Bird & Bird & COVID-19

Hungary: Q&A on the use of patented products and processes without authorisation of patent holder National compulsory licence laws

Introduction

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. In practice, it seems extremely unlikely that patent holders will try to block the use of a patented product or process needed for the fight against COVID-19, motivated by a desire to contribute to the world's response to COVID-19 and avoid any negative PR.

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

Two widely reported examples are 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. Many companies have also taken the "Open COVID pledge"[1] by virtue of which they agree to offer royalty-free licences to their IP (patents or otherwise) to anyone interested in tackling the pandemic. At an international level, the WHO is also considering resolutions designed to set up mechanisms for patent pools.[2]

Any potential disputes over patent rights or patent protected products are therefore more than likely to be resolved in the short term through decisions to sell or licence for free (or at most cost plus). Nevertheless, it is useful to know the scope to which patent law enables national governments to grant compulsory licences, should they chose to do so. Indeed, the mere existence of these provisions will at least in some cases encourage right-owners to agree to sell and/or licence on reasonable terms.

Compulsory licensing is a term which 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 law countries such as Germany as State Use Orders). On the other hand, it covers use by private companies for themselves either to meet an unmet public health demand or for purely commercial reasons (e.g., a dependent patent). 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.

As a matter of international law, compulsory licensing laws, at least for WTO member states, is governed by Article 31 and 31bis of TRIPS (Other Use without Authorization of the Right Holder).[3] 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 those 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 back 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 31bis 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 first, because

[1] https://openCOVIDpledge.org/
[2] https://medicinespatentpool.org/mpp-media-post/the-medicines-patent-pool-and-unitaid-respond-to-access-efforts-for-COVID-19-treatments-and-technologies/
[3] https://www.wto.org/english/docs_e/legal_e/31bis_trips_04c_e.htm

the manufacture of most drugs these days has been outsourced to China and India, they now lack domestic manufacturing capability and second, they chose to opt out of the inbound aspects of the Article 31bis regime[4]. For many higher income countries, it remains to be seen whether their national compulsory licence laws will be of any use in practice. That said, it is notable that some higher income countries are seeking to increase their domestic manufacturing capacity especially of potential COVID-19 vaccines.

For most countries, therefore, whilst their national patent law includes compulsory licensing 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.

In the longer term, the position with regard to patent rights will likely become less straightforward. Some of the rights that are acquired during the pandemic may have value beyond COVID-19. It should also be borne in mind that commercial licences, as well as any compulsory licences granted in the public interest during the pandemic itself, are likely to be limited e.g., to demand, to the duration of the pandemic, or to another set period of time. Therefore, as the pandemic hopefully starts to abate, companies should start considering whether any renegotiation of COVID-19-related licences will be required.

This overview is intended to summarise the established and recently introduced national compulsory licensing laws in order to assist our clients in understanding the position. This document does not constitute legal advice and if you require more information, please feel free to reach out to the country contacts in this document.

[4] See: https://medicineslawandpolicy.org/2020/04/never-say-never-why-the-high-income-countries-that-opted-out-from-the-art-31bis-wto-trips-system-must-urgently-reconsider-their-decision-in-the-face-of-the-COVID-19-pandemic/

Hungary

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

No. In the context of health emergencies, the Hungarian Patent Act contained provisions for compulsory licensing relating only to the manufacture of pharmaceuticals for export to countries with public health problems. However, see below for details of a new governmental decree resulting from the COVID-19 pandemic.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

Yes, a governmental decree - Governmental Decree 212/2020 - was published in the Hungarian Official Journal which contains provisions on health emergency related compulsory licensing. This decree entered into force on 17 May 2020.

Further, recently enacted non-patent laws can provide for the possibility of the State introducing compulsory licensing provisions or requesting patent holders to provide licenses due to COVID-19. These laws are in particular, but not limited to the followings:

- Government Decree No. 40/2020 on declaration of state of emergency;
- Act XII of 2020 on Protection against Coronavirus;
- Act CXXVIII of 2011 on Disaster Management.

a Describe in general terms the scope of the new law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

The key provisions of Governmental Decree 212/2020 (Hungarian language version here) are as follows:

1. A compulsory license is issued by the HIPO based on the communication of the Hungarian pharma regulator (OGYÉI) in relation to domestic needs to tackle health emergency situation.
2. The subject of a compulsory license can be any of the followings:
    a. use of *medicinal product* or *active ingredient* being subject to a patent or a Supplementary Protection Certificate (SPC), or *medical device* or *investigational medicinal product* subject to a patent (referred jointly as "*health product*"); or
    b. use of *process, equipment or device necessary for manufacturing of health product*.
3. The scope of a compulsory license is limited to supply domestic needs mentioned in point 1. above.
4. The license is not exclusive and the licensor cannot issue a sub-license [note: the decree is silent on transfer of a license].
5. The period of the compulsory license is defined by the HIPO based on the information of the OGYÉI according to the needs to tackle the health emergency, but the final date of a compulsory license shall be 31 March 2021.
6. The licensor is entitled to *"appropriate" remuneration* for the compulsory license. The amount of such remuneration shall reflect the economic value of the compulsory license, in particular it shall be proportionate with a license fee which would have to paid under a normal license agreement. The remuneration is determined by the HIPO.

7. A compulsory license terminates once
    a. the licensee waives it;
    b. it expires; or
    c. the subject matter patent or SPC expires.

8. A compulsory license does not terminate if the licensee obtains a new compulsory license before the expiry of an earlier compulsory license.

9. If there is a pending litigation matter based on the relevant patent or SPC then this shall be stayed until the HIPO's decision on the compulsory license. The same applies for a pending preliminary injunction.

10. Decisions on a compulsory license shall be entered into the HIPO's patent/SPC registers and should be published in the Official Gazette of the HIPO.

11. The HIPO's decision on a request for a compulsory license is appealable according to the general rules of the Patent Act but a granted compulsory license is immediately applicable/enforceable regardless of an appeal. Practically the same applies to OGYÉI's decisions in relation compulsory licenses.

Additionally, Art 2(1) of Act XII of 2020 on Protection against Coronavirus authorizes the State to suspend the application of laws or to deviate from provisions by taking emergency measures.

This Act allows the government to limit the fundamental rights beyond what is allowed by the necessity test of the Fundamental Law of Hungary: the government may adopt laws and regulations only which are proportionate and necessary to prevent, manage and eliminate the COVID-19 pandemic and prevent or fend off its harmful effects.

Act CXXVIII of 2011 on Disaster Management regulates emergency measures in case of disasters such as COVID-19.

Art 47(4) of this Act provides the possibility of imposing obligations to conclude contracts to ensure production, supply and service obligations. Further the provisions on emergency measures can now be expanded by government decrees on the basis of the above mentioned authorization or the government may take emergency measures directly.

b Has this new law been used in the present COVID-19 pandemic?

We are not aware of any expropriation of patents based on these provisions.

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Art 31-33/A of the Hungarian Patent Act provides for a compulsory license in the following cases:

1 failure to commence exploitation;

2 dependency of patents;

3 to address public health problems (under the conditions set out in Regulation (EC) No. 816/2006).

We consider that case 1) and 2) are unlikely to be of relevance, but in theory it may be referred to under certain circumstances in the context of a pandemic such as COVID-19.

We consider that case 3) may only be relevant in the context of COVID-19, in case the State prohibits the exporting of certain pharmaceutical products or active substances by decree; as such a license is generally listed as an exemption. As this is the case for the prohibition of exporting hydroxychloroquine sulphate and pharmaceutical products containing that substance from Hungary.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the

treatment of patients infected by COVID-19.

In case of "failure to commence exploitation" pursuant to Art 31 the Metropolitan Court shall decide on the grant of a compulsory license if:

- the holder of the patent did not exploit the invention, made any effective and genuine arrangements therefor, or did not license the exploitation to others
- within Hungary
- in the interest of satisfying domestic demand
- during the four (4) years from the application date or - if this period is longer - during the three (3) years from the grant of the patent.

In case of "dependency of patents" as per Article 32 of the Hungarian Patent Act the Metropolitan Court may grant a compulsory licence to the holder of a pending patent for the exploitation of the impeding patent if:

- the patented invention cannot be exploited without infringing the impeding patent, and
- the invention of the dependent patent constitutes significant technical progress of considerable economic interest compared with the invention claimed in the impeding patent.

In both cases the applicant must demonstrate that:

- the conditions for granting such license exist
- the holder of the patent was not willing to grant a license voluntarily within a reasonable time in spite of the fact all requirements are satisfied
- he has the ability to exploit the invention to the extent required.

In both cases, a compulsory license is a non-exclusive license and may be granted predominantly for serving domestic demand.

The patent holder is entitled to appropriate remuneration for granting such license. Failing an agreement, this fee is set by the court. Similarly the extent, scope and time limit of such license is established by the court.

The holder of a compulsory license cannot grant a further license for exploitation, also there is a prohibition on assignment or transfer.

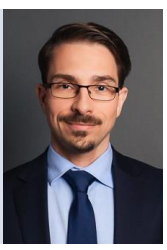
Compulsory licenses must be registered in the patent register.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

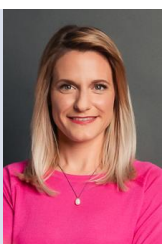
Balint Halasz
Partner, IP

Tel: +36 1 301 8900
Balint.halasz@twobirds.com



Bettina Kovecses
Associate, IP

Tel: +36 1 301 8900
Bettina.kovecses@twobirds.com



About us

Through a combination of our strong experience in the life sciences sector and our legal expertise, our mission is to develop both short and long term commercial solutions that will assist you in taking your idea from inception to market place and beyond.

Bird & Bird is a global law firm. Altogether, we have over 1,100 lawyers and legal practitioners working on our clients' issues and business goals worldwide. Our core objective is to select and develop people who possess a rare and invaluable grasp of strategic commercial issues.

By combining this talent with exceptional legal expertise and deep industry knowledge, our advice is always informed, up to date, focused and relevant.

With over 240 experts globally and a wealth of hands-on experience from working inside life sciences companies and regulatory bodies, clients choose us as their strategic partner to guide them through some of their most complex legal challenges.

Our recommendations are practical, realistic and clear.

For more information or useful materials and contacts visit us here at our website or at our specialist news hub page, BioTalk.

twobirds.com

Abu Dhabi & Amsterdam & Beijing & Berlin & Bratislava & Brussels & Budapest & Copenhagen & Dubai & Dusseldorf & Frankfurt & The Hague & Hamburg & Helsinki & Hong Kong & London & Luxembourg & Lyon & Madrid & Milan & Munich & Paris & Prague & Rome & San Francisco & Shanghai & Singapore & Stockholm & Sydney & Warsaw