

Intellectual Property advocacy in the fields of:

- IP Infrastructure
- IP Valuation
- M & A
- IP Policy
- Technology Transfer
- Innovation Research
- Patent Law
- Licensing
- Data Management
- Copyright
- Collaborations
- Balance for Rights & Obligations

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Editorial

To “grant or not to grant” has been a vexed question facing the Government of India as regard the grant of Compulsory license (CL) for vaccines and anti-COVID drugs such as Remdesivir. Many Indian companies other than the five or seven who have been granted Voluntary License by Gilead have been seeking permission from the Government to commence launch and marketing of generic Remdesivir. The Hon’ble High Court of Delhi (*Rakesh Malhotra vs Government Of National Capital Territory Of India And Ors in W.P.(C) 3031/2020 dated 20/04/2021*) has recently made an “order in passing” regarding provisions in the Patents Act, 1970 for grant of CL under Section 84, Section 92 and Section 100. The relevant paragraphs 27 and 28 are reproduced in this issue.

In the ongoing *suo moto* proceedings in the Hon’ble Supreme Court (*SMW (C) No.3/2021 In Re : Distribution Of Essential Supplies And Services During Pandemic order dated 30/04/2021*), the Apex court flagged the issue for the consideration grant of CL under Section 92 or Section 100 including acquiring Patent under Section 102, in view of national emergency and extreme urgency, for anti-COVID drugs and vaccines. The Apex court clarified 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 and 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*”.

Giving consideration to the observation of the Courts, the DCGI (Drugs Controller General of India) has started granting new permissions for the manufacture of generic Remdesivir other than to the licensees of Gilead. This is a welcome development.

In the meantime, a call for generic waiver for all Patent Rights for COVID drugs and vaccines is pending in the WTO. On 26/04/2021, Hon’ble Prime Minister of India Shri Narendra Modi informed Hon’ble President of USA, Mr. Biden, during his telephone conversation regarding

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India's initiative at the WTO for the relaxation in the norms of the agreement on TRIPS. This proposal at the WTO was initiated by India and Africa and supported by nearly 130 countries of the World but rejected by EU and USA. We hope better sense will prevail and the developed countries will drop their opposition to the waiver proposal and allow the resolution to be passed at the WTO.

USA has, in the meantime, once again come up with the Super-101 Watch List ritual in spite of the on-going pandemic.

The second wave of Pandemic in India is "on". Even a third wave of the Pandemic is predicted in the imminent future. India and all citizens need to follow the "COVID Protocol" more stringently and desist from breaking the guidelines issued by the Health authorities and the Government. Our Nation is facing vaccine shortage, consequent to the embargo by the Biden administration, on export of vaccine raw material to SII, which has now been released, pursuant to the appeal by top leaders of India.

Let us hope and pray that the entire Nation will rise above petty politics and stand united to fight the virus in the best interest of the Nation and its people. Let us pray for the mental and physical health and well-being of all our brothers and sisters and the communities at large- not only in India, but also all over the World.



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Delhi High Court Order Dated APRIL 20, 2021

Rakesh Malhotra vs Govt Of National Capital Territory Of India & Ors in W.P.(C) 3031/2020

"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 to 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 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."

Prime Minister's Office

Prime Minister's telephone conversation with President Biden of the United States of America.

Posted On: 26 APR 2021 10:32PM by PIB Delhi

Prime Minister Narendra Modi had a telephone conversation today with His Excellency Joseph R. Biden, President of the United States of America.

The two leaders discussed the COVID-19 situation in their respective countries, including India's ongoing efforts to contain the second wave of COVID-19 through expedited vaccination efforts, and ensuring supply of critical medicines, therapeutics and healthcare equipment.

President Biden conveyed solidarity with India and affirmed that the United States was determined to support India's efforts by quickly deploying resources such as therapeutics, ventilators and identifying sources of raw materials to be made available for the manufacture of Covishield vaccines.

Prime Minister Narendra Modi conveyed his heartfelt appreciation for the offer of assistance and support from the Government of the United States of America. He mentioned India's commitment to contain the COVID-19 pandemic globally through Vaccine Maitri, and its participation in COVAX and the Quad Vaccine Initiatives. The Prime Minister underscored the need to ensure smooth and open supply chains of raw materials and inputs required for manufacture of vaccines, medicines, and therapeutics related to COVID-19.

Both leaders underlined the potential of the India-US partnership in vaccine development and supply to address the COVID-19 pandemic, and directed their respective officials to maintain close coordination and cooperation in their efforts in this domain.

Prime Minister Narendra Modi also informed President Biden about India's initiative at the WTO for a relaxation in the norms of the Agreement on TRIPS to ensure quick and affordable access to vaccines and medicines for developing countries.

The two leaders agreed to remain in regular touch.

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शैलेन्द्र सिंह, अपर सचिव

MINISTRY OF COMMERCE AND INDUSTRY
(Department for Promotion of Industry and Internal Trade)
(IPR-Estt. Section)
NOTIFICATION

New Delhi, the 22nd April, 2021

S.O. 1668(E).—In Pursuance of the Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance, 2021 vide Notification No. CG-DL-E-04042021-226364 dated 04th April, 2021, the Intellectual Property Appellate Board established vide section 83 of the Trade Marks Act, 1999 stands dissolved with effect from 04th April, 2021.

[F. No. P-24017/28/2021-IPR-I]
SHAIENDRA SINGH, Addl. Secy.

Supreme Court Restores Order Extending Limitation; Period From 14.03.2021 Excluded From Computing Limitation Period Until Further Orders

The Supreme Court on Tuesday extended limitation period for the filing of cases in courts and tribunals with effect from 14.03.2021 until further order. The bench extended all periods of limitation ending on 14.03.2021 until further orders, by restoring the order passed on March 23, 2020, which had extended the limitation period.

Source: <https://www.livelaw.in/top-stories/supreme-court-extends-limitation-period-for-filing-cases-from-march-14-2021-until-further-orders-173177>

Tech Mahindra, Reagene to file patent for coronavirus attacking molecule

"We have found a molecule that can potentially attack coronavirus. We have applied for a joint patent and cannot reveal the name of the molecule unless the patent process is completed," Malhotra said. Tech Mahindra and Reagene Biosciences are in the research process. Makers Lab started the computational modelling analysis of the coronavirus. Based on computational docking and modelling studies, Tech Mahindra and its partner shortlisted 10 drug molecule from a list of 8,000 FDA-approved drugs.

Source: https://www.business-standard.com/article/companies/tech-mahindra-reagene-to-file-patent-for-coronavirus-attacking-molecule-121050200662_1.html

MSD has signed agreements with Cipla Ltd., Dr. Reddy's Laboratories, Emcure Pharmaceuticals Ltd., Hetero Labs Ltd. and Sun Pharmaceutical Industries Ltd

MSD Pharmaceuticals Pvt. Ltd., a wholly-owned subsidiary of Merck Sharp & Dohme and known as Merck & Co., Inc., has entered into non-exclusive voluntary licensing agreements with five top Indian generic manufacturers for supply of Molnupiravir, an investigational oral antiviral agent currently being studied in a Phase-3 trial for the treatment of non-hospitalised patients with confirmed COVID-19, in India.

Source: <https://www.thehindu.com/business/Industry/msd-ties-up-with-5-indian-pharma-majors-for-supply-of-oral-covid-19-drug-molnupiravir/article34422728.ece>