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

Date of Decision: 13th May, 2021

\+ **W.P.(C) 5173/2021**

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, Advs. 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.

CM APPL. 15878/2021(for exemption)

2. Allowed, subject to all just exceptions. Application is disposed of.

CM APPLs. 15879-80/2021(exemption from filing court fee and attested affidavits)

3. These are applications seeking exemption from filing court fee and duly notarized affidavits. Binding the deponent of the affidavit to the

contents of the application, the exemption is granted. Insofar as the court fee is concerned, the same be deposited within one week. Applications are disposed of. Registry to submit a report in case the court fees is not filed after a month.

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4. 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.

5. Vide order dated 6th May 2021, this court had recorded that *Tocilizumab 400 MG* had been made available for the Petitioner's brother and was administered to the patient. Mr. Tandon, ld. Counsel for the Petitioner further submitted, as recorded in order dated 10th May 2021, that the patient's medical condition is better.

6. On 6th May 2021, this court had also impleaded another patient Smt. Kamlesh Gupta as Petitioner No. 2, who was also prescribed *Tocilizumab 400 MG*, however despite repeated efforts could not get access to the same. 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. Today, however, Mr. Kunal Tandon, ld. Counsel for the Petitioner No.2, submits that the Petitioner No.2 is now stable, and she does not require the said dose of *Tocilizumab 400 MG*, for the time being.

7. On the issue of availability of *Tocilizumab 400 MG*, on the last date i.e., 10th May 2021, this court had issued the following directions:

> *"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."*

8. Further to the directions passed in the last order dated 10th May 2021, three affidavits have been emailed to the court master-

- On behalf of Roche Products (India) Pvt. Ltd. (*hereinafter, "Roche India"*);
- On behalf of the Deputy Drugs Controller (India);
- On behalf of the Office of the Controller General of Patents, Designs and Trademarks,

The same have been received and perused by this court. Let the same be brought on record by the respective counsels for the parties.

9. As per the affidavit that has been filed on behalf of Roche India, the drug *Tocilizumab* is stated to be manufactured by the Roche Group of Companies under the brand name "Actemra". However, the exact entity name, which manufactures the same, has not been mentioned in the said affidavit. On a query from the court to this effect, the ld. Counsel has emailed the packaging of "Actemra' to the court master, upon a perusal of which, it appears that the manufacturer and the entity from whom Roche India is importing the same is shown as F. Hoffman- La Roche Ltd., Switzerland at Chugai Pharma Manufacturing Company Ltd., Japan.

10. Insofar as the global figures of manufacture of this drug are concerned, the affidavit, at paragraph 4 was ambiguous. Ld. Counsels have after obtaining instructions informed that the global demand of *Tocilizumab 400 mg* for the period of March 2020- April 2021 was in excess of 2.5

Million vials/doses and Roche's current manufacturing capabilities have not been able to meet the said demand. The affidavit also mentions that Roche has tied up with external partners in two other entities, namely Novartis and Samsung, to establish supply and manufacturing of this drug to meet the demand. Relevant paragraphs of the affidavit filed by Roche India, are as under:

> *"4. During the COVID-19 pandemic, the demand for the drug tocilizumab/Actemra has been increasing for both approved indications such as Rheumatoid Arthritis (RA) and the non-approved COVID-19 treatment. The global demand for Tocilizumab/ Actemra was in excess of 2.5 Mn vials/ doses for both regular treatment of RA Patients and COVID-19 treatment and Roche's current global manufacturing facilities haven't been able to meet this demand.*
>
> *5. The Tocilizumab/Actemra imported in India for the year 2019 were about 8,900 vials and since the beginning of the COVID-19 pandemic, Roche India has already imported 210,000 vials, which is an increase of almost 22 times or 2200%.*
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> *6. I further state that during May 2021, Roche India has imported an additional 100,000 vials equivalent to 20,000 doses of Tocilizumab/ Actemra 400 mg and half of these stocks are being donated to the Government of India. These supplies have already reached India and should be available for distribution in the coming week.*
>
> *……..*
>
> *10. I state that Roche India has also obtained Emergency Use Authorization for its investigational antibody cocktail Casirivimab and Imdevimab used in the treatment of COVID-19, especially for the treatment of mild to moderate*

> *COVID-19 in patients who are at high risk of severe COVID-19. This drug significantly reduces the risk of hospitalization or death by 70% and it can also significantly shorten the duration of symptoms by four days. I further state after obtaining the Emergency Use Authorization from the Health Authorities, the Company is in the process of fast-tracking the import of this drug into the country, and it shall endeavor to make this drug available in the next 3-4 weeks.*
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> *11. I further state that Roche is striving for an equitable distribution of Tocilizumab/Actemra, and Roche India will try to meet the demand in India as much as possible. Roche India will also be focusing more on getting the supplies of Casirivimab and lmdevimab Antibody Cocktail."*

11. Insofar as the affidavit filed on behalf of the Deputy Drug Controller (India) is concerned, the same records that there are two other companies/entities who have applied for clinical trials of the said drug, in various phases, for being administered to COVID-19 patients. One company has applied for the same for the use of the drug in rheumatoid arthritis indication. The relevant paragraphs of the affidavit filed on behalf of the Deputy Drug Controller (India), reads as under:

> *"9. It is submitted that as per information available, recently Central Drugs Standard Control Organization (hereinafter referred to as "CDSCO") has permitted conduct of clinical trials with Tocilizumab in either rheumatoid arthritis or COVID-19 indication to various firms. The details of the same are as submitted hereinbelow:-*
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> *i. M/s Dr. Reddy's Laboratories Limited is presently conducting Phase I (PK-PD) trial with the drug in healthy adult volunteers. The*

objective of the trial is to generate results for conduct of Phase III trial in the country in Rheumatoid arthritis indication;

ii. *M/s JSS Medical Research India Private Limited is presently conducting Phase III clinical trial in COVID-19 patients which was approved on 08.05.2020. The objective of the trial is to evaluate the outcomes and safety of Tocilizumab usage along with current standard of care compared with standard of care alone in hospitalized patients with moderate to severe COVID-19 disease associated cytokine release syndrome (CRS). A copy of clinical trial permission dated 08.05.2020 granted to Mis JSS Medical Research India Private Limited is annexed herewith and marked as Annexure R-4 /2;*

iii. *M/s Hetero Biopharma Limited was granted permission on 23.04.2021 to conduct Phase III clinical trial in patients with Rheumatoid Arthritis. The objective of the trial is to compare the efficacy of Hetero-Tocilizumab with Roche-Tocilizumab in patients with Rheumatoid Arthritis. A copy of clinical trial permission dated 23.04.2021 granted to M/s Hetero Biopharma Limited is annexed herewith and marked as Annexure R-4/3.*

iv. *M/s Hetero Biopharma Limited has been granted permission on 12.05.2021 to conduct Phase III clinical trial with Tocilizumab injection in COVID-19 after due deliberation and recommendations of Subject expert committee dated 11.05.2021. The objective of the trial is to evaluate the efficacy of Hetero-Tocilizumab compared to RMP-Tocilizumab, Roche in combination with Standard of Care (SOC) for the treatment of cytokine storm of*

> *severe Coronavirus Disease (COVID-19) Pneumonia with respiratory rate >30 breaths/min or Sp02. A copy of clinical trial permission dated 12.05.2021 granted to M/s Hetero Biopharma Limited is annexed herewith and marked as Annexure R-4/4.*
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> *10. It is respectfully submitted that CDSCO has issued a letter dated 19.04.2021 to urgently import and provide Tocilizumab Injection, Actemra (brand name) in large quantities on regular basis at earliest from the date of issuance of the said letter. A copy of letter dated 19.04.2021 is annexed herewith and marked as Annexure R-4/5."*

12. Mr. Neeraj Kishan Kaul, ld. Sr. counsel with Ms. Ruby Singh Ahuja, ld. Counsel, appearing for Roche India, submits that the consignment of 45000 *Tocilizumab 80 mg* vials, to cater to 9000 patients, have arrived in India last week, as assured to the Court. This is in the form of a humanitarian aid that has been extended by Roche. In fact, as per the affidavit filed by Roche, 100,000 vials of *Tocilizumab 80 mg*, to cater to 20,000 doses, has already been imported by Roche India, prior to the stipulated date of 15th May, and the same is scheduled to reach the distributor, M/s Cipla Ltd, today. This has been confirmed by Ms. Sahadev, ld. Counsel appearing for M/s Cipla Ltd.

13. Mr. Kaul, ld. Sr. counsel also highlights the fact that insofar as licensing issues of the said drug are concerned, the Union of India has taken a stand before the Supreme Court in ***Suo Moto Writ Petition (C) No. 3/2021*** titled ***In Re : Distribution of Essential Supplies and Services during Pandemic*** that the question of voluntary or compulsory licences for the said drug, and the invocation of the provisions of the Patents Act, 1970 is a

policy decision, and the Government of India is currently dealing with the said issue at a global level, through diplomatic channels. He submits that the Union of India's stand in the said affidavit is that any invocation of these provisions, at this stage, would be counter-productive to the interests of India.

14. Ld. Sr. Counsel, has taken this Court through the various paragraphs of the affidavit filed before the Supreme Court and has also highlighted the order dated 6th May, 2021, passed by the Supreme Court in ***SLP (C) No. 11622/2021*** titled ***Union of India v. Rakesh Malhotra***, to point out that insofar as the measures being taken for essential drugs and medicines are concerned, the same is one of the mandates of the "*National Task Force*" which has been constituted by the Supreme Court. The documents relied upon including the orders, have been emailed to the court master today by Ms. Ahuja, ld. Counsel appearing for Roche India.

15. Mr. Kunal Tandon, ld. Counsel appearing for the Petitioner, points out that the Supreme Court's order dated 30th April 2021, in ***In Re: Distribution of Essential Supplies and Services during Pandemic (supra)***, clearly upholds the power of granting licences which are to be resorted to by the Government, in public interest. He also submits that contrary to the last order dated 10th May 2021, passed by this court, the global manufacturing and production details of the drug- *Tocilizumab* have not been placed by record by Roche India. Mr. Tandon, ld. Counsel, further, highlights the fact that there is an enormous demand for *Tocilizumab 400 mg*, and doctors have been prescribing the same *qua* patients suffering from COVID-19, as is clear from the case of the two patients who are Petitioners before this Court itself.

He finally submits that the shortage of the said drug has resulted in high prices as the drug is being sold in black market.

16. Ms. Archana Sahadeva, ld. Counsel appearing for Cipla Ltd., has pointed out that the Clinical Guidelines for the management of Adult COVID-19 patient protocol, that has been issued by ICMR on 22th April, 2021 has prescribed *Remdesivir*, *Tocilizumab* and *Convalescent plasma* as three drugs which can be used on a *EUA/ Off label* basis for the treatment/ management of COVID-19 patients, in certain specific circumstances. The ICMR could consider revising the said Guidance protocols, in case of presence of an alternative for the said drugs, if required.

17. Finally, on behalf of the Union of India, Mr. Anurag Ahluwalia submits that insofar as placing of orders is concerned, sufficient orders, which reflect the demand of *Tocilizumab 400 mg*, have been placed with Roche India, however, Roche India has been unable to supply the same. The Union of India is following up with Roche India, through various channels and is coordinating with them, in order to increase the quantum of imports to India

18. Insofar as the stand of the Union of India in respect of the DCGI's affidavit filed today, and the details of the applications for clinical trials filed by third parties is concerned, he seeks time to take instructions in the matter, and to clarify as to whether Phase III trials can be exempted/ waived or not.

19. Heard submissions on behalf of the parties.

20. Upon hearing the parties today, it is clear that the stand of the importer M/s.Roche India, who enjoys the licence of the manufacturer, in India, is that there is no certainty in respect to the further imports of the said drug- *Tocilizumab* that are to be made to India. This is clear from a reading

of paragraph 11 of the affidavit filed by Roche India, as extracted above. The global manufacturing figures of this drug have also not been filed before this Court despite specific directions. No assurance is being given as to further stocks that can be supplied to India. One of the justifications for the same by Roche is that the investigational antibody cocktail- Casirivimab and lmdevimab, as mentioned in paragraph 10 of the affidavit filed by Roche India, may be a better treatment for COVID-19 patients. According to Roche India, its current focus is to supply the said antibody cocktail. According to counsels, 1,00,000 doses of the said investigative antibody cocktail, which is stated to have been approved for emergency use and authorization in India, is likely to be sent to India by the end of May. The unequivocal stand of Roche India is clearly that more imports and supply of *Tocilizumab* in India would only be endeavoured upon, and there is no clear assurance or undertaking to meet the required market demand, despite there being patients who are willing to pay for the medicine.

21. The UOI's stand as per its affidavit before the Supreme Court is to be perused by the Court, before proceeding further. In the meanwhile, the Union of India, to file an affidavit on the following aspects:

i. Whether the demand for *Tocilizumab 400 mg* would be reduced, if the new antibody cocktail of *Casirivimab and lmdevimab* now approved for Emergency Use and Authorisation, is supplied by Roche and if so what quantities would be required of the said antibody cocktail?

ii. If *Tocilizumab 400 mg* is required for Covid-19 patients, how does it intend to obtain the supplies of the said drug through Roche India, or through its global manufacturers namely F.

Hoffman- La Roche Ltd., Switzerland at M/s Chugai Seiyaku Kabushki Kaisha, Japan?

iii. When are the results for the Phase III trials for the drug *Tocilizumab*, which have now been approved on 12th May, 2021, in favour of two Indian companies - M/s Hetero Biopharma Ltd., and M/s JSS Medical Research India Pvt. Ltd., expected and details of the applicable guidelines?

22. Let the Union of India file its affidavit in respect of the above three issues, at least two days before the next date of hearing, with advance copies to all the other parties in this petition.

23. All the affidavits and documents that have been filed through an email to the court master, shall also be filed on record with the Registry.

24. List on 27th May, 2021.

25. The digitally signed copy of this order, duly uploaded on the official website of the Delhi High Court, www.delhihighcourt.nic.in, shall be treated as the certified copy of the order for the purpose of ensuring compliance. No physical copy of orders shall be insisted by any authority/entity or litigant.

PRATHIBA M. SINGH
JUDGE

MAY 13, 2021
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