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

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Judgment delivered on: 25.01.2017

+ W.P.(C) 229/2017

MENDINE PHARMACEUTICALS PVT LTD Petitioner

Versus

UNION OF INDIA AND ORS

..... Respondents

Advocates who appeared in this case:

For the Petitioner : Mr. Gopal Jain, Sr. Advocate with Mr. Snehal
Kakrania, Advocates.

For the Respondents : Mr. Anurag Ahluwalia, CGSC for the respondent No.1.
Mr. Amit Mahjan, CGSC with Mr. Rishikant Singh, Mr. Nitya
Sharma and Ms. Gunjan Sharma, Advocates for respondent
No.2.
Mr. Joydeep Mazumdar with Mr. Debojyoti Bhattacharya and
Mr. Parijat Sinha, Advocates for respondent No.3.

CORAM:-

HON'BLE MR JUSTICE SANJEEV SACHDEVA

JUDGMENT

25.01.2017

SANJEEV SACHDEVA, J. (ORAL)

CM No.1047/2017 (exemption)

Exemption is allowed subject to all just exceptions.

CM No.1048/2017 (permission to file lengthy synopsis and list of dates)

For the reasons stated in the application, the application is allowed.

The lengthy synopsis is taken on record.

W.P.(C) 229/2017 & CM No.1049/2017 (for interim relief)

1. The petitioner impugns show cause notice dated 13.10.2016, whereby, the respondent No.2 has stated that the application of the petitioner for the manufacturing and marketing of Fixed Dose Combination (hereinafter referred to as FDC) of Fungal Diastase (1:800) IP 50mg (derived from *Aspergillus oryzae*) + Papain IP 2.5 mg + Nux Vomica Tincture IP 0.0125 ml + Cardamom Tincture BP 0.075 ml + Casein Hydrolysed 225 mg per 5 ml Syrup (CARMOZYME Syrup) has been examined in the light of the documents submitted by the petitioner and the said FDC has been found to be irrational. The petitioner has been required to show cause as to why the manufacturing licence, in respect of the above FDC, may not be deemed to have been cancelled.

2. Learned senior counsel for the petitioner submits that the respondents have prejudged the issue and have already concluded that the said FDC of the petitioner is irrational. He submits that no opportunity has been granted to the petitioner to establish that the said FDC has a scientific justification and is rational. It is further submitted that no purpose would be served in proceeding with the show cause inasmuch as the respondents have already formed an opinion and have prejudged the issue and the show cause notice is an empty formality.

3. Learned counsel for the respondents submits that the show cause notice was issued consequent to a report of an Expert Committee, which had examined FDCs of various individuals and entities including that of the petitioner. It is submitted that the Expert Committee was constituted by the Central Government and all individuals and entities were required to submit

their documents justifying their respective FDCs. Even the petitioner had submitted the documents, based on which, the Expert Committee has submitted a report to the Government opining that there was no scientific justification for the subject FDC of the petitioner.

4. Learned counsel for the respondents further submits that the report is in public domain and is available on the website of the respondent No.2. He further submits that the respondent No.2 has not prejudged the issue or concluded the matter. The recommendation made by the Expert Committee with regard to irrationality is still under consideration.

5. It is submitted that the show cause notice has been issued so that the petitioner can respond to the finding of the Expert Committee that the FDC has been found to be irrational. Unless the petitioner is able to show that the FDC is rational or that there is a scientific justification for the FDC, the manufacturing licence of the petitioner shall be deemed to be cancelled. It is only where the petitioner is able to show that the FDC is rational and has a scientific justification that the approval for manufacturing the FDC shall be accorded. He submits that the finding in the impugned show cause notice is only *prima facie* based on the recommendations of the Expert Committee and the competent authority has still to form an opinion, for which purpose the show cause notice has been issued.

6. He submits that the competent authority shall examine the response of the petitioner with an open mind without holding that the findings of the Expert Committee are conclusive or binding on the competent authority.

7. In view of the stand of the respondent, that the report of the expert

committee is only an opinion and the competent authority shall examine the response of the petitioner with an open mind, it is directed as under:

- (i) petitioner shall file a response to the show cause notice within a period of two weeks from today;
 - (ii) respondents shall be at liberty to proceed with the disposal of the show cause notice in accordance with law;
 - (iii) the findings in paragraph 3 of the show cause notice i.e., “FDC has been found to be irrational” shall be treated as only *prima facie* observations,
 - (iv) the competent authority shall examine the response of the petitioner with an open mind without holding that the findings of the Expert Committee are conclusive or binding on the competent authority
8. The writ petition is disposed of in the above terms.
9. *Dasti* under the signatures of the Court Master.

JANUARY 25, 2017
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SANJEEV SACHDEVA, J