

Patent Exceptions In The Time Of A Pandemic

By Jean E. Akl

The blistering race and competition to find a COVID-19 vaccine is ongoing at a very fast pace. Pharmaceutical companies are scurrying to secure a legal monopoly for the treatment, to control the largest market share, and to ensure a considerable return on their investment, since the demand thereon would be immediate, global, and possibly extending for years and decades to come.

Whether it is Gilead's Remdesivir or any other treatment or vaccine that is ultimately found to have a proven curative or preventive outcome, researchers are ramping up their efforts, all while anticipating that a second wave of coronavirus is expected to swipe the globe again, as the Spanish flu did a century ago.

In this event, governments of the world would seek to buy substantial quantities of said vaccine/treatment to avoid the recurrence of the shortage of N95 respirators or to counter laws that prohibit, under any pretext, the exportation of treatment-related materials and agents, should the new global wave of the virulent disease materialize and be worse than the first wave.

A preventive treatment and/or vaccine for COVID-19 symptoms will undoubtedly be found, successfully tested and then marketed, but at what price?

Pharmaceutical companies will strive to build a strong patent portfolio, including both offensive and defensive positions, to secure as many patents as possible for the treatment, prevention, use and manufacture in order to be able to command a profitable market price or dictate licensing agreements.

The economic gap between higher-GDP countries and developing countries will widen in terms of the availability and acquisition of the patented remedies, placing the latter in an unfavorable position for acquiring and dispensing these medications.

As COVID-19 has been labeled a pandemic by the WHO and a *force majeure* event in many jurisdictions, governments will likely take proactive actions in adopting pre-emptive measures against the monopoly that may be imposed on access to the potential treatments or vaccines, in the interest of public health.

Patent laws generally include provisions for a legal measure known as compulsory licensing (CL), pursuant to which a government can suspend the marketing exclusivity of a patent if a national dire need or neces-

sity thereto justifies such a suspension. Accordingly, a country can allow the import, manufacture and sale of a generic copy of the patented invention in order to meet the national need and demand. It is a *casus belli* needed to fight the deadly pandemic. For example, Chile has clearly stated that the pandemic justifies the implementation and approval of compulsory licenses. Certain laws even specifically mention public health as a reason for the issuance of compulsory licenses.

Back in 2001, the Doha Declaration on the TRIPS agreement and Public Health¹ had mentioned that the TRIPS Agreement "does not and should not prevent Members from taking measures to protect public health." Said declaration was a positive response to the WHO's concerns about the necessity that WTO member states make full use of the safeguard provisions of the TRIPS Agreement in order to protect public health and enhance access to medicines for poor countries.

However, the issuance of compulsory licenses requires an administrative procedure and sometimes a Cabinet decision requiring at least the health ministers of the relevant countries to approve the issuance of the licenses. Some countries have actually proceeded with alleviating the procedures needed for the issuance of compulsory licenses, even before the filing of COVID-19 related patents for the vaccine/treatment, in anticipation of a possible crisis. Germany and Canada have already amended their patent laws to allow a swift grant of compulsory licenses under specific circumstances or conditions. For example, Germany has passed the "Act for protecting the Population in the Event of an Epidemic Situation of National Importance."² According to said text, the government can issue "Use orders" according to the German patent law,

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1. Ministerial Declaration at the WTO Ministerial Conference in Doha. https://www.who.int/medicines/areas/policy/doha_declaration/en/ (30 June 2020).

2. Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen passed on 27 March 2020 (30 June 2020).

where the provisions stipulate that the patent does not have any effect insofar as the Federal Government orders that the invention be used in the interest of public welfare.

Similarly, Canada has passed the Bill C-13,^{3,4} known as the *COVID-19 Emergency Response Act*, which amended the Canada Patent Act and allowed the Commissioner of Patents, based on an application by the Minister of Health, to grant an authorization to the Government of Canada or another specified person to supply a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern. Other countries, like Ecuador, passed resolutions to enable their Health Ministers to issue compulsory licenses for all COVID-19 patents.

U.S. patent law, however, does not comprise provisions regarding compulsory licenses. Instead, legislation known as the Bayh-Dole Act allows what is known as “march-in” rights for patents related to research that is fully or partially funded by the federal government. According to such march-in rights, the government can, in special conditions, march in with a compulsory license in such situations where action is necessary to alleviate health or safety needs. The government has the ability to force the company with the inventions generated by public funding to license its rights to a third party to bring the patented invention to market “upon terms that are reasonable under the circumstances.”⁵

With evidence that a second wave of the COVID-19 pandemic is imminent, Arab countries will certainly follow the lead of compulsory licenses (where their laws allow it) and, if they have not already started, begin looking into ways and solutions to ensure that once a treatment or vaccine is available on the market, the likely high price thereof would not constitute an obstacle to providing these remedies to the general public. Compulsory licensing is one of these legal solutions. Considering that most countries have acceded to the Paris Convention and TRIPS agreements, they are legally bound to the protection of IP rights. There will be ample time for law amendments or for the issuance of ministerial decisions needed to secure compulsory licenses rather quickly, and in the simplest procedural

way. However, this does not come without a price. Multinational pharmaceutical companies may not welcome the proliferation of compulsory licenses on a global scale and may certainly be looking for solutions and options for offsetting the heavy investment of the task of bringing new and safe remedies to the market.

Worldwide patent filing and prosecution incurs elevated costs, let alone the complexity of examination. If, on top of that, a company filing for the patent of a COVID-19-related remedy is already aware that global compulsory licenses are waiting for its invention to come forth, this may be a deterrent to the pace of, and investment into, such remedies.

Governments should also consider offering incentives to large multinational pharmaceutical companies that suspend the enforcement of their patents during a pandemic, or those whose patent is subject to a compulsory license. Incentives may take the form of patent extensions, annuity exemptions, or even tax exemptions for pharmaceutical products in the relevant countries.

Additionally, some patent laws also allow the patent owner to have the compulsory license canceled, if the reason for the issuance thereof has been addressed. More importantly, the issuance of a compulsory license is not exclusive; this means that the patent owner would still operate as a non-exclusive distributor in providing the treatment or vaccine throughout the duration of the CL.

The protection that a patent grants to its owner can only be destabilized at the strictest and narrowest end of the spectrum, in order to allow for large investments in the field to reap the fruit of years of dedicated research and development. The enthusiastic push by activists lobbying to get compulsory licenses to any treatment found to be effective against COVID-19 must be well-controlled to ensure that the interests of the companies doing all the effort are protected as well. To ignore this fact and aim for a treatment that is free for all would be, simply and justly, an Alfarabius utopian fantasy. ■

Available at Social Science Research Network (SSRN): <https://ssrn.com/abstract=3658629>

3. <http://www.mondaq.com/canada/operational-impacts-and-strategy/919256/covid-19-impact-changes-to-the-canadian-compulsory-licensing-scheme> (30 June 2020).

4. <https://www.keionline.org/32837> (30 June 2020).

5. <https://www.jdsupra.com/legalnews/keep-an-eye-on-the-bayh-dole-act-in-61764/> (30 June 2020).