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

***Date of Decision: 5th May, 2021***

\+ **W.P.(C) 5173/2021 & CM APPLs. 15878-80/2021**

DHARMENDRA KUMAR AGGARWAL ..... Petitioners

Through: Mr. Kunal Tandon, Ms. Niti Jain and 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 &2.
Mr. Anurag Ahluwalia, CGSC with Mr. Abhigyan Siddhant and Mr. Nitnem Singh Ghuman, Advocates for UOI.
Ms. Ruby Singh Ahuja, Advocate for R-5/Roche Products (India) Pvt. Ltd.

**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 patient was detected as positive for COVID-19 on 30th April 2021 and a CT scan is stated to have been conducted on him. He was diagnosed with multiple patchy areas in his lungs and with COVID-19 pneumonitis. On 3rd May, 2021, the medical condition of the patient deteriorated, and he was admitted to the said hospital. He is currently stated to be on high-flow oxygen as also BiPAP. The doctors at the said hospital, on 4th May, 2021, prescribed the drug- *Tocilizumab 400 mg* for being administered to the patient. However, despite repeated efforts, it is the case of the Petitioner, that the said drug/ injection has not been made available for its administration to the patient. He submits that the condition of the patient is continuously deteriorating, and the said drug is urgently required.

4. The matter was taken up on the morning session today, and the Petitioner has, thereafter, filed certain further documents on record during the lunch hour, as per which, the concerned doctor at the Malik Radix Health Care Hospital has also reported that the patient has not responded to the injection *Bevacizumab 400mg* and thus, requires injection *Tocilizumab 400 mg* for recovery.

5. Ld. Counsel for the Petitioner has emailed an amended memo of parties, during the lunch hour, wherein the Petitioner now seeks to implead the GNCTD, Drug Controller of Delhi, Union of India, Drugs Controller General of India and Roche Products (India) Pvt. Ltd. He orally also seeks the impleadment of the Union of India, through the Secretary, Department of Pharmaceuticals. Ordered accordingly. The amended memo of parties, be filed by 5 P.M today by the Petitioner's Counsel and emailed to the court master accordingly.

6. The Respondent no.5, Roche Products (India) Pvt. Ltd., (`*Roche*

*India'*) has been impleaded on the ground that it is the company dealing with the Tocilizumab injection Actemra, which has been prescribed for the patient. Ms. Ruby Singh Ahuja, ld. Counsel, has appeared for Roche India, before this Court, and submits that she was informed of the filing of the present writ petition and the impleadment of Roche Products (India) Pvt. Ltd., by ld. Counsel for the Petitioner during the lunch hour around 2 pm, and accordingly, she has entered appearance in the matter when it was taken up at 2.30pm.

7. The issues relating to the shortage of *Tocilizumab* injection have been highlighted previously by the Supreme Court in its order dated 30th April, 2021 in ***Suo Moto WP(C) No. 3/2021*** titled ***In Re: Distribution of Essential Supplies and Services during the pandemic***, as also by the ld. Division Bench of this Court in the order dated 20th April, 2021, in ***WP(C) 3031/2020*** titled ***Rakesh Malhotra v. GNCTD***.

8. The Supreme Court has, in ***Suo Moto WP(C) No. 3/2021 (supra)*** in paragraphs 42 to 46 as also 51 & 54 captured the position relating to various drugs such as *Remdesivir* and *Favipiravir*, as also *Tocilizumab*. The scheme of the Patents Act and the provisions relating to compulsory licensing etc., have also been considered in the said order of the Supreme Court. The relevant portion of the order of the Supreme Court is set out below:

> ***"F. Potentiality of Compulsory Licensing for vaccines and essential drugs***
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> *42 Several drugs that are at the core of the COVID treatment protocol are under patents in India including Remdesivir, Tociluzumab and Favipiravir. On 2 October 2020, a communication was issued by the UOI, along with South Africa, to the Council for Trade-*

*Related Aspects of Intellectual Property which stated that there were several reports about intellectual property rights hindering timely provisioning of affordable medical products to patients. The communication also reported that some members of the World Trade Organization had carried out urgent amendments to their national patent laws to expedite the process of issuing compulsory/government use licenses.*

*43 In India, the patent regime is governed by the Patents Act, 1970, Section 92 of which envisages the grant of a compulsory license, inter alia, in circumstances of national emergency and extreme urgency. Once a declaration of national emergency is made, and the relevant patents notified, any person interested in manufacturing the drug can make an application to the Controller General of Patents who can then issue a compulsory license. The patentee would be paid a reasonable royalty as fixed by the Controller General of Patents. Further, under Section 100 of the Patents Act, the Central Government can authorize certain companies to use any patents for the "purpose of the government". Indian companies can begin manufacturing the drugs while negotiating the royalties with the patentees. If the Central Government or its authorized company is not able to reach an agreement with the patentee, the High Court has to fix the reasonable royalty that is to be paid to the patentee. Another alternative is for the Central Government to acquire the patents under Section 102 from the patentees. If the Central Government and the patentee is not able to reach a consensus on the price of the patents, it is up to the High Court to fix the royalty. Additionally, under Section 66 of the Patents Act, the Central Government is also entitled to revoke a patent in the public interest.*

*44 The utilization of these flexibilities has also been*

*detailed in the Trade Related Aspects of Intellectual Property Rights Agreement. Even as TRIPS obliges countries to ensure a minimum level of patent protection, it creates a permissive regime for the carving out of exceptions and limitations that further public health objectives. This is evident from a conjoint reading of Articles 7, 8, 30 and 31 of TRIPS. Article 7 outlines the objectives of the TRIPS as being to ensure the effective enforcement of intellectual property in a way that, inter alia, is "conducive to social and economic welfare". Article 8 gives member countries the freedom to take measures that protect public health and nutrition. Article 8(2) allows for the taking of TRIPS-compatible measures aimed at preventing the abuse of intellectual property rights. Articles 30 and 31 deal with exceptions to the rights of patent owners, by allowing grant of compulsory licenses. It leaves countries with significant breathing space to determine how the compulsory licensing or government-use levers can be triggered. While such determinations must be made on the individual merits of each case, the aforesaid caveat does not apply when the compulsory license grant is for national emergency, extreme urgency or public non-commercial use.*

*45 According to the 2001 Doha Declaration, TRIPS should be interpreted in a manner supportive of the right of members to protect public health and to promote access to medicines. It recognizes the right of WTO members to use the full extent of the TRIPS flexibilities to secure this objective. Para 5(b) of the Doha Declaration provides the freedom to each member to grant compulsory licenses and to determine the grounds on which the licenses are granted. Para 5(c) leaves it up to each nation to determine what constitutes a national emergency or extreme urgency. In the context of the COVID-19 pandemic, we note that several countries such as Canada and Germany have relaxed*

*the legal regimes governing the grant of compulsory licenses.*

*46 Whether and if so, the extent to which these provisions should be utilized is a policy decision for the Central Government. We have flagged the issue for its consideration. We have only outlined the legal framework within which the Central Government can possibly consider compulsory licensing and government acquisition of patents. The Central Government is free to choose any other course of action that it deems fit to tackle the issue of vaccine requirements in an equitable and expedient manner, which may involve negotiations with domestic and foreign producers of vaccines. We clarify that it is up to the Central Government to choose the best possible measures it can undertake during the current crisis keeping in mind that public interest is of paramount importance.*

**…..**

*51 We have been informed by the Central Government in its affidavit that NPPA has revised the maximum retail price of Remdesivir to Rs 3500. However, it has come to our notice that several other drugs which are being prescribed by doctors for treating COVID-19 patients like Favipiravir, Tociluzumab, Enoxaparin, Ivermectin, Methylprednisolone, Paracetamol and Hydroxy-chloroquine are being priced at exorbitant rates creating issues of access and affordability. While this is not a direction of this Court, the Central Government can consider invoking its statutory powers under paragraphs 19 and 20 of the Drugs Price Control Order, 2013. Under paragraph 19 of the Drugs Price Control Order, 2013 the Government in extraordinary circumstances, if it considers necessary in public interest, can fix a ceiling price or retail price of the drug for a certain period. COVID-19 is a crisis of an unprecedented nature and qualifies as an extraordinary*

> *circumstance. It will be in public interest to ensure that the price of essential drugs is fixed in such a manner that it is available even to the most marginalized sections of the society. The Government can even monitor the prices of the drugs under paragraph 20 of the Drugs Price Control Order, 2013 and ensure that no manufacturer increases the prices of the drugs by more than 10% of the maximum retail price during the preceding 12 months and where the increase is beyond 10% of the maximum retail price, it can oblige the manufacturer to reduce it to the level of 10% for the next 12 months.*
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> **…..**
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> *54 It has been submitted on behalf of the Central Government that on 24 April 2021, DoP, NPPA and DGCI reviewed the production and supply of drugs such as Favipiravir, Enoxaparin, Ivermectin, Methylprednisolone, Paracetamol and Hydroxy-chloroquine. The supply of Remdesivir and Tociluzumab is already under the consideration of the Central Government. A meeting was also held on 25 April 2021 by DoP, NPPA and DGCI with the manufacturers to review stock position, availability and production plans. The Central Government should provide details of estimated demand of essential drugs mentioned above, production capacity, existing stocks, details of allocation and supply of such drugs."*

9. Similarly, the ld. Division Bench of this court has also dealt with this position in its order dated 20th April, 2021 in ***Rakesh Malhotra (supra),*** observing that:

> *27. There are a number of other drugs which are being used for treatment Covid-19 patients, such as Tocilizumab, Favipiravir, Ivermectin, Dexamethasone, Methylprednisolone, Dalteparin, Enoxaparin, HCQ and Baricitinib. As per news reports, there are shortages of some, if not all, of the aforesaid drugs. Looking to the*

*emergent situation, we direct the Central Government to immediately reach out to the manufacturers/ patent holders/ licensees so as to forthwith ramp up the production capacities of the above, and all such other medications, as are essential for treatment of Covid positive patients. We may take note of the fact that the Patents Act provides for Compulsory Licenses under Section 84, and Special Provision for Compulsory Licenses or Notifications by the Central Government, under Section 92. Section 100 provides the power of the Central Government to use inventions for purposes of the Government.*

*28. Looking at the present day situation, there can be no doubt that a case is made out for exercise of its power by the Central Government/ Controller under the aforesaid provisions of law. At the same time, the interests of the Patent holders/ licensees should be kept in mind, since it on account of their investments, inventions and hard work that such like medicines are made available to the public at large. The best course would be to encourage the existing manufacturers to ramp up their production on a war footing. They should also be encouraged to grant voluntary licenses to other entities to manufacture the requisite drugs.However, if such efforts do not fructify soon enough, the Government/ Controller should not hesitate to invoke their jurisdiction and powers under the aforesaid provisions of the Patents Act, since the lives of thousands of people are being lost each day in the country due to COVID. The lives of the people take priority over everything else. Even if such like powers are exercised, the patent holders/ manufacturers can be adequately compensated by fixation of fair license fee. The Central Government should swing into action in terms of this order in this regard without any delay, and report progress on the next date of hearing."*

10. A perusal of the two orders above, clearly shows that there is a severe shortage of the drug *Tocilizumab* across the country. A reading of the above orders also shows that the issues relating to pricing, shortages and steps to be taken at the National level, including by the Central Government are being considered therein. In Delhi too there is shortage and several critical patients are being prescribed this drug.

11. Presently this Court is considering the question of immediate availability of the drug to the Petitioner and considering that there may be similarly situated patients in Delhi, submissions have been heard. As per the recent allocation letter dated 30th April 2021, issued by Mr. Rajiv Wadhawan, Director, Ministry of Health Welfare and Mr. Navdeep Rinwa, Joint Secretary, Department of Pharmaceuticals, Government of India initially an interim allocation of 3245 vials of Tocilizumab was made for States/UTs along with Central institutions. A further quantity of 1200 vials, have been allocated to it for further allocation to the North Eastern States, UTs and Central Government institutions. From the said quantities the States/UTs/Ministries have been asked to approach the Ministry in case of requirement. Out of the said vials recently received, which have been distributed across the country, Delhi has been allocated a total quantity of 500 vials.

12. As per Mr. Anuj Aggarwal, ld. Counsel appearing for the GNCTD, the said 500 vials, which have been received by the GNCTD from the Union of India, have been further distributed within Delhi to various government as well as private hospitals and in fact, it has been admitted that a large number of hospitals could not even get the said drug for administration to their patients. Ld. Counsel further submits that there are at least 200

hospitals/establishments currently treating COVID-19 patients, and it is a matter of public knowledge that this drug- *Tocilizumab* is being prescribed to a large number of critically ill patients.

13. Considering that there are a large number of hospitals in Delhi, that are currently treating COVID-19 patients, there is a severe shortage in the availability of the said drug - *Tocilizumab*, and 500 vials, being made available, would not be sufficient. There is therefore an imminent need for the said drug in Delhi for critically ill patients who are being prescribed the same.

14. From the publicly available records it is clear that certain patents are stated to have been granted in respect of this drug. The order of the Supreme Court clearly records that the drug is not being manufactured in India. Considering the demand for the drug, even to those patients who are willing to pay and purchase the same, it is clear that adequate quantities are not being made available. The rationing of critical medicines in this manner, owing to lack of supplies from foreign shores and no local manufacturing, is completely unacceptable in a pandemic situation, especially when the consumers are willing to purchase the drug. In order to ensure immediate availability of the drug for administration of the same to critically ill COVID-19 patients who are prescribed the same, in Delhi, the following directions are issued:

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.

15. On a query to Ms. Ahuja as to what percentage of the global quantities of Tocilizumab manufactured, is being allocated to India, she submits that the said data may not be readily available by tomorrow but she agrees to endeavour to obtain the same.

16. It is further noted, that insofar as the Petitioner's brother i.e., the patient in the current petition is concerned, the Union of India and the GNCTD assure this Court that they would make efforts through their good offices, to make the required doses of the said drug- *Tocilizumab 400 mg* available to the brother of the Petitioner.

17. List on 6th May, 2021 at 2:30 pm.

**PRATHIBA M. SINGH**
**JUDGE**

**MAY 5, 2021**/*dk/Ak*