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The Relevance of Compulsory Licensing in the Fight Against the COVID-19 Pandemic


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Background

The COVID-19 pandemic has sparked speculation in the media about the extent to which patents might be used to block the manufacture, sale or use of medical devices, diagnostic kits, therapeutic drugs and vaccines and whether governments can overcome such outcomes by means of compulsory licences.

In the short term (i.e., during the pandemic itself), it seems likely that companies that have or develop products protected by patents (be they medical devices, diagnostic kits, drugs or vaccines) will choose to make those products available at an affordable price (cost plus) if not for free. Insofar as companies are unable or unwilling to meet demand themselves they will likely not enforce their rights/license them royalty-free or at most charge an affordable royalty.

By way of evidence of this approach are two widely reported examples from earlier this year: Gilead's decision to withdraw its orphan drug designation in the US for remdesivir; and AbbVie's announcement that it would not seek to enforce its patent rights covering Kaletra (lopinavir-ritonavir combination).

During the current pandemic there has also been a heightened focus on collaboration between companies and/or research institutions. For example, some companies have taken the "Open COVID Pledge" by virtue of which they agree to offer simple, uniform and self-executing royalty-free licences to their IP (patent or otherwise) to anyone interested in tackling the pandemic. Most of the companies who have signed up to date however are in the IT, social media or AI fields as opposed to the pharmaceutical field. Further, in May 2020, WHO announced that it had set up a mechanism for a COVID-19 patent pool as a means of facilitating poorer countries with access to treatments for and vaccines against COVID-19. At present, however, the take up especially by the wealthier countries is low and the pharmaceutical industry has in general been dismissive of the notion, limiting its usefulness.

As stated above, it seems likely that any potential disputes between governments and companies over patent rights or patent protected products would be resolved in the short term (i.e., during the pandemic) through decisions by the right owning companies to sell their products or licence their rights on reasonable terms (for free or at most cost plus/affordable royalty rate). However, it is important to appreciate that in the background to any such negotiations most national patent laws provide mechanisms to enable national governments to grant compulsory licences, should they chose to do so. Therefore, even if compulsory licences are not relied upon, the mere existence of these provisions will at least in some cases encourage right-owners to agree to sell their products and/or licence their patent rights on reasonable terms.

What is Compulsory Licensing?

Compulsory licensing is a term that broadly covers two types of use. On the one hand, it covers use by the government or, more likely, by private companies for or on behalf of the government or state in particular in cases of national health emergencies such as an epidemic (what would be known in the UK and certain Commonwealth countries such as Australia as "Crown Use" and in civil countries such as Germany as "State Use Orders"). On the other hand, it covers use by private companies for themselves in circumstances where they can show an unmet public demand or that there is a dependent patent blocking their exploitation of a technology. In general, the latter type of compulsory licence is procedurally cumbersome to obtain and therefore unlikely to be relevant to meet short term needs in cases of national health emergencies.

The National Dimension

Whilst the national patent laws of most countries include compulsory licence provisions, the precise ambit of those provisions varies considerably from country to country. Furthermore, in the light of the COVID-19 pandemic, some countries have sought to strengthen their national compulsory licensing provisions.

As mentioned above, the UK had already enacted the type of compulsory licence provision that enables companies in effect to override patent rights in order to supply the state with a product e.g., a drug in cases of national health emergencies such as a pandemic. This seldom used Crown Use provision was in fact relied upon recently in a case concerning a mobile telephone system: *IPCom v Vodafone* [2020 EWHC 132 (Pat)]. Vodafone had allegedly infringed IPCom's patent, the invention of which was used as part of the framework of the Mobile Telecommunications Privileged Access Scheme ("MTPAS"), a system that provides privileged access for mobile phone networks to organisations involved in responding to an "Emergency", as defined in the Civil Contingencies Act 1994. The MPTAS system was activated by means of a request sent to a mobile phone network by or on behalf of the senior police office in charge of the emergency response. The Judge held that the Crown Use provision was wide enough to provide Vodafone with a defence to the claim to infringement. It is clear from the Judgment in that case that the Crown Use provision would be more than adequate to protect a company manufacturing or more likely supplying a patent protected drug, vaccine or product used in the fight against COVID-19.

Other European countries such as Germany and France have sought to strengthen their existing patent laws by introducing or enhancing such state use type provisions.

In France, Articles L. 613-16 and 613-17 of the Intellectual Property Code provide mechanisms whereby a non-exclusive licence can be obtained in cases of a health emergency subject in

each case to certain conditions being fulfilled and certain procedures being followed. The French government has recently enacted various other provisions designed to assist in the fight against the COVID-19 pandemic that could arguably be used to in effect permit the government to grant compulsory licences. These include Article L. 3131-15 of the Public Health Code that permits the Prime Minister to "*order the requisition of all goods and services necessary for the fight against sanitary disaster*" and "*where necessary take all measures to provide patients with appropriate medicines for the eradication of the health disaster*". Both of these provisions arguably permit the government to grant compulsory patent licences in the case of a health emergency.

In Germany, Sec. 13(1) of the German Patent Act ("GPA") authorises the Federal Government to order that a "*patent shall not have the effect insofar as (…) the invention be used in the interest of public welfare or in the interest of the security of the Federation*". Such an order is known as a Use Order. In April 2020, the German government sought to strengthen the legislative position by introducing Section 5(2) of the German Act on the Prevention and Control of Infectious Diseases in Humans ("IfSG"). Section 5(2) in effect modifies Section 13(1) of the GPA so as to authorise the Ministry of Health to make use orders within the context of an "*epidemic situation of national importance*". Use Orders based on Section 5(2) are limited to "*an invention relating to one of the products mentioned in no 4*", which in turn lists the following: medicinal products; narcotics; active ingredients; starting materials and auxiliary materials for these products; medical devices; laboratory diagnostics; aids; personal protective equipment and products for disinfection.

So far, there are no examples in Europe of compulsory licences having been granted in the context of the COVID-19 pandemic under any of these national provisions. Interestingly, earlier this year, the Israeli government granted a compulsory licence in respect of the importation of the drug Kaletra i.e., it permitted generic versions of the drug to be imported and sold in Israel. In fact, this turned out to be of no avail as Kaletra has been shown in at least the Recovery Trial (the UK's COVID-19 phase III trial) to have no benefit to patients with COVID-19 as a result of which its use in the trials has been abandoned.

The International Dimension

As a matter of international law, compulsory licensing laws, at least for WTO (World Trade Organization) Member States, are governed by Article 31 and 31*bis* of TRIPS (Other Use without Authorization of the Right Holder). Under Article 31, national laws authorising the grant of compulsory licences are permitted subject to certain conditions, including that efforts have been made to obtain a licence from the right holder, that such use is predominantly for the supply of the domestic market and that the right holder is compensated. An exception to the first of these conditions is a case of national emergency, although even then the right holder should be notified.

In response to the difficulties of certain lower income countries obtaining access to anti-virals to treat HIV in the 1990s, the "predominantly for the supply of the domestic market" condition of Article 31 was finally amended a few years ago by the addition of Article 31*bis* so as to permit compulsory licensing of drugs for export to countries lacking domestic manufacturing capabilities. So far, so good. However, the position of the various WTO Member States under Article 31bis is not straightforward. The problem for many high income countries is that firstly, they may lack domestic manufacturing capability, and secondly, they chose to opt out of the inbound aspects of the Article 31*bis* regime. For many higher income countries, it remains to be seen whether their national emergency licence laws will be of any use to them in practice. That said, it is notable that some higher income countries are seeking to increase their domestic manufacturing capacity especially for potential COVID-19 vaccines.

In What Circumstances in Practice is Compulsory Licensing Likely to be Relevant in the Fight Against COVID-19?

It is important to distinguish between drugs, kits and products that (1) already exist and are known to be of benefit in the fight against COVID-19 or are being investigated to see whether they can be repurposed to provide a benefit in the fight against COVID-19 and those that (2) are being developed in response to the pandemic.

Examples of products that are already known to be of benefit would include: ventilators; personal protective equipment (PPE); and other types of hospital equipment. Examples of products that are being repurposed would include remdesivir, hydroxychloroquine and dexamethasone – in some cases successfully, in other cases not: hydroxychloroquine has been now been abandoned from most clinical trials as showing no benefit to patients with COVID-19; dexamethasone has showed considerable clinical benefits in the early reports from the trials; and the jury is still out on remdesivir although it seems to have produced marginally improved recovery rates for hospitalised patients.

The main class of products that are being developed in response to the pandemic are vaccines.

There are two reasons for drawing this distinction. First, it is relatively straightforward for a third party to access (i.e., manufacture or supply) an existing pharmaceutical product such as a re-purposed drug (such as a small molecule or even an antibody), whereas it is much less straightforward for a third party to access (i.e., manufacture or supply) a newly developed vaccine. It is simply not possible to develop and manufacture a generic version of a biological product such as a vaccine in the same way that it is possible to manufacture a generic version of a known small molecule drug. Second, to a greater or lesser extent, the R&D needed to develop the potential vaccine candidates and the clinical trials needed to establish the efficacy of those candidates are being funded by the national governments of the wealthier countries. Those wealthier countries either individually like the UK and the US or collectively like the EU will either have preferential access to those vaccines by virtue of their own investments in the development of them or through mere spending power will be able to secure supplies of the other vaccines from the various companies who will be responsible for developing and/or manufacturing them. Furthermore, given the severity and infectiousness of the disease coupled with its devastating effect on the world economy, it is in the interests of those wealthier countries to ensure that not only their own citizens but also those of poorer countries are vaccinated against COVID-19. To this end, 172 countries (80 self-financing and 92 low and middle income countries) have now engaged in discussions to participate in COVAX, an initiative co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance and WHO. Its ultimate goal is to ensure that COVID-19 vaccines are available worldwide to both higher- and lower-income countries.

At the end of the day, therefore, it would seem that compulsory licensing is unlikely to be relevant in the fight against COVID-19, save possibly in the unlikely event that in the longer term access by poorer countries to therapeutic drugs (re-purposed or novel) shown to be useful in the treatment of COVID-19 is restricted through pricing in the same way that access to HIV drugs was restricted in the 1990s. At that point, Article 31bis and the national legislation implemented in the light of it may start to come into its own.

Neil Jenkins's practice is focused on patent and trade secret litigation. It also encompasses such associated matters as regulatory data exclusivity, and supplementary protection certificates.
Neil speaks regularly at IP conferences and contributes to the leading IP journals on many aspects of IP law and litigation as well as being the editor of *International Intellectual Property Litigation* (published by Butterworths).

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Georgina Straughan, as an associate in Bird & Bird's London IP Group, has experience across a broad range of intellectual property matters with a particular interest in the Life Sciences and Healthcare sector. To date, Georgina has acted for international pharmaceutical companies in multi-jurisdictional patent and trade mark disputes and has advised clients on EU-wide patent enforcement projects. Georgina has also undertaken a virtual secondment to a pharmaceutical company, providing legal advice on a variety of IP licensing matters.

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