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Dr. Pradeep is a Registered Patent Agent and has a professional experience of more than 18 years in teaching, research and IP. He has a Master's degree in Biotechnology and a Ph.D. in Biomedical Science. He has a rich experience in patent drafting, patent analysis, patent prosecution and due diligence in patent matters. He is involved in advising on technical and legal aspects of patenting and contentious IP matters. Dr. Pradeep was reviewer for the Journal of Cardiovascular Diabetology and for the Indian Council of Medical Research, Government of India and various other research bodies of the Indian government. He was also an IP consultant with the Council of Scientific and Industrial Research (CSIR).



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Anmol holds a Master's degree in Toxicology and has about 3 years of experience in the area of patents. He regularly works on projects involving patent search and analytics, such as name based search, patentability search, knock out search, validity search, Infringement search including evidence of use, Freedom to operate search including claim charts, patent landscape including white space analysis, etc. He also drafts provisional and complete patent specifications in the field of Life Science.

## Safeguard In The Indian Patents Act To Combat Situation Like Covid-19 Pandemic

Coronavirus disease 2019 (COVID-19) pandemic is among the one of most disastrous things witnessed world over in recent decades. COVID-19 pandemic has crippled the normal functioning of many activities, as several countries across the world to contain spreading infections by implementing wide-ranging social-distancing and lockdown strategies.

Management of the immediate health crisis is vital and necessary for economic stability of every individual, organization and the countries itself. WHO in its 97th Situation Report on COVID-19 has highlighted that public health systems are under severe strain due to COVID-19 pandemic and countries must continue to focus on other health emergencies and to strengthen vaccination against vaccine-preventable disease outbreaks during the COVID-19 pandemic. In situation like the one, the cost of vaccines, life-saving drugs and other important medications and devices required to combat health crisis is pivotal to many countries, which does not have a strong public health care system. Most of the advanced vaccines, drugs and devices are patented products and holds a much higher price brackets, limiting their affordability and availability. Benefits of such patented products may not be thus available to a significant percentage of global population. As governments across the world are under pressure to assure the public that IP will not be barrier to fight against the disease and governments like of Canada, US, Chile, Colombia, France, Germany, Greece and Hungary have enacted legislative provisions to deal with COVID-19 pandemic. Witnessing severity of COVID-19 pandemic, Israel's government have allowed generic versions of AbbVie Inc.'s HIV drug "Kaletra" to be imported for treatment of coronavirus patients. More recently, the UK government have indemnified ventilator manufacturers to shield from IP enforcement. Thus COVID-19 pandemic may also lead to many such serious repercussions on patent protection of antiviral drugs, ventilators and other devices, which may be required to deal effectively with COVID-19 pandemic.

It is circumstances akin to one due to COVID-19 pandemic, for which provisions of Sections 92, 92A, 100 and 102 of the Indian Patents Act are meant for, which provide a safeguard mechanisms that can be invoked, if necessity arises. In India, there is no patent corresponding to "Kaletra" as the related Indian patent applications 339/MUMNP/2006, 726/MUMNP/2009 and 2474/DELNP/2009 did not proceed to grant. However, in intense efforts to treat COVID-19, many existing drug molecules like lopinavir, remdesivir, oseltamir, azithromycin, ribavirin, kevsara and chloroquine that have been primarily developed for treating other ailments have been identified for putative repurposing for treating COVID-19 and thus underway different studies. Most of such potential drugs like azithromycin, remdesivir, ribavirin, kevsara are protected by patents.

Issuance of Compulsory licences under Section 84 of the Indian Patents Act has been observed in case of Natco Pharma for the generic production of Bayer Corporation's Nexavar, a lifesaving medicine for treating liver and kidney cancer.

Section 92 of the Indian Patents Act provides a special provision for compulsory licences on notifications by Central Government, particularly in circumstances of national emergency or extreme urgency or public non-commercial use including public health crises, related to Acquired Immuno Deficiency Syndrome, Human Immuno Deficiency Virus, tuberculosis, malaria or other epidemics, without adhering to procedure as required to grant compulsory licence under Section 84. While, Section 92A provides an enabling provision for exportation of patented drugs to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, where the importation of the patented pharmaceutical products from India has been permitted through some mechanism by the importing country.

Similarly, Section 100 of the Indian Patents Act empowers the Central Government or any person authorized in writing by Central Government may use the invention for the purposes of Government, which also include circumstances of national emergency or extreme urgency or public non-commercial use as covered by Section 92, wherein procedural compliance is relaxed. Another provision is provided under Section 102 of the Indian Patents Act, that empowers the Central Government to acquire all rights in respect of a patent application or patent by a notification to that effect in the Official Gazette, on satisfaction that it is necessary to acquire the patent application or patent from the applicant or the patentee for a public purpose.

Learning that the Indian Patents Act has enough safeguard provisions that can be invoked if need arises, we also witness that scientists across the globe and particularly pharmaceutical companies are pushing the limits to fight the COVID-19 pandemic. All public and private scientific research organizations in India have geared themselves to boost the activities to complement the products and technologies to monitor and control the spread of COVID-19.

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