

WILL NATCO PHARMA BE GRANTED COMPULSORY LICENSE YET AGAIN?

This is not a hidden truth that India is in a grave situation and is facing one of the biggest health emergencies in the world. The recent reports state that India has more than 20 million patients of Covid-19. The figures also state that while over a lot of people have been recovered from Covid-19, but the number of people who continue to be afflicted is also huge, and official deaths recorded are in millions.

Covid-19 or the virus has been proved as a fatal disease and has been declared as a pandemic by the World Health Organization (WHO). Since then, a number of scientists, universities, pharma companies all over the world are looking for a permanent cure to this disease but with no great success as the virus of Covid-19 is mutating at a faster speed. Every other day, extensive research is happening all over the world to find the better treatment to cure the virus instead of using hit and trial treatments to cure the said virus.

Recently, there have been few research papers/articles that show that the Baricitinib (herein referred to as "drug"), which is originally used to cure moderate to severely active rheumatoid arthritis in adults, could be trailed for use in Covid-19 treatment. This was based on AI modelling and the reports having data that supported further evaluation of the ant cytokine and anti-viral activity of Baricitinib, and also on further assessment in randomized clinical trials in hospitalized Covid-19 patients. The report in the New England Journal of Medicine reported that Baricitinib + Remdesivir was superior to Remdesivir alone in reducing recovery time and accelerating improvement in clinical status among patients with severe symptoms of Covid-19, therefore, it can be said that it is the undeniable fact that Baricitinib is an essential medicine for Covid-19 treatment as an adjunct to Remdesivir prescription, particularly in patients requiring oxygen support and non-invasive ventilation. The said combination also has been approved by the United

States Food & Drug Administration for emergency use in treating Covid-19 patients. In fact, the Delhi High Court has also noted and recognized the relevance and criticality of Baricitinib in the treatment of Covid-19.

As per the records, Baricitinib has already been patented for curing arthritis under Patent No. 270765 dated 05.07.2018 by Incyte Holdings Corporations, which was licensed to an entity called Eli Lilly & Co., (herein referred to as "licensee") for manufacturing the said drug.

Given the above, the only pharmaceutical company that has come forward to file a request for the compulsory license (CL) under Section 92 of the Patents Act is Natco Pharma Limited (herein referred to as "Natco"). The license is requested via compulsory license application (herein referred to as "application") to the Indian Controller of the Indian Patent Office, to manufacture the drug for use in treating Covid-19 patients on May 3, 2021. The aim of Natco is to obtain an approval for manufacturing the said drug and to provide an adequate amount of the drug at the reasonable rate to the population having a varying range of income.

Further, it has been seen from the application that Natco has reached out to the Patentee but in vain as the Patentee has not returned back yet. Instead, the licensee on the behalf of the Patentee has demanded certain confidential details from Natco, to which the licensee has not been entitled to. Therefore, Natco has proceeded to file the request for CL under Section 92 of the Patents Act.

It has been noted that CL has not been filed under Section 84 of the Patents Act instead it has been filed under Section 92 of the Patents Act. The reason could be there is a critical requirement to file CL is that the said CL can only be applied after three years of the grant of the patent. In that case, the said timeline would only be met by July 5, 2021, and hence, waiting till that period would have worsened the situation in India as it would cause a delay in serving the patients with the drug, which is the need of the hour now. Therefore, the said application is filed under Section 92 of the Patent Act. The present CL application is filed on the following grounds, thereby invoking section 92 of the Act:-

- Existence of a national public health emergency.

- Unmet need in India due to lack of manufacturing. The total number of Covid-19 patients currently undergoing treatment is over 3.4 million, and the numbers are only increasing on a daily basis. Therefore, the importation of the drug for such a huge population might not be possible. If in case, it is possible, chances of making the drug available on time, keeping in mind the population of India, is slime.
- Unmet need to due to lack of supply. It is also an admitted position that Eli Lilly only imports the tablets and that too in limited quantities. Eli Lilly itself has a very narrow distribution network making it difficult for it to service the needs of the Indian population for Baricitinib in times of Covid-19 pandemic.
- Unmet need due to price/lack of affordability. The per tablet cost is INR 3230.00. For a 14-day treatment regimen, the price comes out to be INR 45220.00 per patient. The said amount cannot be afforded by the common people of India.

Given the above, it is submitted that if the Controller issues the Compulsory license to Natco for manufacturing and distributing Baricitinib to treat Covid-19 patients, then it is not only the second compulsory license granted to Natco but would be second granted the compulsory license in India since 2012. It will be interesting to see the stance of the patent office on the CL application by Natco. However, if Natco moves ahead with a drug rollout without waiting for the CL, it risks being sued by the patent holder for patent infringement.

Source of Information: Compulsory Application filed by Natco Pharma Limited at the Indian Patent Office on May 03, 2021.

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