Affordable access to Covid-19 drugs: Are voluntary patent licences here to stay?

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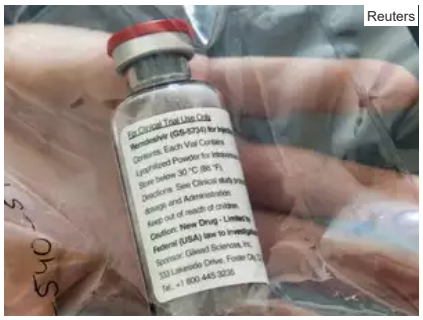

COVID-19 CASES	Confirmed	Deaths
India World	425,282	13,699

By Anusuya Nigam & Vrinda Pathak

In an official statement released yesterday, Gilead Sciences has announced signing voluntary patent licensing agreements with four Indian pharmaceutical companies, giving them rights to manufacture and sell the drug Remdesivir to 127 countries. Remdesivir is presently considered the most promising candidate for the treatment of COVID-19, and is the subject matter of three Indian patents granted in 2016, 2019 and early 2020 respectively. Through the licenses, the licensee companies will be provided transfer of technology and would be able to set their own prices for the drug. Possibly the most relevant term in the licenses from an access to medicine standpoint, is that the licenses will be royalty free till such time the pandemic is declared resolved, or till a vaccine is developed and approved. This breaking news is a silver lining in the otherwise dark cloud of the coronavirus pandemic for intellectual property enthusiasts and public health activists alike, since affordable access to Remdesivir has gained ample traction, with appeals to pharma companies to ensure #nopandemicprofiteering.

This article endeavours to assess from a legal standpoint, the various alternative approaches that have been available to Gilead and other potential stakeholders to ensure affordable access of Remdesivir, and the motivation towards adopting voluntary licensing models.

Broadly, the alternative courses of action include the knee jerk reaction of granting compulsory licenses for the Remdesivir patents. Compulsory licensing (CL) allows third parties to interfere with patentees' exclusive rights under certain conditions – by granting a third party a statutory license to manufacture and sell the patented subject matter by way of an order of the Controller of Patents. The law provides patentees time to work their inventions and make drugs available adequately, and therefore, mandates that no application for CL may be filed till three years of the grant. As the three year period has not yet expired for the Remdesivir patents in India, CL applications would have most likely failed on technical grounds alone.

From a diplomatic standpoint, if it were to grant CLs, India would face immense pressure

from international fora, where it is rightly considered the appropriate jurisdiction for mass scale manufacture of the drug to fulfil local and global requirements. Granting a CL and effectively rendering nugatory the patentee's rights in a scenario like the present would cause more harm than benefit to India's global image without promising any gains of access to the drug. The possible advantage of a CL is that pricing would be controlled by the Government; however, price control can also be achieved through other means as discussed later in this article.

The next are a series of alternative approaches involving the Central Government, which include a declaration by the Central Government that the Remdesivir patents are subject matter of a 'national emergency', or 'circumstances of extreme urgency' or 'public non - commercial use', as a result of which CLs ought to be granted at any time after the grant of the patent. This does away with the three year moratorium on a CL as discussed above. Following such a notification, persons interested may apply to the Controller for a CL, and CLs may be granted in favour of such persons or entities. Apart from this, the Central Government also has the power to revoke a patent that is being exercised in a manner mischievous to the state or generally prejudicial to the public. The effect of such a revocation is that Gilead would lose all rights over the patents, and the patents would be open to all and sundry to exploit as they wish. Another provision in the law also allows the Central Government or any person authorized by it to use the patented invention for the 'purposes of the government'. It would be considered prudent for the Government to take any of these steps only in extreme circumstances. Such an occasion has not arisen as even before the announcement of the licensing deals, Gilead had been in active negotiations with various entities since the first phase of COVID-19, thus showing positive steps towards making the drug available.

A third alternative strategic decision rests on the shoulders of Indian pharma companies who could choose to launch the drug 'at-risk', meaning thereby, that one or more Indian pharma company could take the decision to flout Gilead's rights in the patents in favour of accessibility and affordability of the drug for the public at large. In usual course, a long drawn and expensive litigation would follow, wherein Gilead would assert its patents, and the defences taken by the Defendant Indian companies would typically include that Gilead's patents are invalid and unpatentable, that Gilead did not take steps to make the drug available to the public, and that affordable access is paramount. For Courts deciding this issues, it would be necessary to strike a balance between patent rights and access to medicine at affordable pricing. Jurisprudence indicates that defences mounted purely on public interest have failed in the past, and Courts require a credible challenge to the validity of patents to be raised in order to allow third parties to manufacture and commercialize drugs in public interest.

The fourth, and arguably the most pragmatic strategic measure available to Gilead and the Indian pharma companies is a series of licensing deals, what may be known as voluntary licensing under the scheme of patent law in India. Such a voluntary license (VL) is akin to a contract, governed by the usual terms of contract law, apart from certain conditions imposed by patent law. Generally, VLs are increasingly the most suitable course of action in mature patent systems as far as patentees are concerned as they effectively do away with all the above adversarial steps, and ensure affordable access to medicine in the shortest possible time frame. As for the licensees, entering into VLs ensures manufacture and sale, and consequent access to medicine is virtually guaranteed. The third party in this bipartite agreement, that is the patient body and the public at large, emerges victorious as it gains immediate affordable access. Thus, all stakeholders stand to gain.

However, voluntary licensing does not come without problems, of course, as it a contract

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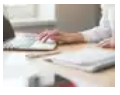
'Bug bounty' helps techies make a killing amid lockdown 

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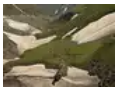
China needs rethink but India can't take forever 

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unsupervised by a third party. The most glaring problem is the fear of exploitation, and access and affordability being reduced to mere jargon with one or both parties to the agreement viewing profit over the altruistic goals of affordable access. The licensing regime can work successfully only if parties make honest and wholehearted attempts to make it work keeping in mind the vital nature of the drug and not mere self-interest.

The Remdesivir VL model, based on the information available, appears to have addressed the potential defects in the licensing system. In fact, the VL goes a step further. With the license being royalty free for the time being, Gilead has struck gold from a PR point of view. As a matter of fact, any approach where Gilead sought to assert rights on the patents would have caused irreparable damage to Gilead's reputation. The cost of research and development can be recouped once other drugs hit the market, or the severity of the disease is reduced, and royalty rates may be decided favourably for Gilead, once the most distressing times are past. Needless to say, Gilead is rightly being applauded for its efforts to ensure affordability of Remdesivir in the shortest possible time frame. A non-exclusive royalty free license goes a long way in ensuring that the drug remains affordable in the times to come. Price control will also be achieved since the licenses are non-exclusive, and each manufacturer will endeavour to provide the drug at the lowest possible price, with usual market forces in play.

As the VLs allow manufacture for export to more than half the globe, the first big step in ensuring access has also been taken. News reports suggest that the supply of the drug would be dangerously low – which is a problem easily met through outsourcing manufacture to India. With their capacity and resources for mass production and export, Indian pharma companies can meet the enormous global demand for the drug. Licenses to manufacture and export to 127 countries during a pandemic would put the Indian pharma industry on the map like never before, and retain its proud legacy of being the pharmacy of the world.

The VL route can prove to be successful if an agreement be reached between pharmaceutical companies – both foreign and Indian, to keep their profit guided motives aside. Instead, the focus has to necessarily be on affordable access to the drug, and all actions must be taken to support this end. Gilead, on its part, seems to playing its cards right, with providing the drug free of cost for local manufacture, in an altruistic move rarely witnessed before. It is now time for Indian pharma to keep its end of the bargain, and to take all steps necessary and expedient towards affordable access to Remdesivir. As the license allows the licensees to set their own price for the drug, Indian companies would need to ensure minimum or no profit margins and rapid manufacture and export. The Government must also play its part and provide all support necessary such as immediately granting manufacturing licenses, export approvals etc. Indian pharma could well lead the Prime Minister's call for a self-sufficient India, and take

In conclusion, the Remdesivir VLs are well placed for success owing to Gilead's public spirited and humanitarian actions - action which should become guidelines for all big pharma owning patents for other drugs that can help treat COVID-19, and may well lay the course for future licensing deals even once the pandemic has passed. Needless to say, if the license contains any inimical terms which are not yet revealed, there are ample measures in place, some of which have been discussed in this article, to ensure that affordable access will be guarantee, which would include the Government as an involved third party. A voluntary license would become a success against our new invisible enemy only if all stakeholders switch gears from "we can't afford to help" to "we can't afford not to".

(Anusuya Nigam is an Associate Partner at Singh & Singh Law Firm LLP. She has expertise in pharmaceutical patent litigation and represents major pharmaceutical companies in contentious patent matters across courts and tribunals. Vrinda Pathak is an Associate at Singh & Singh Law Firm LLP. She handles Intellectual Property litigation matters and has specific interest in pharmaceutical patent litigation.)

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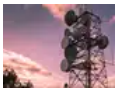

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