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The Open COVID Pledge: Design, Implementation and Preliminary Assessment of an Intellectual Property Commons

Jorge L. Contreras

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THE OPEN COVID PLEDGE:
DESIGN, IMPLEMENTATION AND PRELIMINARY ASSESSMENT
OF AN INTELLECTUAL PROPERTY COMMONS

Jorge L. Contreras*

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ABSTRACT

Early during the COVID-19 pandemic, a number of widely-publicized incidents gave rise to concerns that holders of patents and other intellectual property (IP) rights could hinder the development, manufacture and distribution of essential medical devices, protective equipment and biomedical products. The global response to these concerns was swift and included the issuance of compulsory licensing orders by several national governments, as well as the proposal of a technology pool by the World Health Organization (WHO). Alongside these efforts, a group of scientific, engineering and legal experts created a lightweight, open framework under which IP holders could voluntarily pledge not to assert their rights against those responding to the COVID-19 pandemic. This effort – known as the Open COVID Pledge (OCP) – attracted significant participation from some of the world’s largest IP holders, with nearly 500,000 patents and patent applications, as well as significant copyrighted material, pledged to date. The OCP has also been adopted as part of the framework of the WHO’s COVID Technology Access Pool (C-TAP), a multinational initiative to make particular biomedical innovations more accessible around the world. This article describes the development of the OCP, including the design choices that shaped its legal structure and implementation. It also assesses the adoption of the OCP across market sectors including biopharmaceuticals, diagnostics, medical devices, protective equipment and digital innovations. It finds that while pledges in the

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biopharmaceutical sector have been infrequent, many other critical technologies in the fight against COVID-19 have been made broadly available to users through this and related pledging mechanisms, creating a favorable environment for open innovation, new market entry and equitable access to technology. As such, the OCP may both help to address the current pandemic and serve as a useful model for IP sharing platforms to address to future public health emergencies.
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INTRODUCTION

On December 31, 2019, the World Health Organization (WHO) office in Beijing was notified that a cluster of idiopathic pneumonia cases had been diagnosed in Wuhan, a medium-sized city located in the central Chinese province of Hubei.1 On January 9, 2020, the WHO announced that the source of the infection was a novel coronavirus,2 subsequently designated SARS-CoV-2. On January 30, with nearly 8,000 confirmed cases in China and 100 elsewhere, the WHO characterized the outbreak as a public health emergency of international concern.3 And on March 11, with more than 118,000 cases in 114 countries and 4,200 deaths worldwide, the Director-General of the WHO declared that “COVID-19 can be characterized as a pandemic”.4

The international biomedical research community mobilized rapidly in response to the escalating crisis. Concerns about patents arose just as quickly. Many potential vaccines, diagnostics and treatments for COVID-19 were originally targeted at related diseases including malaria, hepatitis C, influenza, Marburg virus, Ebola, Middle East Respiratory Syndrome (MERS), severe acute respiratory syndrome (SARS), and human immunodeficiency virus (HIV).5 Many of these compounds were covered by existing patents and patent applications. One March, 2020, study by the American Chemical Society identified over 2,000 patents relating to SARS and MERS treatments alone.6 These patents were held by a range of companies and institutions across North America, Asia and Europe. Another study identified over 120 different entities holding patents covering diagnostic tests relevant to COVID-19.7 In addition to these biochemical patents, researchers identified a large number of patents covering the manufacture, operation and components of devices and equipment used to treat the symptoms of COVID-19

3 SARS-CoV-2
6 Cynthia Liu, et al., Research and Development on Therapeutic Agents and Vaccines for COVID-19 and Related Human Coronavirus Diseases, ACS CENTRAL SCI., Mar. 9, 2020, https://dx.doi.org/10.1021/acscentsci.0c00272
7 Id. See also Patents – Coronaviruses, 38 NATURE BIOTECH. 695 (2020) (identifying patents related to vaccines and methods of treatment of coronaviruses).
and to monitor and contain its spread, including respirators, ventilators, diagnostic kits, facial masks, algorithms, mobile apps, and the like.\(^8\)

Some began to view this sizeable body of patents as a potential impediment to research, development, manufacture and distribution of critical supplies, products and equipment. Early in the pandemic, a number of high-profile incidents involving patents galvanized public concern over these issues. For example,

- In February 2020, the Wuhan Institute of Virology announced that it had filed a patent application claiming the use of Gilead Sciences’ experimental antiviral drug remdesivir to treat COVID-19.\(^9\) The announcement caused significant controversy, given that the Wuhan Institute did not develop the drug and its effectiveness against COVID-19 was still unproven.\(^10\)

- In March 2020, two engineers in Brescia, Italy, a region that was particularly hard-hit by the pandemic, used a desktop 3D printer to fabricate replacement valves for more than a hundred ventilator machines used at a local hospital.\(^11\) Early news reports claimed that a ventilator manufacturer threatened to sue the engineers for infringing patents covering the valves.\(^12\) While the existence of the threat and the patents themselves remains murky, the incident sparked a flurry of commentary regarding the risks that volunteers and hospitals could face from patents.\(^13\)

- Later in March, patent assertion entity (PAE) Labrador Diagnostics sued French firm bioMérieux and its Utah-based subsidiary BioFire Diagnostics for patent infringement. Labrador alleged that diagnostic kits being developed for COVID-19 infringed patents that it had acquired from defunct blood testing

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company Theranos. News of the lawsuit sparked a wave of negative publicity that quickly persuaded Labrador’s parent company, Fortress Investments, to end the lawsuit and offer royalty-free licenses to anyone conducting COVID-19 testing.

- On April 1, Kentucky governor Andy Beshear publicly called on 3M Corporation to grant broad access to more than 400 patents covering “N95” respirators used by healthcare and other individuals at high risk of infection. Beshear was responding to severe shortages of such protective equipment in his state, which he and others attributed to patents that prevented firms other than 3M from manufacturing them. He is reported to have urged 3M to license its patents to “the nation” as its “patriotic duty” in a time of national crisis.

- Beginning in April, another PAE, Swirlate IP, brought patent infringement suits against a more than a dozen manufacturers of products including ventilators and blood glucose monitors. The asserted patent covered wireless communications technology and was originally owned by Panasonic.

- In July, Vancouver-based AbCellera Biologics sued rival Berkeley Lights for the infringement of eight patents originally issued to the University of British Columbia. In the suit, AbCellera sought an injunction to prevent Berkeley from selling its Beacon Optofluidic System, which is being used for the discovery and development of antibodies against COVID-19.

- From the earliest weeks of the pandemic, patents were also perceived as hindering research efforts relating to COVID-19. As one senior molecular biology researcher recalls:

  [F]rom the first moment we started having these [COVID-19] meetings there were discussions of patents. There were discussions of things that we couldn't do because they were patented; there were discussions of things where we didn't know if we could do them, if they were valid things that we could use to pursue strategies to deal

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17 See Unified Patents, supra note 17.
18 See Unified Patents, supra note 17.
with the pandemic because of patents. And even more astonishingly to me, there were already discussions about patenting the things that were going to happen in these COVID labs.\(^20\)

- Finally, in the crucial area of vaccine research, it soon became apparent that a patent “gold rush” was on. One news report in May 2020 announced “Virus Researchers Race to File Patents …”,\(^21\) long before any vaccine candidate was close to approval. Echoing concerns over the inaccessibility of patented vaccine technologies during the SARS and Ebola outbreaks, the WHO urged governments and the private sector to make patents broadly available in the fight against COVID-19.\(^22\)

These examples indicate that specter of patent liability and litigation manifested itself from the early days of the pandemic in areas ranging from basic research\(^23\) and vaccine development to the manufacture, supply and distribution of medical supplies and equipment.

The public sector reaction to these concerns was swift and included the issuance by a half dozen countries of compulsory licensing orders for COVID-related biomedical technologies\(^24\) and the formation by the WHO of a COVID-19

\(^{20}\) Michael B. Eisen, Howard Hughes Medical Institute, University of California Berkeley, Oral Comments delivered at Lee E. Teitelbaum Utah Law Review Symposium – The Law & Ethics of Medical Research (Nov. 20, 2020).


\(^{23}\) One notable area in which patents have not played a role in the COVID-19 pandemic is genomesequencing. The researchers that first elucidated the genomic sequence of the SARS-CoV-2 virus did not seek to patent it, but instead released it in the publicly-accessible GenBank data repository. Their release of this critical data enabled the scientific community to mobilize rapidly and conduct research on a range of diagnostic, vaccine and therapeutic applications based on the viral RNA sequence. See Michael A. Martin, David VanInsberghe, Katia Koelle, Insights from SARS-CoV-2 sequences, 371 SCIENCE 466, 466 (2021) (“More than 260,000 [SARS-CoV-2 ] sequences are now available in public databases, about a year after the viral genome was first sequenced. These sequences and their associated metadata have allowed researchers to estimate the timing of SARS-CoV-2 spillover into humans, characterize the spread of the virus, and gauge virus adaptation to its new host”), Michael J. Mina & Kristian G. Andersen, COVID-19 testing: One size does not fit all, 371 SCIENCE 126, 126 (2021) (“Tests for detecting … SARS-CoV-2 were developed within days of the release of the virus genome”). Had the researchers who first sequenced SARS-CoV-2 sought patent protection for their discovery, as earlier research teams had during the SARS, H1N1 and H5N1 outbreaks (Rimmer, 2004), global research relating to COVID-19 could have been less efficient and more costly. One of the reasons that patents are no longer sought on genomic sequences is the U.S. Supreme Court’s decision in Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013), which established that a sequence of naturally-occurring nucleotides is an unpatentable “product of nature”. See Jorge L. Contreras, COVID-19 as an Example of Why Genomic Sequence Data Should Remain Patent Ineligible.

\(^{24}\) See Part I.B.2, infra.
Technology Access Pool (C-TAP). Voluntary efforts also emerged to address perceived areas in which patents and other intellectual property could hinder the response to COVID-19. Ventilator manufacturers such as Medtronic and Smiths Group made product designs available for free over the web, and several large universities and national laboratories offered to license pandemic-relevant technologies on a royalty-free basis.

Alongside these efforts, an independent group of legal experts, scientists and engineers coalesced to develop a common framework that would enable intellectual property holders to commit their rights to the COVID-19 response on a compensation-free basis without the need for governmental intervention or the administrative complexities of IP pooling arrangements. This work resulted in the Open COVID Pledge (OCP), a standardized licensing platform for patents and copyrights that was launched on April 7, 2020. At its launch, the OCP included over 70,000 patents licensed by Intel, and within a few weeks Microsoft, Facebook, Uber, Amazon, Hewlett-Packard Enterprise, Sandia National Laboratory and other large patent holders had joined the effort. To date, it is estimated that close to 500,000 patents have been pledged under the OCP framework, and the OCP has been included as an integral “operational part” of the WHO’s C-TAP program. As such, the OCP has helped to promote an open innovation landscape in key areas of COVID-19 research and production.

This article discusses the genesis and formation of the OCP, including the goals and design choices that shaped its development. The remainder of this article

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26 [Nature Bio paper]
27 [Nature Bio paper]
28 The group, which referred to itself as the “Open COVID Coalition” and the “OCP Steering Committee”, consisted of ten individuals: Jorge Contreras, Michael Eisen, Ariel Ganz, Mark Lemley, Jenny Molloy, Diane Peters, Alexander James Phillips, Mark Radcliffe, Eric Steuer and Frank Tietze.
31 Estimating the number of patents held by different entities is an inexact art, and is confounded by reporting (both by patent holders and third parties) that is inaccurate, outdated and inconsistent. Compounding these problems are differing standards for how patents, patent applications, patent families, and international filings are treated. Based on available public records and reports, OCP estimates that between 417,000 and 500,000 worldwide patents have been pledged to date.
32 See Part x, infra.
33 See Anita M. McGahan et al., Tackling Societal Challenges with Open Innovation, 63 CALIF. MANAGE. REV. 49, 55 (2021) (“it was not until the COVID-19 pandemic swept the world that we saw how a sense of urgency can truly fuel open innovation. Through initiatives like the Open Covid Pledge firms started to offer free licenses to their IP for the purpose of fighting the pandemic”). See also Part IV.C, infra.
proceeds as follows: Part I provides a brief summary of patent law and the economic incentives that patents provide for innovation and product development, then explores how patents may serve to limit access to necessary products and services during times of crisis. Part II discusses conventional mechanisms used to expand access to biomedical technologies, including public sector approaches such as compulsory licensing, march-in rights and government use, and private approaches such as patent pools and clearinghouses. Part III then shifts to the open licensing models that informed the development of the OCP, including open source software and Creative Commons licensing, and concludes with a discussion of other pledges that have been made in response to the COVID-19 pandemic. Part IV discusses the design and organization of the OCP, which combines features of open source and Creative Commons licensing with IP pledges. Part V describes the implementation and adoption of the OCP, including an assessment of its impact in different industry sectors. Part VI analyzes the OCP in the broader context of patent pledges, describing its future prospects and considers other contexts in which IP-sharing platforms such as the OCP may be useful.

I. PATENTS, ACCESS AND BIOMEDICAL INNOVATION

A. The Access versus Innovation Debate

A patent confers on its owner a twenty-year period during which the owner has the exclusive right to make, use, sell and import the patented invention. This grant of exclusivity gives the patent owner the ability to exploit the market for the patented invention to the exclusion of others during the patent term, and thus to charge prices for that invention that are not constrained by market competition. At a basic level, patents thus afford two principal and related benefits to their owners: the ability to operate within a particular market without competition, and the ability to charge supra-competitive prices.

Given these factors, two competing sets of goals influence policy discussions relating to the patent system: allocation and innovation. Allocative considerations relate to the distribution of existing resources among potential users. In terms of many patented technologies – e.g., smart phones, aircraft engines, food additives – market forces act efficiently to allocate products to those who value them most highly. However, in some cases, simple market forces may not work to achieve

34 See 35 U.S.C. §§ 154, 271. The focus of this article is on U.S. law. However, the basic protections of patent law are common to most countries.
35 See William M. Landes & Richard W. Posner, The Economic Structure of Intellectual Property Law (2003). Of course, many patents cover only minor technical improvements to existing technologies or small components of large, complex products that may be covered by thousands of separate patents. In these cases, the patent holder is not likely to enjoy a monopoly, or even market power, in any given product market. See Illinois Tool Works Inc. v. Independent Ink, Inc., 547 U.S. 28 (2006). Nevertheless, this simplified economic model best illustrates the competing concerns raised by patents.
36 Landes & Posner, supra note 35.
maximum social benefit. Thus, in the case of patented drugs and healthcare equipment, a manufacturer’s optimal price may be unaffordable to segments of the population.\(^{37}\)

Moreover, even if the holder of a patent is willing to price a healthcare product at a level that will ensure broad access, it may lack the production capacity to meet the demand for that product. It may thus be necessary to allow others to operate under that patent in order to supply sufficient quantities of the product in question. In the event that a patent holder is unwilling to grant its existing and potential competitors adequate rights to operate under its patents, a research or supply “bottleneck” may arise.\(^{38}\) Because these allocative issues concern the supply of patented technologies at a particular time (e.g., when the need for them arises), they are sometimes referred to as “static” considerations. Static allocative issues have been at the forefront of the debate over COVID-19 and innovation policy.\(^{39}\)

In contrast, “dynamic” considerations concern the market conditions that are needed to ensure the creation of an optimal quantity of new technologies over time. Patents give their owners exclusive rights to exploit their inventions commercially, and thus provide financial incentives to those who make commercially valuable discoveries and inventions.\(^{40}\)

Thus, some argue that increasing the availability and enforceability of patents is likely to increase overall innovation and the quantity of socially beneficial technologies that are available, particularly in response to a public emergency.\(^{41}\) Such arguments have been made in varying forms in the context of the COVID-19 pandemic. For example, the Director General of the World Intellectual Property Organization (WIPO) has argued that instead of lowering IP barriers to access to

\(^{37}\) Will Zerhouni, Gary J. Nabel & Elias Zerhouni, *Editorial - Patents, economics, and pandemics*, 386 SCIENCE 1035, 1035 (2020) (“Patents give a time-limited exclusivity to the innovator who can then set premium pricing that maximizes the return on R&D investment. Such pricing can hinder wide dissemination once vaccines or therapies are developed, often leaving many patients unable to afford these products.”)

\(^{38}\) See, e.g., Jorge L. Contreras & Jacob S. Sherkow, *CRISPR, surrogate licensing, and scientific discovery*, 355 SCIENCE 698 (2017) (discussing the risk of research bottlenecks when broad patent rights are held by entities that are unable to exploit all of those rights themselves and do not wish to license others).

\(^{39}\) See Bhaven N. Sampat & Kenneth C. Shalden, *The COVID-19 Innovation System*, 40 HEALTH AFF. (MILLWOOD) 1, 5 (2021) (Perhaps an even harder policy challenge than generating the innovations will be scaling up production to manufacture the volumes of doses that the world needs.”)

\(^{40}\) Because their payoff is entirely market-driven, patents incentivize innovations that are likely to be the most lucrative, rather than the most beneficial (hence the tendency of some firms to focus R&D dollars on hair loss treatments and weight loss pills rather than the eradication of rare diseases). As a result, patents are not always optimally calibrated to address social needs.

\(^{41}\) See Andrew W. Torrance, *Patents to the Rescue – Disasters and Patent Law*, 1 DEPAUL J. HEALTH L. 309 (2007) (arguing that patents are well-situated to incentivize the creation of lifesaving technologies).
biomedical technologies, “governments should instead be pursuing policies to incentivize scientific innovation through strong IP rights.”

In the U.S., commentators have used the pandemic as a vehicle for airing longstanding grievances about the Supreme Court’s patent jurisprudence, blaming its 2012 decision in Mayo v. Prometheus, which held that diagnostic tests based on the observation of naturally-occurring physiological reactions are not eligible for patent protection, for the shortage of reliable COVID-19 diagnostic tests. And in an effort to accelerate the issuance of patents relating to COVID-19, the U.S. Patent and Trademark Office (PTO) introduced a prioritized examination program. The PTO also created the Patents 4 Partnerships IP Marketplace Platform – an online resource showcasing COVID-19 related patents available for commercial licensing.

Yet a broad range of economic incentive structures other than patents exists to incentivize socially-beneficial innovation. These include government grants, subsidies, prizes, and tax incentives. In the context of the COVID-19 pandemic, perhaps the most significant financial incentive of all may be governmental procurement, under which the United States government alone has allocated tens of billions of dollars to purchase vaccines, protective equipment and other technologies. While incentives like these reward desired innovation, they do not achieve it through grants of market exclusivity.

42 Steve Brachmann, WHO’s C-TAP Initiative Pushes for Non-Exclusive Global Licensing Amid Pharma Industry Concerns, IPWatchdog, May 31, 2020 (citing Francis Gurry, Director General of WIPO).
48 See Sampat & Shalden, supra note 39, at 4 (describing governmental procurement funding in the U.S. and elsewhere).
The “access versus incentives” tradeoff is one of the fundamental tensions in intellectual property law today. It is often unclear whether dynamic or static issues should take priority in any given situation, and advocates often promote one over the other depending on their own preferences (e.g., access to technology or obtaining patents). Policy makers have adopted a range of strategies to strike the right balance between expanding access to protected technological products while continuing to incentivize future innovation. In this respect, the COVID-19 pandemic resembles earlier public crises in which debates over access versus incentives have played out.

Finally, it is worth remembering that removing patent barriers to the production of a pharmaceutical product or device will not ensure that it is supplied in significant quantity or at an acceptable level of quality. Many vaccines, diagnostics, drugs and medical devices are regulated by governmental agencies such as the U.S. Food and Drug Administration (FDA). Thus, notwithstanding patent authorizations, a secondary supplier of a regulated drug or device will often be required to obtain regulatory approval of the product that it wishes to produce, as well as its own manufacturing facilities and processes.

The next Part reviews a number of potential public and private interventions that have been proposed and implemented to increase access to patents covering critical technologies in connection with the COVID-19 pandemic.

**B. Expanding Access To Patents: Governmental Interventions**

This Part B reviews both public and private mechanisms that have been proposed both within the U.S. and internationally to expand access to patented technologies in the context of the COVID-19 pandemic. These mechanisms are designated for the procurement and distribution of coronavirus vaccines and treatments and $22 billion for testing, tracing, and mitigation of coronavirus”) (visited Jan. 26, 2021).

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51 **See, e.g., Jorge L. Contreras, Bronwyn H. Hall & Christian Helmers, Pledging Patents for the Public Good: Rise and Fall of the Eco-Patent Commons, 57 HOUS. L. REV. 61, 64 (2019) (“In the area of climate change mitigation … a variety of proposals to increase innovation and diffusion of technology have been made, many of them involving adjustments to the patent system. Such proposals have encompassed strategies to increase the number of green/clean tech patents to encourage private sector investment in innovation and to decrease either the number or potency of such patents in an effort to reduce the costs of innovation globally”) (emphasis in original)); Jesse L. Reynolds, Jorge L. Contreras & Joshua D. Sarnoff, *Solar Climate Engineering and Intellectual Property: Toward a Research Commons, 18 MINN. J. L. SCI. & TECH. 1, 71-72 (2017) (describing PTO initiatives both to limit and accelerate patent grants, particularly in the area of green technology).**

then compared with patent pledges, and the Open COVID Pledge specifically, in Parts II and III.

1. Compulsory Licensing

In an effort to ensure that diagnostics, vaccines, therapeutics and medical equipment necessary to respond to COVID-19 are developed, manufactured and made available rapidly and in large quantities, governments around the world have explored and enacted compulsory licensing measures for privately held patents. Generally speaking, when a government orders compulsory licensing, the holder of a patent is required to license it (usually at a reasonable rate) to other manufacturers in order to ensure the continuity of, or an increase in, production and supply of the patented article.  

Before the COVID-19 pandemic, the global dialogue around compulsory patent licensing had focused largely on making essential medicines available in the developing world, and most cases in which compulsory licenses were ordered in countries such as Brazil, India and Thailand involved drugs targeting HIV/AIDS and cancer. But the emergence of the COVID-19 pandemic reignited the debate over compulsory licensing around the world. Early in the pandemic, compulsory licensing measures relating to patented technologies relevant to COVID-19 were authorized in countries including Chile, Ecuador, Israel, Germany and Canada.

Unlike many countries, the United States lacks a general statutory framework for compulsory patent licensing. Thus, in the U.S., the discussion around compulsory licensing has centered on two statutory mechanisms: federal march-in rights under the Bayh-Dole Act, and governmental use under 28 U.S.C. § 1498.


2. March-In Rights under the Bayh-Dole Act

The Bayh-Dole Act of 1980\textsuperscript{56} was intended to rationalize the previously chaotic rules governing the ownership of federally-funded inventions. Most importantly, it allowed research institutions to patent inventions arising from government-funded research and penalized institutions that failed to pursue patent protection for such inventions.\textsuperscript{57} In return, the Act gives the federal government a non-exclusive, paid-up license under each patent covering a federally-funded invention,\textsuperscript{58} and authorizes the government to exercise so-called ‘march in’ rights to compel the owner to license it to one or more third parties to the extent necessary, among other things, to address health or safety needs.\textsuperscript{59}

Over the years, numerous petitions have been filed requesting that federal agencies exercise their march-in rights under the Bayh-Dole Act, primarily in cases involving under-supplied or costly pharmaceutical products.\textsuperscript{60} To date, however, neither NIH nor any other federal agency has exercised its march-in rights during the 40+ years that the Bayh-Dole Act has been in effect.\textsuperscript{61} Moreover, march-in rights apply only to inventions that were made using federal funding.\textsuperscript{62} While the foundational discoveries underlying many new drug candidates were made by federally-funded university laboratories, a significant amount of biomedical research is conducted by pharmaceutical and medical device companies without federal support. As a result, march-in rights under the Bayh-Dole Act have been of little practical relevance during the COVID-19 pandemic.

3. Governmental Use and § 1498

The provisions of 28 U.S.C. § 1498, which traces its origins to the 1910 Government Use Statute,\textsuperscript{63} is not a compulsory licensing law, but a limited waiver by the U.S. government of its immunity to suit in the federal courts.\textsuperscript{64} Under this statute, if the federal government (itself or through its contractors) uses or manufactures an invention patented in the United States without permission of the owner, the owner is granted a remedy – the pursuit of a claim for “reasonable and

\textsuperscript{56} 35 U.S.C. § 200 et seq.
\textsuperscript{57} 35 U.S.C. § 202(c)(3).
\textsuperscript{58} 35 U.S.C. § 202(c)(4); 37 C.F.R. § 401.14(c)(3).
\textsuperscript{59} 35 U.S.C. § 203(a); 37 C.F.R. §§ 401.14(j).
\textsuperscript{61} See Thomas, supra note 60.
\textsuperscript{62} 35 U.S.C. § 201(e).
\textsuperscript{64} 28 U.S.C. § 1498(a).
entire compensation” in the U.S. Court of Federal Claims.\textsuperscript{65} No other remedy is permitted, and the patent owner cannot seek to enjoin the government’s use of the invention.

Since its enactment, § 1498 has been invoked periodically in cases relating to the procurement of military technology and other equipment.\textsuperscript{66} Though less frequently, § 1498 has also been used to bolster the U.S. supply of drugs and biomedical technologies at prices lower than those charged by patent holders. Milton Silverman and Philip Randolph Lee report that during the 1960s, the Department of Defense’s Military Medical Supply Agency (MMSA) utilized § 1498 to obtain supplies of approximately fifty drugs, including the antibiotic tetracycline, from producers in countries where the drugs were not patented.\textsuperscript{67} Though the federal government’s use of § 1498 in the pharmaceutical sector declined by the 1970s,\textsuperscript{68} the Department of Health and Human Services threatened to invoke the statute again in 2001 during the post-9/11 anthrax scare.\textsuperscript{69} Since then, commentators have proposed using the government’s powers under § 1498 to drive down drug prices,\textsuperscript{70} but no meaningful utilization of this power has occurred for pharmaceutical products in nearly two decades.

With the advent of the COVID-19 pandemic, and highly-publicized shortages of testing kits, respirators, ventilators and other critical supplies,\textsuperscript{71} the prospect of U.S. government intervention through § 1498 again gained traction.\textsuperscript{72} Nevertheless, for what appears to be a range of political and practical reasons, there has been little meaningful movement in the United States toward the exercise of government use rights. It is possible that opposition from the private sector is partially responsible. Moreover, any such intervention might contradict the stance that the United States has repeatedly taken in the international arena, in which it routinely condemns the

\textsuperscript{65} Id.
\textsuperscript{66} See, e.g., Honeywell Int’l, Inc. v. United States, 609 F.3d 1292 (Fed. Cir. 2010) (patents on night vision goggles).
\textsuperscript{67} MILTON SILVERMAN & PHILIP RANDOLPH LEE, PILLS, PROFITS, AND POLITICS 187 (1974).
\textsuperscript{68} Brennan, et al., supra note 52, at 306.
\textsuperscript{69} See id. at 303 (the government’s proposal to import doses of low-cost generic ciprofloxacin caused the domestic manufacturer Bayer to reduce its price by half).
\textsuperscript{71} See Peter Baker and Eileen Sullivan, U.S. Virus Plan Anticipates 18-Month Pandemic and Widespread Shortages, N.Y. TIMES, Mar. 17, 2020, https://www.nytimes.com/2020/03/17/us/politics/trump-coronavirus-plan.html (White House plan predicts “potentially critical shortages of diagnostics, medical supplies (including personal protective equipment) and pharmaceuticals), and staffing in some locations.”)
issuance of compulsory patent licenses by developing countries. Interestingly, the most significant result of possible government intervention in this area may have been the voluntary pledges made by IP holders seeking to forestall more drastic governmental action.

C. Private Ordering: Patent Pools

In addition to governmentally-driven mechanisms for making patented technologies broadly available, private ordering and market forces sometimes work to achieve the same ends. One of the principal private means for clearing blocking patent positions and enabling industry cooperation is the patent pool.

1. Patent Pools in the Life Sciences

Patent pools are private arrangements among patent holders that enable the participants to operate under one another’s patents, to manage and administer the pooled patents through a centralized mechanism, and often to grant licenses of the pooled patents to third parties, with the proceeds allocated among the participants according to an agreed formula. Patent pools have been around for more than a century in industries ranging from oil refinement to aircraft to semiconductors to digital media. In all of these cases, pools have enabled the efficient consolidation of patents in a manner that has facilitated licensing and commercialization.

Historically, however, patent pools have not enjoyed much commercial success in the biomedical sector. As I have previously explained,

Several factors could explain the absence of pooling in this arena: the need for at least some market exclusivity in an environment with extremely high costs of product development, clinical trials and regulatory approval; patent holders’ desire to retain control over their assets; and concern over compromising commercial secrecy by collaborating with others.

Patent pools have also been suggested as mechanisms to address more acute public health crises such as disease outbreaks. Patent pooling structures were actively discussed and considered in response to the SARS outbreak of 2002-03.

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73 See Sapna Kumar, Compulsory Licensing Of Patents During Pandemics (working paper Jan. 28, 2021).
74 See Part II.C, infra. See also Thomas Prock, et al., 3D printing and IP in a pandemic, INTELL. ASSET MGT., Apr. 3, 2020 (“it would be advantageous for IP rights holders to be proactive by licensing IP on their own terms before the decision is made for them by the government.”)
the H5N1 influenza outbreak of 2005, and the H1N1 influenza pandemic of 2009. Yet despite the perceived need for aggregation of distributed patent rights in order to combat these diseases, patent pools were never formed for a range of practical, administrative and competitive reasons.

In the wake of these outbreaks, the WHO initiated a series of activities to explore the viability of pooling patents relating to public health technologies. Specifically, the WHO’s 2011 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) called for an examination of the “feasibility of establishing voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices.” Yet despite support within WHO, no significant progress toward such pools occurred.

One reason that patent pools may not have successfully formed in these areas may relate to antitrust law. A patent pool necessarily includes a variety of patents held by different owners. But when a pool aggregates rights covering technologies that may be substitutes for one another, such as patents covering different types of vaccines, innovation could be reduced (i.e., why try to develop an improved vaccine when all vaccines are licensed under the pool?). On the other hand, when pooled patents are complementary (e.g., several patents covering aspects of the same vaccine), pools are viewed as increasing efficiency and enhancing innovation. It is for this reason that most antitrust enforcement agencies concur that the patents included in a pool should generally be complementary and not substitutes for one another.

Yet the exercise of determining which patents are complementary and which patents are substitutes is not a trivial one. Various studies have estimated the cost of this “essentiality analysis” to be in the range of US$10,000 per patent, a cost

78 See Greene, supra note 76.
79 See, e.g., Beldiman, supra note 77, at 58 (“Because it took an extended period of time to agree which patents to include, to craft the pool structure agreement and its licensing terms, and to ensure that antitrust and other regulations were met, the SARS outbreak was contained before the pool was ever completed.”)
81 Id. at 13.
that can easily reach millions of dollars in heavily-patented areas. Patent pools involve other costs, as well. Professors Robert Merges and Michael Mattioli have estimated the set-up costs of two major patent pools relating to data compression standards -- MPEG Audio and HVEC -- at US $7.8 million and $4.8 million, respectively, with annual operating budgets in the range of $600,000 and $2 million.\(^8^5\)

2. IP Clearinghouses and the Medicines Patent Pool

In addition to formal pooling arrangements, some have sought to address public health needs through more flexible structures. For example, in 2010 the Unitaid arm of the WHO created the Medicines Patent Pool (MPP).\(^8^6\) MPP’s mission is to aggregate patents, clinical trials data and other IP relating to HIV/AIDS, Tuberculosis and Hepatitis-C medications and make them available at low or no cost to manufacturers that commit to produce and sell drugs to users in low-income countries.\(^8^7\)

Despite its name, the MPP is not a patent pool, as that term is commonly understood. Rather, it is a clearinghouse or intermediary that obtains inbound licenses from willing IP holders and then sublicenses those rights to generic drug manufacturers operating in developing countries. These licenses, which may be royalty-bearing or royalty-free, are generally available on an a-la-carte basis, and do not necessarily aggregate all of the rights licensed to MPP (thus avoiding some of the antitrust issues and up-front costs described above). To date, several significant patent holders, including AbbVie, Bristol-Myers Squibb, Gilead Sciences, Pfizer, ViV Healthcare and Johns Hopkins University, have licensed IP to the MPP, which has in turn granted twenty-two sublicenses to generic drug manufacturers for distribution of products in the developing world.\(^8^8\) A similar effort that gained attention around the same time was the Pool for Open Innovation Against Neglected Tropical Diseases (POINT), which has since been folded into the WIPO Re:Search initiative.\(^8^9\)

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\(^8^7\) See *id. See also* Esteban Burrone, *Patent Pooling in Public Health* in THE CAMBRIDGE HANDBOOK OF PUBLIC-PRIVATE PARTNERSHIPS, INTELLECTUAL PROPERTY GOVERNANCE, AND SUSTAINABLE DEVELOPMENT 93, 96-102 (Margaret Chon, Pedro Roffe & Ahmed Abdel-Latif, eds. 2019).


3. The WHO COVID-19 Technology Access Pool (C-TAP)

In the early days of the pandemic, advocates proposed that a patent pool or MPP-like clearinghouse be formed to aggregate technologies responsive to the COVID-19 pandemic. In March 2020, the President and Health Minister of Costa Rica requested that the WHO “undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic.”

On May 29, the WHO announced the creation of the COVID-19 Technology Access Pool (C-TAP), a program “intended to provide a means to accelerate the development of products needed to fight COVID-19 as well as to accelerate the scale-up of manufacturing and the removal of barriers to access in order to make products available globally.” Supported by thirty countries, C-TAP adopts a five-pronged approach to expanding technology access and dissemination in response to COVID-19:

- Public disclosure of gene sequences and data;
- Transparency around the publication of all clinical trial results;
- Inclusion in research funding agreements of requirements for equitable distribution, affordability and the publication of trial data;
- Licensing any potential treatment, diagnostic, vaccine or other health technology to the Medicines Patent Pool; and
- Promotion of open innovation models and technology transfer that increase local manufacturing and supply capacity, including through the Open COVID Pledge and the WHO’s Technology Access Partnership (TAP).

As indicated by the fourth and fifth points above, C-TAP relies on existing IP aggregation and licensing platforms – the MPP, the OCP and the TAP -- rather than attempting to create a new one. The fact that the OCP was included in this multinational UN-backed initiative less than two months after its launch is a testament to its efficient design and broad, rapid adoption in the field.

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91 Letter dated March 23, 2020, from Carlos Alvarado Quesada, President of the Republic [of Costa Rica], and Daniel Salas Peraza, Minister of Health, to Dr. Tedros Adhanom Ghebreyesus, Director-General, World Health Organization [hereinafter Costa Rica Letter].
92 WHO Solidarity Call to Action, supra note 22.
II. OPEN LICENSING MODELS

The Open COVID Pledge offers a structural alternative to governmental compulsory licensing mechanisms, on one hand, and administratively complex patent pools, on the other hand. Its design borrows from a number of existing licensing models that are known for their efficiency and broad adoption, including the public licenses utilized by the open source software community and the lightweight licensing framework developed by Creative Commons for online content. It also adopts the features of prior patent pledges made in a range of industries and those made early in the COVID-19 pandemic.

A. Open Source Software

A computer program’s “source” code is a version of the program written in a human-readable programming language such as C++, PERL, BASIC or Fortran. In order to execute on a computer, this source code is typically compiled or interpreted into machine-readable “object” code, which is unintelligible to most people. Most proprietary software is licensed and distributed in object code form.

Beginning in the 1970s, a group of software developers in Cambridge, Massachusetts, bristling against the restrictive practices of corporate software firms, began to make their source code publicly available.95 This trend began the “free software” or “open source software” (OSS) movement. Despite its emphasis on sharing and open development structures, OSS software today has been embraced by the business community and includes some of the most successful and widely-deployed software in the world, including the Linux and Android operating systems, the Firefox web browser and the Apache web server.96

1. OSS Licensing

The hallmark of OSS software is that its source code is made available to the public, usually without charge. While its developers generally retain their copyrights (and patents) in the software code,97 they indiscriminately grant licenses to anyone who wishes to use, modify or distribute that code.98 These licenses are typically granted via self-executing, publicly-accessible agreements that become effective as soon as the user downloads or uses the software, much like consumer shrinkwrap or clickwrap agreements.99

97 OSS is not contributed to the “public domain”. See Stallman, supra note 95.
98 cite
99 cite
The first OSS licenses were created by the GNU Project, a software development effort led by Richard Stallman, one of the founders of the OSS movement. One of the best known and most widely-deployed OSS licenses is the GNU General Public License or GPL, which now has numerous variants. But, as discussed below, the GPL is complex and contains a number of features that are unattractive to commercial users. As a result, a number of alternative OSS licenses have emerged over the years. Among the most popular of these are the BSD license developed at the University of California Berkeley in 1990,\textsuperscript{100} the MIT License, the Mozilla Public License and the Apache Public License.\textsuperscript{101}

Given the proliferation of licensing structures purporting to be OSS, in 1998 the non-profit Open Source Initiative (OSI) published a set of criteria defining what it meant to be an “open source” license.\textsuperscript{102} These criteria include:

1. Free redistribution of the software must be permitted;
2. Source code must be made available to users;
3. Users must be permitted to create modifications and derivative works of the software;
4. The license may not discriminate against persons, groups or fields of endeavor and cannot be specific to a particular product or technology;
5. The license must automatically apply to anyone to whom the software is redistributed without the need for an additional license.

In addition to publishing and occasionally updating these criteria, OSI certifies the compliance of particular licensing agreements with its criteria. As of December 2020, it had certified 105 such licenses as meeting its definition of OSS.\textsuperscript{103}

2. Other Terms of OSS Licenses

While all OSS licenses include the basic provisions identified in the OSI definition, many include additional terms and conditions, some of which have become controversial. Among these are the following:

a. Attribution.

Most OSS licenses require that distributors of OSS software reproduce any copyright notices that are included in the original source code. When a user modifies a portion of that code, it adds itself to the copyright notice, thereby

\textsuperscript{100} See JORGE L. CONTRERAS, INTELLECTUAL PROPERTY LICENSING AND TRANSACTIONS: THEORY AND PRACTICE 543-44 (0.9 ed. 2021) (discussing BSD licenses).
\textsuperscript{102} OSI, https://opensource.org/osd.html
\textsuperscript{103} https://opensource.org/licenses/alphabetical
creating a list of all contributors to the code like an old fashioned “chain letter”. In this way, contributors to the copyrighted code receive attribution or recognition for their original contributions, an important feature of the OSS ethos.\textsuperscript{104}

\textit{b. Copyleft}

Richard Stallman coined the term “copyleft” (the opposite of copyright) to describe the licensing strategy of the GPL:

Copyleft uses copyright law, but flips it over to serve the opposite of its usual purpose: instead of a means of privatizing software, it becomes a means of keeping software free.

The central idea of copyleft is that we give everyone permission to run the program, copy the program, modify the program, and distribute modified versions—but not permission to add restrictions of their own. Thus, the crucial freedoms that define "free software" are guaranteed to everyone who has a copy; they become inalienable rights.

\textit{c. “Viral” Nature}

If a piece of software is distributed under the GPL, then anyone who redistributes that software, or any modified version of that software, must also distribute it under the GPL. Thus, like a biological virus, the GPL propagates itself from user to user, program to program. But the real threat perceived by the GPL was not the continuing need to license GPL’d code under the GPL, but the risk that the GPL’d code could infect proprietary code with which it was combined, making the entire combined work subject to the GPL.\textsuperscript{105}

\textit{d. Patents and OSS}

Though most OSS licenses deal primarily with copyrights in computer code, some address patent issues as well. For example, the GPL and Mozilla licenses require that a contributor to an OSS program license to users its patents covering every component of that program, even those contributed by others.\textsuperscript{106} Other OSS licenses, such as the Apache license, require a contributor to grant licenses under

\textsuperscript{104} See Benkler, \textit{supra} note 96.

\textsuperscript{105} See \textit{Contreras}, \textit{Licensing}, \textit{supra} note 100, at 546-47 (discussing “viral” nature of GPL and perceived threat to commercial software).

\textsuperscript{106} See General Public License, v3, Section 11, ¶ 2 (each contributor grants to each user of the program “a non-exclusive, worldwide, royalty-free patent license under the contributor's essential patent claims, to make, use, sell, offer for sale, import and otherwise run, modify and propagate the contents of its contributor version”). See also \textit{Contreras}, \textit{Licensing}, \textit{supra} note 100, at 548 (discussing concerns over breadth of GPL and Mozilla patent licenses).
its patents, but only with respect to its own contributions to the OSS program, and not those of third parties.\footnote{See Apache 2.0 License ("each Contributor hereby grants to You a perpetual, worldwide, non-exclusive, no-charge, royalty-free, irrevocable (except as stated in this section) patent license to make, have made, use, offer to sell, sell, import, and otherwise transfer the Work, where such license applies only to those patent claims licensable by such Contributor that are necessarily infringed by their Contribution(s) alone or by combination of their Contribution(s) with the Work to which such Contribution(s) was submitted").}

\section*{B. Creative Commons Licensing}

Creative Commons began in 2004 as an experiment by law professors Larry Lessig, James Boyle and others.\footnote{See Lawrence Lessig, \textit{The Creative Commons}, 64 MONTANA L. REV. 1 (2004).} Its goal was to create a legal framework that would enable individual producers of online content – photographs, videos, poetry, blog posts – to relinquish some of the exclusive rights granted by copyright law and allow others to copy, disseminate and modify their work. The system utilized a simple set of “tags”, each of which specified a particular right being granted to others.

Thus, if a photographer wishes to post a photo to a social media site and make it available for anyone else to use for any purpose so long as they give her credit (attribution), she can tag the photo with the “CC BY” symbol, and the CC Attribution license will apply.\footnote{The attribution feature of CC licenses bears similarities to the attribution feature of some OSS licenses. \textit{See} Part II.A.2.a, \textit{supra}.} If she also wishes to stipulate that her photo cannot be modified in any way, then she can tag it with the “CC BY ND” (Attribution, No Derivatives) license. If she wants to be sure that her photo remains free for all to use, even if someone incorporates it into a proprietary database or web site, then she can add the “SA” (Share Alike) tag.\footnote{Share-alike licensing is similar to the “viral” feature of OSS licenses such as the GPL. \textit{See} Part II.A.2.c \textit{supra}.} And if she wishes to prohibit commercial uses (e.g., using her photo in a corporate ad), then she can apply the “NC” (Non-Commercial) tag. As shown in Figure 1, there are only six permitted combinations of these four licensing tags (out of 15 possible combinations), reflecting the designers’ views of the most frequent and logical types of uses that should be permitted.
The CC suite of licenses appears simple, but a sophisticated legal structure underlies its streamlined user-facing tags. Thus, the tag “CC BY ND” does not itself convey a license to the user. Rather, when a tag is attached to an online image or other content, it includes a hyperlink to a more comprehensive licensing agreement that is hosted on CC’s web site.¹¹¹

Importantly, the CC licenses are “public” licenses. That is, they are not specifically negotiated between copyright owners and users, but are publicly posted and can be “accepted” by anyone who wishes to use the licensed content. Thus, the introduction to the CC BY NC ND 4.0 license reads as follows:

By exercising the Licensed Rights (defined below), You accept and agree to be bound by the terms and conditions of this Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International Public License (“Public License”). To the extent this Public License may be interpreted as a contract, You are granted the Licensed Rights in consideration of Your acceptance of these terms and conditions, and the Licensor grants You such rights in

¹¹¹ For example, the full text of the CC BY NC ND 4.0 license can be found at https://creativecommons.org/licenses/by-nc-nd/4.0/legalcode.
consideration of benefits the Licensor receives from making the Licensed Material available under these terms and conditions.

The Creative Commons website today claims that more than 500 million online images are available under CC licenses. As Lessig and others intended, the appeal of the CC licensing system is its simplicity and its intuitiveness. User can choose to apply one of six different combinations of four different licensing options to their works. Each option is described in simple, plain language and identified by an intuitive icon. Professor Jane Ginsburg points to four important design features that have contributed to the success of the CC model: its overall simplicity, its extension of credit to authors (included in each of the six permitted licenses), its ability to authorize use of the licensed content instantly and forever, and its potential to expand distribution of a work through search engines. These features have made CC licensing a standard feature of online platforms and social media sites today.

C. IP Pledges

As noted in Part II.B above, the formation of a patent pool often requires significant legal planning, negotiation, agreements concerning revenue sharing (if any), and an administrative structure. As a result, IP holders have found it increasingly expedient to make commitments regarding the enforcement and licensing of IP rights without the legal trappings, infrastructure, and overhead of formal pools. These commitments—IP pledges—are voluntary, unilateral promises made by IP holders to limit the enforcement or other exploitation of their IP rights, and are often coupled with more detailed public licensing agreements or statements.  

1. Pledges as Clearing Mechanisms

IP pledges enable a broad range of users to operate freely under the pledged IP. For the most part, such pledges are made without direct compensation or other consideration to the pledgor. This is not to say, however, that IP pledges are economically irrational; they may be supported by motivations ranging from promoting market development to forestalling governmental action to improving employee relations. A number of pledges have also been made to support IP

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112 Jane C. Ginsburg, Authors’ Transfer and License Contracts under US Copyright Law in RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY LICENSING 3, 23 (Jacques de Werra, ed., 2013).
114 The primary exceptions to this rule are the “FRAND” commitments made by participants in some standards-development organizations to license their patents on financial terms that are “fair, reasonable and non-discriminatory”. See, e.g., Contreras, Patent Pledges, supra note 113, at x.
holders’ philanthropic, environmental and corporate social responsibility (CSR) goals.116

Thus, in most of these cases, pledges (and accompanying public licenses) enable users to operate under the pledged IP without fear of infringement. Such freedom to operate can both encourage and enable users to develop, manufacture and sell products otherwise covered by the pledgor’s IP. For example, when Tesla Motors CEO Elon Musk famously pledged in 2014 that Tesla would not assert its patents against others in the electric vehicle market, it was widely believed that the purpose of this pledge was to encourage the rapid development and deployment of electric vehicle infrastructure systems and components, thereby benefiting Tesla over its gasoline-powered competitors.117

Yet few unilateral pledges, and not many collective pledges, can assure a user of complete freedom from IP (specifically patent) risks when it produces a commercial product. In the high technology sector, many products are covered by many thousands of patents held by multiple firms,118 and even biotechnology and pharmaceutical products, once viewed largely as single-patent products, are covered by an increasing number of diversely held patents.119 What’s more, it is increasingly common that, through a combination of expansive claim drafting and shrewd market prediction, a firm’s patents can cover products developed entirely by others and to which the patent holder made no contribution at all.

As a result, even the most carefully orchestrated patent landscape clearing mechanisms -- whether implemented through patent pools or pledges -- cannot assure complete freedom from patent risk; there may always be “outsiders” who are not bound by the patent non-assertion commitments of others.120 For example, the Bluetooth standard for short-range wireless connectivity was developed by a group of firms that each committed to license its applicable patents to manufacturers of Bluetooth-enabled products and components without charge. Yet a non-practicing entity (NPE) that did not participate in the development of the standard held a patent, originally filed in connection with an unrelated technology, that was found by a Texas jury to read on Bluetooth and which entitled the NPE to a multi-million dollar damages award against a manufacturer of Bluetooth-enabled products.121

116 Contreras, Patent Pledges, supra note 113, at 590-92 (identifying philanthropic pledges); Contreras, Evolving Landscape, supra note 115, at 7 (expanding category to encompass broader corporate mission such as corporate social responsibility and employee morale).
119 cite
This being said, it is not essential that complete clearance exist in order for product markets to be made more accessible through pledging programs. The relevant question is how much “freedom to operate” is conferred by a particular pledge or pledge community. If infringement risk is reduced below a certain threshold, then a market may be considered open, even if residual risk exists from outsider patent suits. This point is discussed in greater detail when evaluating the adoption of the Open COVID Pledge within different market segments in Part IV.C, below.

The following sections of this Part discuss IP pledges that have been made in response to global health crises – the EcoPatent Commons, an effort to make green/clean technologies available in the fight against climate change, and a number of recent pledges made in response to the COVID-19 pandemic.

2. The EcoPatent Commons

In January 2008, IBM, Nokia, Pitney Bowes and Sony launched an innovative project known as the EcoPatent Commons (EcoPC), the announced mission of which was “to manage a collection of patents pledged for unencumbered use by companies and IP rights holders around the world to make it easier and faster to innovate and implement industrial processes that improve and protect the global environment.”\(^\text{122}\) A total of thirteen firms eventually joined the EcoPC and collectively pledged a total of 248 “green technology” patents between its formation in 2008 and its discontinuation in 2016.\(^\text{123}\)

However, despite significant coverage in the press and academic literature,\(^\text{124}\) a study conducted by Contreras, Hall and Helmers found that the EcoPC failed to achieve any meaningful diffusion of the pledged technologies.\(^\text{125}\) Through interviews of EcoPC participants and organizers, the authors identified several possible explanations for the EcoPC’s inability to achieve its goals:

[There were] several common critiques of the EcoPC’s structure and operational processes that help explain our quantitative findings, particularly EcoPC’s inability to provide information regarding the usage of contributed technologies. Another major impediment to diffusion was the lack of information provided by pledging companies beyond the patent documents that could have helped potential users (especially in developing countries) see potential applications of the pledged technologies. Finally, no concerted effort was made to group or link patents in the commons to any

Tex. Jun. 5, 2013). See also Contreras, Stranger, supra note 120, at x (finding that a material number of assertions of standards-essential patents are brought by outsiders to the standardization process).


\(^{123}\) See Contreras, et al., EcoPatent, supra note 51, at 74.

\(^{124}\) Id. at 68-69.

\(^{125}\) Id. at 70-71.
particular technology. This lack of coordination may have limited synergies that could have been created through a more deliberate approach to the technologies covered by contributed patents.\textsuperscript{126}

Despite these shortcomings, the EcoPC was an ambitious and innovative effort directed toward an urgent public need. As such, it offers valuable lessons for the designers of future industry-driven efforts to open intellectual property for public use, and in many respects served as a model for the Open COVID Pledge.

3. COVID-19 Pledges

The COVID-19 pandemic gave rise to a number of unilateral and collective IP pledges, several of which were made during the early days of the pandemic.\textsuperscript{127} Several of these are described below.

\textbf{a. Wellcome Trust Publishers Pledge}

The first pandemic-related IP pledge related to copyrights. On January 31, 2020, the Wellcome Trust, a large UK-based medical charity, led a group of approximately thirty scientific and medical publishers in committing to make all peer-reviewed research publications relating to COVID-19 available without charge on an open access basis.\textsuperscript{128} The signatories included publishers such as Elsevier, Cell Press, Karger, the JAMA Network, the New England Journal of Medicine, Oxford University Press, Springer Nature, Taylor & Francis, Wiley and Wolters Kluwer. The initiative echoed earlier pledges of similar scope made with respect to research concerning the earlier Zika and Ebola outbreaks.\textsuperscript{129}

\textbf{b. Ventilator Manufacturers}

Some of the first pandemic-related patent pledges were made by hospital ventilator manufacturers Smiths Group (March 21, 2020) and Medtronic, Inc. (March 30, 2020). In connection with its pledge, each of these companies released the electronic design files associated with a particular ventilator model and

\textsuperscript{126} Id. at 71.
\textsuperscript{127} See Jorge L. Contreras, et al., Pledging intellectual property for COVID-19, 38 Nature Biotech. 1146, 1147, Table 1 (2020). A summary can be found in Table 1, infra.
authorized others to use those files and accompanying software to manufacture and sell ventilator products on a royalty-free basis.\footnote{130}{See Reuters, UK’s Smiths makes ventilator available to other producers, Reuters, Mar. 21, 2020; Medtronic, Medtronic Shares Ventilation Design Specifications to Accelerate Efforts to Increase Global Ventilator Production, Mar. 30, 2020. Though neither the Smiths nor the Medtronic pledge specifically mentions patents, the license grant of the Medtronic pledge speaks in terms of the statutory rights of a patent holder (“Medtronic hereby provides you a non-exclusive, royalty-free, world-wide license to the Design Materials to use, make, have made, manufacture, have manufactured, sell and have sold a ventilator … in response to the COVID-19 pandemic”)}

The Smiths pledge is not publicly available and appears to be extended only to other members of the UK government’s Ventilator Challenge Consortium.\footnote{131}{See Contreras, et al., Pledging, supra note 127, at 1147 Table 1.}

Medtronic requires any user that wishes to download its design files to register on its web site.\footnote{132}{Medtronic, Register to Download Ventilator Files, https://www.medtronic.com/us-en/e/open-files.html?cmpid=vanity_url_medtronic_com_openventilator_Corp_US_Covid19_FY20 (visited Jan. 25, 2021).} It then grants users a non-exclusive license that extends until the later of the end of the WHO-declared Public Health Emergency of International Concern or October 1, 2024.\footnote{133}{Medtronic License, supra note 130.} The license requires users that modify the Medtronic files or software to make those modifications available on terms identical to those extended under Medtronic’s license (i.e., a share-alike or copyleft-style requirement).\footnote{134}{Id. See Parts x and x, supra (discussing share-alike and copyleft licenses).}

c.  \textit{UC Berkeley Innovative Genomics Institute}

The Innovative Genomics Institute (IGI) at University of California Berkeley is a Howard Hughes-funded, semi-autonomous research group that has achieved global recognition for its groundbreaking work on CRISPR-Cas9 gene editing (an accomplishment for which its President, Jennifer Doudna, received the Nobel Prize in Chemistry for 2020). On March 23, IGI released an “Emergency COVID-19 Technology Pledge” in which it committed to make technology that its researchers developed after March 13, 2020 available on a royalty-free basis to any entity conducting research on the diagnosis or treatment of COVID-19.\footnote{135}{https://innovativegenomics.org/news/our-pledge-to-share-covid-19-ip/. See also University of California, Berkeley, Office of Technology Licensing, Special Non-Exclusive Limited License Between [ ] And The Regents Of The University Of California For Covid-19 Limited Applications Of Intellectual Property (copy on file with the author).} To effectuate these rights, a user is required to enter into a license agreement with the University of California enumerating the specific patents that are licensed.
d. Harvard-MIT-Stanford

On April 7, 2020 (the same day that the OCP was launched), several major research universities publicly committed to make their intellectual property broadly available for use in the COVID-19 response. One such effort in the U.S. was led by Harvard University, the Massachusetts Institute of Technology (MIT) and Stanford University (collectively referred to as HMS). The HMS “COVID-19 Technology Access Framework” is described as follows:

We are committed to implementing COVID-19 patenting and licensing strategies that are consistent with our goal of facilitating rapid global access. For most types of technologies, this includes the use of rapidly executable non-exclusive royalty-free licenses to intellectual property rights that we have the right to license, for the purpose of making and distributing products to prevent, diagnose and treat COVID-19 infection during the pandemic and for a short period thereafter.\(^{136}\)

As of January, 2021, twenty additional U.S. research institutions and one non-U.S. university had also “signed” this commitment.\(^{137}\) While the HMS Framework does not utilize a self-executing “public” licensing agreement, the universities commit to using a “rapidly executable” agreement. The licenses to be granted are both non-exclusive and royalty-free, features designed to ensure broad access. The term of the licenses is the COVID-19 pandemic plus “a short period thereafter”, and their scope is limited to making and distributing products intended to prevent, diagnose and treat COVID-19 infection.

One important feature of the HMS licenses is their express expectation that users will commit “to distribute the resulting products as widely as possible and at a low cost that allows broad accessibility during the term of the license”.\(^{138}\) This type of “downstream” pricing constraint is intended to ensure that technology licensed on a royalty-free basis is not priced so high by manufacturers that certain users cannot afford it.

It is unclear at this time how many, and to whom, licenses have been granted under the HMS Framework, and with respect to what intellectual property, as this information does not appear to be publicly available.


\(^{137}\) The full list includes: The Broad Institute of MIT and Harvard, Cornell University, Dartmouth College, Drexel University, Georgetown University, King Abdullah University of Science and Technology, Memorial Sloan Kettering Cancer Center, Mississippi State University, Northeastern University, Ohio State University, Oregon Health & Science University, Oregon State University, RTI International, University of Arkansas for Medical Sciences, University of Louisiana at Lafayette, University of Maryland, College Park, University of Nevada Reno, University of South Alabama, University of Texas at San Antonio, Virginia Commonwealth University, and Yale University. Id. (visited Jan. 27, 2021).

\(^{138}\) Id.
e. Oxford and AstraZeneca

Approximately two weeks after the announcement of the HMS Framework, Oxford University unveiled a similar program. But in August, Oxford is reported to have granted pharmaceutical giant AstraZeneca an exclusive license to the university’s COVID-19 vaccine technology with no pricing constraints. Oxford’s apparent abandonment of its earlier pledge has attracted criticism, but has not yet been challenged on legal grounds.

Interestingly, AstraZeneca itself pledged to distribute the vaccine “at no profit for the duration of the pandemic”, though some debate has emerged regarding the company’s apparent discretion to declare an end to the pandemic far earlier than public health authorities.

f. AbbVie

On March 18, 2020, Israel’s Minister of Health issued a permit for the importation of generic versions of AbbVie’s patented AIDS drug Kaletra for the purpose of treating COVID-19. Two days later, AbbVie announced that it would no longer enforce patents relating to Kaletra anywhere in the world. AbbVie’s pledge was widely viewed as a response to Israel’s action, and was possibly at attempt to avoid compulsory licensing orders by other governments.

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142 See Contreras, Patent Pledges, supra note 113 (discussing legal grounds for enforcement of patent pledges under U.S. law).
144 See Mancini, supra note 140.
145 See note x, supra, and accompanying text.
146 See Donato Paolo Mancini and Hannah Kuchler, AbbVie drops patent rights for Kaletra antiviral treatment, FINANCIAL TIMES, Mar. 23, 2020; Ed Silverman, AbbVie will allow generic copies of its HIV pill in Israel after the government approved a license, STAT, Mar. 20, 2020.
147 See Silverman, supra note 146 (noting AbbVie’s historical “aversion to compulsory licensing” in other contexts (quoting Prof. Brook Baker)).
g. **Open COVID-19 Declaration (Japan)**

In early May, 2020, two Japanese business executives and a professor from Kyoto University organized a Japan-focused pledge community similar to the OCP. The pledge, administered by a venture-backed biotechnology firm called GenoConcierge, quickly attracted major Japanese industrial firms from the automotive, electronics and healthcare industries. Pledgors include LSI Medience and SRL Inc., which provide COVID-19 diagnostic testing, Mitsubishi Chemical, which operates in the health care sector, and Teijin, a pharmaceutical manufacturer. To date, the Japanese program claims that over one hundred organizations have pledged nearly one million patents toward "any activities whose sole purpose is stopping the spread of COVID-19, including diagnosis, prevention, containment and treatment." In addition to patents, the pledge covers utility models, designs and copyrights.

Like the OCP, the Japanese pledge permits firms to modify the terms on which they are willing to make their IP available to users. As reported by one press account, eighteen pledgors had modified these terms by late May, 2020. The modifications include requirements that users notify pledgors of their activities and the patents that they intend to use, and potential limitations to the term of the license extended. Concerns have been raised regarding the language of the pledge, which extends only to activities whose “sole” purpose relates to COVID-19.

h. **Moderna**

On October 8, 2020, mRNA vaccine maker Moderna, Inc. publicly pledged not to enforce its COVID-19 related patents against “those making vaccines intended to combat the pandemic.” In its pledge, Moderna refers to its “special obligation under the current circumstances to use our resources to bring this pandemic to an end as quickly as possible.” Yet other benefits may accrue to Moderna from its commitment not to assert its patents. First, the U.S. National Institutes of Health (NIH), which funded at least some of Moderna’s vaccine R&D, is reported to have

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149 Id.
151 Id.
152 Id.
153 Id.
154 Id. (discussing possible interpretations of “sole purpose”).
156 Id.
claimed an interest in some of Moderna’s patents.\textsuperscript{158} Moderna’s pledge could have helped to persuade NIH to drop its claims to the patents, given their reduced licensing value. In addition, one watchdog group has alleged that Moderna failed to make legally required disclosures of federal funding for the inventions underlying some of its patents, leading to an ongoing investigation by the Defense Advanced Research Projects Agency (DARPA).\textsuperscript{159} Unlike most of the other pledgers discussed above, Moderna was the subject of a significant public campaign to make its vaccine technology more broadly available.\textsuperscript{160}

\textit{Table 1}, below, summarizes the principal terms of these pledges made in response to COVID-19 and situates the Open COVID Pledge chronologically within this group.

\begin{table}...
\end{table}


## Table 1

Intellectual Property Pledges in Response to COVID-19

<table>
<thead>
<tr>
<th>Pledge</th>
<th>Date</th>
<th>Form</th>
<th>Duration</th>
<th>IP</th>
<th>Restrictions and limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wellcome Trust Publishers’ Group</td>
<td>3/16/20</td>
<td>Pledge</td>
<td>n/a</td>
<td>Publications relating to COVID-19</td>
<td>n/a</td>
</tr>
<tr>
<td>Fortress/Labrador</td>
<td>3/17/20</td>
<td>Pledge</td>
<td>n/a</td>
<td>Diagnostic patents relating to COVID-19</td>
<td>n/a</td>
</tr>
<tr>
<td>AbbVie</td>
<td>3/19/20</td>
<td>Pledge</td>
<td>n/a</td>
<td>Kaletra/Aluvia patents</td>
<td>n/a</td>
</tr>
<tr>
<td>Smiths</td>
<td>3/21/20</td>
<td>Pledge</td>
<td>?</td>
<td>Ventilator designs, software, patents</td>
<td>Only offered to members of UK Ventilator Challenge Consortium</td>
</tr>
<tr>
<td>UC Berkeley Innovative Genomics Inst.</td>
<td>3/23/20</td>
<td>Pledge + Bilateral License</td>
<td>Term of patents</td>
<td>Specified patents</td>
<td>Only covers technology invented after 3/13/20</td>
</tr>
<tr>
<td>Medtronic</td>
<td>3/30/20</td>
<td>Public License</td>
<td>PHEIC* or 12/1/24</td>
<td>Designs, software, patents</td>
<td>Sharealike for modifications; User registration/identification</td>
</tr>
<tr>
<td>Open COVID Pledge</td>
<td>4/7/20</td>
<td>Pledge + Public License</td>
<td>Pandemic** + 1 year or 1/1/23</td>
<td>Patents, copyrights</td>
<td>Defensive suspension</td>
</tr>
<tr>
<td>Harvard-MIT-Stanford</td>
<td>4/7/20</td>
<td>Pledge + Bilateral Licenses</td>
<td>Pandemic** + short period</td>
<td>unspecified</td>
<td>Licensed products must be distributed at low cost</td>
</tr>
<tr>
<td>Oxford</td>
<td>4/8/20</td>
<td>Pledge + Bilateral Licenses</td>
<td>Pandemic**</td>
<td>unspecified</td>
<td>Licensed products must be distributed free of charge, at-cost or cost + limited margin</td>
</tr>
<tr>
<td>Open COVID-19 Declaration (Japan)</td>
<td>5/7/20</td>
<td>Pledge</td>
<td>PHEIC*</td>
<td>Patents, utility models, designs, copyrights</td>
<td>Applies to activities whose “sole purpose” is addressing COVID-19. Add'l restrictions may be added by pledgers</td>
</tr>
<tr>
<td>Gilead Sciences</td>
<td>5/12/20</td>
<td>Licenses</td>
<td>Pandemic**</td>
<td>Remdesivir patents</td>
<td>Licensed royalty-free to 5 Indian and Pakistani generic drug makers</td>
</tr>
<tr>
<td>Moderna</td>
<td>10/8/20</td>
<td>Pledge</td>
<td>n/a</td>
<td>mRNA vaccine patents</td>
<td>n/a</td>
</tr>
</tbody>
</table>

* Duration of WHO-declared Public Health Emergency of International Concern
** Duration of WHO-declared COVID-19 pandemic
III. ANATOMY OF THE OPEN COVID PLEDGE

In early 2020, as COVID-19 infections rapidly spread around the world and stories of patent-related impediments to the supply of critical technologies began to surface, groups of scientists, engineers, and advocates came together at conferences and via discussion lists and collaboration platforms to explore ways that they might help. Would it be possible, some wondered, to create a platform that could enable, and thereby encourage, a broad range of organizations to commit their IP to the fight against the pandemic? The legal structures described in Part II – open source code licensing, Creative Commons licenses and earlier IP pledges -- informed the effort to create a generalized platform for the contribution of intellectual property to this cause. This Part III describes the genesis and evolution of this effort and details some of the considerations that went into the design and drafting of the Open COVID Pledge.

A. The Role of a New COVID-19 Pledge Community

As discussed in Part I, there are several ways in which access to critical technologies may be facilitated in times of crisis. These include governmental measures, such as compulsory licensing, as well as voluntary pools coordinated by non-profit or intergovernmental bodies. The sudden onset and evident seriousness of COVID-19 led to rapid interventions by a handful of governments,161 but these initial actions did not precipitate a broader cascade of governmental relaxation of IP rights. Especially in the United States, strong internal opposition to the weakening of IP rights made such interventions unlikely.162 Moreover, formal patent pools, while potentially valuable, require significant time, funding, administrative support and political willpower to develop.163

In contrast, voluntary pledges that a number of IP holders, such as Medtronic, Smiths Group and AbbVie, made early in the pandemic achieved expanded access to key technologies quickly and with a minimum of administrative overhead. But as valuable as these unilateral actions were, they represented one-off interventions designed with a particular company’s rights, goals and markets in mind.

The founders of the Open COVID Pledge believed that a more generalized platform for IP contributions could facilitate pledges by organizations that did not wish to re-invent the wheel (with the concomitant expenditures of managerial and legal resources), or that wished to participate in a collective activity with broad-based industry support. Such a platform could also offer an avenue for meaningful contributions by holders of IP in industries that were not directly targeted by organized pooling efforts (i.e., while vaccines and therapeutics have received

161 See Part I.B.1, supra.
162 See id.
163 See Part I.C.3, supra
significant attention in international pooling proposals, medical equipment and software applications have not).

Such a legal framework, once available, could also be utilized by governments that wished to encourage (or require) parties receiving research grants and procurement funding to make the resulting IP broadly available. In a similar vein, a common legal framework for pledging IP could be used by international pooling efforts such as the WHO’s COVID Technology Access Pool (C-TAP) as a lightweight alternative to a formal IP pool structure.

For all of these reasons, the need presented itself for an independent, lightweight framework to enable IP sharing by a broad range of entities in the fight against COVID-19.

B. Organization – The Open COVID Steering Committee

The Open COVID Pledge arose from discussion threads among researchers at the Innovative Genomics Institute at University of California Berkeley, the Department of Genetics at Stanford University, and the Engineering Department at the University of Cambridge. As these discussions moved toward potential legal interventions, legal academics and practitioners familiar with IP sharing structures were invited to join.

By mid-March, 2020, at least three sets of written proposals for a common IP sharing platform had been circulated by different groups. Shortly thereafter, a self-designated core of volunteers coalesced to reconcile the different approaches. This small group referred to itself as the Open COVID Coalition, and later, as the OCP Steering Committee, and included four academic scientists and engineers, a practicing engineer, two legal academics and two practicing attorneys, with individuals based at various organizations in the western U.S. and the UK.

Most of these individuals had prior professional or personal connections with at least some other members of the group, thereby leveraging personal networks to facilitate both formation and collaboration. Importantly, each individual brought different but overlapping expertise to the group in complementary areas including biological science, product engineering, software development, technology dissemination, patent analysis, and intellectual property licensing.

164 See Jorge L. Contreras, Expanding Access to Patents for COVID-19 in Assessing Legal Responses to COVID-19 at 158, 160 (Report Sponsored by the de Beaumont Foundation and American Public Health Association, Aug. 18, 2020); Frank Tietze [cite]
165 See C-TAP Concept Paper, supra note 93, at 5 (integrating the OCP into WHO’s C-TAP program).
166 The material in this Part is based on the author’s personal recollections, notes and email archives.
167 See note 28, supra.
168 Later, a marketing specialist was added. Additional assistance was provided by a number of student volunteers at Stanford University, Cornell University and elsewhere.
169 The author, for example, had prior connections with four other Steering Committee members.
By mid-March, travel restrictions were in place across much of the world, so frequent meetings were held during late March and early April via Zoom, and document drafting and review progressed rapidly through email, Google Docs and the Slack collaboration platform.

C. Design Requirements

The goal of the Steering Committee was to create a legal framework for the rapid and broad commitment of IP rights to facilitate the discovery, development, manufacture and supply of critical technologies and equipment in the worldwide response to COVID-19. Such a framework would need to accommodate the requirements of both IP holders and IP users across multiple jurisdictions.

As such, a number of fundamental design requirements were recognized early during the drafting process of what would come to be known as the Open COVID Pledge.

The fundamental design requirements for the OCP were:

1. **Legal Enforceability** – any commitment made by IP holders had to be legally enforceable. Mere aspirational statements and expressions of intent were not sufficient. The commitment of IP to the COVID-19 response via this mechanism was intended to be binding and, if need be, enforceable through the legal system. What’s more, given the number of lawsuits brought by PAEs, even in the COVID-19 area, the pledge needed to bind not only the pledgor, but any subsequent holder of the pledged IP.

2. **Broad Use of Pledged IP** – the commitments made through the OCP should ensure the broadest possible use of the committed IP. This principle was recognized as important to ensure that the likely global demand for medical products and compounds would be addressed as expeditiously as possible. It was recognized that a requirement of broad usage would rule out the granting of exclusive licenses. However, it was also believed that the typical rationale for exclusive licensing – the need to give large financial incentives to innovators in order to undertake significant development risks and costs – might be offset in the context of COVID-19 by governmental grant and procurement programs that could provide enormous financial incentives to innovators.

3. **Supplier Acceptance** – the legal framework for making commitments should not be so burdensome or punitive to IP holders that it would dissuade them from participating. That is, the requirements on IP holders (suppliers) should be as

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170 As noted in Part II, both Labrador Diagnostics and Swirlate, which asserted patents covering COVID-19 applications, are PAEs that acquired their patents from prior owners (Theranos and Panasonic, respectively). The binding nature of IP pledges on successive IP holders has been discussed at length in the literature and has been the subject of several disputes. See Jorge L. Contreras, *A Market Reliance Theory for FRAND Commitments and Other Patent Pledges*, 2015 UTAH L. REV. 479, x (2015).

reasonable as possible, within the constraints established by Requirements 1 and 2. In this way, the OCP should reflect the design of other open innovation frameworks “both to keep proprietary technologies safely protected within the boundaries of an integrated firm and to govern the collaboration and knowledge exchange across large ecosystems of actors trying to jointly address complex challenges.”

As illustrated by Figure 2, these three requirements were seen as interacting with and counterbalancing one another. For example, an overly legalistic structure (e.g., one requiring signed and notarized contracts for every transaction) could deter both IP holders and users from participating. Yet an insufficiently binding arrangement, while perhaps attractive to IP holders, would offer little comfort to potential IP users. Likewise, structures that were too accommodating to users, such as contribution of IP to the public domain, might be unattractive to IP holders. What was needed was a balance among these three fundamental requirements.

D. Design Principles

From the three fundamental design requirements for the OCP emerged a set of design principles that guided the creation of the OCP legal instrument. These design principles included the following:

172 McGahan, et al., supra note 33, at 55.
173 While some scholars have advocated an increased use of the public domain for open innovation (see, e.g., Clark D. Asay, A Case for the Public Domain, 74 OHIO ST. L.J. 753 (2013)), this approach is often less appealing to IP holders than pledges because it represents an apparent abandonment of potentially valuable assets, it eliminates the holder’s ability to enforce IP against unauthorized uses (i.e., beyond the scope of the relevant pledge or license) and it relinquishes a potential weapon that can be used defensively in IP litigation. For these reasons, even OSS licenses do not constitute a contribution to the public domain. See note 97, supra.
1. **Simplicity** – in order to drive adoption by both IP holders and users, it was determined that the legal structure for the OCP should be as simple and intuitive as possible. In this respect, the Creative Commons suite of licenses was viewed as an exemplar – the top-level CC ‘tags’ are straightforward and elegant in their design and understandable to non-lawyers around the world, yet each tag is linked to a comprehensive licensing agreement that contains a range of necessary terms and conditions.\(^{174}\)

2. **Uniformity** – in order to engender trust and to accelerate adoption, it was determined that the OCP should offer a uniform set of terms for adoption by IP holders. Like the Creative Commons licenses and popular OSI-certified OSS licenses, the use of a known set of terms that have been vetted and adopted by others is likely to achieve rapid uptake by IP holders. Likewise, from the perspective of users, there is significant benefit in using IP that is licensed under a consistent and well-understood set of terms, rather than a patchwork of bespoke licenses that varies from licensor to licensor. Uniform in-license terms enable a user to conduct its business without concern that certain licenses may not permit the desired activity, and without detailed monitoring of multiple licensing arrangements.

3. **Self-Execution** – it was determined that, like Creative Commons and OSS licenses, as well as many patent pledges, the OCP should be a self-executing and anonymous license that did not require negotiation or signature by either party. Interposing administrative steps such as these into the licensing process would, it was felt, substantially lengthen the time required for each transaction and reduce the overall uptake of contributed IP. Likewise, the introduction of a negotiated license, as well as requirements for tracking and reporting of use, could deter small and unsophisticated parties from using contributed IP. Thus, unlike the pledge frameworks proposed by Berkeley IGI and HMS, the OCP would not require any form of written or electronic acknowledgement by users. Rather, the OCP would make IP available to anyone who wished to use it with no strings attached.

4. **Limited Scope** – from the standpoint of attracting IP holders, it was important to limit the scope of the Pledge to the COVID-19 pandemic and no more. As noted above, potential therapies, medical equipment and response systems that could be used in connection with COVID-19 might have existing and new uses beyond the pandemic. Yet asking IP holders to relinquish all potential applications of their technology would be excessive. Thus, the scope of the OCP was limited to the COVID-19 pandemic and related activities. In this sense, the OCP resembled the pledge made by pharmaceutical manufacturer AbbVie, which pledged not to assert patents covering its drug Kaletra, but only to the extent that the drug was used as a therapy for COVID-19 and not as a treatment for AIDS (the drug’s principal use and source of revenue).\(^{175}\) In a complementary vein, it is possible that a pledge of rights could popularize a particular technology developed by the

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\(^{175}\) See notes x, *supra*, and accompanying discussion.
pledgor, leading to potential commercial licensing opportunities after the end of the pandemic or in fields beyond COVID-19.176

5. **No Charge** – the crux of the OCP commitment is that it allows the use of pledged IP without charge. There is little public benefit to facilitating or promoting paid licenses by IP holders. IP holders who wish to charge for licenses to use their IP are already in a position to do so, and potential users may approach them to negotiate a license on commercial terms.177

In some industries, particularly electronics and telecommunications, participants in technical standards development organizations (SDOs) are required to commit to license their patents to users of standards on terms that are “fair, reasonable and nondiscriminatory” or FRAND.178 This type of pledge seeks to ensure broad adoption of the standardized technology while allowing patent holders to recoup their investment in technology development. The Steering Committee rejected this approach, however, as the meaning of FRAND, even in industries where it has been used for decades, is hotly contested and has led to significant litigation around the world.179

In order to achieve the broadest possible dissemination and use of pledged IP, the Steering Committee determined that licenses must be free of charge, even if the inability to charge deters some IP holders from participating.180 Moreover, the absence of usage charges substantially contributes to the simplicity, uniformity and self-executability of the Pledge, as it does with Creative Commons and open source software licenses.

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176 This “loss leader” strategy has been used to explain other IP pledges as well. See Contreras, *Patent Pledges*, supra note 113, at 573 (describing “inducement” type pledges in which “the pledgor calculates that it is likely to derive greater benefit from the behavior that it seeks to induce in others than from using its patents to exclude others from the market.”)

177 For this reason, we saw little value in the U.S. Patent and Trademark Office’s vaunted “Patents 4 Partnerships IP Marketplace Platform”, *supra* note x.


180 See discussion of potential financial motivations for lack of participation in Part x, *infra*. 
E. Legal Structure

The legal structure for the Open COVID Pledge is driven by the fundamental Design Requirements and Principles described in Parts C and D, above. The requirement for legal enforceability, including the need to ensure that subsequent holders of IP are bound by the pledgor’s commitments, suggested that the OCP be supported by a legally binding license agreement.\textsuperscript{181} Yet the design principle of simplicity dictated that the OCP be presented in a short and non-technical format, easily understandable to researchers and other non-lawyers. In this respect, the Creative Commons licenses offered an attractive model. As discussed in Part II.B, the different CC licensing modes are described with intuitive labels and graphical icons that are unobtrusively linked to more comprehensive legal licensing agreements in a two-tier structure. Though the formal CC licensing agreements are legal documents requiring a degree of legal sophistication to understand, most users rely primarily on the simple descriptors of licensing terms when deciding how to license their works.

This being said, the license agreements utilized by CC are, like OSS licenses, “public” licenses that bind all persons and entities electing to download or use the licensed content, rather than bilateral, signed licensing agreements. While the Berkeley IGI, HMS and Oxford pledges require users to execute individual license

\textsuperscript{181} While numerous legal arguments have been advanced regarding the enforceability of IP pledges standing alone (see Contreras, Market Reliance, \textit{supra} note 170, at x (discussing pledge enforcement theories based on contract, antitrust, estoppel and property law)), a more conservative approach utilizes a written licensing agreement, as licenses are typically interpreted as running with the licensed IP, notwithstanding a change of underlying ownership. See [CONTRERAS, LICENSING, \textit{supra} note 100, at x.]}
agreements, the design principle of self-execution suggested that the OCP use the simpler approach of CC and OSS, with public licenses that do not require individual signature and delivery.

Accordingly, a one-sentence “pledge” statement was developed, stating, at a high level, that the IP holder pledged certain IP to the fight against COVID-19. This pledge sentence was preceded by two introductory sentences describing the urgent need for such a pledge. After the pledge, a sentence referencing the more formal licensing agreement was added. The final text of the OCP, as released, read as follows:

Immediate action is required to halt the COVID-19 Pandemic and treat those it has affected. It is a practical and moral imperative that every tool we have at our disposal be applied to develop and deploy technologies on a massive scale without impediment.

**We therefore pledge to make our intellectual property available free of charge for use in ending the COVID-19 pandemic and minimizing the impact of the disease.**

We will implement this pledge through a license that details the terms and conditions under which our intellectual property is made available.

To implement a self-executing system for the OCP, a clickable “Make the Pledge” button was inserted below the text of the pledge. When the button is clicked, the user is taken to a set of instructions for formalizing the relevant licensing terms. Three steps are required in order for an IP holder to make the pledge:

1. It must issue a public statement that it is making the Open COVID Pledge (i.e., by posting on a web site, issuing a press release, etc.),

2. It must adopt a licensing agreement (see below) detailing the terms and conditions under which its intellectual property is made available, and

3. It must email the Pledge organizers a link to the public statement and license, as well as a point of contact and a copy of the organization’s logo.

The above approach ensures that the IP holder informs the public that it has pledged certain IP under the terms of the OCP, and enables the Steering Committee to announce this fact as well. In practice, the Steering Committee has posted the logos of pledgors on its own web site shortly after they have made the pledge, both as recognition of their commitment and also to inform the user community that IP held by these entities is available under the terms of the Pledge.

**F. Key License Terms**

Armed with a set of design principles and an overarching legal structure, the Steering Committee, with input from the legal departments of a handful of early potential pledgors, next developed a set of formal licensing terms to effectuate the
Pledge. These terms were incorporated into a set of “template” license forms (referred to as Open COVID Licenses) that could easily be designated and adopted by pledgors.\textsuperscript{182} Below are some of the considerations that informed the development of the Open COVID Licenses, as well as a number of concessions and trade-offs that were dictated by the design principles described above. For reference, the full text of an Open COVID License is included in Appendix A.

1. Licensed Rights

The Open COVID Licenses cover two forms of intellectual property: patents and copyrights. As described above, concerns regarding patents motivated the project from the beginning. Nevertheless, the Steering Committee debated whether to require pledgors to license their entire worldwide portfolio of patents, or to allow pledgors to select certain patents for licensing. From an administrative standpoint, a blanket portfolio license would be easier to execute, whereas a license of specified patents could become complex with detailed descriptions of particular patent families and jurisdictions. Because simplicity was an overriding concern of the Steering Committee, it was decided that the Open COVID Licenses would be drafted as worldwide portfolio licenses, but pledgors would be permitted to adopt customized licenses covering only selected patents (see Compatibility Assessment – Part III.G, below).

The decision was made to include copyrights within the scope of the OCP given their importance to software and digital design files, both of which are integral to equipment and systems used in response to the pandemic. The pledge of copyrighted scientific articles by the Wellcome Trust group (see Part II.C.3.a, above) also weighed in favor of including copyrights in the Open COVID Licenses. However, given sensitivities of some potential pledgors in the software industry,\textsuperscript{183} the OCP allows pledgors to choose a form of license that covers both patents and copyrights, only patents or only copyrights.

Other forms of intellectual property are not covered by the OCP. Trademarks are specifically excluded, as a licensee that manufactures a patented or copyrighted product under an OCL should not be permitted to label it with the licensor’s brand or logo absent a commercial relationship between the two.\textsuperscript{184} Such relationships typically require strict quality control procedures, which often involve the licensor’s careful selection of potential licensees and monitoring of the licensee’s

\textsuperscript{182} It was anticipated from the beginning that some pledgors would insist on drafting their own licensing agreements. To accommodate this approach, a set of compatibility criteria were developed. See Part x, infra.

\textsuperscript{183} For example, a software vendor might be willing to allow others to develop and distribute their own software that is covered by the pledgor’s patents, but not to copy and distribute the pledgor’s software without payment.

\textsuperscript{184} See Theodore C. Max & Lindsay van Keulen, 3M Takes Action to Protect Its Brand from Price Gouging And Trademark Infringement, 10 NATL. L. REV. No. 126 (May 5, 2020); Michael R. Justus, Unmasking the Takeaways from 3M’s Lanham Act Litigation Against N95 Mask Price Gouging, 10 NATL. L. REV. No. 218 (Aug. 5, 2020).
product quality. Because such activity could impose substantial costs on the pledgor, and could not practically be effected through a lightweight public license, no trademark or related rights are granted.

Similarly, the OCP does not cover trade secret, know-how or similar rights, nor does it require that the pledgor provide licensees with training, technical assistance, knowledge transfer or materials. The Steering Committee was aware that, for certain products such as vaccines, patent licenses alone may be insufficient to enable a secondary supplier to manufacture the product. As the author has previously observed, “complex technologies often cannot be understood and implemented, especially by non-experts working in the developing world, merely through patent disclosures.”

For this reason, initiatives such as the Medicines Patent Pool and the proposed WHO COVID-19 pool aspire to include a broad range of enabling rights, materials and knowledge beyond patent rights. Nevertheless, the overriding design principles of simplicity and pledgor acceptability ruled out any requirement that pledgors take affirmative steps to train or enable licensees to make use of licensed rights. As with trademark quality control, it was felt that imposing costly and potentially unbounded obligations on pledgors would make the OCP unattractive to many pledgors. Instead, the approach of the OCP is to make available legal rights only, without affirmative service or technology delivery obligations. While this could make the OCP less useful in the context of know-how-heavy products such as vaccines (see Part IV.B.2, below), this compromise was felt to be necessary to secure a broad range of patent and copyright licenses that could be profitably utilized without the provision of additional services or materials.

2. License Scope

The scope of the Open COVID Licenses encompasses “diagnosing, preventing, containing, and treating COVID-19,” including all research relating to COVID-19. While this field of use is broad, it is also constrained. As noted above, many

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185 See CONTRERAS, LICENSING, supra note 100, at x.
187 Contreras, et al., EcoPatent, supra note 51, at 82-83 (identifying lack of technology transfer as a significant shortcoming of the EcoPatent Commons). See also Reynolds et al., supra note 51, at x (discussing need for technology transfer in order to create effective ‘research commons’ for solar climate engineering).
188 See Part x, supra.
189 See OCP FAQ, supra note x (“The Open COVID License is simply a grant of legal rights. It does not require any cooperation, training, technical assistance or consultation by the pledgor, nor does it require reporting or consultation by the licensee, though we encourage those taking advantage of the pledge to share how they are using the pledge if appropriate, in order to encourage others to join in. If a cooperative arrangement would benefit both parties, we encourage them to negotiate one separately, with compensation if desired.”)
190 Open COVID Pledge, FAQs, https://opencovidpledge.org/faqs/ (“Is research covered by the Pledge? Yes. All forms of research are covered.”) (visited Jan. 30, 2021) [hereinafter OCP FAQ].
technologies used in the response to COVID-19, whether diagnostics, therapeutics, protective gear, medical devices or hospital equipment, have applications and uses beyond COVID-19. A hospital ventilator, for example, can be used to treat a range of indications causing respiratory stress, and many therapeutics being tested for use against COVID-19 were originally developed and approved in connection with a range of other autoimmune disorders and infectious diseases.\textsuperscript{191} For example, AbbVie’s Kaletra drug, primarily used to treat AIDS, was considered as a potential COVID-19 therapy, and AbbVie’s unilateral pledge relating to Kaletra was limited to use in treating COVID-19.\textsuperscript{192}

The OCP is designed specifically to address the COVID-19 pandemic, not to open patents across the board for medical usage. Thus if a particular patented product is useful against both COVID-19 and another disease indication, only the use against COVID-19 is licensed under an Open COVID License; the patent holder may continue to charge for other uses.

Of course, this type of “single indication” license is vulnerable to abuse, especially as licensees are not required to report on their usage to pledgors. A licensee could conceivably sell products purportedly for COVID-19 use, with the understanding that they can (or will) be used otherwise. The Steering Committee felt that the risk of such abuse was not worth imposing more stringent reporting requirements on licensees (i.e., to achieve the goal of broad adoption). If a licensee engaged in the large-scale sale of licensed products into non-COVID markets, it is likely that the pledgor would eventually discover this abuse; it could pursue an action for infringement.\textsuperscript{193} But at the margin, the Steering Committee determined that the risk of undetected unlicensed uses did not outweigh the need for a lightweight licensing framework without onerous reporting and monitoring provisions.\textsuperscript{194}

3. Waiver of Regulatory Exclusivities

In the U.S., manufacturers of FDA-approved drugs receive a period of regulatory market exclusivity under the Hatch-Waxman Act\textsuperscript{195} that is independent of the patent protection that they may also enjoy. Exclusivity periods range from six months (for the first generic version of a drug that is approved) to three years (for a new use of a previously approved drug) to five years (for a new drug compound) to seven years (for a new “orphan” drug).\textsuperscript{196} These periods may run

\textsuperscript{191} See note 5, supra, and accompanying text.
\textsuperscript{192} See notes x, supra, and accompanying text.
\textsuperscript{193} See Contreras casebook at x (exceeding the scope of an IP license results in an unlicensed and infringing use).
\textsuperscript{194} Even in high-value commercial licensing arrangements it is difficult to prevent the sale of all licensed products for unauthorized or off-label uses. See Contreras casebook at x.
concurrently with patent protection, but because they arise independently of patent rights, the grant of a patent license does not necessarily authorize the licensee to manufacture or sell the relevant product. As a result, the Open COVID Licenses require the pledgor to waive the enforcement of any regulatory exclusivities associated with products covered by the licensed IP rights. 197

4. Term and Post-Termination Commitments

The term of the Open COVID Licenses is defined as follows:

This license is effective as of December 1, 2019 and lasts until one year after the World Health Organization declares the COVID-19 Pandemic to have ended, but in any event not beyond January 1, 2023, unless otherwise extended by the Pledgor. 198

The effective date for all licenses is December 1, 2019 to coincide roughly with the emergence of COVID-19 in Wuhan. This early date ensures that any potentially infringing activity undertaken by a licensee will be licensed retroactively once the license is granted and avoids the anomalous situation in which a licensee is authorized to operate under the licensed IP going forward, but remains liable for past infringing activity.

The license extends until the end of the WHO-declared COVID-19 pandemic plus one year. At the end of the license term (which of course may be extended by mutual agreement of the parties), the licenses granted will be terminated and of no further force or effect. Thus, if a user wishes to continue to use the licensed IP after this date, or wishes to use the licensed IP for applications other than COVID-19, it must negotiate a separate license with the IP holder.

The one-year “tail” period following the end of the pandemic is intended to permit licensees to wind down their licensed activity, recognizing that COVID-19 infections may still be prevalent in some parts of the world after COVID-19 ceases to qualify as a global pandemic. The one-year wind-down period is also intended to give licensees a reasonable period to negotiate commercial licenses with pledgors for post-pandemic usage.

The “outside date” of January 1, 2023 is intended to address the situation in which the WHO does not act expeditiously to lift its pandemic declaration. Such an outside date is not required, and the OCL permits pledgors to offer licenses that

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197 See Open COVID License – Patent Copyright – v. 1.1, Para. 3 (“REGULATORY EXCLUSIVITY - The Pledgor will not assert any regulatory exclusivity against any entity or individual for use of the Licensed IP in accordance with the license granted in Section 1, and we will not seek injunctive or regulatory relief to prevent any entity or individual from doing so.”)

198 Open COVID License – Patent Copyright – v. 1.1, Para. 2.
have no outside date, or which do not expire at all (i.e., allowing licenses to run for the full duration of the licensed IP rights).

There is no obligation on the part of pledgors to grant post-termination licenses, or to price post-termination licenses at fair or reasonable rates. Some have suggested that this lack of post-termination commitment by pledgors could result in “hold-up”, a situation in which users make substantial investments to manufacture and deploy licensed technology during the term of the license and are thus pressured to pay elevated rates to continue their use following termination.\footnote{[Siebrasse on Hold-Up]} Though the threat of hold-up is a real one, the Steering Committee deemed it more critical to make the Pledge as attractive as possible to IP holders by limiting its duration and scope solely to the COVID-19 pandemic. Unlike hold-up scenarios in other industries, in which a patent threat may be unknown prior to the investments made by users,\footnote{[wireless telecom]} potential users of pledged IP know, in advance, when the Open COVID Licenses terminate. Thus, users should have sufficient information to price their products in a manner that recoups their investments during the term of the license, without any assurance of post-license continuation.

5. No Sharealike or Grantbacks

As discussed in Part II, CC “Share-Alike” and OSS “Copyleft” licenses require that a licensee make its own modifications and improvements to the licensed technology available to others on the same open terms as the underlying rights were made available to it.\footnote{See Parts x, supra.} This approach was adopted by Medtronic in its COVID-19 ventilator pledge.\footnote{See note x, supra.} The theory behind such requirements is that the licensee obtains the licensed rights for free, and should thus contribute its own improvements to the community on a similar basis (or should at least be prevented from suing others who wish to use those improvements).\footnote{See Contreras casebook, discussing these provisions.}

The Steering Committee debated whether or not to include a Share-Alike provision in the OCL, but determined, on balance, that such a provision could dissuade potential users from adopting and using (or at least improving) the licensed IP.\footnote{One indication of this is the reluctance that many commercial enterprises have to using software that is licensed on a copyleft basis. See [Contreras, casebook].} Given the primary goal of promoting the broadest possible usage of the pledged IP, it was felt that greater dissemination would occur if users were not subject to such requirements. Thus, licensees are not required to grant any licenses with respect to their modifications and improvements to the licensed technology. This being said, pledgors who wish to impose Share-Alike requirements in their license agreements may do so and have their licenses certified as acceptable “OCL-

\footnote{[Siebrasse on Hold-Up]}\footnote{[wireless telecom]}\footnote{See Parts x, supra.}\footnote{See note x, supra.}\footnote{See Contreras casebook, discussing these provisions.}\footnote{One indication of this is the reluctance that many commercial enterprises have to using software that is licensed on a copyleft basis. See [Contreras, casebook].}
Alternative” licenses. Moreover, the Steering Committee encourages all IP holders, including licensees, to make their own pledges under the OCP.

6. Defensive Suspension

Some fields relevant to COVID-19 are characterized by frequent patent disputes and the unconditional pledging of an organization’s patents could place it at a significant disadvantage if it became involved in such a dispute. Thus, the OCL includes a clause that automatically suspends a license “if the licensee or any entity affiliated with the licensee threatens or initiates a suit or legal proceeding alleging the infringement of any patent or other intellectual property right against the Pledgor or any entity affiliated with the Pledgor.” This “defensive suspension” clause permits a pledgor to assert its IP “defensively” against a licensee that brings its own IP infringement against the pledgor.

One of the reasons that such a clause is necessary is because, as discussed in Part F.5, above, the OCL does not require that a licensee grant the pledgor any rights to modifications or improvements that the licensee makes to the licensed technology. Thus, a pledgor could find itself in the unenviable position of granting a free license to a competitor, the competitor improving the licensed technology and obtaining IP protection for that improvement, and then suing the original pledgor for using a similar improvement. The defensive suspension clause, which suspends the effect of the OCL if the licensee threatens or brings such a suit, allows the pledgor to assert its IP covering the underlying IP against the licensee. Of course, it is not a goal of the OCP to enable further IP litigation, but to orient the parties’ rights in such a manner that they are more likely to negotiate a satisfactory

205 See Part x (compatibility), infra.
206 See OCP FAQ, supra note x, (“Is the licensee required to grant any rights back to the IP holder? No. The license granted under the Open COVID Licenses is a one-way commitment from the pledgor to licensees. Licensees are not required to grant rights back to the pledgor. While this imbalance may seem unfair or inequitable in some ways, we believe that it will result in the greatest adoption of licenses by manufacturers and institutions around the world. And, of course, we encourage all holders of IP relating to COVID-19 to make the pledge as to their own IP.”)
207 The field of vaccine development is one such field. See [Rutschman]
208 For example, a party that has licensed its IP to its competitors cannot thereafter assert such IP in a counterclaim if a competitor later sues it for infringement.
209 The license is temporarily suspended rather than terminated outright to address the situation in which one division or subsidiary of a large organization asserts IP against an OCP pledgor without realizing that another division or subsidiary of the same organization is making use of a license granted under the OCP. In effect, the suspension may be “cured” by the withdrawal of the infringement claim. See OCP FAQ, supra note x (“If a licensee threatens or sues the pledgor for infringing any IP relating to COVID-19, then the license will automatically be suspended until that threat or suit is withdrawn.”)
210 Open COVID License – Patent Copyright – v. 1.1, Para. 4.
211 Such clauses are well-known in the licensing field. See, e.g., CONTRERAS, LICENSING, supra note 100, at 551 (discussing “defensive termination” clause in Apache OSS license), AM. BAR ASSN. COMM. TECH. STANDARDIZATION, STANDARDS DEVELOPMENT PATENT POLICY MANUAL 62-67 (Jorge L. Contreras, ed., 2007) (discussing defensive suspension clauses in standards policies) [hereinafter ABA Standards Manual].
commercial arrangement covering use of the licensee’s improvements. The defensive suspension clause achieves this orientation.

7. No Downstream Pricing Controls

Downstream pricing controls are used in licensing agreements to ensure that the licensee does not charge excessive prices for licensed products. For example, A grants a license to B, and requires that any products sold by B under authority of the license be priced at cost, or at reasonable levels.

Controls such as this are particularly salient when the license from A to B is granted without compensation – if A grants a free license to B, then it is not unreasonable for A to expect that B will not make excessive profits by selling licensed products. Such “downstream” pricing controls were utilized by the U.S. National Institutes of Health during the 1990s in its Cooperative Research and Development Agreements (CRADAs) with private industry, and more recently have been used in licensing agreements with the Medicines Patent Pool. The COVID-19 licensing frameworks developed by Oxford University and Harvard-MIT-Stanford also include pricing limitations for licensed products.

However, the OCL does not include downstream pricing controls for a number of reasons. First, implementing and enforcing such controls would require significant reporting by licensees and monitoring by pledgors. This, in turn, would require the establishment of confidentiality relationships between pledgors and licensees, as pricing information is often confidential. All of which substantially increases the complexity of the relationship. Second, agreements relating to product pricing, particularly if made among competitors, invariably give rise to antitrust concerns, as they (or their enforcement) could enable illegal price fixing or coordination. Finally, as noted in Part x, above, it is notoriously difficult to determine what “fair and reasonable” prices are. Imposing a condition that product pricing meet any subjective standard could be a recipe for litigation. For all of these reasons, it was determined that including pricing controls on downstream products in the OCL would introduce significant administrative burdens and disincentives for user adoption, while offering only modest benefits during the limited duration of the Pledge.

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213 [cite]
214 See Part II.C.2.c, supra. Universities have long experimented with pricing controls for products destined for sale in the developing world. See Nine Points and CONTRERAS, LICENSING, supra note 100, at 396-98 (discussing university humanitarian licensing initiatives).
8. No Warranties or Indemnities

The OCL is intended as a broad immunity from suit, rather than a guaranty that any particular product can be manufactured, sold or marketed. Thus, pledgors are not required to make any representations or warranties to licensees, and all IP is licensed on an “AS IS” basis. Licensees must assume responsibility for clearing their products against any applicable IP (including IP that is not licensed under the OCL), as well as regulatory and other governmental requirements. This approach is similar to that adopted by most OSS and CC licenses, and even with many royalty-bearing academic patent licenses.

G. Compatibility Assessment

The principle of uniformity requires that the terms on which pledged IP are licensed to users are as uniform as possible across IP holders. In order to encourage uniformity, the Steering Committee developed a set of “template” licensing agreements – one for the licensing of patents only and one for the pledging of patents and copyrights. These “Open COVID Licenses” (OCL) are posted on the OCP web site and may be adopted by any pledgors.

However, the Steering Committee quickly realized that many IP holders, particularly large organizations, have individual sensitivities and concerns that make them unwilling to use a standardized licensing agreement. In order to increase the attractiveness of the OCP to potential pledgors, the Steering Committee implemented a process whereby potential pledgors may submit proposed licensing agreements to the Committee for review, much as the creators of new OSS licenses may submit them to OSI. If, after review, the Committee determined that the terms of the proposed license were consistent with those of the OCP template agreements, the proposed license was deemed “OCL-Compatible”. If the terms of the proposed license were mostly consistent with the terms of the Open COVID Licenses, but deviated in one or more ways deemed nevertheless to preserve the intent of the OCP, the proposed license was deemed to be an acceptable “OCL-Alternative” license. If, however, the proposed license deviated in some material way with the Open COVID Licenses, it was deemed “incompatible” and an IP holder adopting it would not be considered to have made the Pledge.

215 See OCP FAQ, supra note x (“Does the pledge guarantee that a licensee will be able to manufacture or sell any particular product? No. Some products may be covered by IP that is held by multiple parties. In order to manufacture or sell such products, the manufacturer must ensure that it has obtained rights from all holders of IP. We recognize that it may be difficult to determine who owns all of these rights. But that is a problem that exceeds the scope of what the Open COVID License can accomplish except through identification of some pledgors and, if provided, the IP rights made subject to the pledge. Our hope, of course, is that all major holders of COVID-related IP will adopt the pledge, making the production of these technologies free from IP risk. However, this cannot be guaranteed.”)

216 OSI review
A list of compatibility criteria were developed to guide the review process.\footnote{https://opencovidpledge.org/licenses/} For example, certain CC and OSS licenses are automatically deemed to be OCL-compatible. In order to be deemed OCL-Compatible, customized licenses must contain certain minimum terms such as a scope and duration at least as broad as the Open COVID Licenses and may not bear royalties or other charges. OCL-Alternative licenses may include one or more specified terms that, on their face, are inconsistent with the OCL Licenses, but which, overall, preserve the intent of the OCP. Terms that are permitted in OCL-Alternative but not in OCL-Compatible licenses include share-Alike, copyleft and grant back clauses that require the licensee to make modifications and derivatives of licensed IPR available on similarly open terms, limiting licensees to particular countries, or excluding particular countries, but only when required by applicable legal regulations, limiting the field to medical and research use only (e.g., excluding home entertainment applications, even when related to COVID-19), or requiring that the licensee to register as a user.

However, some restrictions and limitations are deemed to be so inconsistent with the spirit of the OCP and its fundamental design principles that licenses containing them will not certified as either OCL-Compliant or OCL-Alternative. For example, restrictions on commercial use could severely limit the use of pledged rights, and will thus make a proposed license non-compliant. Likewise, “downstream” pricing requirements (e.g., requiring that the licensee make licensed products available at no charge, at cost or at “fair and reasonable”) charges could reduce users’ willingness to utilize the licensed rights and thus limit their usefulness in combatting the pandemic. Prohibiting the licensee from making derivatives or modifications of the licensed IP or requiring the licensee to assign to the licensor rights in derivatives or modifications of the licensed IP would also be significant disincentives for users to use and improve the licensed IP. Of course, the licensor’s charging fees of any kind, including reimbursement of expenses, disqualifies licenses from the OCP, as does requiring the licensee to report sales or other utilization to the licensor. Finally, a duration that is shorter than the OCL term (the earlier of the end of the COVID-19 pandemic plus one year, or January 1, 2023) is disqualifying, both because of its significant potential to reduce uniformity among licenses, and because it limits the usefulness of pledged IP to address the pandemic.

\section*{H. Notice of Pledged IP}

In order for an IP pledge to achieve the pledgor’s goals, potential users must be made aware of the pledge as well as the IP that is available for use – the so-called “notice function” of IP pledges.\footnote{See Contreras, \textit{Patent Pledges}, supra note x, at 596 (“In order for a pledge to achieve the pledgor’s desired effect … broad public dissemination or “notice” of the pledge is desirable. Likewise, in order to extend the benefit of the pledge to the entire intended category of beneficiaries … broad public notice is also desirable”). \textit{See also} Clark D. Asay, \textit{The Informational Effects of}
broad use of pledged IP is a lack of widely disseminated information about the IP that is available for use.219

In the case of the OCP, the dissemination of information relating to pledged IP presents several challenges. First, the large number of patents pledged (see Part IV.A, below) makes any attempt to list individual patents infeasible.220 Several early pledgors held tens of thousands of patents each and, as any patent practitioner knows, the “docket” information for such portfolios is voluminous, complex and constantly changing. Listing individual patents would impose an insurmountable burden on the pledgers’ in-house legal departments, and would have been impossible for any outsider to compile accurately. What’s more, a listing of tens or hundreds of thousands of patents, whether organized by assignee, issuance date or patent number, would be of little use to potential users.221 Finally, copyrights, which lack even the registration information of patents, are notoriously difficult to catalog with any degree of specificity.

Though a comprehensive listing of pledged IP was neither feasible nor particularly useful for the OCP, the Committee sought ways to disseminate information regarding pledged IP to potential users and to make this information easily accessible. It undertook two approaches in this regard, and has developed plans for a third.

1. Featured IP

One of the methods adopted by the OCP to highlight pledged IP was to develop a number of vignettes describing pledged IP and how it was being, or could be, used in the response to COVID-19. Each of these vignettes identifies the relevant

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See Contreras, Patent Pledges, supra note x, at 596 (“despite [the] pressures toward broad dissemination and notice of pledges, many patent pledges falter as to the notice function”), Contreras, et al., EcoPatent, supra note 51, at 82 (notification of pledged IP “was not particularly intuitive or informative”, contributing to lack of use), Nicole Shanahan, Overcoming Information Asymmetry in Patent Pledge Records in PATENT PLEDGES, supra note 218, at 301 (“The way patent pledges are publicized and made available today is not effective in reaching an optimal level of distribution of the underlying open access contained in these pledges.”), Colleen V. Chien & Evan Hastings, Spurring and Clearing the Path for Open COVID Innovation Through Contextual Patent Disclosure, Patently-O blog, May 21, 2020, https://patentlyo.com/patent/2020/05/innovation-contextual-disclosure.html (“without context, in particular reliable assignee or product information, may be hard-pressed to find relevant technology”).

There was some disagreement within the Steering Committee regarding this conclusion. This article reflects the views of the author. But see Meredith Jacob, Best Practices for Making Patent Pledges in PATENT PLEDGES, supra note 218, at 317, 318 (recommending enumeration of each patent pledged).

Even the EcoPatent Commons, which included a list of only __ patent families, was viewed as difficult for potential users to understand. See Contreras, et al., EcoPatent, supra note 51, at 82.
pledgor and includes a short textual description, some keywords (tags), an illustrative image, and a list of relevant patent numbers or other technical details (if the viewer clicks the “Learn More” button). Below are four examples of featured IP on the OCP website:

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**Figure 4**  
*Featured IP on the Open COVID Pledge Website*

It was hoped that these use cases would inspire potential users to explore the pledged IP and use it in creative ways. As of this writing, approximately thirty “Featured IP” vignettes are posted on the OCP website [and an effort is under way to develop more with student volunteers.]

2. Patent Searching

The second prong of OCP’s IP dissemination effort involves a natural language processing (NLP) search engine that enables users to search patents pledged under the OCP. Search functionality is provided by Swedish analytics firm IPScreener, a third party that adapted its existing NLP to target OCP-pledged patents. It is hoped that this search functionality will enable potential users to identify patents relevant to particular areas in which they may wish to operate.

3. Topical Index

Another goal of the OCP is to create a comprehensive “index” of topics covered by pledged IP, with links to relevant IP. Thus, relevant IP would be indexed and collected under topic headings such as ventilators, respirators, contact tracing apps.

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222 https://opencovidpledge.org/partner-ip/
223 https://opencovidpledge.org/ip/
diagnostic kits, disinfecting solutions, vaccines, therapeutics, and many more. The beginnings of this system already exist in the keyword tags identified in the Featured IP vignettes. It is anticipated that, once completed, such a resource will be useful in informing potential users of the types of technology projects that can be undertaken using IP pledged under the OCP.

I. The OCP Environment

Though issues relating to website hosting and design may seem mundane, these and other aspects of the “environment” surrounding the Pledge played an important role in its planning and launch. Initially, the OCP was hosted on an independent website controlled by a Steering Committee member. In August, 2020, the site was transferred to Creative Commons, which assumed the responsibility for “stewardship” of the project.\(^{224}\) Then in [February, 2021], the OCP website was transferred to the Program for Information Justice and Intellectual Property (PIJIP) at American University Washington College of Law, which currently hosts and stewards the project.

The OCP website includes a number of relatively standard features such as a “frequently asked questions” (FAQ) page, news releases and blog posts,\(^{225}\) information about the organizers, and a list of online resources. Prior to launch, the OCP also contracted for the design of a logo that could be used to generate brand recognition, identity and loyalty.

![The OCP logo](image)

The institutional steward of the OCP maintains a Twitter account for the OCP (@OpenCovidPledge), which it uses, in addition to blog posts on the website, to disseminate news regarding new pledgors, interactions with other groups, publications by Steering Committee members and other news relevant to the OCP.

\(^{224}\) https://opencovidpledge.org/2020/08/27/creative-commons-to-steward-the-open-covid-pledge/

\(^{225}\) Much of the public outreach for the OCP, including press releases and news announcements, was handled by Creative Commons, first on a volunteer basis, and then as the steward of the OCP from September 2020 to February 2021.
In addition to pledgors of IP, the OCP sought to attract endorsements from organizations that are supportive of the OCP’s mission. While such organizations did not pledge IP (and often control no relevant IP), the accumulation of a large number of “Supporters” from around the world both validated the legitimacy of the OCP program and demonstrated broad support for its goals among well-respected groups.

As of this writing, there are forty-four OCP Supporters, including academic centers,226 advocacy groups, foundations and professional service providers.227 Supporters are featured on the OCP website with links to their own websites.228 A complete list of OCP Supporters is included in Appendix C.

IV. LAUNCH AND ADOPTION OF THE OPEN COVID PLEDGE

The Open COVID Pledge was “launched” on April 7, 2020, with Intel as its first major pledgor.229 Within two weeks, Amazon, Facebook, Hewlett Packard Enterprise, IBM, Microsoft, and Sandia National Laboratories also joined the OCP with pledges of tens of thousands of additional patents and other IP.230 In May, the WHO recognized the OCP in its global Solidarity Call to Action, calling on IP holders to help end the pandemic by sharing “relevant knowledge, intellectual property and data to enable widescale and worldwide production, distribution and use of such technologies and necessary raw materials” through mechanisms including the OCP.231 By mid-June, 2020, the OCP had attracted more than thirty pledgors with an estimated 500,000 pledged patents. This Part IV analyzes the adoption patterns of the OCP and assesses the value of the OCP in fields in which adoption has been high and low.

A. Profile of Pledgors and Pledges

1. Overall Statistics

As of February 1, 2021, thirty-two entities had formally made the Open COVID Pledge (see Appendix C). These included twenty-six corporate entities, four non-

226 Academic centers are policy-focused centers within academic institutions that do not represent the views of their larger institutions or technology licensing offices.
228 https://opencovidpledge.org/partners/
231 WHO Solidarity Call to Action, supra note 22.
profit entities (universities or research institutes) and two U.S. national laboratories. Twenty-six pledgors are based in the U.S., four in Europe and two in Japan.

![Type of Pledgor (n = 32)](image)

**Figure 6**
*Types of Entities Making the Open COVID Pledge*

With regard to the IP rights pledged, four entities pledged copyrights and twenty-nine pledged patents (with one entity pledging both patents and copyrights). Of the patent pledgors, twenty pledged all patents, while nine pledged selected patents or patent applications only.

2. **Timing of Pledges**

In terms of timing, the large majority of pledgors committed to the OCP during the first month after launch, April, 2020. A handful of additional pledgors committed in the following two months, with only one pledgor per month in August through October, after which no additional pledgors have joined.
This trend does not correlate with the steady rise in COVID-19 cases or fatalities worldwide. Rather, it reflects an initial burst of interest, followed by a steady decline in new pledge commitments. There are several possible explanations for this trend.

First, there may be a natural limit to the number of IP holders willing to pledge their IP for a cause such as the COVID-19 response. However, given that only thirty-two out of tens of thousands of IP holders have made the Pledge, it seems unlikely that the natural limit of pledgors has been reached.

Second, IP holders may find few benefits to making the Pledge substantially after the OCP’s launch. Entities that joined early enjoyed the publicity of being associated with a new endeavor that was attracting attention from the media as well as international bodies and governments. It is possible that latecomers, not anticipating any significant attention so long after the launch of the OCP, do not feel that the benefits of making the Pledge outweigh its potential negative effects or even the internal effort required to review it and seek internal management approval.

Third, entities that adopted a “wait and see” approach to the Pledge may have concluded, following its debut, that the benefits enjoyed early adopters were not as significant as originally anticipated, and that negative effects from not joining did not materialize. As such, for these entities, the cost-benefit balance might continue to weigh in favor of not making the Pledge.

Fourth, IP holders might perceive the possibility of negative publicity from making the Pledge so long after OCP’s launch, particularly if the pandemic is close to ending. That is, an entity might not want to be lampooned as a “Johnny come lately”, making the Pledge only after it is hardly worth making anymore.
Finally, after a significant initial effort to recruit pledgors and supporters in anticipation of the OCP’s launch, the Steering Committee itself flagged in its efforts to recruit new pledgors. This decline likely resulted from a combination of competing time demands on Steering Committee members, the lack of a permanent administrative staff that could take the laboring oar with respect to recruitment efforts and the lack of a coherent recruitment strategy. In this respect, the recruitment difficulties of the OCP bear similarities to those of the earlier EcoPC and Defensive Patent License group.

B. Adoption Trends

Patterns of adoption began to emerge almost immediately after the launch of the OCP. Organizations in some industry sectors, such as information technology (IT), embraced the Pledge in significant numbers, while those in the biopharmaceutical sector did not. This Part IV.B discusses some of the industry-specific factors and considerations that may have driven, or deterred, adoption of the OCP during its first year of operation.

I. Crisis-Critical Products

Frank Tietze (a Steering Committee member) and co-authors have previously identified five categories of product innovation that are critical when responding to a major infectious disease outbreak such as COVID-19 (“crisis-critical products”). These categories include:

- Vaccines and treatments
- Diagnostic tests
- Medical equipment (especially hospital/ICU devices such as ventilators)
- Personal protective equipment (PPE)
- Digital innovation, including “artificial intelligence (AI)-enabled tracking apps for cases and spreaders and epidemic modeling to monitor

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232 Recruitment of pledgors fell to the personal contacts of key Steering Committee members, as well as a handful of student volunteers who eventually redirected their efforts to their studies and other activities.

233 See Contreras, et al., EcoPatent, supra note 51, at 103 (“Most trade associations have dedicated personnel for membership development, and enrolling members takes significant time and effort. Without these resources, it is not surprising that the EcoPC was unable to recruit a larger body of members nor that WBCSD and ELI spent few additional funds for EcoPC recruitment”); Jorge L. Contreras, The Evolving Patent Pledge Landscape, CIGI Papers No. 166, Apr. 3, 2018 at 10 (“It is possible that the lack of a dedicated membership and recruitment mechanism as part of the DPL has disadvantaged it as compared to the [License on Transfer network], just as this absence seems to have worked against the success of the EcoPC”).

234 Tietze, et al., supra note x, at 3.
and understand the spread and development of the virus across populations.”

Intellectual property in each of these crisis-critical product categories has been pledged to the COVID-19 response under the OCP. The following discussion summarizes and offers examples of pledges in each of these categories.

2. Biopharmaceuticals (Vaccines and Cures)

a. Private Sector

The biopharmaceutical sector – particularly vaccine development and manufacture -- has been among the most visible in the public debate over patents and COVID-19. Not surprisingly, given the large amounts at stake, patent assertions and litigation have affected this sector from an early date.\footnote{See notes 21-22, supra, and accompanying text (describing early concerns over patents in the vaccine industry). See also Hailey Konnath, Pfizer, Regeneron Hit With Patent Suits Over COVID-19 Tech, LAW360, Oct. 5, 2020.} As a result, repeated calls have been made by government officials to open access to vaccine-related patents.\footnote{See Bill de Blasio, Biden’s Covid order lets Big Pharma companies waive vaccine patents. They must do so, NBC Think, Jan. 29, 2021, https://www.nbcnews.com/think/opinion/covid-vaccine-supply-dangerously-low-will-biden-s-executive-order-ncna1256171?_sm_au_=iVv8v3Nyf7WPZTvMFckK0232C0F (calling on vaccine developers to “follow Moderna’s lead and stand down on its patents” because “[i]n a global pandemic, ‘intellectual property’ should not matter. Human lives should.”), David M. Herszenhorn, Charles Michel says EU could invoke ‘urgent measures’ in response to vaccine shortfall, POLITICO, Jan. 28, 2021, https://www.politico.eu/article/charles-michel-says-eu-could-invoking-urgent-measures-response-coronavirus-vaccine-shortfall/# (reporting that the President of the European Council suggested that the European Union could “force vaccine-makers to share their patents, or other licenses, and take other steps to ramp up production of the desperately sought-after vaccines”).}

Yet compared to other market sectors, there has been comparatively little adoption of the OCP, or any voluntary pledging activity, with respect to IP covering COVID-19 vaccines or therapeutics (a few exceptions being the unilateral pledges made by AbbVie\footnote{See Part x, supra.} and Moderna,\footnote{See Part x, supra.} and pledges by a number of Japanese firms in the biomedical sector\footnote{See Part x, supra.}). Most firms in the biopharmaceutical sector have likewise avoided participation in the WHO’s C-TAP pool.\footnote{See Part x, supra.}

Simple economic forces may be at work here, as firms that anticipate a direct and significant windfall from the sale of COVID-19 products to governments and health plans may be less inclined to commit their IP to a public cause or to make it available to their competitors. In addition, biopharmaceutical firms point to legitimate concerns about the quality and safety of products that may be

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\footnote{See Part x, supra.}
manufactured under open licensing regimes.\textsuperscript{241} For all of these reasons, it is not surprising that companies in the biopharmaceutical sector have had limited participation in the OCP and other pledging and pooling initiatives.\textsuperscript{242}

However, not all vaccine-related initiatives are profit-seeking. The Rapid Deployment Vaccine Collaborative (RADVAC), which was formed by researchers affiliated with Harvard Medical School, seeks the “rapid development, testing, and free and open-source sharing of vaccine designs and essential protocols.”\textsuperscript{243} RADVAC freely shares all information on its vaccine designs, production, self-administration, and testing on its website under the OCP.\textsuperscript{244}

In addition, a number of large firms that are not directly engaged in the biopharmaceutical industry have contributed potentially valuable IP to the development of vaccines and therapies targeted at COVID-19. For example, a pledged IBM patent covers the use of cationic polyamines for the treatment of viruses.\textsuperscript{245} Moreover, as described in Part IV.B.6.a, below, numerous firms have pledged IP covering artificial intelligence and computational methods for enhancing drug discovery, design, testing, manufacture and administration.

\textbf{b. Universities}

A large amount of biomedical innovation in the U.S. and elsewhere originates in academic research institutions, much of which is funded by governments and charitable foundations. Yet no major research institution has yet participated in the OCP with respect to biopharmaceutical inventions. The lack of broader OCP adoption by research universities has been disappointing, given that universities generally have broad public charters that would seem to support the advancement of public health.\textsuperscript{246}

Twenty-four academic research institutions have committed to use the Harvard-MIT-Stanford COVID-19 Technology Access Framework described in Part II.C.3.d, above.\textsuperscript{247} This Framework, announced on the same day as the Open COVID Pledge, shares many of the OCP’s fundamental design features including royalty-free licensing of IP related to the COVID-19 response. While the HMS Framework is more administratively burdensome than the OCP, in that it appears

\begin{footnotesize}
\begin{itemize}
\item\textsuperscript{241} Id. (quoting Corey Salsberg, head of IP affairs for Novartis).
\item\textsuperscript{242} This being said, a number of vaccine manufacturers have made other public commitments relating to product access and pricing during the COVID-19 pandemic. See Adam Houldsworth, \textit{Your guide to covid-19 vaccine stakeholders’ IP strategies}, INTELL. ASSET MGT., Nov. 19, 2020.
\item\textsuperscript{243} https://radvac.org
\item\textsuperscript{244} Id.
\item\textsuperscript{245} U.S. Pat. No. 9,682,100 (“Cationic polyamines for treatment of viruses”) (assigned to IBM).
\item\textsuperscript{246} See Natl. Acad. Sci., Comm. on Management of Univ. Intell. Prop., Managing University Intellectual Property in the Public Interest 24 (Stephen A. Merrill & Anne-Marie Mazza eds. 2010) (“the first goal of university technology transfer involving (intellectual property) is the expeditious and wide dissemination of university-generated technology for the public good”).
\item\textsuperscript{247} In addition, Oxford University announced a licensing framework similar to that of HMS. See Part II.C.2.d, \textit{supra}.
\end{itemize}
\end{footnotesize}
to require bilateral, signed licensing agreements between participating universities and licensees, and also imposes downstream pricing constraints on licensees, such arrangements have yielded beneficial results, for example, in the Medicines Patent Pool. It is not known how many, if any, licenses have been executed under the HMS Framework.

But even with these programs, the vast majority of academic research institutions worldwide248 have declined to make any pledge whatsoever with respect to their intellectual property. There are several possible explanations for this lack of interest. First, some universities may genuinely believe that the granting of exclusive licenses to patents covering fundamental discoveries is most likely to result in the commercialization of products based on those discoveries. This may explain Oxford University’s reportedly exclusive license of vaccine technology to AstraZeneca,249 and was cited by a representative of at least one major U.S. research university with whom the author spoke in connection with the OCP.250

Alternatively, like private firms, universities may wish to maximize revenue generation from their intellectual property portfolios. While such a profit-maximizing motivation may seem incongruous with the public missions of many universities, it has been well-documented over the past several decades.251

c. **UAEM and Free the Vaccine**

One of the most heartening, and unexpected, developments arising from the release of the OCP was its adoption in June 2020 by the student activist group Universities Allied for Essential Medicines (UAEM). UAEM got its start more than twenty years ago during the controversy over Yale University’s exclusive license of the AIDS treatment stavudine to Bristol-Myers-Squibb (BMS). Student protests helped to persuade the university administration to require BMS to distribute the drug, for which Yale earned approximately $40 million per year, at substantially reduced prices in Africa.252

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249 See Part II.C.2.d, supra.


During the summer of 2020, UAEM turned its attention to the COVID-19 crisis and the anticipated cost of the vaccines under development. It created a campaign known as “Free the Vaccine for COVID-19” which advocates the creation of a free “People’s Vaccine” based on publicly-funded research. In its calls to action, Free the Vaccine promoted the Open COVID Pledge as the preferred mechanism for securing public rights to develop and manufacture such vaccines:

We call for universities, organizations, and companies receiving public funds for COVID research to sign the Open COVID Pledge, a legal commitment to open licensing the intellectual property needed for the cure.

The principal focus of UAEM’s and Free the Vaccine’s advocacy was the university community, where most of its members were students. They organized specific initiatives to encourage universities including Vanderbilt, Arizona State, University of California and Georgetown to adopt the OCP and contribute their patented technologies toward the creation of a public vaccine. Members of the Steering Committee participated in meetings with UAEM and university representatives to discuss the legal specifics of the OCP.

To date, these efforts have not resulted in further pledges by universities. However, unlike medical equipment, vaccine manufacture and distribution is still in a relatively early phase, and additional pressure to make vaccines more widely available at lower prices will likely continue, particularly with respect to the developing world. The same can be said for therapeutics targeting COVID-19, another area in which grassroots activism can potentially help to broaden access and lower prices. In both of these areas, it is possible that continued pressure from groups such as UAEM will persuade more research universities to commit their IP to the COVID-19 response.

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253 UAEM, UAEM Activists Launch Free The Vaccine Campaign, Apr. 11, 2020, https://www.uaem.org/free_vaccine_campaign
254 Free the Vaccine for COVID-19, Support a People’s Vaccine, https://freethervaccine.org/why-sign-on/?fbclid=IwAR2Z0eprv3JRLtqXzK-Mnh8QN1-DZQs3MnERlvYG0jM6XsEmFZIVF1wkwU
256 UAEM, List of Institutions, https://www.uaem.org/list_of_institutions
3. Diagnostics

Patents covering COVID-19 diagnostic tests gained prominence early in March, 2020, when Labrador Diagnostics asserted patents that its parent Fortress Investments acquired from defunct blood testing firm Theranos against diagnostic test makers.\(^{257}\) As discussed above, Fortress and Labrador eventually bowed to public pressure and withdrew those suits, instead pledging not to assert their patents against COVID-19 diagnostics.

Numerous other pledges relating to diagnostic equipment, testing and methods have been made through the OCP. Intel, for example, holds a patent covering methods for detecting target bioanalytes using ferromagnetic microdisks.\(^{258}\) IBM holds and has pledged several relevant patents, including one claiming a method for detecting a nucleic acid (e.g., DNA or RNA) sequence using a cellular phone, and a pending patent application claiming a microfluidic device with programmable verification features\(^{259}\) – a technology similar to that allegedly developed by Theranos. Sandia National Laboratory, which holds a number of patents covering

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\(^{257}\) See Part x, supra.

\(^{258}\) U.S. Pat. No. 7,973,398 ("Resonant magnetic disks for bioanalyte detection"). For a discussion of the potential of magnetic nanoparticles in diagnosing COVID-19, see Wudan Yan & David Schneider, The Race for a Here and Now COVID-19 Test, IEEE SPECTRUM, Oct. 2020, at 61, 64.

the detection of proteins and other organic molecules.\textsuperscript{260} has also pledged IP relating to the design of a “low-cost, easy-to-use outdoor shelter for healthcare workers to conduct safer COVID-19 drive-up or walk-up testing.”\textsuperscript{261} Together, these pledges represent a meaningful body of technology that can be useful in the development of new diagnostic tests for COVID-19, the improvement of existing diagnostic tests, and the efficient manufacture and supply of diagnostic test kits with reduced concerns of patent infringement.

4. Medical Equipment

As noted in the Introduction, the lack of hospital ventilators and ventilator replacement parts during the early weeks of the pandemic was one of the precipitating factors that led to calls for greater access to proprietary IP. The unilateral Medtronic and Smiths Group pledges with respect to ventilator equipment were significant steps toward opening these markets to broader participation. The Open Ventilator System Initiative (OVSI), an OCP participant, is a UK-based project that has designed a portable and affordable ventilator device for deployment in low- and middle-income countries.\textsuperscript{262} With these pledges, significant progress has been made in the area of hospital ventilator equipment.

IP covering number of other medical products and devices relevant to COVID-19 has also been pledged. These products include simple yet innovative devices such as a nasal forcep swab for sample collection\textsuperscript{263} and a plastic device for spiking IV bags.\textsuperscript{264} These devices, produced by smaller entities, may be protected by a single patent application. Yet by joining the OCP alongside some of the largest corporations in the world, these entities highlight their products in a favorable light.

5. Personal protective equipment (PPE)

Shortages of personal protective equipment (PPE) such as masks and face shields became acute during the early months of the pandemic and have continued to plague hospitals, clinics and testing sites. Both Sandia National Laboratory and the NASA Jet Propulsion Laboratory (JPL) were early contributors of PPE intellectual property to the fight against COVID-19. Sandia analyzed 200,000 designs for face coverings and 900 designs for face shields made using commonly available materials and made its findings publicly available.\textsuperscript{265} JPL published the digital design files for four different 3D printed respirators.\textsuperscript{266} And a small business,
ProBuccal, pledged its intellectual property in an oral bioaerosol shield for dental applications.  

Though not as highly publicized as PPE, other technologies have become important for preventing and containing the spread of infection. The use of ultraviolet radiation as a powerful disinfecting agent has attracted significant attention during the COVID-19 pandemic. A pledged IBM technology sanitizes touchscreen devices using ultraviolet light after use. In a slightly different vein, recent patents and patent applications held by Microsoft and Intel, respectively, cover the authentication of a user’s identity using contactless gestures in three-dimensional space (i.e., avoiding the need for direct contact between an individual and a device). Technologies such as these are being utilized with increasing frequency as concern over contamination and the spread of contagion through human touch remains high.

6. Digital Innovation

Both in terms of number of pledgors and number of patents, the greatest uptake of the OCP has been in the information technology (IT) sector. Large multinational firms such as Intel, IBM, Microsoft, Facebook, Fujitsu, Uber, Mitsubishi Electric, Amazon and SAP have each made thousands or tens of thousands of patents available through the OCP. Any accurate inventory of the close to a half million patents pledged in this area is impossible. However, some of the industry sub-sectors into which such patents fall are summarized below:

a. Biopharmaceutical research tools

Over the past decade, drug discovery and development have become increasingly dependent on computational methods and machine learning. A number of patents covering artificial intelligence systems and algorithms for computational drug discovery and design (including vaccine design) have been pledged under the OCP by firms including Microsoft and Fujitsu. One example of patents covering these technologies are:

- U.S. Pat. No. 9,772,714 (“Touch input device with pathogen transmission mitigation”).
- U.S. Pat. No. 8,845,431 (“Shape trace gesturing”).
- U.S. Pat. App. No. 16/716,983 (Gesture-Based Signature Authentication).
- See Emily Waltz, AI Takes its Best Shot, IEEE SPECTRUM, Oct. 2020, at 25, 26 (machine learning systems and computational analysis assist researchers in understanding virus structure, immune response, choosing vaccine elements, tracking virus mutations and understanding experimental data), Megan Scudellari, Automating Antivirals, IEEE SPECTRUM, Oct. 2020, at 45 (predicting that AI and automation will reduce drug discovery cycles from five years to six months).
particularly relevant Microsoft patent covers the use of machine learning algorithms to facilitate the assembly of vaccine cocktails for pathogens, such as HIV, that evolve quickly under immune pressure of the host.\textsuperscript{275} And a recent IBM patent claims methods for identifying clinical trial site locations based on epidemiological and demographic factors.\textsuperscript{276}

In addition, Hewlett-Packard Enterprise has pledged its substantial portfolio of IP relating to data handling and exchange in cryo-electron microscopy systems, important research tools for drug discovery and development.\textsuperscript{277} With respect to the administration of therapeutics, IBM has pledged IP covering a computerized decision support tool for optimizing long-term drug therapy.\textsuperscript{278} The fact that these advanced digital innovations have been pledged may enable firms in the biopharmaceutical sector to research and develop COVID-19 vaccines and therapeutics more effectively and rapidly, without exposure to patent infringement.

\textit{b. Contact tracing and epidemiology}

The rapid spread of COVID-19, its long latency period, and the uncertainty surrounding its precise vectors of transmission has led to a need for reliable and pervasive methods of modeling, predicting and tracing the spread of contagion.\textsuperscript{279} So-called “contact tracing” applications, which allow users to track the individuals with whom they have had contact, have helped epidemiologists to understand the nature of the disease and its spread.\textsuperscript{280}

Numerous patents claiming contact tracing methods and technologies, as well as epidemiological modeling techniques, have been issued. One such contact tracing patent held by Utah-based BlyncoSy, Inc.\textsuperscript{281} was the subject of a successful public call for prior art by Unified Patents, a participant in the OCP.\textsuperscript{282} Unified alleged that BlyncoSy was asserting this patent against firms developing and deploying contact tracing technology for COVID-19.

\textsuperscript{275} U.S. Pat. No. 8,478,535 (“Systems and methods that utilize machine learning algorithms to facilitate assembly of aids vaccine cocktails”).
\textsuperscript{276} U.S. Pat. No. 10,515,099 (“Medical clinical trial site identification”).
\textsuperscript{281} U.S. Pat. No. 10,198,779 (“Tracking Proximity Relationships and Uses Thereof”).
\textsuperscript{282} See Unified Patents, $2,000 for BlyncoSy Prior Art, Oct. 21, 2020, https://www.unifiedpatents.com/insights/2020/2000-blyncoSy. Unified Patents is a member-supported organization that, among other things, seeks to invalidate patents that have been asserted by PAEs through \textit{inter partes review} (IPR) proceedings at the Patent Trial and Appeal Board (PTAB). See Unified Patents, FAQ, https://www.unifiedpatents.com/faq. As part of this effort, Unified conducts competitions with cash prizes for those identifying prior art that can be used to invalidate such patents. See Unified Patents, Patroll – Contests, https://patroll.unifiedpatents.com/contests (visited Feb. 4, 2021).
Notwithstanding such assertions, a significant number of patents, patent applications and other IP relating to contract tracing and epidemiological modeling have been pledged under the OCP by firms including apheris AI,283 IBM,284 Mitsubishi Electric285 and Microsoft.286 These contributions, together with the prior art identified by Unified Patents, are likely to provide significantly enhanced freedom to operate in the area of contract tracing technology.

c. **Infrastructure and logistics**

Though seldom making headlines, the COVID-19 pandemic has placed unexpected strains on global physical and network infrastructures, supply chains and transportation systems. As governments and institutions struggle to cope with aging systems, new technologies are being deployed to ensure the rapid, safe and efficient allocation of resources across physical spaces. In many cases, these technologies are covered by IP that has been pledged through the OCP.

For example, IBM, which has pledged all of its patents under the OCP, has developed significant technology to secure the medical product supply chain, particularly for compounds (such as vaccines) requiring refrigeration.287 Hewlett-Packard Enterprise, which has also pledged its patents under the OCP, has deployed wireless technology and location-based services to enable pop-up clinics and hospitals, including at least one shipboard “floating” hospital in Italy.288 And another pledgor, Mitsubishi Electric, has contributed IP relating to the efficient allocation of personnel to service machines across multiple locations, such as hospitals.289


286 See https://opencovidpledge.org/2020/05/19/microsoft-bing/ (describing “A dataset of anonymized Bing queries relating to the COVID pandemic, useful for research on the spread and containment of the pandemic…”)


Efficiently routing emergency vehicles through traffic is particularly important during spikes in demand. One pledged AT&T patent application covers methods for optimally routing ambulances and other emergency vehicles to hospitals.290 A patent pledged by Uber allows drivers to select routes based on safety conditions, which can be particularly relevant for families with children or drivers wishing to avoid congested or crowded areas during pandemic conditions.291

d. Information reliability

One highly publicized development that has emerged from the COVID-19 pandemic is the spread of misinformation about the disease and its prevention and treatment. Much of this misinformation is spread via social media, and numerous firms operating in the IT space have developed methods for assessing the reliability and accuracy of information posted to social media accounts. For example, Facebook has developed methods for automatically generating and collecting contextual information about posts, including credibility indicators, additional content and statistical information, and displaying this information for users.292 Microsoft has also developed methods for using credibility-related data in conjunction with servicing web requests such as a search queries.293 And IBM has developed methods for aggregating data from multiple sources to validate incidents reported via social media,294 and also for measuring the degree of trust that a recipient should place in an online message.295 The patents and patent applications underlying these and many other technologies for increasing the accuracy and reliability of public information have been pledged under the OCP.

C. Creating an Open Innovation Landscape

As discussed in Part III.A, above, patent pledging efforts will seldom, if ever, result in the complete elimination of IP risks for technology developers or users. Even when efforts are closely coordinated by all principal developers of a particular technology, there remains a risk that “outsiders” will emerge to assert patents reading on a particular technology. Nevertheless, the clearance of even some level of IP risk can encourage users to enter new markets that they otherwise might not have entered. This possibility is enhanced if prominent IP holders have made their

295 U.S. Pat. No. 10,051,069 (“Action based trust modeling”).
IP broadly available to users in connection with a common cause such as pandemic response.

*Table 2,* below, offers an (admittedly subjective and non-quantitative) assessment of the adoption of the OCP by providers of the five crisis-critical product categories discussed in Part B, based on a three-tier assessment (low, medium, high) of the quantity of IP pledged in each category. In addition, *Table 2* includes an assessment by category of the IP pledges made in such category when combining the OCP with the other unilateral and collective pledges described in Part II.C.

**Table 2 – Pledges of Crisis-Critical Product IP**

<table>
<thead>
<tr>
<th>Product category</th>
<th>Pledged through OCP</th>
<th>Pledged through all Pledges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopharma</td>
<td>Low</td>
<td>Low-Medium</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>Low</td>
<td>Medium</td>
</tr>
<tr>
<td>Medical equipment</td>
<td>Low-Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Personal protective equipment (PPE)</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Digital innovation</td>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>

As shown in *Table 2*, there is wide variation in pledging activity among product categories. The lowest degree of activity has occurred with respect to biopharmaceutical products such as vaccines and treatments, most likely due to the substantial economic factors discussed in Part IV.B.2. Vaccine-related pledges such as those by Moderna and RADVAC could facilitate the development and production of vaccines by alternate sources, though the majority of technologies in this space remain fully protected by proprietary rights.

At the other end of the spectrum, a significant amount of IP has been pledged in the areas of PPE and digital innovation. With respect to PPE, pledged IP appears sufficient to enable the manufacture of respirators and other forms of equipment without significant risk of infringement—an achievement that has an immediate potential benefit to society.

Likewise, numerous categories of digital innovation appear to be substantially “opened” to innovation and product development through pledging mechanisms. This effect is particularly striking in areas such as contact tracing, in which pledges by leading multinational firms signal an openness to market entry that should be attractive to innovators in this area. Moreover, even if innovators are unaware of specific pledged IP, or even the existence of such pledges, the resulting lack of IP enforcement in these market segments should, itself, encourage further
development and innovation that might otherwise be chilled in an atmosphere of active IP enforcement.296

The broad nature of most OCP pledges, and its public licensing structure, further contribute to the open innovation landscape that is fosters. That is, within fields in which OCP (and related) pledge coverage is high, potential users of pledged IP need not identify specific patents or copyrights that they wish to use, as required by the various university COVID-19 frameworks described in Part II.C.3. Such an identification exercise is both time consuming and technically difficult, and requires an investigation of each pledgor’s IP portfolio with a degree of expertise that may be unavailable to many potential users. The OCP’s public license structure also eliminates the need to identify individual IP licensors and negotiate licenses with each of them, another time consuming and potentially daunting exercise for a small entity not inured to the legal culture of the U.S.

Thus, while quantitative measurement of the precise impact of IP pledges on markets is difficult, particularly given the large number of patents pledged under the OCP and similar programs,297 there is cause to be optimistic that such pledges may be having an effect, direct or indirect, on the willingness of innovators to invest in the development of products that can contribute to the containment of the COVID-19 pandemic. This “opening” of fields to innovation and new market entry is among the principal benefits of the OCP.

V. SUSTAINABILITY AND FUTURE DIRECTIONS

Pledges made under the OCP are irrevocable and will survive notwithstanding the fate of the OCP organization itself. Nevertheless, as shown by the experience of the EcoPC, it is desirable for such pledge communities to continue to recruit new pledgors and to promote and disseminate information about IP that is available for use. The long-term success of the OCP thus depends, in part, on its continued operation and expansion. This Part V briefly explores the prospects for the OCP’s continued operation as well as potential future directions.

A. Stewardship and Financial Security

One of the principal failings of the EcoPC was its lack of a committed organizational steward. While the project received significant support and attention from its corporate sponsors prior to and immediately after its launch, its ongoing operations were subsequently delegated to two non-profit organizations that did not commit substantial personnel or financial resources to its upkeep or expansion.298

296 See Chien & Hastings, supra note 219 (referring to OCP as “a useful non-assertion covenant that helps to clear the path for innovation”).
297 See Part V.E, infra.
298 See Contreras, et al., EcoPatent, supra note 51, at 102-03.
As a result, no new members were recruited, and no new patents were pledged, during the last five years of its existence. The host organizations were not to blame for allowing the project to languish, as their assumption of the Commons came with no financial assistance from its corporate members.\textsuperscript{299} Thus, their activity was limited primarily to hosting and maintenance of the Commons web site, but little was done to expand membership or disseminate information about patents that were made available under the pledge.

With this experience in mind, the Steering Committee carefully considered the ongoing stewardship of the OCP from its inception. As noted in Part III.I, responsibility for hosting the OCP website was transferred from an individual Steering Committee member to Creative Commons in August, 2020, and then to the PIJIP program at American University in [February, 2021]. Each of these transitions was intended to entrust the ongoing stewardship of the project to an entity with goals and a mission aligned with those of the OCP.

Nevertheless, as the example of the EcoPC demonstrates, providing more than a minimal level of services is difficult without a reliable source of funding. While the OCP made efforts at fundraising during the summer and fall of 2020, these efforts, undertaken during the height of the pandemic, did not yield meaningful financial contributions. Nevertheless, it is hoped that additional attempts to raise funds for the ongoing maintenance and expansion of the project will come to fruition in the future.

\textbf{B. Community}

One of the original goals of the OCP was to create a community of users making beneficial use of pledged IP. Such communities can be valuable channels for information dissemination. They can both “spread the word” about potential uses of the IP, and give users an opportunity to share know-how and experiences concerning practical aspects of that use. It is hoped that Creative Commons, which has established online communities and chapters around the world, may facilitate the formation of these user communities.

\textbf{C. Internationalization}

In October, 2020, Creative Commons led an effort to translate the OCP into the six official languages of the United Nations: Arabic, Chinese, English, French, Russian, and Spanish.\textsuperscript{300} These translations, which are available on the OCP website,\textsuperscript{301} are intended to make the Pledge accessible and understandable to individuals around the world for whom English is not a native language. Future

\textsuperscript{299} Id.
\textsuperscript{300} https://opencovidpledge.org/2020/08/27/creative-commons-to-steward-the-open-covid-pledge/
\textsuperscript{301} https://opencovidpledge.org/the-pledge/
activities could include translating the OCP into additional languages, as well as translating the Open COVID Licenses into languages beyond English.

Figure 9
Arabic and (Simplified) Chinese Translations of the Open COVID Pledge

D. Integration with Complementary Efforts

The OCP is only one of several coordinated efforts around the world that is intended to facilitate the pledging and contribution of IP to the COVID-19 response. Both the Japanese Open COVID Declaration and the WHO’s COVID Technology Access Pool (C-TAP) have also achieved some success in meeting these goals. It is thus important that such efforts expand their coordination and cooperation, particularly in the area of enhancing public information about IP that has been made available for use.

E. Measuring Impact

One of the principal shortcomings of the EcoPC was its failure to track or report on the use of pledged IP.302 This failure made the case for further contributions weak, and eventually contributed to the discontinuation of the project.303 Accordingly, the OCP has, from the outset, recognized the need to understand and communicate how pledged IP is used.

Unfortunately, the task of measuring the use of IP when users are not required to enter into bilateral licensing agreements, register with IP holders or even identify

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302 See Contreras, et al., EcoPatent, supra note 51, at x.
303 Id.
themselves publicly, is difficult.\textsuperscript{304} In addition, unlike the EcoPC, which had just over 240 pledged patents, the OCP has close to 500,000, most of which are not directly relevant to the purpose of the pledge. Thus, using forward citation analysis to determine the value and subsequent use of pledged patents, as researchers did with the EcoPC, is not likely to be illuminating. These difficulties are compounded by the fact that counterfactuals are lacking – while the OCP seeks to create an open innovation landscape around COVID-19, it is not possible to know how much innovation or development would have occurred without the pledges that have been made. For all of these reasons, quantitative tracking of use of pledged patents may not be feasible. However, the Steering Committee is currently considering ways to assess user take-up of pledged IP through direct community outreach and consultation with user groups.

\section*{F. Extensibility of the OCP beyond COVID-19}

While the OCP was developed as a direct response to the COVID-19 pandemic, the IP pledging framework that it establishes is not unique to COVID-19. Rather, the OCP provides a lightweight, legally enforceable mechanism for the coordinated pledging of intellectual property rights within a defined scope and for a limited period. As such, the OCP may be a useful model for the response to future public health emergencies in which intellectual property rights may constrain research, development or the supply of crisis-critical products.

Such an IP-sharing framework may not, however, be suitable for addressing all public health crises. For example, there are many devastating health conditions, such as cancer and heart disease, with far higher mortality rates than COVID-19. Yet broad IP-sharing mechanisms may not be well-suited to addressing conditions such as these. One of the defining characteristics of COVID-19 and other disease outbreaks is the strain that they unexpectedly place on existing resources, infrastructure, manufacturing capacity and supply. IP-sharing can help to alleviate bottlenecks in the supply chain by authorizing additional producers to enter the market and to meet sudden spikes in demand for critical products. Thus, while there are innumerable societal challenges associated with chronic health conditions – cost, reimbursement, unequal access and the like – broad IP sharing mechanisms that are effective to increase the supply of critical products may not be the ideal solutions for these public health issues.

Another looming health crisis is posed by climate change. Limited IP pledging efforts, including the EcoPC,\textsuperscript{305} have been undertaken in this area for some time, yet none has made available significant amounts of IP. Climate change poses many daunting challenges -- technological, social and political -- and it is not clear

\textsuperscript{304} Understanding how particular patents cover particular products is challenging and complex, even when the patents and products are known. See Besen & Meurer, 2005.
\textsuperscript{305} See Contreras, et al., EcoPatent, supra note 51.
whether IP is currently blocking or promoting progress toward their solution.\textsuperscript{306} Moreover, it is not clear that a generalized pledging framework would achieve meaningful gains when issues are tied to local conditions (sea rise, drought, storms), require substantial services, know-how and technical expertise to address, and do not lend themselves to commoditized solutions that are usable by large segments of the affected populations.\textsuperscript{307} Thus, the adaptation of IP pledging frameworks to such future challenges will require careful consideration of the specific design requirements and principles suggested by those challenges. For example, Reynolds et al. have proposed a research commons for solar climate engineering, combining a commitment to data sharing with an IP pledge that could be subject to royalties.\textsuperscript{308} Thus, even if the OCP is not adaptable wholesale to future crises, it is hoped that its design and features may help to inform future efforts to coordinate the public IP response to national and international public health emergencies.

CONCLUSION

The Open COVID Pledge was conceived as a legal framework to facilitate the voluntary contribution of intellectual property rights to the COVID-19 response. It was modeled on successful public licensing structures previously developed by the open source software community, Creative Commons and other pledge communities, and sought to extend the gains made by a number of unilateral pledges made early during the COVID-19 pandemic. In this respect, the OCP sought to offer a lightweight alternative to direct governmental intervention through compulsory licensing and to administratively complex patent pools.

The public response to the launch of the OCP was both heartening and instructive. A large number of patents – approaching 500,000 – were pledged under the OCP within a short period of time. However, the willingness of IP holders to make pledges varied considerably by market segment. At one end of the spectrum, few pledges were made with respect to biopharmaceutical products such as vaccines and treatments, most likely due to the substantial economic windfalls that await the successful producers of those products. In this area, more direct governmental intervention may be required to encourage IP holders to make their IP more broadly available to expand access to lifesaving vaccines and therapies.

At the other end of the spectrum, however, a significant amount of IP has been pledged in the areas of PPE and digital innovation, and to a lesser degree in the areas of diagnostics and medical devices. Pledges that have been made to date

\begin{footnotesize}

\textsuperscript{307} See Reynolds, et al, supra note 51, at 54-56 (discussing importance of trade secrets in climate-related innovation).

\textsuperscript{308} Id. at 101-06.
\end{footnotesize}
through the OCP and other mechanisms have already enabled the development and manufacture of hospital ventilators and replacement parts, respirators, and a variety of other medical tools and devices. In addition, very large quantities of IP covering digital innovation have been pledged for public use, including biopharmaceutical discovery tools, contact tracing methodologies, disease modeling algorithms, emergency response systems, supply chain enhancements, and social media mechanisms for ensuring the accuracy of information disseminated to the public. The participation of multiple leading multinationals in this effort signals an openness to market entry that should be attractive to innovators in a broad range of technology markets. Moreover, even if innovators are unaware of specific pledged IP, or even the existence of such pledges, the resulting lack of IP enforcement in these market segments should, itself, encourage further development and innovation that might otherwise be chilled in an atmosphere of active IP enforcement.

Thus, while precisely measuring the impact of IP pledges on markets is difficult, particularly given the large pledges made under the OCP and similar programs, there is cause to be optimistic that such pledges may be having an effect on the willingness of innovators to invest in the development and supply of products that will contribute to the containment and eventual eradication of the COVID-19 pandemic. This “opening” of fields to innovation and new market entry is among the principal benefits of the OCP.

Regrettably, however, COVID-19 is not likely to be the last public health emergency to afflict the world. Future pandemics, as well as global climate change and its associated health impacts, will create an even greater demand for access to innovative, lifesaving technologies. It is hoped that the OCP, which was carefully designed to balance the competing interests of broad user adoption with acceptability to IP holders in a lightweight and legally-enforceable manner, may be a useful model for future IP sharing endeavors.
APPENDIX A - OPEN COVID LICENSE

Open COVID License - Patent and Copyright (OCL-PC) 1.1

Having made the Open COVID Pledge, we (the “Pledgor”), in order to speed the development and dissemination of the technologies needed to end the COVID-19 Pandemic and mitigate the effects of the disease, grant the license described below. Our intent in doing so is to advance the shared cause of ending the COVID-19 Pandemic, and we do so without any expectation of consideration or compensation, and with knowledge of the rights we are licensing.

1. GRANT AND SCOPE

The Pledgor grants to every person and entity that wishes to accept it, a non-exclusive, royalty-free, worldwide, fully paid-up license (without the right to sublicense) under Pledgor’s patents and copyrights that we have the right to license (the “Licensed IP”) to make, have made, use, sell, and import any patented invention, and reproduce, adapt, translate, distribute, perform, display, modify, create derivative works of and otherwise exploit any copyrights, solely for the purpose of diagnosing, preventing, containing, and treating COVID-19.

2. TIME LIMITATION

This license is effective as of December 1, 2019 and lasts until one year after the World Health Organization declares the COVID-19 Pandemic to have ended, but in any event not beyond January 1, 2023, unless otherwise extended by the Pledgor.

3. REGULATORY EXCLUSIVITY

The Pledgor will not assert any regulatory exclusivity against any entity or individual for use of the Licensed IP in accordance with the license granted in Section 1, and we will not seek injunctive or regulatory relief to prevent any entity or individual from doing so.

4. DEFENSIVE SUSPENSION

The license and non-assertion covenant granted above shall automatically be suspended, and the Pledgor shall be free to assert the Licensed IP against the licensee, if the licensee or any entity affiliated with the licensee threatens or initiates a suit or legal proceeding alleging the infringement of any patent or other intellectual property right against the Pledgor or any entity affiliated with the Pledgor.

5. NO WARRANTY

The license granted herein is “AS IS” without any warranties, express or implied.

All copyright and related rights in the Open COVID License are waived via CC0.
## APPENDIX B – OCP PLEDGORS AND SUPPORTERS

### PLEDGORS, DATE AND LICENSE TYPE

<table>
<thead>
<tr>
<th>Pledger</th>
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**OCP SUPPORTERS**

Creative Commons  
Universities Allied for Essential Medicines  
Mozilla  
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