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Covid 19 pandemic, patents and licensing models: The need for a balanced approach

Industry

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While the entire world is awaiting results of the trial involving the drug Remdesivir to treat patients affected by the Covid 19 pandemic, serious concerns have been raised in countries like India where the drug has been patented. Gilead Incorporated's patented invention titled "Compounds for treating Filoviridae virus infections" relates generally to methods and compounds for treating Filoviridae virus infections and particularly to methods and nucleosides for treating Ebola virus, Marburg virus and Cueva virus.

Gilead filed its patent application with the Indian patent office in April 2017 and the patent had been granted in February 2020. Thus, Gilead now has the exclusive right to prevent third parties from the act of making, using, selling or importing that product in India under section 48 of the Indian Patents Act 1970 (IPA). However there is no need to panic at this stage as IPA contains robust safeguards to deal with such situations and one of the most efficient legal remedy is the provisions relating to compulsory licensing of patented inventions.

IPA contains elaborate provisions on compulsory licenses and the existing provisions were included by way of the 2002 Amendment to IPA. The 2002 Amendment provides three grounds for seeking a compulsory patent license. The law in general provides very liberal grounds for seeking a compulsory patent license and it also covers the case of non-working of patented inventions. Such a license can be sought only after the expiry of three years from the sealing of the concerned patent. Secondly, there is another provision for grant of compulsory licenses on notification of the Indian government in circumstances of national emergency or extreme urgency like the breakout of epidemics. Thirdly there is a provision for compulsory licenses in the case of certain patents which are so essential for the efficient working of some other patented inventions.

Interestingly before the 2002 Amendment, the IPA contained a right known as Licences of Right. Under this concept, process patents pertaining to medicines, food etc were automatically deemed to be endorsed with the words “licences of right” which would make them available for compulsory licensing by all applicants after three years from the patent grant. The patent owner gives his consent to receive a pre-determined amount as remuneration to use of his invention and if the user pays the required amount, the patent owner has no right to prevent him from using the invention any longer.

Dealing with the specific provisions on compulsory licensing the IPA provides that any person can make an application for a grant of a compulsory license for a patent three years after grant of that patent. The grounds upon which such licence can be granted are given below:

a) Reasonable requirements of the public with regard to the patented invention have not been satisfied, or
b) That the patented invention is not available to the public at a reasonably affordable price, or
c) The patented invention is not worked in India’s territory

The Patent Controller shall consider a number of factors when evaluating a compulsory licensing application. The relevant factors to be considered include the nature of the invention, applicant’s ability to work the invention to benefit the public, applicant’s ability to assume the risk in raising capital and working the invention if the application were granted, and whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions. Thus it is very clear from the provisions of IPA that the compulsory license which is to be issued by the controller has to

safeguard the interest of license and the patent holder. This goes hand in hand with the ultimate objective behind grant of any patent which is to encourage creativity while granting a private right and protect the larger public interest by providing certain limited exceptions which will not unfairly prejudice the patent holder.

Apart from the abovementioned provision, in order to deal with any national emergency triggered by epidemics the IPA also provides for procedures where the compulsory license can be granted by the controller with regard to any existing patent in situations of national emergency or in circumstances of extreme urgency or in case of public non-commercial use. This provision will be very useful to tackle situations like the Covid-19 pandemic. Unlike the normal compulsory license which can be granted only after three years from the date of patent grant this kind of compulsory license which is issued to combat national health emergencies can be granted any time after the sealing of the patent.

After the pharmaceutical product patent regime became fully applicable to India in 2005 the country began to seriously consider the options available through compulsory licenses which can be issued on such patents. Thus, in March 2012 the Patent Controller for the first time issued a compulsory license in favour of an Indian generic drug manufacturer called Natco Pharma with respect to a pharmaceutical patent granted to Bayer sold under the brand name Nexavar (Sorafenib).

Foreign companies are also willing to work with many Indian companies to license their patented product on a voluntary basis. In 2014, Gilead (which holds the patent for Remdesivir) licensed its Hepatitis C drug Sovaldi (Sofosbuvir) to seven Indian pharmaceutical companies including Cipla. It is expected that this strategy of voluntary licensing will be followed by many MNCs in India and Indian companies may prefer this approach instead of legal confrontations with foreign counterparts. There are media reports that Gilead may soon announce voluntary licensing agreements with several Indian pharmaceutical companies to permit them to produce generic versions of Remdesivir. The news if confirmed would result in a mutually beneficial partnership and could shape the landscape of various voluntary licensing models in the field of pharmaceutical patents.

It is expected that in the coming days there will be a serious dialogue amongst all stakeholders on the manner in which the poor and needy can afford the drugs which are covered by product patents. Similarly, companies that own product patents may work with Indian generic companies to reach a viable licensing mechanism that satisfies both sides. If the Covid-19 pandemic can result in such outcomes that would be the real silver lining to this crisis.

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