attend the meeting of NDAC and was only asked regarding the expert opinions which was duly answered with material support that was also submitted to the Respondent No. 2 prior to getting approval. Further the reasons for prohibiting the FDC, by way of the Impugned Notification, were never conveyed to the Petitioner No.1 thereby, depriving it of an opportunity to explain

and prove to the Respondents the efficacy and safety of the FDC. The Petitioner No.1 should have been given an opportunity of personal hearing before issuing the impugned Notification, particularly when the Respondent No.2 has specifically approved manufacture of the said FDC by the Petitioner No. 1.

K. BECAUSE the impugned notification is further violative of Article 14 in as much as different FDCs with different strengths of various components that they comprise of, have been painted with the same brush. It is submitted that the impugned Notification goes on to prohibit the FDC, without specifying as to the strength or the quantity in which each component In the FDC should have been used to render it unsafe. It is submitted that such a

blanket action, without specifying exact strengths or quantities of each component in the FDC, reeks of total non- application of mind and makes it writ large that the Impugned Notification have been issued on an absolutely unscientific basis, it is submitted that the strength of each component used in making the FDC by the Petitioner No. 1, ensures that the said FDC are safe for consumption and are beneficial to the patients who consume the same.

L. BECAUSE the Impugned Notification does not take into consideration the fact that each individual component of the said FDC can still be prescribed/ sold separately, as the same is beyond the ambit of the prohibition sought to be imposed by the Impugned Notification. The said fact

further shows that the Impugned Notification has been issued with complete non-application of mind and an unscientific manner. That the said FDC when taken in the fixed combination has been found to be safe by virtue of its continued use over the past several years, without any adverse incident having been reported. However, the same cannot be said if each of the individual components were to be consumed separately, albeit desiring the same result. Accordingly, the impugned Notification in fact jeopardies the health and interest of consumers at large.

M. BECAUSE the impugned Notification is bad in law as there is no provision in the Act or the Rules empowering the Respondents to hold a FDC as 'irrational'. Thus, the

Respondents have travelled beyond the scope & powers of the Act and the Rules and hence the actions of the Respondents are arbitrary and without jurisdiction.

N. BECAUSE from a perusal of the Act and the Rules, it is submitted that a very elaborate and stringent procedure has been prescribed for the purposes of ensuring that the powers conferred on Respondent No. 1 under the Act and in particular under Section 26A is not misused or exercised in an arbitrary and irrational manner. The Act specifically provides for the constitution of the Drugs Technical Advisory Board ("DTAB") under Section 5. The constitution of such an expert body has been provided to enable the Central Government to receive informed advice so as to warrant the

exercise of such drastic powers which is required to be based on relevant consideration and material placed before it. Without prejudice to the aforesaid, it is humbly submitted that the consultation with the duly appointed DTAB is a sine-qua-non before the exercise of power under Section 26A of the Act. In the absence of such consideration/ consultation, the action of Respondent No.1 would be wholly vitiated especially when it is not equipped/ competent in the specialized field of science. The failure and/ or neglect on part of the Respondents to obtain the specific report/ findings of the DTAB in respect of the said FDC establish the mala tides of the Respondents in issuing the Impugned Notification. On the aforesaid ground

alone, the Impugned Notification deserves to be quashed/ set aside.

O. BECAUSE the DTAB under Section 5(5) of the Act can at most constitute sub-committees for a period not exceeding three years for consideration of particular matters but does not have power to delegate function of making recommendation. The said power/function is vested only with the DTAB.

P. BECAUSE even the DCC under Section 7 of the Act can only advise DTAB, Central Government or State Government as the case may be. However, DTAB and Central Government have to apply their mind independently. Thus, there is scope under the Act for the NDAC to give recommendations.

Q. BECAUSE under the Terms of Reference of the Order dated 31.03.2011 vide which NDAC was constituted, the NDAC has limited role to give recommendation on the applications made specifically to NDAC for evaluation of new drug substance of chemical and biological origin to be introduced for the first time in the country, global clinical trials and FDC to be introduced for the first time in the country, in the case in hand, the said FDC obtained approval in 2009 and has been in rotation since then. Thus, the terms of reference of the NDAC itself does not give power to the NDAC to decide on the therapeutic justification of the said FDC.

R. BECAUSE evaluation of the FDC concerned herein has already been done at the time of getting approval granted for

Court of Madras in the case of Cipla Ltd. v. Union of India, (2011) 8 MLJ 281. Admittedly, there has been no such consultation with either the DTAB or the DCC prior to issuing of the Impugned Notification. Therefore, in the absence of such consideration/ consultation, the action of the Respondent No. 1 is wholly vitiated illegal and contrary to the judgment of this Hon'ble Court, especially when the Respondent No.1 has no technical skill and competence within the specialized field' of science.

T. BECAUSE the impugned Notification deserves to be struck down also on the ground of the same being in violation of the precious right of the Petitioner No.1, enshrined under and guaranteed by Article 19(1)(g) of the Constitution of India. It is

submitted that the Impugned Notification strike at the fundamental right of the Petitioner No.1 to carry on a lawful trade or profession. It must be noted that the Petitioner No.1 has been manufacturing and marketing the said FDC for the past several years, in total compliance with the statutory requirements. That for the Respondents to now declare the same as illegal, in an arbitrary and illegal manner, as elaborated above, is an action which is not sustainable in the eyes of law.

U. BECAUSE the impugned Notification is also liable to be struck down as the same is not in consonance with the scope of Section 26A of the Act, under which, they have been declared to have been issued. That it is pertinent to note that the power under Section 26A of the Act can be

exercised only in furtherance of public interest. It is settled law that any action, purporting to further public interest, must be premised on a triggering point or a triggering event that warranted the taking of such an action. In the present case, the Respondents have exhibited no such event or ground, which warranted the taking of the impugned action and that too, making it applicable with immediate effect.

V. BECAUSE contrary to what the Respondents have claimed, the Petitioners humbly submit that the said FDC furthers public interest, in as much as the efficacy, safety and benefits of the same have been empirically verified. The fact that the said FDC has been in the market for several years, in itself admits of the safety of the same as the said fact also naturally admits

of repeated sales, having satisfied patients in previous uses. It is submitted that withdrawing the said FDC, will be to the detriment of the public at large and thus, the Impugned Notification is in fact against the mandate of Section 26A of the Act and accordingly, deserves to be quashed.

W. BECAUSE the FDC is entirely manufactured in India, at a low cost and the benefit of the same is passed on to the patients/consumers in India. Therefore, the said FDC furthers public interest by making itself easily available to the public at large in India, it is humbly submitted that a very large population of patients will be adversely affected if the said FDC is banned.

X. It is submitted that on account of the impugned Notification directing a ban/ prohibition on the manufacture, distribution and sale of the subject drug, shall result in exposing Petitioner No. 1 to various civil/ criminal prosecution. Petitioner No. 1 has in fact been imposed with such a prohibition in gross violation of the settled principles of law of audi alteram partem by the Respondents. It is nearly impossible to effect such a ban/ prohibition overnight due to the fact that the subject drug is in the hands of several lakh retail outlets across the territory of India, over which Petitioner No. 1 has no control. It is therefore humbly submitted that the enforcement of such ban/ prohibition is beyond the control and capability of Petitioner No. 1.

Y. Because the Respondents cannot exercise its power under Section 26A of the Act on the recommendation of NDAC.

Z. Because NDAC did not have jurisdiction or competence to advise the Respondents to ban the FDC. It is submitted that NDAC is only mandated to the review the application for clinical trials.

AA. Because the Respondents have not considered the latest scientific literature, medical recommendations and data before issuing the Impugned Notification.

BB. Because the Respondents did not take any action on the recommendation of the NDAC for a period of almost 3 years.

CC. Without prejudice to the above grounds, the Impugned Notification is also liable to be quashed as the same further reeks of

unreasonableness and is excessively harsh in as much as the same has been made applicable with immediate effect, thereby, requiring the Petitioner No.1 to immediately stop the manufacturing, distribution and sale of the said FDC. That without prejudice to the other grounds of challenge to the impugned Notification, it is humbly submitted that such an action on part of the Respondents is excessively harsh as it does not take into account the fact that stock worth crores of rupees has been sought to be rendered unusable overnight. The present ground of challenge must be considered in the light of the fact that the Respondents have not exhibited any urgency or ground to showcase how the FDC has suddenly become so dangerous for human consumption overnight, so as to warrant

such a harsh action against them; that too, when the same has been in active use by the public at large for the past several years, without any adverse incident having been reported in relation to its use.

DD. BECAUSE the Impugned Notification is based on conjectures and surmises which are factually incorrect and hence liable to be quashed.

EE. BECAUSE there is Nothing on record to indicate as to how the use of the said FDC would be against public interest. An administrative action banning a drug by invoking public interest is required to satisfy, on a stricter parameter, as to how the continued use would not be, and the ban would be, in public interest. There is no material placed in public domain by the

Respondents to even prima facie justify the Impugned Notification on the ground of being issued in public interest.

FF. BECAUSE due to the publication of the impugned Notification, the sales of the subject drug have come to a grinding halt causing immense loss to the Petitioner No.1 as well as to the consumers/ patients at large. The implementation of the impugned Notification would severely impact and lead to grave consequences in respect of such medical institutions as well as the millions of the patients all over the country.

GG. For the abovementioned reasons the Impugned Recommendation is also liable to be set aside by this Hon'ble Court.

8. The Petitioners crave leave of this Hon'ble Court to add to, alter, amend, or change, any of the aforesaid grounds, which are without prejudice to each other. The Petitioners crave leave to produce such further documents as may be deemed necessary and are filing, the present Writ Petition in view of grave urgency due to an immediate ban.

9. That the Petitioners are left with no other efficacious alternative remedy but to approach this Hon'ble Court by way of the present Writ Petition.

10. That it is humbly submitted that if the relief(s) prayed for in the present Petition are not granted by this Hon'ble Court, the Petitioners will suffer grave and irreparable loss.

11. That the balance of convenience lies in favour of the Petitioners and against the Respondent.

12. That this Hon'ble Court has the territorial jurisdiction to adjudicate upon the disputes between the parties as the Respondents carries on its activities within the territorial jurisdiction of this Hon'ble Court. Further the Impugned Notification has been issued within the territorial jurisdiction of this Hon'ble Court.

13. The present Writ Petition has been filed at the earliest and without any delay.

14. That no other same/ similar Petition/ proceeding has been filed by the Petitioners on the cause of action set out in this petition either before the Hon'ble Supreme Court of India or any other High Court in the country.

15. This petition is being made bonafide and in the interest of justice.

PRAYER

In the facts and circumstances narrated above, it is most humbly prayed that this Hon'ble Court may be pleased to:

a) Issue a writ of certiorari or any other appropriate writ, order or direction quashing the impugned Notification bearing S.O. No. 1855 (E) dated 8 June 2017 issued by the Respondent No. 1;

b) Issue a writ of certiorari, or any other appropriate writ, order or direction quashing the Impugned Recommendation dated 19 February 2014 of the New Drugs Advisory Committee;

c) Issue a writ, order or direction declaring any action taken by the Respondents in furtherance of the impugned Notification bearing S.O. No. 1855 (E) dated 8 June 2017 as null and void;

d) Pass any other Order(s) as this Hon'ble Court may deem fit in the given facts and circumstances of the present case.

Sd/- Sd/- Sd/-
[AJAY BHARGAVA] /[ARVSND KUMAR RAY]/[SHREYA AGRAWAL] D/186/1997(R) D / 2327 / 2005 D / 2277 / 2014

KHAITAN & CO
ADVOCATES FOR THE PETITIONERS
12th FLOOR, ASHOKA ESTATE 24,
BARAKHAMBA ROAD NEW DELHI- 110 001
PHONE NO: + 91 9990524846

PLACE: NEW DELHI
DATED:

IN THE HON'BLE HIGH COURT OF DELHI

AT NEW DELHI

(EXTRAORDINARY ORIGINAL CIVIL JURISDICTION)

WRIT PETITION (CIVIL) NO.____OF 2017

IN THE MATTER OF:

IPCA LABORATORIES LIMITED & ANOTHER

...PETITIONERS

VERSUS

UNION OF INDIA AND ANOTHER ...RESPONDENTS

AFFIDAVIT

I, Harish P. Kamath, son of Shri Pandurang W. Kamath, aged about 57 years, working for gain at Ipca Laboratories Ltd. do hereby solemnly affirm and declare as under:

1. That I am the Authorised Representative/ Company Secretary of the Petitioner No. 1 in the present matter, and am well conversant with the facts of the present case and

competent to affirm this affidavit on behaLf of the Petitioner No. 1.

2. That I have read and understood the contents of the accompanying Writ Petition, which has been drafted under my instructions and state that the contents of the same are true and correct to my knowledge based on the records maintained by the Petitioner No. 1.

3. I say that the contents of the para no. 1 and 2 of the affidavit are true and correct.

DEPONENT

VERIFICATION:

I, the Deponent above named, do hereby verify that the contents of foregoing affidavit are true and correct to my knowledge, no part of ft is false and nothing material has been concealed therefrom.

Verified at Mumbai on this 20th day of June, 2017.

DEPONENT

ANNEXURE P-6

IN THE HIGH COURT IN DELHI AT NEW DELHI

EXTRAORDINARY WRIT JURISDICTION

WRIT PETITION (C) NO. 5397 OF 2017

IN THE MATTER OF:

Ahlcon Parenterals India Ltd. .... Petitioner

Versus

UnioOn of India & Anr. .... Respondents

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PETITIONER

THROUGH:

Sd/-
PRA LAW OFFICES
R. JAWAHAR LAL
ENR. NO. D-933/1992
ADVOCATE FOR THE PETITIONER
W-126, GROUND FLOOR
GREATER KAILASH PART-II
NEW DELHI-110 048
Ph: 011-40676767
Mob. 9958996312
e-mail: jawahar@pralaw.in

NEW DELHI
DATED: 16.06.2017

IN THE HIGH COURT OF DELHI

AT NEW DELHI

EXTRAORDINARY ORIGINAL WRIT JURISDICDTION

WRIT PETITION (C) NO._____OF 20 17

IN THE MATTER OF:

Ahlcon Parenterals India Ltd. .... Petitioner

Versus

Union of India & Anr. .... Respondents

MEMO OF PARTIES

Ahlcon Parenterals India Limited
a company existing under the
Companies Act, 2013 having its
registered office at:
Plot No. 30 & 30E, 2nd Floor
Shivaji Marg, Najafgarh Road
Industrial Area, New Delhi-110 015
through its Authorized Signatory
Mr. Ranjan Kumar Sahu ....Petitioner

-Versus-

1. Union of India
   through Secretary
   Department of Health and Family
   Welfare Ministry of Health and Family Welfare
   Nirman Bhawan,
   New Delhi-110 001

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

PETITIONER

THROUGH:

Sd/-

PRA LAW OFFICES
R. JAWAHAR LAL
ENR. NO. D-933/1992
ADVOCATE FOR THE PETITIONER
W-126, GREATER KAILASH PART-II
NEW DELHI-110 048
Ph: 011-40676767
Mob. 9958996312

NEW DELHI
DATED: 29.06.2017

SYNOPSIS

The Petitioner is invoking the extraordinary writ jurisdiction of this Hon'ble Court under Article 226 of the Constitution of India challenging Notification S.O. No. 1852 (E) dated 08.06.2017, whereby the Respondent No.1, in purported exercise of its powers under Section 26A of the Drugs and Cosmetics Act, 1940 ("D&C Act") prohibited the manufacture for sale, sale and distribution for human use of the fixed dose combination (drug with more than one active ingredient, in short referred to as "FDC") of Ofloxacin + Ornidazole injection, with immediate effect on the purported ground that the same there is no rational or therapeutic justification. The decision to prohibit manufacture for sale, sale and distribution of the FDC by the Impugned Notifications is based on the recommendation

of the New Drugs Advisory Committee constituted by Respondent No.1. The Petitioner submits that the New Advisory Committee is not a statutory body, contemplated under the D&C Act. The Petitioner submits that the Impugned Notifications dated 08.06.2017 is ex-facie illegal, arbitrary and irrational and is therefore likely to be quashed by this Hon'ble Court as:

1. The Impugned Notification has been issued by the Respondent No.1 in contravention of Sections 5, 6, 7 and 26A of the D&C Act, inasmuch exercise of powers under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers of the concerned FDCs and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act viz.

Drugs Technical Advisory Board, Central Drugs Laboratory and Drugs Consultative Committee. In, this context, it is respectfully submitted that on 10.03.2016, the Respondent No.1 had issued 344 Notifications, banning a large number of FDC. While considering the challenge to 344 Notifications, the Hon'ble Court in its Judgment (in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) dated 01.12.2016, held that any exercise of powers by the Respondent No.1 under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act. In the present case also, prior to issue of

the Impugned Notification, the Respondent No.1 did not consult the manufacturers or sought the advice and recommendation of the aforesaid statutory bodies. The Respondent No.1 had acted unilaterally on the basis of recommendation of New Drugs Advisory Committee (a non-statutory Committee appointed by the Respondent No.1), which is impermissible under the statutory regime of D&C Act and in particular Sections 5,6,1 and 26A thereof

2. In the present case, the FDC was approved by the Respondent No.2 on 17.08.2009; therefore by virtue of Explanation (ii) to Rule 122E they cease to be a New Drug by 17.08.2013 (i.e. upon expiry of 4 years from the date of approval by DCGI (Respondent No. 2).

Therefore, even assuming without admitting that the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to "new drugs" (as defined in Rule 122 E of the D&C Rules), such Committee cannot consider ban of existing FDC, especially when the FDC, in the present case, ceased to be New Drug, as defined in Rule 122E of the D&C Rules (per Explanation (ii) to Rule 122B of the D&C Rules).

3. The Petitioner respectfully submits that Sections 5, 6 and 7 of the D&C Act: are mandatory in nature and cannot be in any manner ignored or by-passed by the Respondent No.1, as held by this Hon'ble Court in Pfizer Limited. The purpose of constitution of Drugs Technical Advisory

Board is to advice the Respondent No. 1 on technical matters arising out of administration of the Act and to carry out other functions assigned to the Respondent No. 1 under the D&C Act and the purpose of constitution of the Drugs Consultative Committee is to advice the Respondent No. 1 and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C Act provide that the Respondent No. 1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and hold consultation with Drugs Technical Advisory Board and Drugs Consultative Committee. Moreover the functions of Drugs Technical Advisory Board under Section 5 of the D&C Act, is

not only to advice on technical matters but also to carry out "other functions assigned1 to the Respondent No.1 under the D&C Act.

4. Indisputably, the New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act, as the D&C Act does not provide for constitution of such a Committee. The New Drugs Advisory Committee is a committee functioning under the Central Drugs Standard Control Organization (in short "CDSCO"), which itself is not a statutory body under the D&C Act. Thus, the very act of the Respondent No.1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go-by to the statutory authorities constituted under the D&C Act vitiates the

Impugned Notification and renders it unsustainable, in the eyes of law, as the Respondent No.1 in exercise of powers vested under the D&C Act, cannot take away the statutory powers vested in DTAB, DCC and vest them in a Committee unilaterally formed by the Respondent No.1.

5. In addition, for any action under Section 26A of the D&C Act, has to be preceded by hearing all stake holders (manufacturers etc.), unless there is grave urgency, for which reasons should be recorded, as held by this Hon'ble Court in Pfizer Judgment. It is submitted that prior to issue of the Impugned Notifications, no such notice or opportunity of hearing was afforded to the

Petitioner, who manufactures the FDC in question.

6. The Petitioner submits that the fact that there was no grave urgency warranting exercise of powers under Section 26A of D&C Act is evident from the fact that the Impugned Notifications themselves mention that the prohibition is premised on the fact that the use of FDC in question is not rational as the FDC does not have any therapeutic justification and the two drugs which are the constituents of FDQ are best administered separately. The prohibition is not premised on any adverse health consequences or risk to human beings and therefore it can be safely said that there were no compelling circumstances in giving a go-by to the requirement of issuance of notice and

opportunity of hearing to manufacturers before prohibiting the FDC. Thus, the Impugned Notification dated 08.06.2017 is violative of Article 14 of the Constitution of India as it is arbitrary and unreasonable and violative of principles of natural justice.

7. It is pertinent to mention here that the said FDC has been approved by the Respondent No.2, Drug Controller General of India on 17.08.2009 and the Petitioner has been manufacturing the same from 2010 after getting a licence from the State Licencing Authority, Rajasthan. After having approved the FDC, there is no justification whatsoever to ban the FDC, that too without following the mandatory procedure specified under the D&C Act.

8. It is also relevant to state here that there is no adverse report about the FDC. The Impugned Notification is not based on any adverse report, viz. Pharmacovigilance Report or otherwise. Further the FDC in question cannot lead to any drug resistance or any adverse impact.

LIST OF DATES & EVENTS

17.08.2009	The Respondent No. 2 approved the FDC Ofloxacin 2 mg per ml + Ornidazole 5 mg per ml Infusion
09.08.2012	The Petitioner was also granted licence to manufacture the FDC in question by the State Licencing Authority, Rajasthan and it was renewed on 09.08.2012. The Petitioner has been manufacturing the FDC from 2010

10.03.2016	The Respondent No. 1 issued 344 Notifications prohibiting manufacture for sale, sale and distribution of FDCs
01.12.2016	This Hon'ble Court vide Judgment in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) quashed the 344 Notifications on the ground that the Respondent No. 1 while issuing the notifications has acted in contravention of the statutory regime under D&C Act, including Section 5, 6, 7 & 26A thereof

08.06.2017	The Respondent No. 1 has issued the Impugned Notifications S.O. No. 1852 (E) prohibiting manufacture for sale, sale and distribution of the two FDC, Ofloxacin + Ornidazole injection
28.06.2017	Hence the present Writ Petition

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRA ORDINARY WRIT JURISDICTION

WRIT PETITION (C) NO._____ OF 2017

IN THE MATTER OF:

Ahlcon Parenterals India Limited
A company existing under the
Companies Act, 2013 having
its registered office at:

Plot No. 30 & 30E, 2nd Floor
Shivaji Marg,
Najafgarh Road Industrial Area,
New Delhi-110 015
through its Authorized Signatory
Mr. Ranjan Kumar Sahu ...Petitioner

-Versus-

1. Union of India
through Secretary
Department of Health and
Family Welfare Ministry
of Health and Family Welfare
Nirman Bhawan,

New Delhi-110 001

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

AND IN THE MATTER OF:

WRIT PETITION UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA, 1950 SEEKING A WRIT OF CERTIORARI OR ANY OTHER WRIT, ORDER OR DIRECTION IN THE NATURE OF CERTIORARI CATLING FOR THE RECORDS AND QUASHING NOTIFICATION BEARING S.O. NO. 1852 (E) DATED 08.06.2017 (ANNEXURE P-1) ISSUED BY RESPONDENT NO.1, IN PURPORTED EXERCISE OF POWERS UNDER SECTION 26A OF THE DRUGS AND COSMETICS ACT, 1940; IMPUGNED

NOTIFICATION ARE ARBITRARY, ILLEGAL AND IRRATIONAL AND ISSUED IN VIOLATION OF SECTIONS 5, 6, 7 AND 26A OF THE DRUGS AND COSMETICS ACT, 1940

To

THE HON'BLE ACTING CHIEF JUSTICE AND HER COMPANION JUSTICES OF THE HON'BLE HIGH COURT OF DELHI AT NEW DELHI

THE HUMBLE PETITION OF THE PETITIONER NAMED ABOVE

MOST RESPECTFULLY SHOWETH:

1. The Petitioner is invoking the extraordinary writ jurisdiction of this Hon'ble Court under Article 226 of the Constitution of India challenging Notification S.O. No. 1852 (E) dated 08.06.2017 (in short the "Impugned

Notification"), whereby the Respondent No. 1, in purported exercise of its powers under Section 26A of the Drugs and Cosmetics Act, 1940 (in short the "D&C Act") prohibited the manufacture for sale, sale and distribution for human use of the fixed dose combination (drug with more than one active ingredient, in short referred to as "FDC") of Ofloxacin + Ornidazole Injection, with immediate effect on the purported ground that there is no rational or therapeutic justification for the FDC, The decision to prohibit manufacture for sale, sale and distribution of the FDC by the Impugned Notification is based on the recommendation of the New Drugs Advisory Committee constituted by Respondent No. 1. In this context, it is relevant to submit that the New Advisory Committee is not a statutory body, contemplated under the D&C Act. True typed copy of the Notification S.O. Nos.

1852 (E) dated 08.06.2017 issued by the Respondent No. 1 are annexed and marked as Annexure P-1.

2. The Petitioner submits that the Impugned Notification dated 08.06.2017 is ex-facie illegal, arbitrary and irrational and is therefore likely to be quashed by this Hon'ble Court as:

2.1 The Impugned Notification has been issued by the Respondent No. 1 in contravention of Sections 5,6,1 and 26 A of die D&C Act, inasmuch exercise of powers under Section 26 A of the D&C Act has to be preceded by consultation with the manufacturers of the concerned FDCs and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act viz. Drugs Technical Advisory Board, Central Drugs Laboratory and Drugs Consultative

Committee. In this context, it is respectfully submitted that on 10.03.2016, the Respondent No. 1 had issued 344 Notifications, banning a large number of FDC While considering the challenge to 344 Notifications, the Hon'ble Court in its Judgment (in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) dated 01.12.2016, held that any exercise of powers by the Respondent No. 1 under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers and ought to be based on the advice of statutory bodies constituted under Sections 5,6 and 7 of the D&C Act. In the present case also, prior to issue of the Impugned Notification, the Respondent No. 1 did not consult the

manufacturers or sought the advice and recommendation of the aforesaid statutory bodies. The Respondent No. 1 had acted unilaterally on the basis of recommendation of New Drugs Advisory Committee (a non-statutory Committee appointed by the Respondent No. 1), which is impermissible under the statutory regime of D&C Act and in particular Sections 5, 6, 7 and 26A thereof.

2.2 In the present case, the FDC was approved by the Respondent No. 2 on 17.08.2009; therefore by virtue of Explanation (ii) to Rule 122E they cease to be a New Drug by 17.08.2013 (I.e. upon expiry of 4 years from the date of approval by DCGI (Respondent No. 2), Therefore, even assuming without admitting that the Respondents could

constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to "new drugs" (as defined in Rule 122 E of the D&C Rules), such Committee cannot consider ban of existing FDC, especially when the FDC, in the present case, ceased to be New Drug, as defined in Rule 122E of the D&C Rules (per Explanation (ii) to Rule I22E of the D&C Rules).

2.3 The Petitioner respectfully submits that Sections 5, 6 and 7 of the D&C Act axe mandatory in nature and cannot be in any manner ignored or by passed by the Respondent No. 1, as held by this Hon'ble Court in Pfizer Limited. The purpose of constitution of Drugs Technical Advisory Board is to advice the Respondent No.1 on technical matters arising out of

administration of the Act and to carry out other functions assigned to the Respondent No.1 under the D&C Act and the purpose of constitution of the Drugs Consultative Committee is to advice the Respondent No.1 and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C Act provide that the Respondent No.1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and hold consultation with Drugs Technical Advisory Board and Drugs Consultative Committee. Moreover the functions of Drugs Technical Advisory Board under Section 5 of the D&C Act, is not-only to advice on technical matters but also to carry out "other functions

assigned5 to the Respondent No.1 under the D&C Act.

2.4 Indisputably, the New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act, as the D&C Act does not provide for constitution of such a Committee. The New Drugs Advisory Committee is a committee functioning under the Central Drugs Standard Control Organization (in short "CDSCO"), which itself is not a statutory body under the D&C Act. Thus, the very act of the Respondent No.1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go-by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notification and renders it unsustainable in the eyes of law, as the

Respondent No.1 in exercise of powers vested under the D&C Act, cannot take away the statutory powers vested in DTAB, DCC and vest them in a Committee unilaterally formed by the Respondent No. 1.

2.5 In addition, for any action under Section 26A of the D&C Act, has to be preceded by hearing all stake holders (manufacturers etc.), unless there is grave urgency, for which reasons should be recorded, as held by this Hon'ble Court in Pfizer Judgment. It is submitted that prior to issue of the Impugned Notifications, no such notice or opportunity of hearing was afforded to the Petitioner, who manufactures the FDC in question.

2.6 The Petitioner submits that the fact that there was no grave urgency warranting exercise of powers under Section 26A of D&C Act is evident from the fact that the Impugned Notifications themselves mention that the prohibition is premised on the fact that the use of FDC in question is not rational as the FDC does not have any therapeutic justification and the two drugs which are the constituents of FDC are best administered separately, The prohibition is not premised on any adverse health consequences or risk to human beings and therefore it can be safely said that there were no compelling circumstances in giving a go-by to the requirement of issuance of notice and opportunity of hearing to manufacturers before prohibiting the FDC. Thus, the Impugned Notification dated 08.06.2017

is violative of Article 14 of the Constitution of India as it is arbitrary and unreasonable and violative of principles of natural justice.

2.7 It is pertinent to mention here that the said FDC has been approved by the Respondent No.2, Drug Controller General of India on 17.08.2009 and the Petitioner has been manufacturing the same from 2010 after obtaining licence from State Licencing Authority, Rajasthan. After having approved the FDC, there is no justification whatsoever to ban the FDC, that too without following the mandatory procedure specified under the D&C Act.

2.8 It is also relevant to state here that there is no adverse report about the FDC. The Impugned Notification is not based on any

adverse report, viz. Pharmacovigilance Report or otherwise. Further the FDC in question does not lead to any drug resistance or any adverse impact.

3. The brief facts giving rise to the filing of the present Writ Petition before this Hon'ble Court are as under:

3.1 The Petitioner is a pharmaceutical company of repute and is a contract manufacturer of pharmaceutical formulations in India. The Petitioner manufactures a wide range of pharma products including Anti-Diabetic, Antibiotics, Antifungal, NSAIDs, Gastrointestinal, Anthelmintic, Cardiovascular, Dermal, and several other categories of pharma products. The Petitioner is also engaged in formulation developments, technological innovations

conducting stability studies and arranging bio-equivalence studies and clinical trials. The Petitioner aspires to aid the community in leading a healthy life through two parallel objectives: formulating, developing and commercializing medicines, arid delivering affordable and accessible medication that satisfies urgent medical needs. The Petitioner Company has been manufacturing pharmaceutical products for big Indian and Multinational Pharma Companies.

3.2 The Petitioner Company is having sophisticated Research & Development, and Formulation Development Centres. The Petitioner's Laboratory is fully equipped for Physical and metallurgical testing, Micro-biological testing, Effective

controls of process, Chemical testing, Pharmacological testing, Stability Studies etc.

3.3 Fixed Dose Combinations (FDC) refer to products containing two or more active ingredients used for particular indication(s). This term is used generically to mean a particular combination of actives irrespective of the formulation or brand, It may be administered as single entity products given concurrently or as a finished pharmaceutical product. The development of FDCs is becoming increasingly important from a public health perspective. The basic rationale of making "fixed dose combination" medicinal products is either to improve adherence or to benefit from the added effects of the two medicinal products

given together FDCs have shown to be particularly useful in the treatment of diseases like HIV, malaria and tuberculosis and also in cardiology, diabetes and cancer conditions, based on international guidelines recommended by expert bodies, where giving multiple drugs for the management of a given condition is an accepted medical norm and practice, FDCs are also of use in chronic conditions especially when multiple disorders often co-exist. FDCs are known to offer specific advantages over the single entity preparations, such as increased efficacy, and/or better patient compliance dosage, possibly reduced cost and simpler logistics of distribution relevant to situations of limited resources.

3.4 Amongst other pharmaceutical products, the Petitioner manufactures for sale a Fixed Dose Combination of Ofloxacin 2 mg per ml and Ornidazole 5 mg per ml Infusion. The said FDC is manufactured by the Petitioner in its capacity as a contract manufacturer for Mankind Pharma Limited which is a pharmaceutical company of repute. The FDC manufactured by the Petitioner is marketed for sale by Mankind Pharma Limited under the brand name, Zenflox-OZ Infusion.

3.5 The Petitioner was granted licence to manufacture the FDC in question by the State Licencing Authority, Rajasthan and it has been manufacturing the same from the year 2010 onwards. The said licence has been renewed from time to time and the copy of the valid and subsisting

licence dated 06.01.2014 issued by the Drug Licencing and Controlling; Authority, Rajasthan is annexed herewith and marked as Annexure P-2.

3.6 The Impugned Notification dated 08.06.2017 prohibits manufacture for sale, sale and distribution of FDC in question and therefore the Petitioner is a person aggrieved and has the locus to file the Writ Petition. The Petitioner states that the FDC in question has been approved by the Respondent No.2 viz. Drug Controller General of India on 17.08.2009. Infact, the Fixed Dose Combination of Ofloxacin 200 mg and Ornidazole 500 mg in Tablet Form, which Is also an approved FDC has not been prohibited, however the Impugned Notification prohibits the same

combination in the form of infusion/injection, without any rational. This itself evidences a total non-application of mind on the part of the Respondent No.1 while issuing the Impugned Notifications. True copy of the relevant extract of the list of approved FDC by the Respondent No. 2 is annexed as Annexure P-3.

3.7 The FDC in question, viz. Ofloxacin + Ornidazole Injection is used for effective treatment of diarrhea of mixed infection. It is also pertinent to state here that the FDC in question is marketed in several countries. It is submitted that the strength of each composition used in making the FDC, ensures that the said FDC is safe for consumption and is beneficial to the patients to which it is administered. In

fact, large amount of material is available in public domain, including but not limited to .medical rationale of FDC in question, which goes to show that the said FDC has enormous amount of therapeutic justification and relevance. True copy of evidence in the form of rationale for Ofloxacin + Ornidazole is annexed herewith and marked as Annexure P-4.

3.8 The Petitioner states that the referenced FDC has been prescribed by doctors to patients of effective treatment of diarrhea of mixed infection and patients are benefitting from the same. There has been no Adverse Drug Reaction reported to the Petitioner or any serious complaints received by the Petitioner to raise a concern with regard to the safety and efficacy of the said FDC. It is also relevant

to state here that there is no adverse report about the FDC. The Impugned Notification is not based on any adverse report, viz. Pharmacovigilance Report or otherwise.

3.9 In this context, it is stated that Section 5 of D&C Act mandates the Central Government to constitute the Drugs Technical Advisory Board (in short "DTAB") consisting of expert members to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it under D&C Act. The term of office of the nominated and elected members of DTAB has also been prescribed as three years or for so long as they hold the appointment of the office by

virtue of which they are nominated or elected. DTAB, , vide Section 5 (4) has been authorized to frame its bye-laws fixing a quorum and regulating ;its own procedure and the conduct of all business and vide Section 5 (5) to constitute sub-committees for consideration of particular matters. The Central Government has been mandated by Section 5 (7) to appoint a person to be the Secretary of DTAB and to provide DTAB with clerical and other staff necessary.

3.10 Section 6 of D&C Act mandates the Central Government to establish a Central Drugs Laboratory (CLS) under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by the Act or by any Rules made thereunder. Section 6

empowers the Central Government to "after consultation with" DTAB make Rules prescribing the functions of the Central Drags Laboratory and the procedure for analysis or tests of the drugs and for such other matters as may be necessary.

3.11 Section 7 mandates the Central Government to constitute an Advisory Committee to be called the Drugs Consultative Committee (in short "DCC"), to advise the Central Government, the State Governments and DTAB on any other matter tending to secure uniformity throughout India in the administration of D&C Act. The DCC has been prescribed to consist of two representatives nominated by the Central Government and one representative nominated by each of the State Governments.

3.12 The Petitioner states that under Section 26A of the D&C Act, the Respondent No.1 is vested with the powers to regulate, restrict or prohibit manufacture, sale or distribution of a drug or cosmetic which is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do.

3.13 However, the Respondent No. 1 can exercise its powers under Section 26A of the D&C Act only after consultation and on the advice/recommendation of DTAB, DCC etc. under Section 5, 6 and 7 of the D&C Act. This Hon'ble Court in Pfizer Ltd,

(supra) had held that the provisions of Sections 5, 6 and 7 of the D&C Act are mandatory and cannot be given a go-by by the Respondent No.1 while passing any Order under Section 26A of the D&C Act.

3.14 Rule 122E of the Drugs and Cosmetics Rules, 1945 defines New Drug. In terms of Rule 122E of D&C Rules, a FDC of two or more drug, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims viz. indications dosage, dosage form and route of administration will be a New Drug. Further, in terms of the Explanation to Rule 122E, a New Drug shall continue to be consider as New Drug

for a period of four years from the date of its first approval [Explanation (ii) to Rule 122E].

3.15 The Petitioner states that it is an irrefutable position on record that the Respondent No.2 had approved the FDC in question on 17.08.2009 therefore by virtue of Explanation (ii) to Rule 122E, the FDCs in question cease to be a New Drug on or after 17.08.2013. Hence, there is no requirement of obtaining approval from Respondent No. 2 treating the two FDCs, as "New Drug" within the meaning of Rule 122 E of the D&C Rules on or after 17.08.2013.

3.16. Hence, even assuming without admitting that the Respondents could constitute a New Drugs Advisory

Committee, for the purpose of considering grant of license to new drugs, such Committee cannot consider banning existing FDCs, especially when the FDCs, in the present case, do not fall within the definition of New Drugs, under Rule 122E of the D&C Rules, as in terms of Explanation (ii) to Rule 122E of the D&C: Rules, any drug which was granted approval four years earlier by the Respondent No.2, ceases to be a new drug, within the meaning of Rule 122E of the D&C Rules.

3.17 However to the utter shock and surprise of the Petitioner, the Respondent No.1 has issued the Impugned Notification on 08.06.2017 and has prohibited the manufacture for sale, sale and distribution for human use of the FDC with immediate

effect as in its opinion it is not rational. The said decision of Respondent No.1 is based on the recommendation of New Drugs Advisory Committee constituted by Central Government which has come to a conclusion that the FDCs in question does not have therapeutic justification and the two drugs are best administered separately on as required basis. It is evident that the Respondent No.1 while issuing the Impugned Notifications has completely ignored the mandatory consultative process as provided under Sections 5, 6 and 7 of the D&C Act inasmuch as the decision of the Respondent No.1 is not based on any advice/recommendation of DTAB, DCC, etc. Further Section 26A of D&C Act, enjoins the Respondent No.1 to give an opportunity of hearing to stakeholders,

including the manufacturers, marketers, distributors, etc. No notice, in this regard was received by the Petitioner. It is also relevant to state here that there is no adverse report about the FDC. The Impugned Notification is not based on any adverse report, viz. Pharmacovigilance Report or otherwise.

3.18 In this context, it is submitted that the National Pharmaceutical Pricing Authority, a body existing under the supervision of Respondent No.1 has created an Integrated Pharmaceutical Data Base Management System (in short "IPDMS"), wherein all the pharmaceutical companies are required to file extensive details in relation to all drugs manufactured/marketed by them. Hence, it is clear that the Respondents have

information about the fact that the FDC in question is manufactured by the Petitioner. Hence, the Petitioner ought to have been heard, prior to issue of the Impugned Notification dated 08.06.2017.

4. The Petitioner submits that the Impugned Notification dated 08.06.2017 is illegal and arbitrary as the purported exercise of power by the Respondent No.1 under Section 26A of D&C Act is de-hors the statutory scheme of D&C Act and in particular the mandatory procedure prescribed under of Section 5,6,7 & 26A of D&C Act.

5. Feeling aggrieved, the Petitioner is filing the present Writ Petition on inter-alia following amongst other grounds:

GROUNDS

A. FOR, the Impugned Notification dated 08.06.2017 suffer from manifest error of law apparent on the face of record;

B. FOR, the Impugned Notifications are ex-facie illegal, arbitrary, irrational and unreasonable and is therefore violative of Article 14 of the Constitution of India;

C. FOR, the Impugned Notification has been issued by the Respondent No.1 in contravention of Sections 5, 6, 7 and 26A of the D&C Act. This Hon'ble Court has in Pfizer Ltd. (supra) dated 01.12.2016 has held that any exercise of powers by the Respondent No.1 under Section 26A of the D&C Act has to be preceded by consultation with the statutory bodies constituted under Sections 5, 6 and 7 of

the D&C Act viz. DTAB, Central Drugs Laboratory and DCC and any action under Section 26A of the D&C Act by the Respondent No. 1 is to be based on the advice of the aforesaid statutory bodies constituted under the D&C Act. In case the Respondent No.1 acts unilaterally or does not seek advice of the aforesaid statutory bodies then any action of the Respondent No.1 under Section 26A is unsustainable and shall be struck down/set aside by the Hon'ble Court;

D. FOR, in the present case, it is manifest from the Impugned Notifications that the Respondent No.1 has not consulted or sought the advice and recommendation of the aforesaid statutory bodies while prohibiting the FDC in question and has unilaterally acted on the basis of

recommendation of New Drugs Advisory Committee, which is impermissible under the statutory regime of D&C Act and in particular Sections 5, 6, 7 and 26A thereof;

E. FOR, this Hon'ble Court in Pfizer Ltd. (supra), in identical circumstances (wherein also while issuing 344 Notifications prohibiting FDCs, the Respondent No.1 had failed to consult, seek advice and recommendation of DTAB, Central Drugs Laboratory and DCC), bad struck down the Notifications on me ground that it constitutes violation of Sections 5, 6, 7 and 26A of the D&C Act.

F. FOR, Sections 5, 6 and 7 of the D&C Act are mandatory and cannot be in any manner ignored or by-passed by the

Respondent No.1. Sections 5 & 7 of the D&C Act provide that the purpose of constitution of DTAB is to advice the Respondent No.1 on technical matters arising out of administration of the Act and to carry out other functions assigned to the Respondent No.1 under the D&C Act and that the purpose of constitution of the DCC is to advice the Respondent No. 1 and DTAB on any matter tending to secure uniformity throughout India in the administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C Act which provide that the Respondent No.1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and hold consultation with DTAB and DCC, is mandatory. Moreover the functions of DTAB under Section 5 is not only to advice on technical

matters but also to carry out "other functions assigned" to the Respondent No.1 under the D&C Act. If the Respondent No.1 of its own was found fit to exercise the functions under the D&C Act including of a technical nature and have the wherewithal therefore, there was no need for constituting the DTAB and DCC;

G. FOR, the Petitioner submits that New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act. The D&C Act does not contemplate creation of the New Drugs Advisory Committee and thus it is not a statutory body under the D&C Act. The New Drugs Advisory Committee is a body functioning under CDS CO which is itself not a statutory body under the D&C Act,

This has been held by this Hon'ble Court in Pfizer Ltd. (supra). Thus, the very act of the Respondent No.1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go-by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notifications and renders it unsustainable in the eyes of law;

H. FOR, in addition to being in consonance with Sections 5, 6 and 7 of D&C Act, any action of the Respondent No.1 under Section 26A of the D&C Act, has to be preceded by giving notice and opportunity of hearing to the manufacturers of the FDC unless there is a grave urgency for which reasons should be recorded. In the present case, no such notice or opportunity of hearing has been afforded

to the Petitioner who is one of the leading manufacturer of the prohibited FDC;

I. FOR, the FDCs in question has been approved by the Respondent No.2 on 17.08.2009. The Petitioner was also granted licence to manufacture the FDC in question by the State Licencing Authority, Rajasthan arid it has been manufacturing the same from the year 2010 onwards. The said licence has been renewed from time to time. In such circumstances, it is difficult to contemplate that there were any urgency situation warranting the exercise of powers under Section 26A of D&C Act without issuance of notice and affording an opportunity of hearing to the manufacturers including the Petitioner. Thus, the Impugned Notification is

contrary to the principles of natural justice;

J. FOR, even assuming without admitting that the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to new drugs, such Committee cannot consider banning existing FDCs, especially when the FDCs, in the present case, do not fall within the definition of New Drugs, under Rule 122E of the D&C Rules, as in terms of Explanation (ii) to Rule 122E of the D&C Rules, any drug which was granted approval four years earlier by the Respondent No.2, ceases to be a new drug, within the meaning of Rule 122 E of the D&C Rules.

K. FOR, the fact that there was no grave urgency warranting exercise of powers

under Section 26A of D&C Act is also evident from the fact that the Impugned Notification dated 08.06.2017 itself mention that the prohibition is premised on the fact that the use of FDCs in question is not rational as the FDCs do not have any therapeutic justification and the two drugs which are the constituents of FDC are best administered separately. The prohibition is not premised on any adverse health consequences or risk to human beings and therefore it can be safely said that there were no compelling circumstances in giving a go-by to the requirement of issuance of notice and opportunity of hearing to manufacturers before prohibiting the FDC. There is no adverse report about the FDC. The Impugned Notification is not based on any adverse report, viz. Pharmacovigilance

Report or otherwise. Further the FDC in question cannot lead to any drug resistance or any adverse impact. This itself evidences a total non-application of mind on the part of the Respondent No. 1 while issuing the Impugned Notifications dated 08.06.2017. Thus, the Impugned Notification is violative of Article 14 of the Constitution of India as it is arbitrary and unreasonable;

L. FOR, the Fixed Dose Combination of Ofloxacin 200 mg and Ornidazole 500 mg in Tablet Form, which is also an approved FDC has not been prohibited, however the Impugned Notification prohibits the same combination in the form of infusion/ injection, without any rational. This itself evidences a total non-application of mind on the part of the Respondent No. 1 while

issuing the Impugned Notifications dated 08.06.2017;

M. FOR, the Respondent No. 1 has issued the Impugned Notification on 08.06.2017 and has prohibited the manufacture for sale, sale and distribution for human use of the FDC with immediate effect as in its opinion it is not rational. The said decision of Respondent No.1 is based on the recommendation of New Drugs Advisory Committee constituted by Central Government which has come to a conclusion that the FDCs in question does not have therapeutic justification and the two drugs are best administered separately on as required basis. It is evident that the Respondent No. 1 while issuing the Impugned Notifications has completely ignored the mandatory

consultative process as provided under Sections 5, 6 and 7 of the D&C Act inasmuch as the decision of the Respondent No: 1 is not based on any advice/recommendation of DTAB, DCC, etc. Further Section 26A of D & C Act, enjoins the Respondent No. 1 to give an opportunity of hearing to stakeholders, including the manufacturers, marketers, distributors, etc. No notice, in this regard was received by the Petitioner. In this context, it is submitted that the National Pharmaceutical Pricing Authority, a body existing under the supervision of Respondent No.1 has created an Integrated Pharmaceutical Data Base Management System (in short "IPDMS"), wherein ail the pharmaceutical companies are required to file extensive details in relation to all drugs manufactured/

marketed by them. Hence, it is clear that the Respondents have information about the fact that the FDCs in question are manufactured/marketed by the Petitioner. Hence, the Petitioner ought to have been heard, prior to issue of the Impugned Notifications dated 08.06.2017;

N. FOR, any pharmaceutical company to make available alternate drugs, minimum time gap of six months is required considering the time consumed in preparation of new formulations, packaging preparations, approvals by the authorities under the D & C Act etc. and also the time consumed in development, analysis, stability studies, etc. Thus, the immediate ban is drastic especially when crores of worth formulations are lying distributed in retail drug shops in the

country and it is practically very difficult to withdraw the products besides the huge loss that will be caused to manufacturers. It would also result in denial of access to medicines to patients across the country and to consumers who have been using FDCs products regularly;

O. FOR, Rule 74 (b) D&C Rules clearly provides that "the licencee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the Rules, these would come into force, four months after publication in the Official Gazette" especially when violation of the provisions of Section 26A of the D&C Act is

punishable under Section 28B of the D&C Act with imprisonment and fine. Considering such scheme of the D&C Act, it is improbable that the Legislature ever intended that a ban can be imposed with immediate effect especially when the decision making process has not been notified to all the stakeholders. Furthermore, the stocks on hand of the manufacturers can by itself expose the parties to penal actions. It is submitted that it is a statutory obligation of the Respondent No. 1 specifically incorporated in the D & C Act itself that while taking a decision in imposing any prohibition/ restriction under the D&C Act, the entitlements/obligations respectively which have come into existence thereby also creating vested rights, should always

be suitably provided for in any subsequent policy;

P. FOR, the Petitioner Company is having huge inventory of the Product which becomes a waste immediately after the Impugned Notification ; as Petitioner is a contract manufacturer and is manufacturing several brands under the said composition. Customers and trade associations, retailers and distributors have been writing to Petitioner for returning the Products and also not lifting the finished Products. The manufacturer and further distributors and stockiest have paid excise and sales tax on the products. Under the circumstances it is bound to happen that there will be shortage of medicine due to this ban and stock lying in the market will become useless and

public at large will suffer owing to the lack of the medicines in the market. The Petitioner will also lose business.

Q. FOR, the Petitioner submits that the Impugned Notifications dated 08.06.2017 is in teeth of the Judgment of this Hon'ble Court in Pfizer Ltd. (supra) & Anr. Though the Respondent No. 1 has filed a Special Leave Petition before the Hon'ble Supreme Court from the Judgment, the same pending and there is no stay of the Judgment of this Hon'ble Court. The Impugned Notification is therefore likely to be quashed by this Hon'ble Court;

6. The grounds urged above are without prejudice to each other and the Petitioner craves leave to add, alter, amend or modify the same if deemed necessary.

7. The Petitioner has no alternative efficacious remedy other than to invoke the extraordinary jurisdiction of this Hon'ble Court under Article 226 of the Constitution.

8. The Petitioner has not filed any other petition before this Hon'ble Court or before the Hon'ble Supreme Court on the facts and circumstances of the present case and in respect of the Impugned Notifications which forms the subject matter of the present writ petition.

9. The Petitioner has no alternate efficacious remedy under the D&C Act in respect of the Impugned Notifications which forms the subject matter of the present writ petition.

10. That the present writ petition is filed by the Petitioner through its Authorized Signatory Mr. Ranjan Kumar Sahu, who has been duly authorized vide Board Resolution dated

13.06.2017, to file the present writ petition, on its behalf.

PRAYER

In view of the aforesaid facts and circumstances, the Petitioner most respectfully prays that this Hon'ble Court may be graciously pleased to:-

(i) issue a writ of Certiorari or any other writ, order or direction in the nature of Certiorari calling for the records and quashing the Notifications bearing S.O. No. 1852 (E) dated 08.06.2017 (Annexure P-1) issued by Respondent No. 1; and

(ii) award cost(s) of the present petition to the Petitioner; and

(iii) pass any other appropriate order/orders as this Hon'ble court may deem fit and proper in the facts and circumstances of the case.

PETITIONER

THROUGH:

Sd/-
PRA LAW OFFICES
R. JAWAHAR LAL
ADVOCATE FOR THE PETITIONER
W-126, GREATER KAILASH PART-II
NEW DELHI-110 048
Ph: 011-40676767

NEW DELHI
DATED: 28.06.2017

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY ORIGINAL WRIT JURISDICTION

WRIT PETITION (C) NO.____OF 2017

IN THE MATTER OF:

Ahlcon Parenterals (I) Ltd. ....Petitioner

Versus

Union of India & Anr. ....Respondents

AFFIDAVIT

I, Ranjan Kumar Sahu, aged about 44 years, son of Mr. Gouranga Charan sahu, having office at 2nd Floor, 30 & 30E, Shivaji Marg Najafgarh. Road, New Delhi-110015, presently in Delhi do solemnly state and affirm as under: -

1. That I am the Authorized Signatory of the Petitioner Company in the Writ Petition and as such well conversant with the facts of the case.

2. I have gone through the accompanying Writ Petition and the contents thereof are true to my knowledge and belief. No part of it is false

and nothing material has been kept concealed therefrom.

3. The annexures annexed with the Writ Petition are true copies of their, respective originals

DEPONENT

VERIFICATION:

Verified at New Delhi on this 28nd day of June, 2017, that the contents of the foregoing affidavit are true and correct to my knowledge. No part of the affidavit is false and nothing material has been concealed therefrom.

DEPONENT

/TRUE COPY/

ANNEXURE-P-7

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY WRIT JURISDICTION

WRIT PETITION (C) NO.5398 OF 2017

IN THE MATTER OF:

J.K. Printpacks. ...Petitioner

Versus

Union of India & Anr. ...Respondents

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6.	ANNEXURE P-1:	

True typed copy of the Notification S.O, No. 1855 (E) dated 08.06.2017 issued by the Respondent No.1

7. ANNEXURE P-2:

True copy of the valid and subsisting licence dated 06.01.2016 issued by the Drug Licencing and Controlling Authority, Uttarakhand

8. ANNEXXJRE P-3:

True copy of the relevant extract of the list of approved FDC by the Respondent No. 2

9. An Application under section 151CPC for stay with supporting affidavit

10. An application under Section 151 CPC for exemption from filing

original documents with

supporting affidavit

11. Vakalatnama and Reconstituted

Partnership Deed

12. Court fee

PETITIONER

THROUGH:

PRA LAW OFFICES
R. JMVAHARLAL ENR.KO.D-933/1992
ADVOCATE FOR THE PETITIONER
W-126, GROUND FLOOR GREATER
KAILASH PART-II,
NEW DELHI-110 048
Ph:011-40676767
Mob. 9958996312
e-mail: iawahar@pralaw.in

NEW DELHI
DATED: 29.06.2017

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY WRIT JURISDICTION

WRIT PETITION (C) NO.5398 OF 2017

IN THE MATTER OF:

J.K. Printpacks. ...Petitioner

Versus

Union of India & Anr. ...Respondents

MEMO OF PARTIES

J.K. Printpacks

a Partnership Firm

having its office at:

C-14 to C-17

Sara Industrial Estate Ltd.

VPO Rampur, Dehradun-248 110

through its Partner

Mr. Veerpal Singh .....Petitioner

VERSUS

1. Union of India

through Secretary

Department of Health and Family Welfare

Ministry of Health and Family Welfare

Nirman Bhawan,

New Delhi-110 001

2. The Drug Controller General of India

FDA Bhawan

ITO, Kotla Road

New Delhi-110 002 ..... Respondents

PETITIONER

THROUGH:

PRA LAW OFFICES
R. JMVAHARLAL ENR.KO.D-933/1992
ADVOCATE FOR THE PETITIONER
W-126, GROUND FLOOR GREATER
KAILASH PART-II,
NEW DELHI-110 048
Ph:011-40676767
Mob. 9958996312
e-mail: iawahar@pralaw.in

NEW DELHI
DATED: 29.06.2017

SYNOPSIS

The Petitioner is invoking the extraordinary writ jurisdiction of this Hon'ble Court under Article 226 of the Constitution of India challenging Notification S.O. No.1855 (E) dated 08.06.2017, whereby the Respondent No.1. in purported exercise of its powers under Section 26A of the Drugs and Cosmetics Act, 1940 ("D&C Act") prohibited the manufacture for sale, sale and distribution for human use -of the fixed dose combination (drug with more than one active ingredient, in short referred to as "FDC") of Etodolac + Paracetamol, with immediate effect on the purported ground that the same there is no rational or therapeutic justification. The decision to prohibit manufacture for sale, sale and distribution of the FDC by the Impugned Notifications is based on the recommendation of the New Drugs Advisory Committee constituted by

Respondent No.1. The Petitioner submits that the New Advisory Committee is not a statutory body, contemplated under the D&C Act. The Petitioner submits that the Impugned Notification dated 08.06.2017 is ex-facie illegal, arbitrary and irrational and is therefore likely to be quashed by this Hon'ble Court as:

1. The Impugned Notification has been issued by the Respondent No.1 in contravention of Sections 5, 6, 7 and 26A of the D&C Act, inasmuch exercise of powers under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers of the concerned FDCs and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act. viz. Drugs Technical Advisory Board, Central Drugs Laboratory and Drugs Consultative

Committee. In this context, it is respectfully submitted that on 10.03.2016, the Respondent No.1 had issued 344 Notifications, banning a large number of FDC. While considering the challenge to 344 Notifications, the Hon'ble Court in its Judgment (in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) dated 01.12.2016, held that any exercise of powers by the Respondent No. 1 under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act. In the present case also, prior to issue of the Impugned Notification, the Respondent No.1 did not consult the

manufacturers or sought the advice and recommendation of the aforesaid statutory bodies. The Respondent No. 1 had acted unilaterally on the basis of recommendation of New Drugs Advisory Committee (a non-statutory Committee appointed by the Respondent No.1), which is impermissible under the statutory regime of D&C Act and in particular Sections 5, 6} 7 and 26A thereof.

2. In the present case, the FDC was approved by the Respondent No. 2 on 01.10.2010; therefore by virtue of Explanation (ii) to Rule 122E they cease to be a New Drug by 30.09.2014 (i.e. upon expiry of 4 years from the date of approval by DCGI (Respondent No.2). Therefore, even assuming without admitting that the Respondents could

constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to "new drugs" (as defined in Rule 122 E of the D&C Rules), such Committee cannot consider ban of existing FDC, especially when the FDC, in the present case, ceased to be New Drug, as defined in Rule 122E of the D&C Rules (per Explanation (ii) to Rule 122E of the D&C Rules).

3. The Petitioner respectfully submits that Sections 5, 6 and 7 of the D&C Act are mandatory in nature and cannot be in any manner ignored or by-passed by the Respondent No.1, as held by this Hon'ble Court in Pfizer Limited. The purpose of constitution of Drugs Technical Advisory Board is to advice the Respondent No.1 on technical matters arising out of

administration of the Act and to carry out other functions assigned to the Respondent No.1 under the D&C Act and the purpose of constitution of the Drugs Consultative Committee is to advice the Respondent No. 1 and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C Act provide that the Respondent No.1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and hold consultation with Drugs Technical Advisory Board and Drugs Consultative Committee. Moreover the functions of Drugs Technical Advisory Board under Section 5 of the D&C Act, is not only to advice on technical matters but also to carry out " other functions

assigned' to the Respondent No.1 under the D&C Act.

4. Indisputably, the New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act, as the D&C Act does not provide for constitution of such a Committee. The New Drugs Advisory Committee is a committee functioning under the Central Drugs Standard Control Organization (in short "CDSCO"), which itself is not a statutory body under the D&C Act. Thus, the very act of th$ Respondent No.1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notification and renders it unsustainable in the eyes of law, as the Respondent No. 1 in exercise of powers

vested under the D&C Act, cannot take away the statutory powers vested in DTAB, DCC and vest them in a Committee unilaterally formed by the Respondent No. 1.

5. In addition, for any action under Section 26A of the D&C Act, has to be preceded by hearing all stake holders (manufacturers etc.), unless there is grave urgency, for which reasons should be recorded, as held by this Hon'ble Court in Pfizer Judgment. It is submitted that prior to issue of the Impugned Notifications, no such notice or opportunity of hearing was afforded to the Petitioner, who manufactures the FDC in question.

6. The Petitioner submits that the fact that there was no grave urgency warranting exercise of powers under Section 26 A of D&C Act is evident from the fact that the Impugned Notifications themselves mention that the prohibition is premised on the fact that the use of FDC in question is not rational as the FDC does not have any therapeutic justification and the two drugs which are the constituents of FDC are best administered separately. The prohibition is not premised on any adverse health consequences or risk to human beings and therefore it can be safely said that there were no compelling circumstances in giving a' go-by to the requirement of issuance of notice and opportunity of hearing to manufacturers before prohibiting the FDC. Thus, the Impugned Notification dated 08.06.2017

is violative of Article 14 of the Constitution of India as it is arbitrary and unreasonable and violative of principles of natural justice.

7. It is pertinent to mention here that the said FDC has been approved by the Respondent No.2, Drug Controller General of India on 01.10.2010 and the Petitioner has been manufacturing the same from 2011 after obtaining licence from State Licencing Authority, Uttarakhand. After having approved the FDC, there is no justification whatsoever to ban the FDC, that too without following the mandatory procedure specified under the D&C Act.

8. It is also relevant to state here that there is no adverse report about the FDC. The Impugned Notification is not based on any

adverse report, viz. Pharmacovigilance Report or otherwise. Further the FDC in question is only anti-inflammatory and anti-pyretic which cannot lead to any drug resistance or any adverse impact.

LIST OF DATES & EVENTS

01.10.2010 The Respondent No. 2 approved the FDC of Etodolac + Paracetamol

06.01.2016: The Petitioner was granted licence to manufacture the FDC in question by the State Licencing Authority, Uttarakhand and the same was lastly renewed on 06.01.2016.

10.03.2016: The Respondent No.1 issued 344 Notifications prohibiting manufacture for sale, sale and distribution of FDCs.

01.12.2016: This Hon'ble Court vide Judgment in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) quashed the 344 Notifications on the ground that the Respondent No.1 while issuing the notifications has acted in contravention of the statutory regime under D&C Act, including Section 5,6,7& 26 A thereof.

08.06.2017: The Respondent No.1 has issued the Impugned Notification S.O. No.1855(E) prohibiting manufacture for sale, sale and distribution of the FDC, Etodolac + Paracetamol.

28.06.2017 Hence the present Writ Petition

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY WRIT JURISDICTION

WRIT PETITION (C) NO.5398 OF 2017

IN THE MATTER OF:

J.K. Printpacks
a Partnership Firm
having its office at:
C-14 to C-17
Sara Industrial Estate Ltd.
VPO Rampur, Dehradun-248 110
through its Partner
Mr. Veerpal Singh .....Petitioner

VERSUS

1. Union of India
through Secretary
Department of Health and Family Welfare
Ministry of Health and Family Welfare

Nirman Bhawan,

New Delhi-110 001

2. The Drug Controller General of India

FDA Bhawan

ITO, Kotla Road

New Delhi-110 002 ..... Respondents

WRIT PETITION UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA, 1950 SEEKING A WRIT OF CERTIORARI OR ANY OTHER WRIT, ORDER OR DIRECTION IN THE NATURE OF CERTIORARI CALLING FOR THE RECORDS AND QUASHING NOTIFICATION BEARING S.O. NO.1855 (E) DATED 08.06.2017 (ANNEXURE P-I) ISSUED BY RESPONDENT NO.1, IN PURPORTED EXERCISE OF POWERS UNDER SECTION 26A OF THE DRUGS AND COSMETICS ACT, 1940; IMPUGNED

NOTIFICATIONS ARE ARBITRARY, ILLEGAL- AND IRRATIONAL AND ISSUED IN VIOLATION OF SECTIONS 5, 6, 7 AND 26A OF THE DRUGS AND COSMETICS ACT, 1940.

TO

THE HON'BLE ACTING CHIEF JUSTICE AND HER COMPANION JUSTICES OF THE HON'BLE HIGH COURT OF DELHI AT NEW DELHI.

THE HUMBLE PETITION OF THE PETITIONER NAMED ABOVE:

MOST RESPECTFULLY SHOWETH:

1. The Petitioner is invoicing the extraordinary writ jurisdiction of this Hon'ble Court under Article 226 of the Constitution of India challenging Notification S.O. No.1855 (E) dated 08.06.2017 (in short the "Impugned

Notification"), whereby the Respondent No.1, in purported exercise of its powers under Section 26A of the Drugs and Cosmetics Act, 1940 (in short the "D&C Act") prohibited the manufacture for sale, sale and distribution for human use of the fixed dose combination (drug with more than one active ingredient, in short referred to as "FDC") of Etodolac and Paracetamol, with immediate effect on the purported ground that there is no rational or therapeutic justification for the FDC. The decision to prohibit manufacture for sale, sale and distribution of the FDC by the Impugned Notification is based on the recommendation of the New Drugs Advisory Committee constituted by Respondent No.1. In this context, it is relevant to submit that the New Advisory Committee is not a statutory body, contemplated under the D&C Act. True typed copy of the Notification S.O. No. 1855 (E)

dated 08.06.2017 issued by the Respondent No.1 are annexed and marked as Annexure P-1.

2. The Petitioner submits that the Impugned Notification dated 08.06.2017 is ex-facie illegal, arbitrary and irrational and is therefore likely to be quashed by this Hon'ble Court as:

2.1 The Impugned Notification has been issued by the Respondent No.1 in contravention of Sections 5, 6, 7 and 26 A of the D&C Act, inasmuch exercise of powers under Section 26 A of the D&C Act has to be preceded by consultation with the manufacturers of the concerned FDCs and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act viz. Drugs Technical Advisory Board, Central Drugs Laboratory and Drugs Consultative Committee. In this context, it is respectfully submitted that

on 10.03.2016, the Respondent No.1 had issued 344 Notifications, banning a large number of FDC: . While considering the challenge to 344 Notifications, the Hon'ble Court in its Judgment (in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) dated 01.12.2016, held that any exercise of powers by the Respondent No.1 under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act. In the present case also, prior to issue of the Impugned Notification, the Respondent No.1 did not consult the manufacturers or sought the advice and recommendation of the aforesaid statutory bodies. The Respondent No.1 had acted unilaterally on the basis of

recommendation of New Drugs Advisory Committee (a non-statutory Committee appointed by the Respondent No. 1), which is impermissible under the statutory regime of D&C Act and in particular Sections 5,6,7 and 26A thereof.

2.2 In the present case, the FDC was approved by the Respondent No.2 on 01.10.2010; therefore by virtue of Explanation (ii) to Rule 122E they cease to be a New Drug by 30.09.2014 (i.e. upon expiry of 4 years from the date of approval by DCGI (Respondent No.2). Therefore, even assuming without admitting that the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to "new drugs" (as defined in Rule 122 E of the D&C Rules), such Committee cannot consider ban of existing FDC, especially when the FDC, in the present

case, ceased to be New Drug, as defined in Rule 122E of the D&C Rules (per Explanation (ii) to Rule 122E of the D&C Rules).

2.3 The Petitioner respectfully submits that Sections 5, 6 and 7 of the D&C Act are mandatory in nature' and cannot be in any manner ignored or by-passed by the Respondent No.1, as held by this Hon'ble Court in Pfizer Limited. The purpose of constitution of Drugs Technical Advisory Board is to advice the Respondent No.1 on technical matters arising out of administration of the Act and to carry out other functions assigned to the Respondent No.1 under the D&C Act and the purpose of constitution of the Drugs Consultative Committee is to advice the Respondent No.1 and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of the P&C Act,

Thus, by its very nature Sections 5, 6 and 7 of the D&C Act provide that the Respondent No.1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and hold consultation with Drugs Technical Advisory Board and Drugs Consultative Committee. Moreover the functions of Drugs Technical Advisory Board under Section 5 of the D&C Act, is not only to advice on technical matters but also to carry out "other functions assigned' to the Respondent No. 1 under the D&C Act.

2.4 Indisputably, the New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act, as the D&C; Act does not provide for constitution of such a Committee. The New Drugs Advisory Committee is a committee functioning under the Central Drugs Standard Control Organization (in short "CDSCO"), which itself is

not a statutory body under the D&C Act. Thus, the very act of the Respondent No. 1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go-by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notification and renders it unsustainable in the eyes of law, as the Respondent No. 1 in exercise of powers vested under the D&C Act, cannot take away the statutory powers vested in DTAB, DCC and vest them in a Committee unilaterally formed by the Respondent No.1.

2.5 In addition, for any action under Section 26A of the D&C Act, has to be preceded by hearing all stake holders (manufacturers etc.), unless there is grave urgency, for which reasons should be recorded, as held by this Hon'ble Court in Pfizer Judgment. It is submitted that

prior to issue of the Impugned Notifications, no such notice or opportunity of hearing was afforded to the Petitioner, who manufactures the FDC in question.

2.6 The "Petitioner submits that the fact that there was no grave urgency warranting exercise of powers under Section 26A of D&C Act is evident from the fact that the Impugned Notifications themselves mention that the prohibition is premised on the fact that the use of FDC in question is not rational as the FDC does not have any therapeutic justification and the two drugs which are the, constituents of FDC are best administered separately. The prohibition is not premised on any adverse health consequences or risk to human beings and therefore it can be safely said that there were no compelling circumstances in giving a go-by to the requirement of issuance of notice

and opportunity of hearing to manufacturers before prohibiting the FDC. Thus, the Impugned Notification dated 08.06.2017 is violative of Article 14 of the Constitution of India as it is arbitrary and unreasonable and violative of principles of natural justice.

2.7 It is pertinent to mention here that the said FDC has been approved by the-Respondent No.2, Drug Controller General of India on 01.10.2010 and the Petitioner has been manufacturing the same from 2011 after obtaining licence from State Licencing Authority, Uttarakhand. After having approved the FDC, there is no justification whatsoever to ban the FDC, that too without following the mandatory procedure specified under the D&C Act.

2.8 It is also relevant to state here that there is no adverse report about the FDC. The Impugned

Notification is not based on any adverse report, viz, Pharmacovigilance Report or otherwise. Further the FDC in question is only anti-inflammatory and anti-pyretic which cannot lead to any drug resistance or any adverse impact..

3. The brief facts giving rise to the filing of the present Writ Petition before this Hon'ble Court are as under:

3.1 The Petitioner is a partnership firm is a contract manufacturer of pharmaceutical formulations in India. The Petitioner manufactures a wide range of pharma products including Anti-Diabetic, Antibiotics, Antifungal, NSAIDs, Gastrointestinal, Anthelmintic, Cardiovascular, Dermal, and several other categories of pharma products.

The Petitioner is also engaged in formulation developments, technological innovations conducting stability studies and arranging bio-equivalence studies and clinical trials. The Petitioner aspires to aid the community in leading a healthy life through two parallel objectives: formulating, developing and commercializing medicines, and delivering affordable and accessible medication that satisfies urgent medical needs. The Petitioner has been manufacturing pharmaceutical products for big Indian and Multinational Pharma Companies.

3.2 The Petitioner is having sophisticated Research & Development, and Formulation Development Centres. The

Petitioner's Laboratory is fully equipped for Physical and metallurgical testing, Micro-biological testing, Effective controls of process, Chemical testing, Pharmacological testing, Stability Studies etc.

3.3 Fixed Dose Combinations (FDC) refer to products containing two or more active ingredients used for particular indication(s). This term is used generically to mean a particular combination of actives irrespective of the formulation or brand. It may be administered as single entity products given concurrently or as a finished pharmaceutical product. The development of FDCs is becoming increasingly important from a public health perspective. The basic rationale

of making "'fixed dose combination" medicinal products is either to improve adherence or to benefit from the added effects of the two medicinal products given together. FDCs have shown to be particularly useful in the treatment of diseases like HIV, malaria and tuberculosis and also in cardiology, diabetes and cancer conditions, based on international guidelines recommended by expert bodies, where giving multiple drugs for the management of a given condition is an accepted medical norm and practice, FDCs are also of use in chronic conditions especially when multiple disorders often co-exist. FDCs are known to offer specific advantages over the single entity preparations, such as increased efficacy, and/or better patient

compliance dosage, possibly reduced cost and simpler logistics of distribution relevant to situations of limited resources.

3.4 Amongst other pharmaceutical products, the Petitioner manufactures for sale a Fixed Dose Combination of Etodolac 400 mg and Paracetamol 500 mg. The said FDC is manufactured by the Petitioner in its capacity as a contract manufacturer for Mankind Pharma Limited which is a pharmaceutical company of repute. The FDC manufactured by the Petitioner is marketed for sale by Mankind Pharma Limited under the brand name Orthokind-P 400 mg. The FDC is used for effective treatment of toothache, joint pain, headache, ear pain, etc. The

Petitioner was granted licence to manufacture the FDC in question by the State Licencing Authority, Uttarakhand and it has been manufacturing the same from the year 2011 onwards. The said licence has been renewed from time to time and the copy of the valid and subsisting licence dated 06.01.2016 issued by the Drug Licencing and Controlling Authority, Uttarakhand is annexed herewith and marked as Annexure P-2.

3.5 The Impugned Notification dated 08.06.2017 prohibits manufacture for sale, sale and distribution of FDC in question and therefore the Petitioner is a person aggrieved and has the locus to file the Writ Petition. The Petitioner states that the FDC in question has

been approved by the Respondent No. 2 viz. Drug Controller General of India on 01. 10.2010. True copy of the relevant extract of the list of approved FDC by the Respondent No. 2 is annexed as Annexure P-3.

3.6 The FDC in question, viz. Etodolac 400 mg and Paracetamol 500 mg is used for effective treatment of toothache, joint pain, headache, ear pain, etc. It is also pertinent to state here that the FDC in question are marketed in several countries. It is submitted that the strength of each composition used in making the FDC, ensures that the said FDC is safe for consumption and is beneficial to the patients to which it is administered. In fact, large amount of material is available in public domain,

including but not limited to medical rationale of FDC in question, which goes to show that the said FDC has enormous amount of therapeutic justification and relevance. It is also relevant to state here that there is no adverse report about the FDC. The Impugned Notification is not based on any adverse report, viz. Pharmacovigilance Report or otherwise. Further the FDC in question is only anti-inflammatory, and anti-pyretic which cannot lead to any drug resistance or any adverse impact.

3.7 The Petitioner states that the referenced FDC has been prescribed by doctors to; patients for effective treatment of toothache, joint pain, headache, ear pain, etc. and patients

are benefitting from the same. There has been no Adverse Drug Reaction reported to the Petitioner or any serious complaints received by the Petitioner to raise a concern with regard to the safety and efficacy of the said FDC.

3.8 In this context, it is stated that Section 5 of D&C Act mandates the Central Government to constitute the Drugs Technical Advisory Board (in short "DTAB") consisting of expert members to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it under D&C Act. The term of office of the nominated and elected members of DTAB has also been prescribed as three

years or for so long as they hold the appointment of the office by virtue of which they are nominated or elected. DTAB, vide Section 5 (4) has been authorized to frame its bye-laws fixing a quorum and regulating its own procedure and the conduct of all business and vide Section 5 (5) to constitute sub-committees for consideration of particular matters. The Central Government has been mandated by Section 5 (7) to appoint a person to be the Secretary of DTAB and to provide DTAB with clerical and other staff necessary.

3.9 Section 6 of D&C Act mandates the Central Government to establish a Central Drugs Laboratory (CLS) under the control of a Director to be appointed

by the Central Government, to carry out the functions entrusted to it by the Act or by any Rules made thereunder. Section 6 empowers the Central Government to "after consultation with" DTAB make Rules prescribing the functions of the Central Drugs Laboratory and the procedure for analysis or tests of the drugs and for such other matters as may be necessary.

3.10 Section 7 mandates the Central Government to constitute an Advisory Committee to be called the Drugs Consultative Committee (in short "DCC"), to advise the Central Government, the State Governments and DTAB on any other matter tending to secure uniformity throughout India in

the administration of D&C Act. The DCC has been prescribed to consist of two representatives nominated by the Central Government and one representative nominated by each of the State Governments.

3.11 The Petitioner states that under Section 26 A of the D&C Act, the Respondent No.1 is vested with the powers to regulate, restrict or prohibit manufacture, sale or distribution of a drug or cosmetic which is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the

public interest it is necessary or expedient so to do.

3.12 However, the Respondent No.1 can exercise its powers under Section 26A of the D&C Act only after consultation and on the advice/recommendation of DTAB, DCC etc. under Section 5, 6 and 7 of the D&C Act. This Hon'ble Court in Pfizer Ltd. (supra) had held that the provisions of Sections 5; 6 and 7 of the D&C Act are mandatory and cannot be given a go-by by the Respondent No.1 while passing any Order under Section 26 A of the D&C Act.

3.13 Rule 122E of the Drugs and Cosmetics Rules, 1945 defines New Drug. In terms of Rule 122E of D&C Rules, a FDC of two or more drug, individually approved

earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims viz. indications dosage, dosage form and route of administration will be a New Drug. Further, in terms of the Explanation to Rule 122E, a New Drug shall continue to be consider as New Drug for a period of four years from the date of its first approval [Explanation (ii) to Rule 122E].

3.14 The Petitioner states that it is an irrefutable position on record that the Respondent No.2 had approved the FDC in question on 01.10.2010; therefore by virtue of Explanation (ii) to Rule 122E,

the FDC in question cease to be a New Drug on or after 30.09.2014. Hence, there is no requirement of obtaining approval from Respondent No. 2 treating the FDC, as "New Drug" within the meaning of Rule 122 E of the D&C Rules on or after 30.09.2014.

3.15 Hence, even assuming without admitting that the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to new. drugs, such Committee cannot consider banning existing FDC. especially when the FDC, in the present case, does not fall within the definition of New Drugs, under Rule 122E of the P&C Rules, as in terms of Explanation (ii) to Rule 122B of the D&C Rules, any drug which was

granted approval four years earlier by the Respondent No.2, ceases to be a new drug, within the meaning of Rule 122 E of the D&C Rules.

3.16 However to the utter shock and surprise of the Petitioner, the Respondent No.1 has issued the Impugned Notification on 08.06.2017 and has prohibited the manufacture for sale, sale and distribution for human use of the FDC with immediate effect as in its opinion it is not rational. The said decision of Respondent No.1 is based on the recommendation of New Drugs Advisory Committee constituted by Central Government which has come to a conclusion that the FDCs in question does not have therapeutic justification and the two drugs are best

administered separately on as required basis. It is evident that the Respondent No.1 while issuing the Impugned Notifications has completely ignored the mandatory consultative process as provided under Sections 5, 6 and 7 of the D&C Act inasmuch as the decision of the Respondent No.1 is not based on any advice/recommendation of DTAB, DCC, etc. Further Section 26A of D&C Act, enjoins the Respondent No.1 to give an opportunity of hearing to stakeholders, including the manufacturers, marketers, distributors, etc. No notice, in this regard; was received by the Petitioner. It is also relevant to state here that there is no adverse report about the FDC. The Impugned Notification is not based on any adverse report, viz.

Pharmacovigilance Report or otherwise. Further the FDC in question is only anti-inflammatory and anti-pyretic which cannot lead to any drug resistance or any adverse impact.

3.17 In this context, it is submitted that the National Pharmaceutical Pricing Authority, a body existing under the supervision of Respondent No. 1 has created an Integrated Pharmaceutical Data Base Management System (in short "IPDMS"), wherein all the pharmaceutical companies are required to file extensive details in relation to all drugs manufactured/marketed by them. Hence, it is clear that the Respondents have information about the fact that the FDC in question is manufactured by the Petitioner.

4. The Petitioner submits that the Impugned Notification dated 08.06.2017are illegal and arbitrary as the purported exercise of power by the Respondent No.1 under Section 26A of D&C Act is de-hors the statutory scheme of D&C Act and in particular the mandatory procedure prescribed under of Section 5, 6, 7 & 26A of D&C Act.

5. Feeling aggrieved, the Petitioner is filing the present Writ Petition oh inter-alia following amongst other grounds:

GROUNDS

[A]. FOR, the Impugned Notification dated 08.06.2017 suffer from manifest error of law apparent on the face of record;

[B]. FOR the Impugned Notifications are ex-facie illegal, arbitrary, irrational and

unreasonable and is therefore violative' of Article 14 of the Constitution of India;

[C]. FOR, the Impugned Notification has been issued by the Respondent No.1 in contravention of Sections 5, 6, 7 and 26 A of the D&C Act. This Hon'ble Court has in Pfizer Ltd. (supra) dated 01.12.2016 has held that any exercise of powers by the Respondent No.1 under Section 26A of the D&C Act has to be preceded by consultation with the statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act viz. DTAB, Central Drugs Laboratory and DCC and any action under Section 26A of the D&C Act by the Respondent No.1 is to be based on the advice of the aforesaid statutory bodies constituted under the D&C Act. In case the Respondent No.1 acts unilaterally or

does not seek advice of the aforesaid statutory bodies then any action of the Respondent No.1 under Section 26A is unsustainable and shall be struck down/set aside by the Hon'ble Court.

[D]. FOR, in the present case, it is manifest from the Impugned Notifications that the Respondent No.1 has not consulted or sought the advice and; recommendation of the aforesaid statutory bodies while prohibiting the FDC in question and has unilaterally acted on the basis of recommendation of New Drugs Advisory Committee, which is impermissible under the statutory regime of D&C Act and in particular Sections 5, 6, 7 and 26A thereof;

[E]. FOR, this Hon'ble Court in Pfizer Ltd. (supra), in identical circumstances (wherein also while issuing 344 Notifications prohibiting FDCs, the Respondent No.1 had failed to consult, seek advice and recommendation of DTAB, Central Drugs Laboratory and DCC), had struck down the Notifications on the ground that it constitutes violation of Sections 5, 6, 7 and 26 A of the D&C Act.

[F]. FOR, Sections 5, 6 and 7 of the D&C Act are mandatory and cannot be in any manner ignored or by-passed by the Respondent No.1. Sections 5 & 7 of the D&C Act provide that the purpose of constitution of DTAB is to advice the Respondent No.1 on technical matters arising out of administration of the Act

and to carry out other functions assigned to the Respondent No.1 under the D&C Act and that the purpose of constitution of the DCC is to advice the Respondent No.1 and DTAB on any matter tending to secure uniformity throughout India in the administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C Act which provide that the Respondent No.1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and hold consultation with DTAB and DCC, is mandatory. Moreover the functions of DTAB under Section 5 is not only to advice on technical matters but also to carry out "other functions assigned" to the Respondent No.1 under the D&C Act, If the Respondent No.1 of its own was found fit to exercise the functions under the D&C

Act including of a technical nature and have the wherewithal therefore, there was no need for constituting the DTAB and DCC;

[G]. FOR, the Petitioner submits that New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act. The D&C Act does not contemplate creation of the New Drugs Advisory Committee and thus it is not a statutory body under the D&C Act. The New Drugs Advisory Committee is a body functioning under CDS CO which is itself not a statutory body under the D&C Act. This has been held by this Hon'ble Court in Pfizer Ltd. (supra). Thus, the very act of the Respondent No.1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go-by to

the statutory authorities constituted under the D&C Act vitiates the Impugned Notifications and renders it unsustainable in the eyes of law;

[H]. FOR, in addition to being in consonance with Sections 5, 6 and 7 of D&C Act, any action of the Respondent No.1 under Section 26 A of the D&C Act, has to be preceded by giving notice and opportunity of hearing to the manufacturers of the FDC unless there is a grave urgency for which reasons should be recorded. In the present case, no such notice or opportunity of hearing has been afforded to the Petitioner who is one of the leading manufacturer of the prohibited FDC;

[I]. FOR, the FDCs in question has been approved by the Respondent No. 2 on

01.10.2010. The Petitioner was also granted licence to manufacture the FDC in question by the State Licencing Authority, Uttarakhand and it has been manufacturing the same from the year 2011 onwards. The said licence has been renewed from time to time. In such circumstances, it is difficult to contemplate that there were any urgency situation warranting the exercise of powers under Section 26 A of D&C Act without issuance of notice and affording an opportunity of hearing to the manufacturers including the Petitioner. Thus, the Impugned Notification is contrary to the principles of natural justice;

[J]. FOR, even assuming without admitting that the Respondents could constitute a

New Drugs Advisory Committee, for the purpose of considering grant of license to new drugs, such Committee cannot consider banning existing FDCs, especially when the FDCs. in the present case, do not fall within the definition of New Drugs, under Rule 122E of the D&C Rules, as in terms of Explanation (ii) to Rule 122E of the D&C Rules, any drug which was granted approval four years earlier by the Respondent No.2, ceases to be a new drug, within the meaning of Rule 122 E of the D&C Rules.

[K]. FOR, the fact that there was no grave urgency warranting exercise of powers under Section 26A of D&C Act is also evident from the fact that the Impugned Notification dated 08.06.2017 itself mention that the prohibition is premised

on the fact that the use of FDCs in question is; not rational as the FDCs do not have any therapeutic justification and the two drugs which are the constituents of FDC are best administered separately. The prohibition is not premised on any adverse health consequences or risk to human beings and therefore it can be safely said that there were no compelling circumstances in giving a go-by to the requirement of issuance of notice and opportunity of hearing to manufacturers before prohibiting the FDC. Thus, the Impugned Notification is violative of Article 14 of the Constitution of India as it is arbitrary and unreasonable;

[L]. FOR, there is no adverse report about the FDC. The Impugned Notification's not based on any adverse report, viz.

Pharmacovigilance Report or otherwise. Further the FDC in question is only anti-inflammatory and anti-pyretic which cannot lead to any drug resistance or any adverse impact. This itself evidences a total non-application of mind on the part of the Respondent No.1 while issuing the Impugned Notifications dated 08.06.2017;

[M]. FOR, the Respondent No.1 has issued the Impugned Notification on 08.06.2017 and has prohibited the manufacture for sale, sale and distribution for human use of the FDC with immediate effect as in its opinion it is not rational. The said decision of Respondent No.1 is based on the recommendation of New Drugs Advisory Committee constituted by Central Government which has come to a conclusion that the FDCs in question does

not have therapeutic justification and the two drugs are best administered separately on as required basis. It is evident that the Respondent No.1 while issuing the Impugned Notifications has completely ignored the mandatory consultative process as provided under Sections 5, 6 and 7 of the D&C Act inasmuch as the decision of the Respondent No.1 is not based on any advice/recommendation of DTAB, DCC etc. Further Section 26A of D & C Act, enjoins the Respondent No.1 to give an opportunity of hearing to stakeholders, including the manufacturers, marketers, distributors, etc. No notice, in this regard was received by the Petitioner. In this context, it is submitted that the National Pharmaceutical Pricing Authority, a body existing under the supervision of

Respondent No.1 has created an Integrated Pharmaceutical Data Base Management System (in short "IPDMS"), wherein all the pharmaceutical companies are required to file extensive details in relation to all drugs manufactured/marketed by them. Hence, the Petitioner ought to have been heard, prior to issue of the Impugned Notifications dated 08.06.2017;

[N]. FOR, any pharmaceutical company to make available alternate drugs, minimum time gap of six months is required considering the time consumed in preparation of new formulations, packaging preparations, approvals by the authorities under the D & C Act, etc. and also the time consumed in development, analysis, stability studies, etc. Thus, the

immediate ban is drastic especially when crores of worth formulations are lying distributed in retail drug shops in the country and it is practically very difficult to withdraw the products besides the huge loss that will be caused to manufacturers. It would also result in denial of access to medicines to patients across the country and to consumers who have been using FDCs products regularly;

[O]. FOR, Rule 74 (b) D&C Rules clearly provides that "the licencee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act, provided, that where such further requirements are specified in the Rules, these would come into force, four months

after publication in the Official Gazette" especially when violation of the provisions of Section 26 - A of the D&C Act is punishable under Section 28B of the D&C Act with imprisonment and fine. Considering such scheme of the D&C Act, it is improbable that the Legislature ever intended that a ban can be imposed with immediate effect especially when the decision making process has not been notified to all the stake-holders. Furthermore, the stocks on hand of the: manufacturers can by itself expose the parties to penal actions. It is submitted that it is a statutory obligation of the Respondent No.1 specifically incorporated in the D&C Act itself that while taking a decision in imposing any prohibition/ restriction under the D & C Act, the entitlements/ obligations respectively

which have come into existence thereby also creating vested rights, should always be suitably provided for in any subsequent policy;

[P]. FOR, the Petitioner is having huge inventory of the Product which becomes a waste immediately after the Impugned Notification as Petitioner is a contract manufacturer and is manufacturing several brands under the said composition. Customers and trade associations, retailers and distributors have been writing to Petitioner for returning the Products and also not lifting the finished Products. The manufacturer and further distributors and stockiest have paid excise and sales tax on the products. Under the circumstances it is bound to happen that there will be shortage of

medicine due to this ban and stock lying in the market will become useless and public at large will suffer owing to the lack of the medicines in the market. The Petitioner will also lose business.

[Q]. FOR, the Petitioner submits that the Impugned Notifications dated 08.06.2017 is in teeth of the Judgment of this Hon'ble Court in Pfizer Ltd. (supra) & Anr. Though the Respondent No.1 has filed a Special Leave Petition before the Hon'ble Supreme Court from the Judgment, the same pending and there is no stay of the Judgment of this Hon'ble Court. The Impugned Notification is therefore likely to be quashed by this Hon'ble Court;

6. The grounds urged above are without prejudice to each other and the Petitioner craves leave

to add, alter, amend or modify the same if deemed necessary.

7. The Petitioner has no alternative efficacious remedy other than to invoke the extraordinary jurisdiction of this Hon'ble Court under Article 226 of the Constitution.

8. The Petitioner has not filed any other petition before this Hon'ble Court or before the Hon'ble Supreme Court on the facts and circumstances of the present case and in respect of the Impugned Notifications which forms the subject matter of the present writ petition.

9. The Petitioner has no alternate efficacious remedy under the D&C Act in respect of the Impugned Notifications which forms the subject matter of the present writ petition.

10. That the present writ petition is filed by the Petitioner through its Partner, Mr. Veerpal Singh and hence competent to sign, verify and file the present writ petition, on its behalf.

PRAYER

In view of the aforesaid facts and circumstances, the Petitioner most respectfully prays that this Hon'ble Court may be graciously pleased to:

(i). issue a writ of Certiorari or any other writ, order or direction in the nature of Certiorari calling for the records and quashing the Notification bearing S.O. No.1855 (E) dated 08.06.2017 (Annexure P-1) issued by Respondent No.1; and

(ii) award cost(s) of the present petition to the Petitioner; and

(iii) pass any other appropriate order/ orders as this Hon'ble court may deem fit and proper in the facts and circumstances of the case.

PETITIONER

THROUGH:

PRA LAW OFFICES
R. JAVAHARLAL ENR.KO.D-933/1992
ADVOCATE FOR THE PETITIONER
W-126, GROUND FLOOR GREATER
KAILASH PART-II, NEW DELHI-110 048
Ph:011-40676767 Mob. 9958996312
e-mail: jawahar@pralaw.in

NEW DELHI
DATED: 28.06.2017

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY WRIT JURISDICTION

WRIT PETITION (C) NO.5398 OF 2017

IN THE MATTER OF:

J.K. Printpacks. ...Petitioner

Versus

Union of India & Anr. ...Respondents

AFFIDAVIT

I, VEERPAL SINGH, aged about 61 years, son of Mr.MEGHRAJ SINGH, having office at C-14 TO 17 SARA INDUSTRIAL ESTATE LTD VPO RAMPUR DISTT- DEHRAPXJN (UJQ, presently in Delhi do solemnly state and affirm as under

1. That I am the Authorized Signatory of the Petitioner Company in the Writ Petition and as such well conversant with the facts of the case.

2. I have, gone through the accompanying Writ Petition and the contents thereof are true to

my knowledge and belief. No part of it is false and nothing material has been kept concealed therefrom.

3. The annexures annexed with the Writ Petition are true 7 copies of their respective originals.

DEPONENT

VERIFICATION:

Verified at New Delhi on this28th day of June, 2017, that the contents of the foregoing affidavit are true and correct to my knowledge. No part of the affidavit is false and nothing material has been concealed therefrom.

DEPONENT



ANNEXURE P-8

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY WRIT JURISDICTION

WRIT PETITION (C) NO. 5399 OF 2017

IN THE MATTER OF:

Windlas Biotech Pvt. Ltd. ....Petitioner

Versus

Union of India & Anr. ..... Respondents

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PETITIONER

THROUGH:

Sd/-

PRA LAW OFFICES
R. JAWAHAR LAL
ENR. NO. D-933/1992
ADVOCATE FOR THE PETITIONER
W-126, GROUND FLOOR
GREATER KAILASH PART-II
NEW DELHI-110 048
Ph: 011-40676767
Mob. 9958996312
e-mail: jawahar@pralaw.in

NEW DELHI
DATED: 29.06.2017

IN THE HIGH COURT OF DELHI

AT NEW DELHI

EXTRAORDINARY ORIGINAL WRIT

JURISDICDTION

WRIT PETITION (C) NO._____OF 20 17

IN THE MATTER OF:

Windlas Biotech Pvt. Ltd. ....Petitioner

Versus

Union of India & Anr. ...Respondents

MEMO OF PARTIES

Windlas Biotech Pvt. Ltd.

a company existing under the

Companies Act, 2013 paying its

office at: Khasra No. 141 to 143 & 145

Mohabewala Industrial Area

Dehradun-248 110

through its Managing Director

Mr. Ashok Kumar Windlas ....Petitioner

-Versus-





1. Union of India
   through Secretary
   Department of Health and
   Family Welfare Ministry
   of Health and Family Welfare
   Nirman Bhawan,
   New Delhi-110 001

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

PETITIONER

THROUGH:

Sd/-

PRA LAW OFFICES
R. JAWAHAR LAL
ENR. NO. D-933/1992
ADVOCATE FOR THE PETITIONER
W-126, GREATER KAILASH PART-II
NEW DELHI-110 048
Ph: 011-40676767
Mob. 9958996312

NEW DELHI
DATE: 29.06.2017

SYNOPSIS

The Petitioner is invoicing the extraordinary writ jurisdiction of this Hon'ble Court under Article 226 of the Constitution of India challenging Notification S.O. No. 1855 (E) dated 08.06.2017, whereby the Respondent No.1, in purported exercise of its powers under Section 26A of the Drugs and Cosmetics Act, 1940 ("D&C Act") prohibited the manufacture for sale, sale and distribution for human use; of the fixed dose combination (drug with more than one active ingredient, in short referred to as "FDC") of Etodolac + Paracetamol, with immediate effect on the purported ground that the same there is no rational or therapeutic justification. The decision to prohibit manufacture for





sale, sale and distribution of the FDC by the Impugned Notifications is based on the recommendation of the New Drugs Advisory Committee constituted by Respondent No.1. The Petitioner submits that the New Advisory Committee is not a statutory body, contemplated under the D&C Act. The Petitioner submits that the Impugned Notification dated 08.06.2017 is ex -facie illegal, arbitrary and irrational and is therefore likely to be quashed by this Hon'ble Court as:

1. The Impugned Notification has been issued by the Respondent No. 1 in contravention of Sections 5, 6, 7 and 26A of the D&C Act, inasmuch exercise of powers under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers of the concerned FDCs





and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act viz. Drugs Technical Advisory Board, Central Drugs Laboratory and Drugs' Consultative Committee. In this context, it is respectfully submitted that on 10.03.2016, the Respondent No.1 had issued 344 Notifications, banning a large number of FDC. While considering the challenge to 344 Notifications, the Hon'ble Court in its Judgment (in Pfizer Ltd. & Anr. Vs, Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) dated 01.12.2016, held that any exercise of powers by the Respondent No.1 under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers and

ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act. In the present case also, prior to issue of the Impugned Notification, the Respondent No.1 did not consult the manufacturers or sought the advice and recommendation of the aforesaid statutory bodies. The Respondent No.1 had acted unilaterally on the basis of recommendation of New Drugs Advisory Committee (a non-statutory Committee appointed by the Respondent No.1), which is impermissible under the statutory regime of D&C Act and in particular Sections 5, 6, 7 and 26A thereof.

2. In the present case, the FDC was approved by the Respondent No.2 on





01.10.2010 therefore by virtue of Explanation (ii) to Rule 122E they cease to be a New Drug by 30.09.2014 (i.e. upon expiry of 4 years from the date of approval by DCGI (Respondent No.2). Therefore, even assuming without admitting that the Respondents could constituted New Drugs Advisory Committee, for the purpose of considering grant of license to "new drugs" (as defined in Rule 122 E of the D&C Rules), such Committee cannot consider ban of existing FDC, especially when the FDC, in the present case, ceased to be New Drug, as defined in Rule 122E of the D&C Rules (per Explanation (ii) to Rule 122E of the D&C Rules).

3. The Petitioner respectfully submits that Sections 5, 6 and 7 of the D&C Act are mandatory in nature and cannot be in any manner ignored or by-passed by the Respondent No.1, as held by this Hon'ble Court in Pfizer Limited. The purpose of constitution of Drugs Technical Advisory Board is to advice the Respondent No.1 on technical matters arising out of administration of the Act and to carry out other functions assigned to the Respondent No. 1 under the D&C Act and the purpose of constitution of the Drugs Consultative Committee is to advice the Respondent No.1 and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C Act provide that the Respondent





No.1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and hold consultation with Drugs Technical Advisory Board and Drugs Consultative Committee. Moreover the functions of Drugs Technical Advisory Board under Section 5 of the D&C Act, is not only to advice on technical matters but also to carry out "other functions assigned" to the Respondent No.1 under the D&C Act.

4. Indisputably, the New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act as the D&C Act does not provide for constitution of such a Committee. The New Drugs Advisory Committee is a committee functioning under the Central Drugs Standard Control Organization (in





short "CDSCO"), which itself is not a statutory body under the D&C Act. Thus, the very act of the Respondent No.1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go-by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notification and renders it unsustainable in the eyes of law, as the Respondent No. 1 in exercise of powers vested under the D&C Act, cannot take away the statutory powers vested in DTAB, DCC and vest them in a Committee unilaterally formed by the Respondent No.1.

5. In addition, for any action under Section 26A of the D&C Act, has to be preceded by hearing ail stake holders (manufacturers etc.), unless there; is





grave urgency, for which reasons should be recorded, as held by this Hon'ble Court in Pfizer Judgment. It is submitted that prior to issue of the Impugned Notifications, no such notice or opportunity of hearing was afforded to the Petitioner, who manufactures the FDC in question.

6. The Petitioner submits that the fact that there was no grave urgency warranting exercise of powers under Section 26A of D&C Act is evident from the fact that the Impugned Notifications themselves mention that the prohibition is premised on the fact that the use of FDC in question is not rational as the FDC does not have any therapeutic justification and the two drugs which are the constituents of FDC are best administered separately.

The prohibition is not premised on any adverse health consequences or risk to human beings and therefore it can be safely said that there were no compelling circumstances in giving a go-by to the requirement of issuance of notice and opportunity of hearing to manufacturers before prohibiting the FDC. Thus, the Impugned Notification dated 08.06.2017 is violative of Article 14 of the Constitution of India as it is arbitrary and unreasonable and violative of principles of natural justice.

7. It is pertinent to mention here that the said FDC has been approved by the Respondent No. 2, Drug Controller General of India on 01.10.2010 and the Petitioner has been manufacturing the same from 01.11.2010 after obtaining





licence from State Licencing Authority, Uttarakhand. After having approved the FDC, there is no justification whatsoever to ban the FDC, that too without following the mandatory procedure specified under the D&C Act.

8. It is also relevant to state here that there is no adverse report about the FDC. The Impugned Notification is not based on any adverse report, viz. Pharmaco vigilance Report or otherwise. Further the FDC in question is only anti-inflammatory and anti-pyretic which cannot lead to any drug resistance or any adverse impact.

LIST OF DATES & EVENTS

01.10.2010	The Respondent No.2 approved the FDC of Etodolac +





	Paracetamol
06.01.2014	The Petitioner was granted licence to manufacture the FDC in question by the State Licencing Authority, Uttarakhand and the same was lastly renewed on 06.01.2014
10.3.2016	The Respondent No.1 issued 344 Notifications prohibiting manufacture for sale, sale and distribution of FDCs.
01.12.2016	This Hon'ble Court vide Judgment in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) quashed the 344 Notifications on the ground that the Respondent No.

	1 while issuing the notifications has acted in contravention of the statutory regime under D&C Act, including Section 5,6,7 & 26A thereof
08.06.2017	The Respondent No. 1 has issued the Impugned Notification S.O. No. 1855 (E) prohibiting manufacture for sale, sale and distribution of the FDC, Etodolac + Paracetamol
28.06.2016	Hence the present Writ Petition

IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY ORIGINAL WRIT

JURISDICTION

WRIT PETITION (C) NO.5399 OF 2017

IN THE MATTER OF:

Windlas Biotech Pvt. Ltd.
a company existing under the
Companies Act, 2013 having its office at:
Khasra No.141 to 143 & 145
Mohabewala Industrial Area
Dehradun-248 110
through its Managing Director
Mr. Ashok Kumar Windlas ....Petitioner

-Versus-

1. Union of India
through Secretary
Department of Health and Family Welfare
Ministry of Health and Family Welfare
Nirman Bhawan,
New Delhi-110 001

2. The Drug Controller
General of India





FDA Bhawan
ITO, Kotla Road
New Delhi-110 002 ....Respondents

AND IN THE MATTER OF:

WRIT PETITION UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA, 1950 SEEKING A WRIT OF CERTIORARI OR ANY OTHER WRIT, ORDER OR DIRECTION IN THE NATURE OF CERTIORARI CALLING FOR THE RECORDS AND QUASHING NOTIFICATION BEARING S.O. NO. 1855 (E) DATED 08.06.2017 (ANNEXURE P-I) ISSUED BY RESPONDENT NO.1, IN PURPORTED EXERCISE OF POWERS UNDER SECTION 26A OF THE DRUGS AND COSMETICS ACT, 1940; IMPUGNED





NOTIFICATIONS ARE ARBITRARY, ILLEGAL AND IRRATIONAL AND ISSUED IN VIOLATION OF SECTIONS 5, 6, 7 AND 26A OF THE DRUGS AND COSMETICS ACT, 1940

To

THE HON'BLE ACTING CHIEF JUSTICE AND HER COMPANION JUSTICES OF THE HON'BLE HIGH COURT OF DELHI AT NEW DELHI

THE HUMBLE PETITION OF THE PETITIONERNAMED ABOVE:

MOST RESPECTFULLY SHOWETH:

1. The Petitioner is invoking the extraordinary writ jurisdiction of this Hon'ble Court under Article 226 of the Constitution of India challenging

Notification S.O. No. 1855 (E) dated 08.06.2017 (in short the "Impugned Notification"), whereby the Respondent No.1, in purported exercise of its powers under Section 26A of the Drugs and Cosmetics Act, 1940 (in short the "D&C Act") prohibited the manufacture for sale, sale and distribution for human use of the fixed dose combination (drug with more than one active ingredient, in short referred to as "FDC") of Etodolac and Paracetamol, with immediate effect on the purported ground that there is no rational or therapeutic justification for the FDC. The decision to prohibit manufacture for sale, sale and distribution of the FDC by the Impugned Notification is based on the recommendation of the New Drugs Advisory Committee constituted by





Respondent No.1. In this context, it is relevant to submit that the New Advisory Committee is not a statutory body, contemplated under the D&C Act. True typed copy of the Notification S.O. No. 1855 (E) dated 08:.06.2017 issued by the Respondent No.1 are annexed and marked as Annexure P-1.

2. The Petitioner submits that the Impugned Notification dated 08.06.2017 is ex-facie illegal, arbitrary and irrational and is therefore likely to be quashed by this Hon'ble Court as:

2.1 The Impugned Notification has been issued by the Respondent No. 1 in contravention of Sections 5, 6, 7 and 26A of the D&C Act, inasmuch exercise of powers under Section 26A of the D&C Act has to be preceded by





consultation with the manufacturers of the concerned FDCs and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act viz. Drugs Technical Advisory Board, Central Drugs Laboratory and Drugs Consultative Committee. In this context, it is respectfully submitted that on 10.03.2016, the Respondent No.1 had issued 344 Notifications, banning a large number of FDC. While considering the challenge to 344 Notifications, the Hon'ble Court in its Judgment (in Pfizer Ltd. & Anr. Vs. Union of India & another (and other connected writ petitions, including writ petitions filed by the Petitioner herein) dated 01.12.2016, held that any exercise of powers by





the Respondent No. 1 under Section 26A of the D&C Act has to be preceded by consultation with the manufacturers and ought to be based on the advice of statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act. In the present case also, prior to issue of the Impugned Notification, the Respondent No.1 did not consult the manufacturers or sought the advice and recommendation of the aforesaid statutory bodies. The Respondent No. 1 had acted unilaterally on the basis of recommendation of New Drugs Advisory Committee (a non-statutory Committee appointed by the Respondent No.1), which is impermissible under the Statutory





regime of D&C Act and in particular Sections 5, 6, 7 and 26A thereof.

2.2 In the present case, the FDC was approved by the Respondent No. 2 on 01.10.2010; therefore by virtue of Explanation (ii) to Rule 122E they cease to be a New Drug by 30.09.2014 (i.e. upon expiry of 4 years from the date of approval by DCGI (Respondent No. 2). Therefore, even assuming without admitting that the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to "new drugs" (as defined in Rule 122E of the D&C Rules), such Committee cannot consider ban of existing FDC, especially when the FDC, in the present case, ceased to

be New Drug, as defined in Rule 122E of the D&C Rules (per Explanation (ii) to Rule 122E of the D&C Rules).

2.3 The Petitioner respectfully submits that Sections 5, 6 and 7 of the D&C Act are mandatory in nature and cannot be in any manner ignored or by-passed by the Respondent No. 1, as held by this Hon'ble Court in Pfizer Limited. The purpose of constitution of Drugs Technical Advisory Board is to advice the Respondent No.1 on technical matters arising out of administration of the Act and to carry out other functions assigned to the Respondent No.1 under the D&C Act and the purpose of constitution of the Drugs Consultative Committee is to advice the Respondent No.1 and the

Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C Act provide that the Respondent No.1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and Hold consultation with Drugs Technical Advisory Board and Drugs Consultative Committee. Moreover the functions of Drugs Technical Advisory Board under Section 5 of the D&C Act, is not only to advice on technical matters but also to carry out "other functions assigned' to the Respondent No. 1 under the D&C Act.

2.4 Indisputably, the New Drugs Advisory Committee is not a statutory body constituted within the realm of D&C Act, as the D&C Act does not provide for constitution of such a Committee. The New Drugs Advisory Committee is a committee functioning under the Central Drugs Standard Control Organization (in short "CDSCO"), which itself is not a statutory body under the D&C Act. Thus, the very act of the Respondent No.1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go-by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notification and renders it unsustainable in the eyes of law, as the Respondent No.1 in exercise of

powers vested under the D&C Act, cannot take away the statutory powers vested in DTAB, DCC and vest them in a Committee unilaterally formed by the Respondent No.1.

2.5 In addition, for any action under Section 26A of the D&C Act, has to be preceded by hearing ail stake holders (manufacturers etc.), unless there is grave urgency, for which reasons should be recorded, as held by this Hon'ble Court in Pfizer Judgment. It is submitted that prior to issue of the Impugned Notifications, no such notice or opportunity of hearing was afforded to the Petitioner, who manufactures the FDC in question.

2.6 The Petitioner submits that the fact that there was no grave urgency warranting exercise of powers under Section 26A of D&C Act is evident from the fact that the Impugned Notifications themselves mention that the prohibition is premised on the fact that the use of FDC in question is not rational as the FDC does not have any therapeutic justification and the two drugs which are the constituents of FDC are best administered separately. The prohibition is not premised on any adverse health consequences or risk to human beings and therefore it can be safely said that there were no compelling circumstances in giving a go-by to the requirement of issuance of notice and opportunity of hearing





to manufacturers before prohibiting the FDC. Thus, the Impugned Notification dated 08.06.2017 is violative of Article 14 of the Constitution of India as it is arbitrary and unreasonable and violative of principles of natural justice.

2.7 It is pertinent to mention here that the said FDC has been approved by the Respondent No. 2, Drug Controller General of India on 01.10.2010 and the Petitioner has been manufacturing the same from 01.11.2010 after obtaining licence from State Licencing Authority, Uttarakhand, After having approved the FDC, there is no justification whatsoever to ban the FDC, that too without following the mandatory





procedure specified under the D&C Act.

2.8 It is also relevant to state here that there is no adverse report about the FDC. The Impugned Notification is not based on any adverse report, viz. Pharmacovigilance Report or otherwise. Further the FDC in question is only anti-inflammatory and anti-pyretic which cannot lead to any drug resistance or any adverse impact.

3. The brief facts giving rise to the filing of the present Writ Petition before this Hon'ble Court are as under:

3.1 The Petitioner is a pharmaceutical company of repute and is a contract manufacturer of pharmaceutical





formulations in India. The Petitioner manufactures a wide range of pharma products including Anti-Diabetic, Antibiotics, Antifungal, NSAIDs, Gastrointestinal, Anthelmintic, Cardiovascular, Dermal, and several other categories of pharma products. The Petitioner is also engaged in formulation developments, technological innovations conducting stability studies and arranging bio-equivalence studies and clinical trials. The Petitioner aspires to aid the community in leading a healthy life through two parallel objectives: formulating, developing and commercializing medicines, and delivering affordable and accessible medication that satisfies urgent medical needs. The Petitioner





Company has been manufacturing pharmaceutical products for big Indian and Multinational Pharma Companies.

3.2 The Petitioner Company is having sophisticated Research & Development, and Formulation Development Centres. The Petitioner's Laboratory is fully equipped for Physical and metallurgical testing, Micro-biological testing, Effective controls of process, Chemical testing, Pharmacological testing, Stability Studies etc,

3.3 Fixed Dose Combinations (FDC) refer to products containing two or more active ingredients used for particular indication(s). This term is used generically to mean a particular





combination of actives irrespective of the formulation or brand. It may be administered as single entity products given concurrently or as a finished pharmaceutical product. The development of FDCs is becoming increasingly important from a public health perspective. The basic rationale of making "fixed dose combination" medicinal products is either to improve adherence or to benefit from the added effects of the two medicinal products given together. FDCs have shown to be particularly useful in the treatment of diseases like HIV, malaria and tuberculosis and also in cardiology, diabetes and cancer conditions, based on international guidelines recommended by expert bodies,

where giving multiple drugs for the management of a given condition is an accepted medical norm and practice. FDCs are also of use in chronic conditions especially when multiple disorders often co-exist. FDCs are known to offer specific advantages over the single entity preparations, such as increased efficacy, and/or better patient compliance dosage, possibly reduced cost and simpler logistics of distribution relevant to situations of limited resources.

3.4 Amongst other pharmaceutical products, the Petitioner manufactures for sale a Fixed Dose Combination of Etodolac 400 mg and Paracetamol 500 mg. The said FDC is

manufactured by the Petitioner in its capacity as a contract manufacturer for Mankind Pharma Limited which is a pharmaceutical company of repute. The FDC manufactured by the Petitioner is marketed for sale by Mankind Pharma Limited under the brand name Orthokind-P 400 mg. The FDC is used for effective treatment of toothache, joint pain, headache, ear pain, etc. The Petitioner was granted licence to manufacture the FDC in question by the State Licencing Authority, Uttarakhand and it has been manufacturing the same from 01.11.2010 onwards. The said licence has been renewed from time to time and the copy of the valid and subsisting licence dated 06.01.2014 issued by the Drug Licencing and

Controlling Authority, Uttarakhand is annexed herewith and marked as Annexure P-2.

3.5 The Impugned Notification dated 08.06.2017 prohibits manufacture for sale, sale and distribution of FDC in question and therefore the Petitioner is a person aggrieved and has the locus to file the Writ Petition. The Petitioner states that the FDC in question has been approved by the Respondent No. 2 viz. Drug Controller General of India on 01.10.2010. True copy of the relevant extract of the list of approved FDC by the Respondent No. 2 is annexed as Annexure P-3.

3.6 The FDC in question, viz. Etodolac 400 mg and Paracetamol 500 mg is





used for effective treatment of toothache, joint pain, headache, ear pain, etc. It is also pertinent to state here that the FDC in question are marketed in several countries. It is submitted that the strength of each composition used in making the FDC, ensures that the said FDC is safe for consumption and is beneficial to the patients to which it is administered. In fact, large amount of material is available in public domain, including but not limited to medical rationale of FDC in question, which goes to show that the said FDC has enormous amount of therapeutic justification and relevance. It is also relevant to state here that there is no adverse report about the FDC. The Impugned Notification is not based on any





adverse report, viz. Pharmacovigiiance Report or otherwise. Further the FDC in question is only anti-inflammatory and anti-pyretjc which cannot lead to any drug resistance or any adverse impact.

3.7 The Petitioner states that the referenced FDC has been prescribed by doctors to patients for effective treatment of toothache, joint pain, headache, ear pain, etc. and patients are benefitting from the same. There has been no Adverse Drug Reaction reported to the Petitioner or any serious complaints received by the Petitioner to raise a concern with regard to the safety and efficacy of the said FDC.





3.8 In this context, it is stated that Section 5 of D&C Act mandates the Central Government to constitute the Drugs Technical Advisory Board (in short "DTAB") consisting of expert members to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it under D&C Act. The term of office of the nominated and elected members of DTAB has also been prescribed as three years or for so long as they hold the appointment of the office by virtue of which they are nominated or elected. DTAB, vide Section 5 (4) has been authorized to frame its bye-laws fixing a quorum and regulating





its own procedure and the conduct of all business and vide Section 5 (5) to constitute sub-committees for consideration of particular matters. The Central Government has been mandated by Section 5 (7) to appoint a person to be the Secretary of DTAB and to provide DTAB with clerical and other staff necessary.

3.9 Section 6 of D&C Act mandates the Central Government to establish a Central Drugs Laboratory (CLS) under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by the Act or by any Rules made thereunder. Section 6 empowers the Central Government to "after consultation





with' PTAB make Rules prescribing the functions of the Central Drugs Laboratory and the procedure for analysis or tests of the drugs and for such other matters as may be necessary.

3.10 Section 7 mandates the Central Government to constitute an Advisory Committee to be called the Drugs Consultative Committee (in short "DCC"), to advise the Central Government, the State Governments and DTAB on any other matter tending to secure uniformity throughout India in the administration of D&C Act. The DCC has been prescribed to consist of two representatives nominated by the Central Government and one





representative nominated by each of the State Governments.

3.11 The Petitioner states that under Section 26 A of the D&C Act, the Respondent No.1 is vested with the powers to regulate, restrict or prohibit manufacture, sale or distribution of a drug or cosmetic which is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do.

3.12 However, the Respondent No.1 can exercise its powers under Section





26A of the D&C Act only after consultation and on the advice/recommendation of DTAB, DCC etc. under Section 5, 6 and 7 of the D&C Act. This Hon'ble Court in Pfizer Ltd. (supra) had held that the provisions of Sections 5, 6 and 7 of the D&C Act are mandatory and cannot be given a go-by by the Respondent No.1 while passing any Order under Section 26A of the D&C Act.

3.13 Rule 122E of the Drugs and Cosmetics Rules, 1945 defines New Drug. In terms of Rule 122E of D&C Rules, a FDC of two or more drug, individually approved earlier for certain claims, which are now proposed to be combined for the first





time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims viz. indications dosage, dosage form and route of administration will be a New Drug. Further, in terms of the Explanation to Rule 122E, a New Drug shall continue to be consider as New Drug for a period of four years from the date of its first approval [Explanation (ii) to Rule 122E].

3.14 The Petitioner states that it is an irrefutable position on record that the Respondent No. 2 had approved the FDC in question on 01.10.2010; therefore by virtue of Explanation (ii) to Rule 122E, the FDC in question cease to be a New Drug on or after





30.09.2014. Hence, there, is no requirement of obtaining approval from Respondent No. 2 treating the FDC, as "New Drug" within the meaning of Rule 122E of the D&C Rules on or after 30.09.2014.

3.15 Hence, even assuming without admitting that the Respondents could constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to new drugs, such Committee cannot consider banning existing FDC, especially when the FDC, in the present case, does not fall within the definition of New Drugs, under Rule 122E of the D&C Rules, as in terms of Explanation (ii) to Rule 122E of the D&C Rules, any drug which was

granted approval four years earlier by the Respondent No. 2, ceases to be a new drug, within the meaning of Rule 122E of the D&C Rules.

3.16 However to the utter shock and surprise of the Petitioner, the Respondent No.1 has issued the Impugned Notification on 08.06.2017 and has prohibited the manufacture for sale, sale and distribution for human use of the FDC with immediate effect as in its opinion it is not rational. The said decision of Respondent No.1 is based on the recommendation of New Drugs Advisory Committee constituted by Central Government which has come to a conclusion that the FDCs in question does not have therapeutic





justification and the two drugs are best administered separately on as required basis. It is evident that the Respondent No.1 while issuing the Impugned Notifications has completely ignored the mandatory consultative process as provided under Sections 5, 6 and 7 of the D&C Act inasmuch as the decision of the Respondent No. 1 is not based on any advice/recommendation of DTAB, DCC, etc. Further Section 26A of D&C Act, enjoins the Respondent No. 1 to give an opportunity of hearing to stakeholders, including the manufacturers, marketers, distributors, etc. No notice, in this regard was received by the Petitioner. It is also relevant to state here that there is no adverse report





about the FDC. The Impugned Notification is not based on any adverse report, viz. Pharmacovigilance Report or otherwise. Further the FDC in question is only anti-inflammatory and anti-pyretic which cannot lead to any drug resistance or any adverse impact.

3.17 In this context, it is submitted that the National Pharmaceutical Pricing Authority, a body existing under the supervision of Respondent No. 1 has created an Integrated Pharmaceutical Data Base Management System (in short "IPDMS"), wherein all the pharmaceutical companies are required to file extensive details in relation to all drugs





manufactured/marketed by them. Hence, it is clear that the Respondents have information about the fact that the FDC in question is manufactured by the Petitioner.

4. The Petitioner submits that the Impugned Notification dated 08.06.2017 are illegal and arbitrary as the purported exercise of power by the Respondent No. 1 under Section 26A of D&C Act is de-hors the statutory scheme of D&C Act and in particular the mandatory procedure prescribed under of Section 5, 6, 7 & 26A of D&C Act.

5. Feeling aggrieved, the Petitioner is filing the present Writ Petition on inter-alia following amongst other grounds:





GROUNDS

A. FOR, the Impugned Notification dated 08.06.2017 suffer from manifest error of law apparent on the face of record;

B. FOR, the Impugned Notifications are ex-facie illegal, arbitrary, irrational and unreasonable and is therefore violative of Article 14 of the Constitution of India;

C. FOR, the Impugned Notification has been issued by the Respondent No.1 in contravention of Sections 5, 6, 7 and 26A of the D&C Act. This Hon'ble Court has in Pfizer Ltd. (supra) dated 01.12.2016 has held that any exercise of powers by the Respondent No.1 under Section 26 A of the D&C





Act has to be preceded by consultation with the statutory bodies constituted under Sections 5, 6 and 7 of the D&C Act viz. DTAB, Central Drugs Laboratory and DCC and any action under Section 26A of the D&C Act by the Respondent No.1 is to be based on the advice of the aforesaid statutory bodies constituted under the D&C Act. In case the Respondent No. 1 acts unilaterally or does not seek advice of the aforesaid statutory bodies then ' any action of the Respondent No. 1 under Section 26A is unsustainable and shall be struck down/set aside by the Hon'ble Court;

D. FOR, in the present case, it is manifest from the Impugned Notifications that the Respondent





No.1 has not consulted or sought the advice and recommendation of the aforesaid statutory bodies while prohibiting the FDC in question and has unilaterally acted on the basis of recommendation of New Drugs Advisory Committee, which is impermissible under the statutory regime of D&C Act and in particular Sections 5, 6, 7 and 26A thereof;

E. FOR, this Hon'ble Court in Pfizer Ltd. (supra), in identical circumstances (wherein also while issuing 344 Notifications prohibiting FDCs, the Respondent No. 1 had failed to consult, seek advice and recommendation of DTAB, Central Drugs Laboratory and DCC), had struck down the Notifications on the





ground that it constitutes violation of Sections 5, 6, 7 and 26A of the D&C Act.

F. FOR, Sections 5, 6 and 7 of the D&C Act are mandatory and cannot be in any manner ignored or by-passed by the Respondent No. 1. Sections 5 & 7 of the D&C Act provide that the purpose of constitution of DTAB is to advice the Respondent No. 1 on technical matters arising out of administration of the Act and to carry out other functions assigned to the Respondent No. 1 under the D&C Act and that the purpose of constitution of the DCC is to advice the Respondent No. 1 and DTAB on any matter tending to secure uniformity throughout India in the





administration of the D&C Act. Thus, by its very nature Sections 5, 6 and 7 of the D&C Act which provide that the Respondent No.1 in exercise of powers, technical or otherwise is enjoined to obtain advice from and hold consultation with DTAB and DCC, is mandatory. Moreover the functions of DTAB under Section 5 is not only to advice on technical matters but also to carry out "other functions assigned" to the Respondent No. 1 under the D&C Act. If the Respondent No. 1 of its own was found fit to exercise the functions under the D&C Act including of a technical nature and have the wherewithal therefore, there was no need for constituting the DTAB and DCC;





Q. FOR, the Petitioner submits that New Drags Advisory Committee is not a statutory body constituted within the realm of D&C Act. The D&C Act does not contemplate creation of the New Drugs Advisory Committee and thus it is not a statutory body under the D&C Act. The New Drugs Advisory Committee is a body functioning under CDSCO which is itself not a statutory body under the D&C Act. This has been held by this Hon'ble Court in Pfizer Ltd. (supra). Thus, the very act of the Respondent No. 1 in acting on the purported recommendation of New Drugs Advisory Committee and giving a go-by to the statutory authorities constituted under the D&C Act vitiates the Impugned Notifications

and renders it unsustainable in the eyes of law;

H. FOR, in addition to being in consonance with Sections 5, 6 and 7 of D&C Act, any action of the Respondent No. 1 under Section 26A of the D&C Act, has to be preceded by giving notice and opportunity of hearing to the manufacturers of the FDC unless there is a grave urgency for which reasons should be recorded. In the present case, no such notice or opportunity of hearing has been afforded to the Petitioner who is one of the leading manufacturer of the prohibited FDC;

I. FOR, the FDCs in question has been approved by the Respondent No. 2 on 01.10.2010. The Petitioner was also





granted licence to manufacture the FDC in question by the State Licencing Authority, Uttarakhand and it has been manufacturing the same from 01.11.2010 onwards. The said licence has been renewed from time to time. In such circumstances, it is difficult to contemplate that there were any urgency situation warranting the exercise of powers under Section 26A of D&C Act without issuance of notice and affording an opportunity of hearing to the manufacturers including the Petitioner. Thus, the Impugned Notification is contrary to the principles of natural justice;

J. FOR, even assuming without admitting that the Respondents could





constitute a New Drugs Advisory Committee, for the purpose of considering grant of license to new drugs, such Committee cannot consider banning existing FDCs, especially when the FDCs, in the present case, do not fall within the definition of New Drugs, under Rule 122E of the D&C Rules, as in terms of Explanation (ii) to Rule 122E of the D&C Rules, any drug which was granted approval four years earlier by the Respondent No. 2, ceases to be a new drug, within the meaning of Rule 122E of the D&C Rules.

K. FOR, the fact that there was no grave urgency warranting exercise of powers under Section 26A of D&C Act is also evident from the fact that the





Impugned Notification dated 08.06.2017 itself mention that the prohibition is, premised on the fact that the use of FDCs in question is not rational as the FDCs do not have any therapeutic justification and the two drugs which are the constituents of FDC are best administered separately. The prohibition is not premised on any adverse health consequences or risk to human beings and therefore it can be safely said that there were no compelling circumstances in giving a go-by to the requirement of issuance of notice and opportunity of hearing to manufacturers before prohibiting the FDC. Thus, the Impugned Notification is violative of Article 14 of the





Constitution of India as it is arbitrary and unreasonable;

L. FOR, there is no adverse report about the FDC. The Impugned Notification is not based on any adverse report, viz. Pharmacovigilance Report or otherwise. Further the FDC in question is only anti-inflammatory and anti-pyretic which cannot lead to any drug resistance or any adverse impact. This itself evidences a total non-application of mind on the part of the Respondent No. 1 while issuing the Impugned Notifications dated 08.06.2017;

M. FOR, the Respondent No. 1 has issued the Impugned Notification on 08.06.2017 and has prohibited the manufacture for sale, sale and





distribution for human use of the FDC with immediate effect as in its opinion it is not rational. The said decision of Respondent No.1 is based on the recommendation of New Drugs Advisory Committee constituted, by Central Government which has come to a conclusion that the FDCs in question does not have therapeutic justification and the two drugs are best administered separately on as required basis. It is evident that the Respondent No. 1 while issuing the Impugned Notifications has completely ignored the mandatory consultative process as provided under Sections 5, 6 and 7 of the D&C Act inasmuch as the decision of the Respondent No. 1 is not based on any advice/recommendation of DTAB,





DCC, etc. Further Section 26A of D & C Act, enjoins the Respondent: No.1 to give an opportunity of hearing to stakeholders, including the manufacturers, marketers, distributors, etc. No notice, in this regard was received by the Petitioner. In this context, it is submitted that the National Pharmaceutical Pricing Authority, a body existing under the supervision of Respondent No. 1 has created an Integrated Pharmaceutical Data Base Management System (in short "IPDMS"), wherein all the pharmaceutical companies are required to file extensive details in relation to all drugs manufactured/marketed by them. Hence, the Petitioner ought to have





been heard, prior to issue of the Impugned Notifications dated 08.06.2017;

N. FOR, any pharmaceutical company to make available alternate drugs, minimum time gap of six months is required considering the time consumed in preparation of new formulations, packaging preparations, approvals by the authorities under the D&C Act, etc. and also the time consumed in development, analysis, stability studies, etc. Thus, the immediate ban is drastic especially when crores of worth formulations are lying distributed in retail drug shops in the country and it is practically very difficult to withdraw the products





besides the huge loss that will be caused to manufacturers. It would also result in denial of access to medicines to patients across the country and to consumers who have been using FDCs products regularly;

O. FOR, Rule 74 (b) D&C Rules clearly provides that "the licencee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act provided that where such further requirements are specified in the Rules, these would come into force, four months after publication in the Official Gazette" especially when violation of the provisions of





Section 26A of the D&C Act is punishable under Section 28B of the D&C Act with imprisonment and fine. Considering such scheme of the D&C Act, it is improbable that the Legislature ever intended that a ban can be imposed with immediate effect especially when the decision making process has not been notified to all the stake-holders. Furthermore, the stocks on hand of the manufacturers can by itself expose the parties to penal actions. It is submitted that it is a statutory obligation of the Respondent No.1 specifically incorporated in the D & C Act itself that while taking a decision m imposing any prohibition/restriction under the D&C Act, the entitlements/obligations respectively





which have come into existence thereby also creating vested rights, should always be suitably provided for in any subsequent policy;

P. FOR, the Petitioner Company is having huge inventory of the Product which becomes a waste immediately after the Impugned Notification as Petitioner is a contract manufacturer and is manufacturing several brands under the said composition. Customers and trade associations, retailers and distributors have been writing to Petitioner for returning the Products and also not lifting the finished Products. The manufacturer and further distributors and stockiest have paid excise and sales tax on the products. Under the circumstances it





is bound to happen that there will be shortage of medicine due to this ban and stock lying in the market will become useless and public at large will suffer owing to the lack of the medicines in the market. The Petitioner will also lose business.

Q. FOR, the Petitioner submits that the Impugned Notifications dated 08.06.2017 is in teeth of the Judgment of this Hon'ble Court in Pfizer Ltd. (supra) & Anr. Though the Respondent No. 1 has filed a Special Leave Petition before the Hon'ble Supreme Court from the Judgment, the same pending and there is no stay of the Judgment of this Hon'ble Court. The Impugned Notification is





therefore likely to be quashed by this Hon'ble Court;

6. The grounds urged above are without prejudice to each other and the Petitioner craves leave to add, alter, amend or modify the same if deemed necessary.

7. The Petitioner has no alternative efficacious remedy other than to invoke the extraordinary jurisdiction of this Hon'ble Court under Article 226 of the Constitution.

8. The Petitioner has not filed any other petition before this Hon'ble Court or before the Hon'ble Supreme Court on the facts and

circumstances of the present case and in respect of the Impugned Notifications





which forms the subject matter of the present writ petition.

9. The Petitioner has no alternate efficacious remedy under the D&C Act in; respect of the Impugned Notifications which forms the subject matter of the present writ petition.

10. That the present writ petition is filed by the Petitioner through its Managing Director Mr. Ashok Kumar Windlas, who is the Managing Director and the principal officer of the Petitioner Company and hence competent to sign, verify and file the present writ petition, on its behalf.

PRAYER

In view of the aforesaid facts and circumstances, the Petitioner most respectfully prays that this Hon'ble Court may be graciously pleased to:-





(i) issue a writ of Certiorari or any other writ, order or direction in the nature of Certiorari calling for the records and quashing the Notification bearing S.O. No.1855(E) dated 08.06.2017 (Annexure P-1) issued by Respondent No. 1; and

(ii) award cost(s) of the present petition to the Petitioner; and

(iii) pass any other appropriate order/orders as this Hon'ble court may deem fit and proper in the facts and circumstances of the case.

PETITIONER

THROUGH

Sd/-
R. JAWAHAR LAL
PRA LAW OFFICES
ADVOCATE FOR THE PETITIONER
W-126, GROUND FLOOR
GREATER KAILASH PART II
NEW DELHI 110 048
PH# 011 40676767

NEW DELHI
DATE: 28.06:2017





IN THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY ORIGINAL

WRIT JURISDICTION WRIT PETITION

(C) NO.5399 OF 2017

IN THE MATTER OF:

Windlas Biotech Pvt. Ltd. ....Petitioner

Versus

Union of India & Anr. .....Respondents

AFFIDAVIT

I, Ashok Kumar Windlass, aged about 67 years, son of Late Sh. Ved Prakash Windlass, Resident of 53-R, Rajpur Road, Dehradun-248110, Uttarakhand, presently in Delhi do solemnly state and affirm as under: -

1. That I am the Managing Director of the Petitioner Company in the Writ Petition and as such well conversant with the facts of the case.





2. I have gone through the accompanying Writ Petition and the contents thereof are true to my knowledge and belief. No part of it is false and nothing material has been kept concealed therefrom.

3. The annexures annexed with the Writ Petition are true copies of their respective originals

DEPONENT

VERIFICATION:

Verified at New Delhi on this 28th day of June, 2017, that the contents of the foregoing affidavit are true and correct to my knowledge. No part of the affidavit is false and nothing material has been concealed therefrom.

DEPONENT

/TRUE COPY/





ANNEXURE-P-9

ITEM NO.1 COURT NO.13 SECTION XIV

S U P R E M E C O U R T O F I N D I A

RECORD OF PROCEEDINGS

Petition(s) for Special Leave to Appeal (C) No(s). 7061/2017

(Arising out of impugned final judgment and order dated 01-12-2016 in WPC No. 2212/2016 passed by the High Court Of Delhi At New Delhi)

UNION OF INDIA & ANR. .....Petitioner(s)

VERSUS

PFIZER LIMITED & ORS. .....Respondent(s)

WITH

SLP(C) Nos. 10170-10178/2017 (XIV)

T.C.(C) No. 29/2017 (XVI -A)

(FOR ADMISSION)





T.C.(C) No. 30/2017 (XVI -A)

(FOR ADMISSION)

T.C.(C) No. 31/2017 (XVI -A)

(FOR ADMISSION)

T.C.(C) No. 32/2017 (XVI -A)

(FOR ADMISSION)

T.C.(C) No. 33/2017 (XVI -A)

(FOR ADMISSION)

T.C.(C) No. 34/2017 (XVI -A)

(FOR ADMISSION)

T.C.(C) No. 35/2017 (XVI -A)

(FOR ADMISSION)

T.C.(C) No. 36/2017 (XVI -A)

(FOR ADMISSION)

T.C.(C) No. 38/2017 (XVI -A)

(FOR ADMISSION)

T.C.(C) No. 39/2017 (XVI -A)

(FOR ADMISSION)

T.C.(C) No. 40/2017 (XVI -A)

(FOR ADMISSION)





Date: 12-07-2017 These matters were called on for hearing today.

CORAM: HON'BLE MR. JUSTICE ROHINTON FALI NARIMAN

HON'BLE MR. JUSTICE SANJAY KISHAN KAUL

Counsel for parties:-

Mr. Ranjit Kumar, SG

Mr. Kirtiman Singh, Adv.

Mr. S. Wasim A. Qadri, Adv.

Mrs. Vimla Sinha, Adv.

Mrs. Saudamini Sharma, Adv.

Mr. S.K. Pathak, Adv.

Mr. Rishikant Singh, Adv.

Mr. Amit Mahajan, Adv.

Mr. Prateek Dhanda, Adv.

Ms. Somya Rathore, Adv.

Waize Ali Noor, Adv.





G.S. Makker, AOR

Mr. Colin Gonsalves, Sr. Adv.

Ms. Tanya Agarwal, Adv.

Mr. Satya Mitra, AOR

Ms. Herinder Kaur Brar, Adv.

Mr. Sarvesh Singh, AOR

Ms. Archana Sahadeva, Adv.

Mr. Vivek Ranjan, Adv.

Mr. Nikhil Lal, Adv.

Mr. Gaurav Sharma, Adv.

Mr. C.S. Vaidyanathan, Sr. Adv.

Mr. Kunal Mimani, Adv.

Mr. Kunal Chaturvedi, Adv.

Mr. Dheeraj Nair, AOR

Mr. Rajeev K. Panday, Adv.

Mr. Rajeev Maheshwaranand Roy, AOR

Mr. Abhinav Vasisht, Sr. Adv.

Mr. Joran Diwan, Adv.

Mr. Mahesh Agarwal, Adv.

Ms. Devika Mohan, Adv.





Mr. E. C. Agrawala, AOR

Mr. Ashwin Sapra, Adv.

Mr. Utkarsh Bhatnagar, Adv.

Mr. Biplab Lenin, Adv.

For M/s. Cyril Amarchand Mangaldas, AOR

Mr. Sachin Gupta, AOR

Mr. Divyesh K. Shrivastava, Adv.

UPON hearing the counsel the Court made the following

O R D E R

List on Tuesday, the 29th August, 2017 along with Diary No. 5508/2017, T.P. Nos. 1729-1737/2016, Diary No. 9155/2017, S.L.P. No.7061/2017 and Diary No. 9715/2017.

Pleadings to be completed in the meantime.

Sd/-
(R. NATARAJAN)
COURT MASTER

Sd/-
(SAROJ KUMARI GAUR)
COURT MASTER

/TRUE COPY/





IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

I.A.NO._____OF 2017

IN

TRANSFER PETITION (C) NO. ___ OF 2017

IN THE MATTER OF :

Union of India and others, ...Petitioners

Versus

Dharmendra Singh & Ors.... Respondents

APPLICATION FOR STAY OF FURTHER PROCEEDING

TO

HON'BLE THE CHIEF JUSTICE OF INDIA AND HIS COMPANION JUDGES OF THE SUPREME COURT OF INDIA.

The humble application of the applicant-petitioner abovenamed.





MOST RESPECTFULLY SHOWETH:

1. That the petitioner is filing present transfer petition under Article 139-A of the Constitution of India read with Order XL Rule 1 of Supreme Court Rules-2013 for withdrawal and transfer of W.P.[C]No.5336 of 2017 [Mankind Pharma Limited V/s Union of India & Anr], W.P.[C]No.5340 of 2017 [Akums Drugs & Pharmaceuticals Ltd V/s Union of India & Anr], W.P.[C]No.5345 of 2017 [J.B. Chemicals & Pharmaceuticals Limited & Ors V/s Union of India & Anr], W.P.[C]No.5391 of 2017 [M/s IPCA Laboratories Limited & Anr V/s Union of India & Anr], W.P.[C]No.5397 of 2017 [Ahlcon Parenterals India Ltd. V/s Union of India & Anr], W.P.[C]No.5398 of 2017 [J.K. Printpacks V/s Union of India & Anr] and W.P.[C]No.5399 of 2017 [Windlas Biotech Pvt. Ltd. V/s Union of India & Anr], pending before the Hon'ble High





Court of Delhi At New Delhi for hearing by this Hon'ble Court along with S.L.P. [C] No.7061 of 2017, [U.O.I V/s Pfizer Pvt. Ltd] and the All India Drug Action Network v/s Pfizer SLP [C] No. SLP [C] No.10170-10178 of 2017.

2. That the detailed facts and circumstances of the case has been set-out in the accompanying Transfer Petition and the petitioners crave leave of this Hon'ble Court to refer to and rely on the same and its contents may be treated as part and parcel of the present petition for sake of avoiding repetition.

3. That in the Writ Petition sought to be transferred and the SLP/TP pending before this Hon'ble Court, a common question of law as to the constitutional validity of Notifications issued by Central Government under section 26-A of the Drugs and Cosmetics-1940,





banning the manufacture sale and distribution of fixed doze combination medicines.

4. That in order to avoid conflicting decision it is prayed that the further proceeding of the writ petition in question may be stayed during pendency of the present transfer petition.

PRAYER

In these premises, the Petitioner most respectfully pray that this Hon'ble Court may graciously be pleased to:-

[a] stay the further proceeding of the W.P.[C]No.5336 of 2017 [Mankind Pharma Limited V/s Union of India & Anr], W.P.[C]No.5340 of 2017 [Akums Drugs & Pharmaceuticals Ltd V/s Union of India & Anr], W.P.[C]No.5345 of 2017 [J.B. Chemicals &





Pharmaceuticals Limited & Ors V/s Union of India & Anr], W.P.[C]No.5391 of 2017 [M/s IPCA Laboratories Limited & Anr V/s Union of India & Anr], W.P.[C]No.5397 of 2017 [Ahlcon Parenterals India Ltd. V/s Union of India & Anr], W.P.[C]No.5398 of 2017 [J.K. Printpacks V/s Union of India & Anr] and W.P.[C]No.5399 of 2017 [Windlas Biotech Pvt. Ltd. V/s Union of India & Anr], pending before the Hon'ble High Court of Delhi At New Delhi AND/OR

[b]. pass such order or further order as may deem fit and proper under the facts and circumstances of the case.

FOR THIS ACT OF KINDNESS THE PETITIONER AS IN DUTY BOUND SHALL EVER PRAY.

DRAWN BY:

S.WASIM A. QADRI
Advocate

FILED BY:

(G. S. Makker)
Advocate-on-Record
for the Petitioner

Drawn On:13.07.2017
Filed on: 07.2017



