**Enabling Access to Medical Technologies: Compulsory Licensing, TRIPS and FRAND**

On Wednesday 20 May 2020, in a BioWednesday Webinar hosted by One Nucleus, EIP’s Andrew Sharples[[1]](#footnote-2) and Monika Rai[[2]](#footnote-3) were joined by University of Leeds Professor Graham Dutfield[[3]](#footnote-4) to discuss access to medical technologies. This included examining compulsory licensing and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, as well as the principles of FRAND and how they might apply in the life sciences sector.

Setting the context, Monika considered how healthcare innovation is often high-risk and resource intensive. The COVID-19 pandemic continues to demonstrate the large-scale investment and effort required to develop novel vaccines, treatments and diagnostic methods. Patents can be crucial for incentivising investments in healthcare innovation and are necessary for creating a thriving innovation ecosystem. This is an important factor which must be taken into account when seeking to enable access to healthcare.

There are several mechanisms within the existing systems which can aid in achieving access to healthcare. Voluntary licensing regimes used in other fields of technology may be applicable to the life sciences and there is the possibility of utilising legislation and emergency provisions provided by national as well as international law. Such mechanisms were explored throughout the webinar.

The TRIPS Agreement and Compulsory Licencing

Professor Graham Dutfield focussed on the compulsory licensing mechanism and TRIPS. TRIPS is an international agreement between the 164 members of the World Trade Organisation (WTO) and attempts to mediate different perspectives on the place of IP in economic development and public policy. It does this in part by allowing governments some flexibility in how to balance long-term incentives for innovation with scope to respond to short-term barriers to access, especially, but not only, in the event of public health emergencies. There are ongoing differences as to whether the allowable scope is sufficient or not. One thing that is explicit is that countries are free to adopt their own policies with regard to parallel importation.

Professor Dutfield explored the history of the TRIPS Agreement and how it permits governments to issue “*compulsory licences*”, which allow a competitor to produce or make use of a patented product or method without the patent owner’s consent, but under certain conditions and subject to adherence to WTO law more generally. Initially TRIPS only allowed such compulsory licenses to be issued “*predominantly for the supply of the domestic market of the Member authorizing such use*”. This original provision led to growing concerns that many countries do not have the capabilities to manufacture pharmaceuticals locally. Thus, during a crisis such as when millions of people became infected with HIV/AIDS, these countries will face significant difficulties.

TRIPS’ embeddedness in trade law is very important to understand. First, not being a stand-alone agreement means there is a lot more at stake than, say, where there is some dispute as to what a provision in a WIPO treaty means; hence there are massive political sensitivities. And different views on the breadth of the above-mentioned ‘scope’ means there is much legal uncertainty. Second, being part of WTO law, there is a dispute settlement structure with real ‘teeth’. Given each country is formally equal, this is a ‘weapon’ any country can use (if not to equal effect). Of the 42 WTO disputes concerning TRIPS, 21 have involved the US, 17 the EU. But some developing countries have raised complaints. Thus, for example, a complaint by the United States against Brazil concerning local working requirements in its patent law was met with a counter-complaint by the latter that the US had similar measures in its own legal code. This led to a truce of sorts. And given that compulsory licensing has over the years been commonly used by the United States’ Federal Trade Commission, taking moral high grounds is a hazardous undertaking especially given the US was found by a WTO panel to have breached its TRIPS copyright obligations and has still not revised its national legislation 20 years later. That said, there is sometimes reluctance to complain, either due to lack of legal capacity, fear of political or diplomatic consequences, or because of the dangers of an adverse report making for an ‘own goal’ as it were. It is worth noting in passing that a few developing countries, most notably India, Thailand and Brazil, have granted compulsory licenses to manufacture medicines domestically, but the vast majority of developing countries have no experience of using the measure.

The 2001 Doha Declaration on the TRIPS Agreement and Public Health recognised the potential issues with compulsory licensing under TRIPS as mentioned above, and affirmed that the Agreement should be implemented in a manner to allow Members to protect public health, and to promote access to medicine for all. This led to the TRIPS Agreement being amended and Article 31 *bis* being introduced to allow for compulsory licenses to be issued by one country to meet the needs of another qualifying country, in the event of a public health emergency. However, despite this change in TRIPS, there is little evidence of countries incorporating such compulsory licensing mechanisms for export to third country importers successfully. In Professor Dutfield’s view, this is likely due to three factors. First, the rules are somewhat complex, and such as not to make it an especially attractive commercial opportunity for generic firms. Second, the extent of the legal and technical expertise needed to draft legislation on the part of importer nations may be a challenge. This is something that could be overcome though, through technical assistance. However, the third factor is that this agreement sits within the framework of international trade law under the auspices of the World Trade Organisation, and that a decision to proceed may have wider trade – and trade law – implications as well as diplomatic fallout that renders countries reluctant to proceed.

Any discussion on use of compulsory licensing, especially in developing countries, should be sensitive to these challenges rather than think only of the undeniable role of intellectual property in incentivising innovation. In the narrow case of an Article 31*bis* compulsory license, Professor Dutfield suggested there may be grounds to argue that generic firms should be incentivised in some way to participate. It should probably be easier for them to obtain some modest profit at the very least.

During the discussion that followed, the availability of the TRIPS mechanism to developed countries such as the United Kingdom was discussed. The Doha Declaration was crafted with the issue of access to medicines by low income countries at the forefront, and does not necessarily cater to the access needs of *all* countries in situations such as a pandemic. The current pandemic is highlighting that global organisations and supply chains may enable the vaccine or diagnostic needs of a country, such as the United Kingdom, to be manufactured in other countries. Access issues in more developed countries may be caused by a surge in demand over a short period of time, rather than the inability of a country to pay for the relevant patented medicine.

FRAND Licencing

Whilst TRIPS encourages harmonisation of IP protection internationally, with an intention to provide access to medicine for all, alternative mechanisms also exist. EIP’s Andrew Sharples explored how FRAND licencing, which is more commonly associated with the high-tech and telecommunications industries, may become a factor in relation to medical technology, including in relation to patent pools in the life sciences sector.

Fair, reasonable, and non-discriminatory (FRAND) terms denote the conditions of a licence that standard-setting organisations may request from an owner of a patent, the subject matter of which is, or may become, essential to a technical standard. These conditions apply not only to the royalty terms, but to the entire scope of the licence. The concept of FRAND can also apply to the conduct of the patent owner in negotiating the licence, and also to a prospective licensee looking to take a licence on FRAND terms, so as to prevent one side from taking advantage of the mechanism. The FRAND concept envisages a commercial return for the licensor, but it is ultimately left to the licensor and licensee to identify what is fair and reasonable. This inevitably leads to disagreements and court disputes, particularly when large sums of money are at stake.

In addition to being fair and reasonable under FRAND, the patent holder must also offer similar (not necessarily identical) licences to parties that are “similarly situated”, in order to satisfy the requirement that the licence is non-discriminatory. Unsurprisingly, disputes also arise over what “similarly situated” means in relation to any particular company.

Similar to the Doha Declaration, the intention underpinning the FRAND undertaking is to enable access to technology, whist providing a fair return for investing in development. Much of the discussion around licensing under FRAND focussed on the issue of hold-up. As companies invest in innovation, they patent their contributions to the standard; however, a holder of an essential patent could potentially refuse to issue licences or insist on unreasonable terms, preventing use if the technology as a whole. In reality, hold-ups of this nature have not been prevalent, and instead “hold-out” has been a more common complication, wherein third parties delay concluding licence terms and resist paying fees for as long as possible.

FRAND commitments have arisen in relation to technologies where technical standards are set, usually to enable interoperability, for example 5G, video processing and cryptography. In recent years, the advent of the “Internet of Things” means that owners of patents which are essential to telecoms standards such as 5G are no longer focussing solely on telecoms companies as potential licensees, but are instead considering a range of technologies which do, or will, incorporate mobile telecoms aspects. An early example of this is the drive to licence telematics units which are now incorporated in modern cars. Although instances of FRAND licencing have been sparse in the medical technology sector, the incorporation of telecoms technology into medical devices will see this increase. Patents deemed essential to the telecoms standard which are then utilised by medical devices will be subject to a requirement to be licenced on FRAND terms.

Patent Pools

When two or more companies separately own patents for subject matter that is required to practice a particular technology, they may agree to licence the related patents jointly, via a “patent pool”. Patent pools can provide a vital pathway to access by lowering transaction costs and streamlining licencing. Patent pools often offer licences on FRAND or FRAND-like terms due to competition law concerns. Competition authorities tend to take an interest in patent pools as they can have anticompetitive effects, arising from collusion between the participating companies. This can occur, for example, if two large patent holders in a field of technology discriminate against a competitor by pooling their patents to licence with excessive rates. To combat cartel-like behaviour, patent pools need to be able to demonstrate their pro-competitive effects, and the EU commission lists licencing on FRAND terms as one way that patent pools may demonstrate compliance with competition laws.

Patent pools have not been at the forefront of life sciences or medical technology innovation. The nature of medical technology means that situations in which a number of patent holders own patents relevant to a broadly applicable technology do not commonly arise. The UNITAID Medicines Patent Pool (MPP), perhaps the best known in its field, is not a patent pool in the conventional sense, but is instead a licencing programme. The licencing programme consists of various medicines, each of which is available to licence under its own separate licencing terms, but with those terms as a whole being directed at enabling access to medicines for particular lower-resource countries. According to UNITAID, as of December 2017, MPP sublicensees had reached people living with HIV, hepatitis C and tuberculosis in 130 countries. There are examples of commercial patent pools in the life sciences sectors, however. The MPEG LA Librassay pool focussed on molecular diagnostics and personalised medicines, with patents mostly contributed by US academics. Despite some licensees signing up, a changing patent landscape in the US (*see Mayo v. Prometheus, 566 U.S. 66, 2012*) rendered a large number of US patents in the field of molecular diagnostics as being potentially invalid. More recently, MPEG LA have launched an initiative to develop a CRIPR-Cas9 licencing platform, and The Broad Institute in collaboration with MilliporeSigma, have also launched their own CRISPR patent pool. Competition laws will undoubtedly mean that FRAND or FRAND-like considerations will be relevant to the terms on which those patent pools offer their technology to the market.

The COVID-19 Crisis

The current global COVID-19 pandemic is calling for novel vaccines, treatments and diagnostic methods. Whilst a number of companies have so far pledged not to assert their patent rights against third parties developing treatments to combat COVID-19, a significant proportion of such pledges are from companies in the high-tech or non-medical sectors. Though the patents of such companies may be relevant to diagnostic systems for COVID-19, this is not the primary purpose of the patented technology against which the pledge is made. In contrast, companies that are specifically investing in novel research are faced with a much greater risk, as well as a need to recuperate their investment directly from the resultant COVID-19 directed products.

Following a proposal by the Costa Rican government, the WHO has announced its plan to launch a voluntary COVID-19 patent pool on 29 May 2020, although this has seen potential resistance from the US, amongst others. As it is a voluntary scheme, even with potentially considerable political pressure, whatever is proposed will need to provide a commercial incentive for patent owners to participate. It will be interesting to see whether what is proposed is truly a patent pool, or instead a pooled licensing regime along the likes of that provided by the Medicines Patent Pool.

1. Andrew Sharples is a partner at EIP and is a UK and European Patent Attorney and Solicitor. Andrew has 20 years’ experience in prosecuting and advising on patents in the life sciences sector. [↑](#footnote-ref-2)
2. Monika Rai is a partner at EIP and is a UK and European Patent Attorney and Solicitor. Monika is a life sciences specialist and has advised a varied client base on patent prosecution and contentious matters in a range of technical areas. [↑](#footnote-ref-3)
3. Graham Dutfield is a Professor of International Governance at the School of Law, University of Leeds and is a leading scholar on life sciences IP rights. Indeed, Graham has been teaching IP law since 2003 and has written several books on the topic, including the recently published second edition of Dutfield and Suthersanen on Global Intellectual Property Law and a forthcoming book on the history of the pharmaceutical industry. [↑](#footnote-ref-4)