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

Date of Decision: 06th May, 2021

\+ **W.P.(C) 5173/2021 & CM APPLs. 15878/2021, 15879/2021, 15880/2021**

DHARMENDRA KUMAR AGGARWAL ..... Petitioner

Through Mr. Kunal Tandon, Ms. Niti Jain & Ms. Kanika Jain, Advocates.

versus

GOVT. OF NCT OF DELHI THROUGH THE SECRETARY & ANR. ..... Respondents

Through Mr. Anuj Aggarwal, ASC, GNCTD with Ms. Ayushi Bansal, Advocate.
Mr. Anurag Ahluwalia, CGSC with Mr. Abhigyan Siddhant & Mr. Nitnem Singh Ghuman, Advocates for UOI.
Ms. Ruby Singh Ahuja, Advocate for Roche India.

CORAM:
JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh, J. (Oral)

1. This hearing has been done through video conferencing.

2. The present petition has been filed by the brother of Shri Sudhir Kumar Agarwal, who is a COVID-19 patient (hereinafter, "patient"), and is currently admitted in Malik Radix Health Care Hospital, Nirman Vihar, New Delhi. The prayer in the petition is to issue directions to the Respondents in the petition, to urgently supply the *Tocilizumab* injection - *Actemra 400 mg* to the said hospital, so that the same can be administered to the patient urgently.

3. The matter was taken up, on an urgent basis, yesterday, and this court

was assured by the ld. Counsels appearing for the GNCTD and UOI, that they would make efforts through their good offices to provide the required dose of the *Tocilizumab* injection - *Actemra 400 mg* to the Petitioner's brother/ patient.

4. Today, Mr. Kunal Tandon, ld. Counsel for the Petitioner, has informed this court that the said dose of *Tocilizumab* has been made available for the Petitioner's brother and has been administered to him.

5. He further submits that today, he has filed a fresh affidavit seeking similar relief, on behalf of one Ms. Preeti Aggarwal who has approached the court on behalf of her mother - Smt. Kamlesh Gupta. As per the said affidavit, the patient - Smt. Kamlesh Gupta is admitted at the Rajiv Gandhi Cancer Institute and Research Centre, and was diagnosed with COVID-19 on 17th April 2021. The doctors at the said hospital are stated to have prescribed *Tocilizumab* to Smt. Kamlesh Gupta on 4th May 2021. However, despite repeated efforts, the patient and the family have been unable to arrange for the same.

6. It is therefore submitted by Mr. Tandon, ld. Counsel, that the case of the said Applicant may also be considered for supply of *Tocilizumab*.

7. As far as the case of Smt. Kamlesh Gupta, the patient, is concerned, this Court has perused the prescription issued by Dr. Dinesh Bhurani, from the Rajiv Gandhi Cancer Institute and Research Centre. As per the said prescription, the said patient requires one vial of the drug- *Tocilizumab 400 mg*. For the reasons stated in the affidavit, Smt. Kamlesh Gupta is impleaded as Petitioner No.2 in the present case.

8. Ld. Counsels for the Union of India and GNCTD assure this court that they will make efforts through their good offices, to make the required dose

of *Tocilizumab 400 mg* available to Mrs. Kamlesh Gupta, the patient, through her daughter - Ms. Preeti Aggarwal (Mob. 9818104970, 9810064376), who has joined the video-conferencing proceedings today.

9. In respect of the broader issue concerning the supply and availability of the drug *Tocilizumab 400 mg*, especially for patients in Delhi, this court had issued the following directions yesterday i.e., vide order dated 5th May 2021:

> *"i. The Union of India to inform this Court, on the next date of hearing, as to how much further stock of Tocilizumab is available for distribution to the hospitals/medical establishments in Delhi.*
> *ii. The UOI to also place on record the details of entities to whom approvals have been granted of Tocilizumab for manufacturing, marketing, importing or selling in India.*
> *iii. Qua the 500 vials of Tocilizumab, which were already allocated to the GNCTD by the Union of India, the GNCTD to inform this Court as to how much of the said stock has been consumed, and if any of the said stock is currently available for administration to any further patients who are being treated in smaller hospitals/ medical establishments, as also to the hospitals where the initial quantity of allocation could not be distributed.*
> *iv. Insofar as the company Roche Products (India) Pvt. Ltd. is concerned, the said company to place before this Court the following data and information:*
> *a) Whether immediate quantities of the drug Tocilizumab can be obtained from any of the manufacturing units engaged in manufacture of the said drug, and made available in India, for the purpose of*

administration to Covid-19 patients in India?

b) *The quantities of the drug Tocilizumab to be made available in India either through itself or through its licensee(s) in India on a monthly basis for the next four months.*

c) *What is the total quantity of this drug-Tocilizumab, that has been imported/sold in India, since March 2020 - either by the company itself or through its licensee(s) or approved importer(s) in India.*"

10. Today, on behalf of the Union of India, Mr. Anurag Ahluwalia, ld. CGSC, has placed the *Form-41* issued under the Drugs & Cosmetics Act, 1940 and Rules framed thereunder. The said form is the *'Registration Certificate to be issued for import of drugs into India under the Drugs and Cosmetics Rules, 1945' (`hereinafter DCA certificate')* in respect of the said drug *Tocilizumab*. He submits that as per the said DCA Certificate there are various entities which have been enlisted as being involved in the manufacturing, packaging and testing of the drug.

11. Mr. Ahluwalia further submits that the Government of India currently does not have any stock of the said drug, *Tocilizumab*, lying with it. The entire stock, which has been received by it, has been distributed to the States/UTs and other institutions.

12. On behalf of Mr. Anuj Aggarwal, ld. Counsel, Ms. Ayushi Bansal, ld. Counsel submits that the entire stock of 500 vials, which was received by the Delhi Government has already been distributed and there is no stock available with the Delhi Government of the said drug, as of today. She further submits that the GNCTD does not collect any data relating to the consumption of the said drug from the hospitals/medical establishments to

whom supplies have been made.

13. Ms. Ruby Singh Ahuja, ld. Counsel appearing for Roche India, submits as under:

- Ld. Counsel confirms that the products are being manufactured in foreign countries and not in India.
- According to the data which she has been able to gather since yesterday, the sudden spurt in demand for this drug- *Tocilizumab,* was totally unexpected.
- In 2019, the demand for total consumption was only about 8,900 vials for the entire year. However, from March 2020 to April 2021, a total of 2,10,000 vials have been supplied to India.
- The latest batch of vials imported was of 11,000 vials on 26th April, 2021. Out of the said batch, 9900 vials were supplied to the Central Government for distribution to COVID-19 related institutions, and 1100 vials were supplied to other Government institutions for being administered to patients suffering from Arthritis.
- Ld. counsel submits that as of today, a future consignment of 50,000 vials of the drug *Tocilizumab,* is likely to arrive in India in mid-May, 2021.
- Ld. Counsel further submits that by mid-June, 2021, a further consignment of 25,000 vials is expected to arrive in India.
- According to ld. counsel, this is an increase of 3300% compared to the consumption in 2019.

14. It is further submitted by her, on behalf of Roche India, that an emergency approval has been obtained for an Antibody Cocktail Treatment

which would be distributed in India, and this would be a treatment meant specifically for COVID-19, unlike Tocilizumab which was originally a drug for arthritis and is only an investigational therapy for COVID-19. Ld. Counsel submits that the distribution of both Tocilizumab and the Antibody Cocktail Treatment approved as of yesterday in India is through its distributor/ licensee - M/s Cipla Ltd.

15. On a query being put to ld. Counsel for Roche India, as to whether the supplies of the said drug- *Tocilizumab* could be increased beyond the quantity that is currently being submitted by her, she seeks time to obtain instructions. She further submits that apart from these quantities which are already scheduled for being imported, since there are no further orders, as on today, from the Government, or any establishment in India, until and unless further orders for the said drug *Tocilizumab*, are placed, it would be difficult to predict as to how much supplies can be made for sale in India.

16. Heard ld. Counsels for the parties. A perusal of the Form-41 shows that the manufacturing of the said drug, is stated to be carried out in Japan by an entity called *Chugai Pharma Manufacturing Co., Ltd.* The formulation site and the primary packaging site of this drug in terms of the DCA certificate is in Japan and the secondary packaging and testing sites are in Switzerland and in Germany respectively. The Registration Certificate under the Drugs and Cosmetics Rules 1945, for the said drug, has been granted under Form 27-A, through the office of the manufacturer/ its authorised agent in India i.e., M/s Roche Products (India) Pvt. Ltd. As per the said registration certificate, Roche India "*will be responsible for the business activities of the manufacturer in India in all aspects.*"

17. It is not in dispute that patent rights are being claimed in the drug

Tocilizumab under the Patents Act, 1970. The Form-41 that has been filed today also shows that the said product is being manufactured, formulated, tested, packed in various other countries. The recognised agent is Roche India, which is represented before this Court today. Further the said form makes it clear that Roche India is responsible for the business activities of the manufacture, in all aspects concerning India.

18. Since the Registration Certificate itself has been issued in favour of Roche India, at this stage, it is not deemed necessary to implead any other group companies of Roche India, as the Court notes that the company states that it is willing to cooperate and endeavour to supply further stocks of the medicine if the demand exists and orders are placed in respect thereof. Since the stand of the Company is that it has no confirmed orders from the Government as on date and is not aware of the actual demand in India, at this stage, to ensure immediate supplies of the medicine, to the large number of patients who are being prescribed the said drug and the acute shortage of the same, the following directions are issued:

(i) A high level meeting shall be called by the official(s) of the Department of Pharmaceuticals and the Ministry of Health and Family Welfare, Government of India. Mr. Rajiv Wadhawan and Mr. Navdeep Rinwa and/or any of their team members, shall accordingly hold a meeting with the representatives of Roche Products (India) Pvt. Ltd. and its distributors in India, in order to communicate and assess the demand for this drug in India. They shall also discuss the modalities for import and supply of the drug as per the expected demand and further logistics for placing orders for the same.

(ii) The said meeting shall be held tomorrow i.e. on 7th April, 2021 at about 12:30 P.M. The meeting shall be minuted, and the agreed minutes of the said meeting, shall be placed before this Court, by ld. Counsel for the UOI/Roche India. The minutes be emailed to the Court master by 6 pm on 9th May 2021.

(iii) Mr. Ahluwalia, ld. CGSC, representing the Union of India, shall also obtain instructions from the Office of the Controller General of Patents, and place on record the documents relating to the Patents that have been granted/ applicable, if any, in relation to the said drug, *Tocilizumab*, along with the working statements filed in respect of the said patents, if any.

(iv) An affidavit shall also be placed on record by Roche India confirming the import, distribution and supply of 50,000 vials and 25,000 vials into India, as per the submissions made above.

19. At this stage, ld. counsel appearing for Roche India, also submits that its distributor/licensee which has better information from the ground i.e. M/s. Cipla Ltd, be also impleaded as Respondent No.7, in the present matter, in order to assist the Court. The said request is allowed.

20. The amended writ petition, along with the amended memo of parties, as per today's directions, be placed on record and be filed with the Registry, with an advance copy, to the other ld. Counsels appearing for the parties, by 4:30 PM on 7th May, 2021.

21. List on 10th May, 2021 at 2:30 p.m.

PRATHIBA M. SINGH
JUDGE

MAY 6, 2021
Rahul/Ak