COVID-19: Overcoming Patent Related Barriers

IPpro Services (India) LLP

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As the huge wave of COVID-19 infections is devouring the world, there is an overwhelming need for relief measures: drugs/therapeutics, vaccines, diagnostic kits and other treatment aids such as ventilators/respirators. The biggest question is whether these relief measures are easily available for tackling the pandemic or are we stuck behind patent rights from gaining access to protected drugs and/or diagnostic aids. This article discusses the provisions available in the patent laws of jurisdictions like India and the US, for overcoming barriers associated with patent rights during the times of extreme urgency.

India

Considering patent laws in India, the provisions of the Patents Act 1970 have preserved public interest at every step along the way restricting undue monopoly that may be enforced in the name of patent rights. To deal with the pandemic crisis, the provisions available under the Patents Act to overcome patent rights related to drugs and/or diagnostics/treatments include the following:

Bar on patenting treatment/diagnostic methods:

According to **Section 3(i)** of the Patents Act, any treatment/diagnostic methods are considered non-patentable.

Compulsory Licensing:

Section 92 of the Patents Act provides provisions for grant of a compulsory license any time after patent grant, in case of a national emergency, extreme urgency or public non-commercial use arising during a public health emergency/crisis such as an epidemic (for example, AIDS, HIV, tuberculosis, malaria or other epidemics). Furthermore, the Patents Act provides a few options where the government can Suo Moto take control of or grant licenses for patents for public use or benefit (**Section 100** and **Section 102** of the Patents Act).

Bolar Exemption:

The provisions of **Section 107A** allows patented drugs/medicines to be used, produced and sold/imported for R&D purposes or for obtaining regulatory approvals, without the permission of the patent holder. Therefore, generic drug companies can use patented drugs for clinical trials concerning COVID-19.

United States

In contrast to patent statutes of many jurisdictions, the US patent law does not include specific compulsory licensing provisions. However, there are implicit provisions in some statutes that may be invoked against patent rights under specific circumstances.

Authorizing the use of patented inventions by others:

28 U.S.C 1498 allows the government to use or authorize others to use any invention described in a US patent. Once such authorization is granted, patent owners will be able to sue the government but only for reasonable royalties. However, the patent owners cannot seek injunctions against private companies working for the government.

Preventing Abuse/Monopoly of Patent Rights – Forced Grant of Licenses:

Anti-Trust Laws: Based on anti-competitive practices by a patent owner, the Government can force him to license out his patents (analogous to a compulsory license).

The Bayh-Dole Act: According to the provisions of the Act, the government can obtain patents ("march-in right") related to inventions made using federal funding or granting licenses to relevant third-parties where health and safety requirements are not met for public use in accordance with the federal regulation.

Encouraging Innovation/R&D in the Pharma Sector:

Orphan Drug Act of 1983: This Act is invoked when a disease is declared as an 'orphan disease' or 'rare disease' when less than 200,000 persons are affected in the US. Under this Act, drug companies are provided with incentives to develop therapies and 'orphan drugs'. This Act enables seven years of market exclusivity and financial incentives for inventors of drugs for orphan diseases. These drugs are also extravagantly priced.

Bad and Good Actors

With the aforesaid provisions in place, it is interesting to note how major drug companies who own patented drugs and medical devices either misappropriate the laws or adopt a philanthropic approach when dealing with the current COVID-19 situation.

A patent troll **Labrador Diagnostics LLC** recently used a portfolio of old patents to sue a company that was manufacturing and distributing COVID-19 tests. It then succumbed to providing royalty-free licenses to allow third parties to develop COVID-19 tests (28 U.S.C 1498).

In another case, upon declaring the COVID-19 as an orphan disease, the FDA granted **Gilead Sciences** orphan drug status for its antiviral drug, Remdesivir, for the treatment of COVID-19 which had over 800,000 cases at the time (evidently it was not an orphan disease). The orphan drug status for Remdesivir was indeed an impediment to other generic drug manufacturers to market the drug to treat COVID-19 as it allowed the 7-year period of market exclusivity to Gilead. Gilead, however, submitted a request to FDA to revoke the orphan drug designation of Remdesivir, making it available to be marketed by other drug companies.

Several other companies such as **AbbVie** (a US-based Bio-pharma company) have suspended their patent rights on all formulations of the HIV medication, Kaletra (Aluvia) to allow other generic drug manufacturers to research and come up with their versions of the drug to treat COVID-19.

In conclusion, an altruistic approach by companies holding patents on 'orphan drugs' is the only solution to combat the crisis that has arisen due to the COVID-19 outbreak. Compulsory Licensing or expropriation of patent rights is to be adopted as a mandatory regulatory measure in the event of unavailability of medical equipment and pharmaceuticals that are crucial during pandemic/epidemic situations such as the COVID-19. Also, Patent Pools and Pledges such as the Open COVID Pledge ensure that royalty-free and non-exclusive licenses are available to drug manufacturers for patented drugs/processes that can be potentially employed to combat COVID-19 infections.

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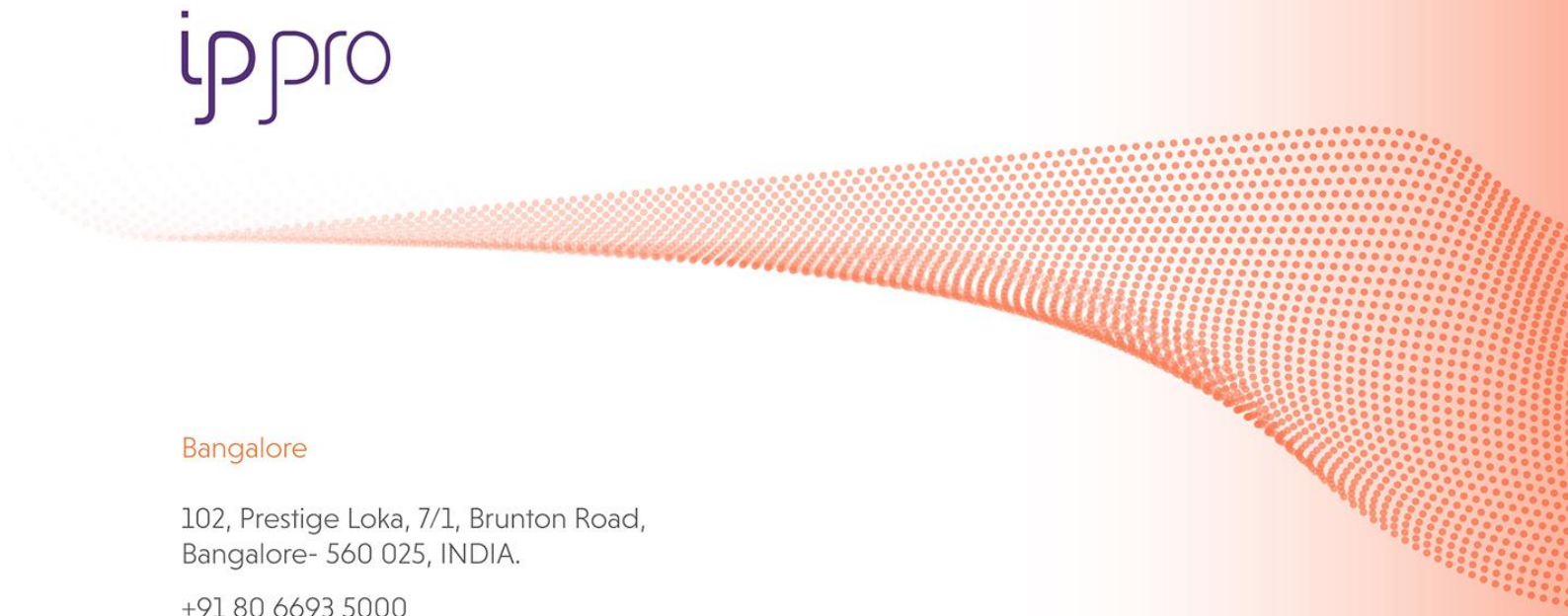

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