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### Pledging Intellectual Property for COVID-19

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## Pledging intellectual property for COVID-19

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***Voluntary pledges to make intellectual property broadly available to address urgent public health crises can overcome administrative and legal hurdles faced by more elaborate legal arrangements such as patent pools and achieve greater acceptance than governmental compulsory licensing.***

Intellectual property rights (IPR) — patents, copyrights and similar forms of legal protection — relate to virtually every aspect of the COVID-19 response, from vaccines, diagnostics and therapeutics to medical equipment, tracking systems, software apps and other innovations<sup>1,2</sup>. Traditionally, IPR offers the developers of new technologies the exclusive right to exploit their innovations while recouping R&D and other expenditures. But IPR also gives its owners the ability to stop others from conducting research as well as manufacturing and distributing products.

During the current COVID-19 coronavirus pandemic, we and others have observed instances in which IPR restrictions, and even fear and uncertainty around IPR, have hindered effective research on vaccines and therapies as well as the development, manufacturing and distribution of ventilators, testing kits, protective equipment and other medical supplies (referred to as “crisis critical products”<sup>1</sup>).

COVID-19 differs from other recent public health crises — cancer, HIV/AIDS, Ebola, malaria, malnutrition — with respect to its sudden onset, its rapid spread, the lack of any

known vaccine or cure and resulting shortages of critical medical equipment. The convergence of these factors has prompted both governments and IPR holders around the world to seek ways to increase the availability of IPR necessary to combat the pandemic. Governmental compulsory licensing, IPR pools and voluntary IPR pledges have all been used in the past, though in situations that differ in important respects from the COVID-19 pandemic. Each is designed to result, to a greater or lesser degree, in a publicly-accessible “commons” of rights and technologies that are broadly available for use to support an important public health goal<sup>3</sup>. Here, we compare and contrast these differing approaches to IPR commons formation and assess their suitability to address the COVID-19 crisis.

### **Voluntary pledges**

A growing number of organizations have publicly committed to make their IPR freely available in the fight against COVID-19. These IPR “pledges” take various forms and have different labels, but share a common lineage that extends back to commitments made for decades by technology firms to support the use of interoperability standards, open software and emerging technology platforms<sup>4,5</sup>. As such, these pledges and the licenses that are associated with them are irrevocable once granted and legally enforceable under precedents that have been recognized in jurisdictions around the world<sup>4</sup>.

As seen in **Table 1**, there are several varieties of IPR pledges<sup>4,6,7</sup>. Some cover different types of IPR (patents, copyrights, designs, etc.) and can impose different restrictions and limitations (e.g., duration, field of use). IPR pledges can be made unilaterally by a single organization (e.g., Medtronic, AbbVie) or through coordinated efforts of organizations that commit to the same basic terms (e.g., Wellcome Trust Publishers’ Pledge, Open COVID Pledge). Some, like the Open COVID Pledge, which was developed by a coalition of scientists, engineers and legal experts (including the authors), are self-executing, inasmuch as any interested organization is automatically granted the right to use the licensed IPR without further paperwork. Others, like the Harvard-MIT-Stanford (HMS) pledge, provide a framework but still require organizations that wish to use pledged IPR to negotiate a separate license agreement with the IPR holder.

Some unilateral pledges, such as the one made by equipment manufacturer Medtronic, cover not only formal IPR, but also data files and designs for equipment and parts, which are often essential when manufacturing such devices. This pledge, like that made by pharmaceutical manufacturer AbbVie, is limited to a particular product (a ventilator in the case of Medtronic, a drug in the case of AbbVie). While these pledges are narrower than open-ended pledges covering all of an organization's IPR, their specificity makes their application to particular technologies clear, which enables usability. It may be more difficult for potential users to determine how they can use IPR that is licensed on a broad but nonspecific basis<sup>8</sup>. The Medtronic pledge also adopts a 'share alike' feature, borrowed from the well-known GNU General Public License (GPL) and certain Creative Commons licenses, which require that the user of pledged IPR make its modifications and improvements openly available on the same terms as the pledged IPR. Such provisions are intended to prevent the users of freely licensed IPR from making proprietary improvements to that IPR to gain a competitive advantage over the pledgor. Protective measures like these could be particularly important when competitors are required to cooperate to supply crisis-critical products.

Like the Wellcome Trust Publishers' Pledge for copyrighted material, the Open COVID Pledge was not developed by a particular IPR owner, but as a neutral mechanism for adoption by an unlimited number of IPR owners. Organizations adopting the Open COVID Pledge can utilize a template license that was developed by the coalition or customize one of their own. These customizations can more specifically detail the IPR pledged, the duration of the license, and specific limitations that may be required by law or prior agreements that bind the IPR owner. Since its launch, the Open COVID Pledge has been adopted by organizations large and small, holding in excess of 250,000 patents worldwide. The similar Japan-based Open COVID-19 Declaration boasts 96 signatories that have pledged close to one million patents. Industry sectors most heavily represented by these pledges include computing, telecommunications, social media, software, equipment, automotive and chemicals.

## **Pledging and pricing**

Despite their variations, all of the IPR pledges described above share a key feature: they enable users, typically anywhere in the world, to use the pledged IPR without the threat of litigation, and to do so for free for at least some period. Though royalty-free pledges do not generate immediate monetary compensation for IPR holders, they are not economically irrational. While the IPR owner necessarily foregoes direct revenue associated with the use of its IPR, it only does so for a limited period (the duration of the pandemic and one year thereafter) and has the ability to negotiate fee-bearing licenses after that period and in fields other than COVID-19.

Previous scholarship has identified a range of motivations that lead IPR holders to make their IPR available for broad use without compensation, including accelerating diffusion of an emerging technology, seeking favor with governmental agencies and courts, enhancing public relations and acting in accordance with corporate social responsibility and philanthropic goals<sup>4,7,9</sup>. IPR pledges that have been made in connection with the COVID-19 pandemic likely fall into several of these categories.

Some IPR owners might be concerned that users of their pledged IPR will charge excessive prices for resulting products, which is not in the spirit of either their pledge or societal expectations in the current pandemic crisis. In order to prevent this behavior, some of the above-mentioned pledges, such as the HMS university pledge and Oxford University's pledge, require that users charge "fair" or no more than "cost-plus" prices for resulting products. The Open COVID Pledge, on the other hand, does not contain such user pricing clauses, as the designers were concerned that such a constraint could deter some producers from using the pledged IPR in a setting where the widespread distribution of needed products and services is paramount.

## **Pledges versus pools**

In addition to the IPR pledges discussed above, proposals have been made, both at the United Nations World Health Organization (WHO) and within the European Union, for the assembly of IPR relating to COVID-19 in one or more formal IPR pools. Whereas a coordinated

pledge is a joint initiative of multiple organizations to share their IPR on similar terms, an IPR pool is typically a private arrangement among IPR owners to operate under one another's IPR, to manage and administer it through a centralized mechanism, and often to license it to third parties, with proceeds allocated among the pool participants according to an agreed formula. IPR pools have been formed for nearly a century in industries ranging from aviation and semiconductors to copyrighted music and performances. One of the major advantages of pools is the consolidation of complementary IPR rights into a single source, overcoming problems of fragmentation and "thickets" that can arise with respect to diversely held IPR<sup>3</sup>.

IPR pools were actively considered in response to the SARS outbreak of 2002–03, the H5N1 influenza outbreak of 2005, and the H1N1 influenza pandemic of 2009<sup>10,11</sup>. Yet despite a perceived need for aggregation of distributed IPR rights, pools, which generally require complex and coordinated negotiations among IPR owners, were never formed in these cases for a variety of practical, financial and competitive reasons<sup>10,11</sup>.

In the case of COVID-19, the precise contours of proposed pooling efforts have not yet been announced. One potential model is the WHO's Medicines Patent Pool (MPP). MPP is not technically an IPR pool. Rather, it serves as an intermediary or clearinghouse to which organizations can license IPR relating to HIV, tuberculosis and hepatitis C. MPP then negotiates outbound sublicenses (sometimes royalty-bearing) with generic drug manufacturers serving low-income countries. To date, several significant IPR holders including AbbVie, Bristol-Myers Squibb, Gilead Sciences and Pfizer have granted royalty-free licenses to MPP, which has in turn granted 22 sublicenses to generic product manufacturers (<http://medicinespatentpool.org>).

While the goals of such government-sponsored arrangements are consistent with those of the IPR pledges, they generally require greater time, financial backing and political willpower to implement than the lightweight and self-executing mechanisms inherent to pledges. And in a time of pandemic, when every day counts, the voluntary pledging approaches discussed here can serve as useful complements to more formalized government-driven arrangements. This being said, passive pledges that lack ongoing stewardship and active efforts to match users with pledged IPR have been shown in the past to underperform<sup>8</sup>. Thus, programs such as the Open COVID Pledge, which is administered and hosted by Creative Commons, have sought to

implement outreach strategies both with respect to IPR holders and potential users of pledged IPR.

### **Pledges versus compulsory licensing**

In addition to the voluntary mechanisms described above, some governments have threatened or taken action to authorize the use of privately held IPR without the consent of the owners. Such compulsory licensing approaches are well known mechanisms with established legal frameworks under national law and international treaty. In the current crisis they have already been enacted in Canada, Israel, Germany, Chile and Ecuador, with active discussions elsewhere<sup>12</sup>. While such measures can address health needs within the countries enacting them, they have limited effectiveness on a global scale, particularly if major countries like the United States and China decline to follow suit. However, this is exactly the scale on which IPR access is needed during the current COVID-19 crisis.

Moreover, compulsory measures are typically opposed by IPR owners, decreasing the likelihood of meaningful cooperation or knowledge transfer among IPR owners and users. And as shown elsewhere, such cooperation above and beyond passive licenses of IPR may be important to the effective deployment of complex technologies for crisis-critical products<sup>8,13</sup>. Indeed, the threat of compulsory licensing and other governmental action has seemingly encouraged some companies to make broader, global pledges. One example of this effect may be AbbVie, which announced the public availability of IPR covering its patented HIV drug Kaletra shortly after the Israeli government authorized generic manufacture of the drug.<sup>14</sup>

### **Pledges versus the public domain**

IPR pledges occupy a legal middle ground between the full exclusivity afforded by the law and an outright contribution to the public domain. Like open source code software licenses, IPR pledges coupled with license agreements enable the IPR owner to retain some degree of control over the IPR in question. Most importantly, many of the pledges described above last for limited periods of time (i.e., during the pandemic and for a short period thereafter) and apply only to limited fields of use (i.e., addressing COVID-19). This limited scope

is important, as many medical and other technologies used to combat COVID-19 have other applications, and it is unlikely that for-profit firms would be willing to relinquish all markets for their products as a condition to contributing to the fight against COVID-19. Moreover, if a user develops a useful product based on pledged IPR, then it will have an incentive to seek a commercial license from the IPR owner if it wishes to continue to market that product after the pandemic. In addition, some pledges, such as the Open COVID Pledge, allow for “defensive suspension” of the licenses granted. That is, if a pledgor is sued for patent infringement, it may suspend any licenses that it previously granted to the aggressor. Thus, while the contribution of IPR to the public domain achieves many of the same access goals as IPR pledges, it can be a less attractive option for commercial entities.

## **Conclusions**

While IPR aims to reward innovators for technological developments, it can also become a barrier to rapid and efficient collective action in the face of an urgent public health emergency. While more draconian measures have been suggested to eliminate IPR barriers to research and manufacturing of products essential to the fight against COVID-19 (e.g., compulsory licensing), a less onerous path involves voluntary pledges made by IPR holders. Such pledges — temporary in duration and narrow in scope — can enable critical public health research and manufacturing of crisis-critical products, while at the same time preserving for their owners the prospect of financial rewards and influence over markets after the pandemic ends. By the same token, such pledges are lightweight and efficient, avoiding the administrative, legal and political delays that have hindered prior pooling proposals in response to public health emergencies.

Nevertheless, the lightweight, self-executing and sometimes broad nature of pledges could challenge users seeking to find specific pledged IP without ongoing stewardship and active assessment of the rights being made available. Although the full economic and health implications of ongoing IPR pledges may take time to be appreciated fully, we recommend that, with respect to the COVID-19 pandemic, governments encourage, and possibly incentivize, the voluntary pledging mechanisms described here.

This being said, the profile of organizations that have made IPR pledges in the current pandemic has been uneven. While there has been significant representation by the technology and equipment sectors, comparatively little voluntary action has been taken to date with respect to IPR covering vaccines or therapeutics (with a few exceptions such as AbbVie's unilateral pledge of Kaletra and pledges by some Japanese chemical firms with pharmaceutical divisions). Simple economic forces may be at work here, as firms that anticipate a direct and significant windfall from the sale of COVID-19 products may be less inclined to commit their IPR to the public cause, or to make it available to their competitors. In these cases, governmental compulsory licensing may be the only realistic mechanism for making IPR broadly available. Moreover, if society wishes to incentivize the discovery of new treatments for COVID-19 (as opposed to the repurposing of existing ones), it is not clear that compulsory licensing will result in the greatest level of private innovation. Thus, for some sectors of the economy, biopharma in particular, neither pledges nor compulsory licensing may achieve optimal results.

Nevertheless, as we have seen, countless technologies from outside the biopharma sector are critical to addressing the COVID-19 pandemic — emergency response, medical equipment, diagnostic kits, protective gear, software modeling, social distancing and many more. To the extent that these technologies can be made broadly available and accessible through voluntary IPR pledges, we believe that the effort to combat the pandemic and to mitigate its effects will be helped immeasurably.

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### **Competing Financial Interests**

Creative Commons is the organizational steward of the Open COVID Pledge. DMP is an employee and General Counsel of Creative Commons. The authors have no other competing financial interests to disclose.

**Table 1 Selected IPR pledges in response to COVID-19\***

IPR holder	Pledge date	IPR pledged	Separate license required?	User restrictions/obligations
<b>Unilateral pledges</b>				
AbbVie	9 March 2020	Patents on Kaletra/Aluvia HIV antiviral drug	No	None
Fortress and Labrador Diagnostics	17 March 2020	Patented diagnostics technology	No	Unknown
SMITHs Group	21 March 2020	PARAPAC Plus lightweight ventilators	Unknown	Only available to members of UK Ventilator Challenge Consortium
UC Berkeley IGI	29 March 2020	New technology related to COVID-19	Yes	Unknown
Medtronic	30 March 2020	Puritan Bennett 560 Ventilator design materials and software	No	Share-alike requirement for modifications User registration/identification
Oxford University	8 April 2020	COVID-19 related IPR	Yes	Resulting products must be offered free of charge, at cost or cost-plus
Allen Institute for AI	April 2020	IPR in COVID-19 data sets	No	None
<b>Coordinated pledges</b>				
Wellcome Trust Publishers' Pledge**	16 March 2020	All publications relating to COVID-19 and coronavirus	No	None
Open COVID Pledge***	7 April 2020	Patents and/or copyrights	No	Defensive suspension of license if licensee asserts patents against licensor
Harvard-MIT-Stanford (HMS)	7 April 2020	All IPR	Yes	Fair pricing of resulting products and services
Open COVID-19 Declaration****	7 May 2020	Patents, utility models, designs, copyrights	No	None

\*All pledges are archived at <http://www.pijip.org/non-sdo-patent-commitments/>. \*\*As of 29 May 2020, includes 30 publishers of scientific journals and proceedings, including American Chemical Society, American Physical Society, British Medical Journal, Cell Press, Elsevier, Karger, Lancet, New England Journal of Medicine, Public Library of Science, Royal Society, Science Journals, Springer Nature, Taylor & Francis, Wiley and Wolters Kluwer. \*\*\*As of 24 August 2020, includes 30 companies and institutions including Amazon, AT&T, Facebook, Fujitsu, Hewlett-Packard Enterprise, IBM, Intel, Microsoft, Mitsubishi Electric, NASA Jet Propulsion Laboratory, New Jersey Institute of Technology, Sandia National Laboratory and Uber, among others. \*\*\*\*As of 24 August 2020, includes 96 Japanese industrial firms.