PATENT EXCEPTIONS DURING A PANDEMIC

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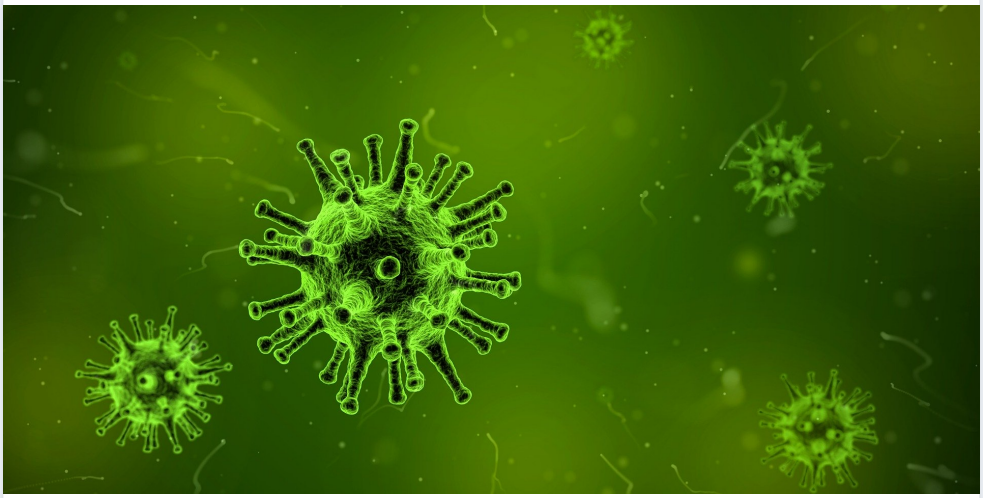

THE THORNY ISSUE OF COMPULSORY LICENSING

The blistering race and competition to find a Covid-19 vaccine is moving at a very fast pace. Pharmaceutical companies are scurrying to secure a legal monopoly for the treatment, to control the largest market share, and ensure a considerable return on their investment, since the

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demand thereof would be immediate, global, and possibly extend for years and decades to come.

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

Governments of the world would seek to buy substantial quantities of the 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 materialise 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 ones, to secure as many patents as possible for the treatment, prevention, use and manufacturing 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 unfavourable position for acquiring and dispensing these medications.

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

Patent laws in many countries 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 necessity thereto justifies such a suspension. Accordingly, a country can allow the import, manufacturing, and selling 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.

Chile has clearly stated that the pandemic justifies the implementation and approval of compulsory licences. Certain laws even specifically mention public health as a reason for the issuance of compulsory licences.

However, the issuance of such licences 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 licences. Some countries have actually proceeded with alleviating the procedures needed for the issuance of compulsory licences, 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 licences under specific circumstances or conditions.

In Ecuador, Congress issued a resolution requesting the President to include the mechanisms for establishing compulsory licenses and other related matters in their executive emergency decree, but we have not seen the Government undertake further action on this matter so far; and according to the reviewed information available to us, no results were found on Ministerial Agreements regarding the grant of compulsory patent licences, and/or the mechanisms thereto.

Arab countries will certainly follow their lead and, if not started already, will 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 licences 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 licences 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, the company filing for the patent of a Covid-19-related remedy is already aware that global compulsory licences are waiting for its invention to see the light, this may be a deterrent to the pace 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 licence. 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 licence cancelled, if the reason for the issuance thereof has been addressed. More importantly, the issuance of a compulsory licence 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 destabilised at the strictest and narrowest spectrum, in order to allow for large investments in the field to reap the

fruit of years of dedicated research and development. To ignore this fact and aim for a treatment that is free for all would be, simply and justly, an Alpharabius utopian fantasy.

NEXT STEPS:

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