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

Date of Decision: 10th 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 for R-1 and 2.

Mr. Anurag Ahluwalia, CGSC with Mr. Abhigyan Siddhant & Mr. Nitnem Singh Ghuman, Advocates for UOI.

Mr. Neeraj Kishan Kaul, Sr. Advocate with Ms. Ruby Singh Ahuja, Mr. Vishal Gehrana, Mr. Shravan Sahny and Mr. Toshi, Advocates for Roche India.

Ms. Archana Sahadeva, Advocate for R-7/CIPLA.

CORAM:
JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh, J. (Oral)

1. This hearing has been done through video conferencing.

2. The present petition is concerned with the supply and availability of the drug *Tocilizumab 400 MG* for COVID-19 patients who are prescribed the same.

3. This petition was 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 patient was prescribed a dose of *Tocilizumab 400 MG*, however after multiple efforts, he was not able to procure the same. Hence the present writ petition was filed by the Petitioner. On 5th May 2021, the Court had recorded the submission of ld. counsels appearing for the UOI and GNCTD that they would use their good offices to make the same available to the Petitioner. The matter was then adjourned to 6th May 2021.

4. As recorded in the last order dated 6th May 2021, Mr. Kunal Tandon, submits that the said dose of *Tocilizumab 400 MG* has been made available for the Petitioner's brother and was administered to the patient. Mr. Tandon further submits that the patient's medical condition is better.

5. On the last date, this court had also impleaded another Applicant/patient, Smt. Kamlesh Gupta as Petitioner No. 2, who was also prescribed *Tocilizumab 400 MG*, but despite repeated efforts, the same was not made available to her. Ld. counsels for the GNCTD and the Union of India had assured the court that they would through their good offices try and make the medicine available. The same is submitted to not have been made available yet, but Mr. Tandon submits that she is currently stable and if the medicine is needed, he would contact the counsels for UOI and GNCTD.

6. Vide order dated 6th May 2021, this court had also impleaded M/s. Cipla Ltd. Ld. counsel for the Petitioner has filed an amended memo of parties in terms of the last order. The same is taken on record.

7. After hearing the parties on the said date, this court had issued the following directions:

(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.

As directed above, a meeting was to be called by senior officials of the UOI along with functionaries of Roche India and its distributors. The agreed minutes of meeting was to be placed on record.

8. Pursuant to the above directions dated 6th May 2021, the minutes of the meetings which were held on 7th and 8th May, 2021, have been placed on record by Mr. Ahluwalia, ld. Counsel appearing for the Union of India. Mr. Ahluwalia, ld. counsel submits, that the said minutes of the meeting have been agreed between the parties.

9. A perusal of the minutes of meeting emailed yesterday to the Court Master, the contents of which have been confirmed by ld. Sr. Counsel and all ld. Counsels appearing for the parties today, shows that the first meeting was held on 7th May 2021 and another meeting was held on 8th May 2021. It was attended by five senior officials from the Department of Pharmaceuticals and Ministry of Health. There were four officials of Roche India and three officials from Cipla Ltd. The said minutes of the meeting record the projected demand made, and the supplies that have come/ been imported of the drug *Tocilizumab 400 MG*. The same is as under:

> *"2. Mr Navdeep Rinwa requested representatives of Cipla to explain the process of placing of demand/orders to Roche India. Representatives of Cipla explained that Cipla provides forecast of the expected quantities of the drug Tocilizumab in India and accordingly shares the demand forecast with Roche India. The lead time between demand and expected supplies is around 45 days. However, there are production and supply constraints in Roche's global supply chain production units. As a result of this and depending upon the requested quantities, not all of the demand projected by Cipla can be converted into supplies, especially when there is huge and unprecedented demand. Roche India confirms a particular quantity which it can supply to Cipla for India sales and after getting the confirmation of a quantity from Roche,*

Cipla then places a confirmed purchase order for that quantity with Roche India. This is the quantity of Tocilizumab, which then is supplied by Roche India to Cipla.

3. The table below shows the Demand forecast projected by Cipla for Tocilizumab 400 mg vials for COVID related demand forecast for the period from January 2021 to May 2021, the quantity confirmed by Roche, orders placed against confirmed quantity and the supplies made against the orders so placed.

Month	***Demand projected by Cipla to Roche***	***Quantity confirmed by Roche against that demand***	***Orders placed by Cipla against Confirmed quantity***	***Supplies made by Roche against the order placed***
January, 2021	*2500*	*2500*	*2500*	*2500*
February, 2021	*2500*	*2500*	*2500*	*2500*
March 2021	*42,400*	*12,350*	*12,350*	*12,350*
April 2021	*1,20,000*	*11,000*	*11,000*	*11,000*
May 2021	*40,000*	*10,000*	*10,000*	*10,000 (expected in Mid May)*

> *3. It is evident from the above figures, that the reason for current shortage or lesser availability of the drug in India is not inadequate demand or orders projected by Cipla limited. The actual reason of shortage is the inadequate quantities confirmed against the projected demand, which in turn is dependent on the production capacities of Roche worldwide.*
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> *4. The representatives of Roche India were requested to provide a figure of the worldwide production capacity of Roche. They submitted that Roche India do not have these figures. They were requested to confirm the quantity demanded by Cipla for India at the earliest so that orders could be placed by Cipla for that much quantity and the current shortage of the drug could be removed. The representatives of Roche expressed their inability to give a timeframe in which the quantity demanded by Cipla could be confirmed as they are only importers and fully dependent on global supply chain."*

10. Today, Mr. Neeraj Kishan Kaul, ld. Sr. Counsel appearing for Roche India along with Ms. Ruby Singh Ahuja, submits that considering the recent spike of the COVID-19 pandemic, Roche India has, on its own, decided to immediately supply 10,000 doses of *Tocilizumab 400 MG*, which is likely to reach India tonight by 2:30am. This according to Mr. Kaul, ld. Sr. counsel is a completely humanitarian gesture on behalf of Roche, considering the pandemic situation in India, and will be free of cost.

11. In addition, Mr. Kaul, submits that 50,000 vials as recorded on the last date which has been clarified in the Minutes being of Tocilizumab 80 MG, would in fact cater to 10,000 patients who require *400 MG* of *Tocilizumab*. Thus, he submits that the total number of doses which shall be supplied by the end of week would be 10,000 doses of *Tocilizumab 400 MG* (which shall

be received tonight) and further 10,000 doses of *Tocilizumab 400 MG* by 15th May, 2021 – a total of 20,000 doses of *Tocilizumab 400 MG*.

12. On a query from the Court to the ld. Senior Counsel appearing for Roche India, as to why the global figures of manufacture and supply of *Tocilizumab 400 MG* could not be supplied by Roche India to the court, in order to determine as to whether India is getting a fair share of the medicine, as also as to whether any timeline can be given for further import of higher quantities of the said drug, Mr. Kaul, ld. Sr. Counsel submits that the manufacturing entity of this drug is M/s Chugai Seiyaku Kabushiki Kaisha. The manufacturing facilities of M/s. Chugai Seiyaku Kabushiki Kaisha are located in Japan. He submits that the said company has to also cater to the global demands of this drug, as this drug is also meant for treating Rheumatoid Arthritis.

13. In so far as ramping of supplies of this drug in order to cater to the demand of patients in India, which currently exists due to the pandemic situation, is concerned, though Roche India does not have the figures readily, Mr. Kaul, ld. Senior Counsel is willing to seek instructions *qua* the same, and make submissions on the next date.

14. Mr. Navdeep Rinwa, Joint Secretary, Department of Pharmaceuticals, as also Mr. Sameer Kumar Swarup, Deputy controller of Patents have also made some submissions.

15. Heard ld. Sr. Counsel and counsels appearing for the parties. A perusal of the minutes of the meeting, extracted above, clearly shows that –

- The demand in India for *Tocilizumab 400 MG* for the months of January and February 2021 was 2500 doses which was supplied.
- For the months of March, April and May 2021 the demand raised is

for 42,400 doses, 1,20,000 doses and 40,000 doses, respectively, approximately totalling to 1,80,000 doses.

- The total supplies made by Roche India which is importing the drug has only been about 33,000 doses over the said three months. Even if in addition, the 10,000 *Tocilizumab 400 MG* doses, which are expected to arrive in India tonight, as a humanitarian aid, along with the 10,000 doses of *Tocilizumab 400 MG* to be supplied by 15th May 2021 (already considered in the table above), are added, the total supply would still amount to approximately 43,000 doses, as against a projected demand of 1,80,000 doses over the last three months. Thus, this would only constitute less than 25% of the required demand of *Tocilizumab 400 MG* projected for patients in India.
- The reasons given by Roche for not meeting the demand, as recorded in the Minutes is *"production and supply constraints in Roche's global supply chain production units"* as the imports depend on *"production capacities of Roche worldwide"*.

16. This court notes positively, that today, there has been some scaling up of supplies by Roche. However, the same would still be grossly insufficient. The concluding paragraph of the Minutes is extremely concerning to this Court as Roche India has expressed its *"inability to give a timeframe"* to cater to the demand in India as it is fully *"dependent on global supply chain"*. The Court thus suggested to Mr. Kaul that the manufacturer can be impleaded in order to ascertain as to how the demand of patients in India, who are willing to pay for the medicine, can be met. However, Mr. Kaul submits that he may be given an opportunity to obtain instructions, if possible.

17. Accordingly, ld. Counsels appearing for Roche India to take instructions from M/s Chugai Seiyaku Kabushiki Kaisha or any other entity involved in the supply chain and make submissions as to whether any further supply of more quantities of *Tocilizumab 400 MG* doses can be made, and if so within what timelines, in order to cater to the actual demand for patients in India. The affidavit, if possible, shall also indicate the global products figures of *Tocilizumab* for the period January-April, 2021. Let an affidavit in pursuance of the same be filed on behalf of Roche India, by 12th May, 2021 at 4:30 PM. The same may be emailed to the Court Master.

18. Further, insofar as the Union of India is concerned, the relevant department, i.e., either the Department of Pharmaceuticals or the Drug Controller General of India, shall place an affidavit on record, stating as to whether there are any other applications for manufacture/import/sale of *Tocilizumab 400 MG*, with the Drug Controller General of India, under the Drugs and Cosmetics Act, 1940. The said affidavit to comprehensively specify the status/ stage of the said applications as well, if any. Let the affidavit of UOI be also filed by 12th May, 2021 through email to the Court Master.

19. Mr. Sameer Kumar Swarup, the Deputy Controller of Patents, has joined the proceedings. Let a status report be filed by him, in respect of the details of the patents stated to be covering *Tocilizumab 400 MG*, as also the working statements in respect thereof, including the date of filing, the term of patent etc., The same be also emailed by 12th May, 2021 through email to the Court Master.

20. Insofar as the doses which are currently being received by tonight and

by 15th May 2021, are concerned, the Union of India as also the GNCTD shall take immediate steps to ensure that the same are allocated to States/UTs and distributed transparently, efficiently and in a timely manner, so that they can be immediately administered to patients who are in need and have been duly prescribed with the same.

21. List for further hearing on 13th May, 2021, at 2:30 PM.

PRATHIBA M. SINGH
JUDGE

MAY 10, 2021
MR/AK