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Voluntary Intellectual Property Pledges and COVID-19

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At the outset of the COVID-19 pandemic, numerous observers recognized the potential for patents and other intellectual property (IP) rights to hinder the development and dissemination of medical equipment and products responsive to the virus. Concerns over the impact of IP rights on pandemic response led to a range of national and international governmental interventions. Yet these concerns also spurred voluntary, private action by IP rights holders. This chapter discusses and assesses these private initiatives, with a focus on the Open COVID Pledge (OCP), an initiative that I helped to organize. The OCP eventually led to the voluntary commitment of an estimated 500,000 patents to the COVID-19 response, was endorsed by Universities Allied for Essential Medicines (UAEM) and adopted by the World Health Organization's (WHO) Covid Technology Access Pool (C-TAP) as a recommended mechanism for making technology available in the COVID-19 response.[1]

1 COVID-19 AND IP RIGHTS CONCERNS

Concerns about patents and other IP rights emerged in early 2020 as the COVID-19 pandemic began to spread globally. 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).[2] A number of these compounds were covered by existing patents and patent applications held by companies and institutions across

Portions of this chapter are adapted from Jorge L. Contreras, *The Open Covid Pledge: Design, Implementation and Preliminary Assessment of an Intellectual Property Commons*, 2021 Utah Rev. 833 (2021) with permission of the author.

[1] WHO, C-TAP: A Concept Paper – Operationalising the Covid-19 Technology Access Pool (C-TAP) 5 (Oct. 27, 2020), https://perma.cc/V3E9-YMFK (last visited Dec. 5, 2023).

[2] Cynthia Liu et al., *Research and Development on Therapeutic Agents and Vaccines for Covid-19 and Related Human Coronavirus Diseases*, 6 ACS Cent. Sci. 315, 318–321 (2020).

North America, Asia, and Europe. One study identified over 120 different entities holding patents covering diagnostic tests relevant to COVID-19.[3] In addition, 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 and to monitor and contain its spread, including respirators, ventilators, diagnostic kits, facial masks, algorithms, mobile apps, and the like.[4]

Early in the pandemic, a number of high-profile incidents involving patents galvanized concern over these issues. For example:

- In February 2020, the Wuhan Institute of Virology in China announced that it had filed a patent application claiming the use of Gilead Sciences' experimental antiviral drug remdesivir to treat COVID-19.[5] The announcement caused significant concern, given that the Wuhan Institute did not develop the drug and its effectiveness against COVID-19 was still unproven.[6] Gilead's own patents on the drug also caused controversy, prompting thirty state attorneys general to request that the US National Institutes of Health (NIH) exercise its march-in rights under the Bayh–Dole Act of 1980 to authorize additional manufacturers to operate under Gilead's patents in order to meet predicted demand for the drug.[7]
- In March 2020, two engineers in Brescia, Italy, a region particularly hard hit by the pandemic, used a desktop 3D printer to fabricate replacement valves for more than 100 ventilator machines used at a local hospital.[8] Early news reports claimed that a ventilator manufacturer threatened to sue the engineers for infringing patents covering the valves.[9] 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.[10]

[3] Sagacious IP, *List of Companies: Diagnostics/Testing Kits for Coronavirus* (2020).

[4] Frank Tietze et al., *Crisis-Critical Intellectual Property: Findings from the Covid-19 Pandemic*, 69 IEEE Transactions Eng'g Mgmt. 2039 (2020).

[5] Jacob Schindler, *Wuhan Lab Says It Will Seek Patent Protection of Gilead Antiviral*, Intell Asset Mgmt. (Feb. 5, 2020), https://perma.cc/KGZ6-XCW3 (last visited Dec. 5, 2023).

[6] See *id.*; Enrico Bonadio & Andrea Baldini, *Covid-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health*, 11 Eur. J. Risk Regl. 390, 390 (2020).

[7] Letter from California Attorney General Xavier Becerra et al., to Alex M. Azar, Sec'y, HHS, Dr. Francis S. Collins, Dir., NIH, & Stephen Hahn, Comm'r, FDA (Aug. 4, 2020).

[8] Cristian Fracassi & Alessandro Romaioli, Opinion, *We Made Copies of Ventilator Parts to Help Hospitals Fight Coronavirus*, N.Y. Times (Mar. 22, 2020), https://perma.cc/G6LU-XEKN (last visited Dec. 5, 2023).

[9] Jay Peters, *Volunteers Produce 3D-Printed Valves for Life-Saving Coronavirus Treatments*, Verge (Mar. 18, 2020), https://perma.cc/ZVD8-DYGN (last visited Dec. 5, 2023).

[10] *See, e.g.*, Lucas Osborn, *3D Printing, Patent Infringement, and the Coronavirus*, Patently-O Blog (Mar. 19, 2020), https://perma.cc/4RXJ-YY3Y (last visited Dec. 5, 2023).

- 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 it had acquired from defunct blood-testing company Theranos.[11] 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.[12]
- 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 workers and other individuals at high risk of infection.[13] Beshear was responding to severe shortages of protective equipment in his state, which he and others attributed to patents that prevented firms other than 3M from manufacturing them.[14] 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 more than a dozen manufacturers of products including ventilators and blood glucose monitors.[15] 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.[16] In the suit, AbCellera sought an injunction to prevent Berkeley from selling its Beacon Optofluidic System, which was 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:

[11] Labrador Diagnostics LLC v. BioFire Diagnostics, LLC, & bioMérieux S.A., No. 1:20-cv-00348, at *6–61 (D. Del. filed Mar. 9, 2020).

[12] Craig Clough, *Fortress Offers IP Rights to Fight Covid-19 after Backlash*, Law360 (Mar. 17, 2020), https://perma.cc/LA5A-2QQ5 (last visited Dec. 5, 2023).

[13] See Health Systems Editorial Team, *The Netherlands Joins Covid-19 IP Pool Initiative; Kentucky Governor Requests 3M Release N95 Patent*, Health Pol'y Watch (Apr. 8, 2020), https://perma.cc/QAL5-8EVJ (last visited Dec. 5, 2023).

[14] Clough, *supra* note 12.

[15] See Patroll/Contests/Contest Swirlate IP LLC – US 7,567,622 (Wireless Communication Systems), Unified Patents, https://perma.cc/PE5V-K2KR (last visited Dec. 5, 2023); Joe Mullin, *New Low for a Bad Patent: Patent Troll Sues Ventilator Company*, Elec. Frontier Found. (May 20, 2020), https://perma.cc/64ZD-F3FJ (last visited Dec. 5, 2023).

[16] *See generally* AbCellera Biologics Inc. v. Berkeley Lights, Inc., No. 1:99MC09999, 2020 WL 3956700 (D. Del. filed Jul. 9, 2020).

> [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 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.[17]

- 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,"[18] 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.[19]

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

2 PRIVATE ORDERING RESPONSES TO COVID-19 IP THREATS

The public reaction to concerns over IP rights was swift and included the issuance by half a dozen countries of compulsory licensing orders for COVID-related biomedical technologies.[20] Later in 2020, calls were made to the World Trade Organization (WTO) to waive trade-related penalties on countries that imposed compulsory licensing requirements on COVID-19 vaccines and other technologies.[21] But voluntary efforts also emerged to address perceived areas in which patents and other IP could hinder the response to COVID-19.

[17] Michael B. Eisen, Howard Hughes Medical Institute and University of California Berkeley, Oral Comments at the University of Utah S.J. Quinney College of Law Lee E. Teitelbaum Utah Law Review Symposium: The Law & Ethics of Medical Research (Nov. 20, 2020), https://perma.cc/B2QP-GZCN (last visited Dec. 5, 2023).

[18] Matthew Bultman, *Virus Researchers Race to File Patents ahead of Research Reveal*, Bloomberg Law (May 15, 2020), https://perma.cc/D5CS-Z9WP (last visited Dec. 5, 2023).

[19] WHO, *Solidarity Call to Action: Making the Response to Covid-19 a Public Common Good*, https://perma.cc/MA69-KMMM (last visited Dec. 5, 2023).

[20] See Sapna Kumar, *Compulsory Licensing of Patents during Pandemics*, 54 Conn. Rev. 57 (2022).

[21] See WTO, *Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19 Communication from India and South Africa* (Oct. 2, 2020).

A *Patent Pools and Clearinghouses*

Patent pools are arrangements among patent holders that typically enable the participants to operate under one another's patents, to manage and administer the pooled patents through a centralized mechanism, and to grant licenses to third parties, with the proceeds allocated among the participants according to an agreed formula. Patent pools have been utilized for more than a century in industries ranging from oil refinement to aviation 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.

Patent pools have also been proposed as mechanisms to address public health crises such as disease outbreaks. Patent pooling structures were actively discussed and considered in response to the SARS outbreak of 2002–2003,[22] the H5N1 influenza outbreak of 2006,[23] and the H1N1 influenza pandemic of 2009.[24] Yet despite the perceived need for aggregation of patent rights to combat these outbreaks, patent pools were never formed for a range of practical, administrative, and competitive reasons.[25]

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). The 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.[26]

Despite its name, the MPP is not a patent pool as that term is commonly understood. Rather, it is a clearinghouse that obtains inbound licenses from willing IP holders and then sublicenses those rights to generic drug manufacturers

[22] *See, e.g.*, James H. M. Simon et al., *Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling*, 83 Bull. World Health Org. 707 (2005); Carmen E. Correa, *Case 2. The SARS Case. IP Fragmentation and Patent Pools*, in Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes 42 (Geertrui van Overwalle ed., 2009); Hillary Greene, *Patent Pooling behind the Veil of Uncertainty: Antitrust, Competition Policy, and the Vaccine Industry*, 90 B.U. L. Rev. 1397, 1399–1400 (2010).

[23] See Dana Beldiman, *Patent Choke Points in the Influenza-Related Medicines Industry: Can Patent Pools Provide Balanced Access?*, 15 Tul. J. Tech. & Intell. Prop. 31, 60 (2012).

[24] *See* Greene, *supra* note 22, at 1400.

[25] *See, e.g.*, Beldiman, *supra* note 23, at 58, Jorge L. Contreras, *The Anticommons at 20: Concerns for Research Continue*, 361 Science 335, 336 (2018).

[26] *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., 2018).

operating in developing countries. These licenses, which may be royalty-bearing or royalty-free, are generally available on an à la carte basis, and do not necessarily aggregate all of the rights necessary to produce a patented product. To date, several significant patent holders, including AbbVie, Bristol–Myers Squibb, Gilead Sciences, Pfizer, ViiV 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.[27]

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."[28] On May 29, the WHO announced the creation of the C-TAP,[29] 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."[30] Supported by thirty countries, C-TAP's goals included the "promotion of open innovation models and technology transfer that increase local manufacturing and supply capacity, including through the Open Covid Pledge."[31] Despite its promising beginnings, however, little or no technology has been contributed to the C-TAP to date.

B *IP Pledges*

The formation of a patent pool often requires significant legal planning, negotiation, and an administrative infrastructure. 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 and overheads of formal pools. These commitments – IP pledges – are voluntary commitments 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.[32]

[27] Medicines Patent Pool, Supporting Universal Health Coverage through Affordable Medicines: Annual Report 2019, 15 (2020), https://perma.cc/H7H6-EB3U (last visited Dec. 5, 2023).

[28] Letter from Carlos Alvarado Quesada, President, Costa Rica, & Daniel Salas Peraza, Minister of Health, Costa Rica, to Dr. Tedros Adhanom Ghebreyesus, Dir.-Gen., WHO (Mar. 23, 2020), https://perma.cc/86NP-VMQS (last visited Dec. 5, 2023).

[29] WHO, *Solidarity Call to Action*, *supra* note 19.

[30] WHO Team C-TAP, Medicines Selection, IP and Affordability, C-TAP: A Concept Paper – Operationalising the COVID-19 Technology Access Pool (C-TAP) 1 (Oct. 27, 2020), https://perma.cc/V3E9-YMFK (last visited Dec. 5, 2023).

[31] *See* Press Release, WHO, *International Community Rallies to Support Open Research and Science to Fight Covid-19: WHO and Costa Rica Launch Landmark Covid-19 Technology Access Pool* (May 29, 2020), https://perma.cc/A6E8-X66E (last visited Dec. 5, 2023).

[32] *See* Jorge L. Contreras, *Patent Pledges*, 47 Ariz. St. L.J. 543, 564–572 (2015).

Pledges as Landscape Clearing Mechanisms

Intellectual property 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.[33] 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.[34] A number of pledges have also been made to support IP holders' philanthropic, environmental, and corporate social responsibility (CSR) goals.[35]

Intellectual property pledges can be unilateral – made independently by a single entity – or collective – part of a group effort that relies on a single set of principles.[36] All of these pledges typically enable users to operate under the pledged IP without fear of infringement. This 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 benefitting Tesla over its gasoline-powered competitors.[37]

COVID-19 Pledges

The COVID-19 pandemic gave rise to a number of unilateral and collective IP pledges in addition to the OCP. Several of these are described below.

(A) WELLCOME TRUST PUBLISHERS PLEDGE The first pandemic-related IP pledge addressed 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

[33] 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., id.*, at 546.

[34] *See id.*, at 573–592; Jorge L. Contreras, *The Evolving Patent Pledge Landscape* 7–8 (Center for International Governance Innovation (CIGI), Working Paper No. 166, 2018); *see also* Jonas Fabian Ehrnsperger & Frank Tietze, *Motives for Patent Pledges: A Qualitative Study* 15–17 (Centre for Technology Management, Working Paper No. 2019/11, 2019), https://perma.cc/TVN4-VA4F (last visited Dec. 5, 2023); Colleen V. Chien, *Opening the Patent System: Diffusionary Levers in Patent Law*, 89 CAL. REV. 793 (2016), Jonathan M. Barnett, *The Host's Dilemma: Strategic Forfeiture in Platform Markets for Informational Goods*, 124 HARV. REV. 1861 (2011).

[35] Contreras, *Patent Pledges*, *supra* note 32, at 590–592 (identifying philanthropic pledges); Contreras, *Evolving Landscape*, *supra* note 34, at 7 (expanding category to encompass broader corporate mission such as corporate social responsibility and employee morale).

[36] *See* Contreras, *supra* note 32, at x.

[37] *See id.*, at 544–545.

COVID-19 available without charge on an open-access basis.[38] The initiative echoed earlier Wellcome-led pledges made with respect to research concerning the Zika and Ebola outbreaks.[39]

(B) FORTRESS/LABRADOR As discussed in Section 1, in March, 2020 PAE Labrador Diagnostics sued bioMérieux and BioFire for the infringement of patents, allegedly claiming diagnostic test kits being developed for COVID-19. The patents had been acquired by Labrador's parent company, Fortress Investments, from defunct blood-testing company Theranos. News of the lawsuit sparked a wave of negative publicity that soon persuaded Fortress to end the lawsuit and publicly offer royalty-free licenses under the patents to anyone conducting COVID-19 testing.

(C) VENTILATOR MANUFACTURERS Some of the first pandemic-related patent pledges were made by hospital ventilator manufacturers Smiths Group (March 21, 2020)[40] and Medtronic, Inc. (March 30, 2020).[41] In connection with its pledge, each of these companies released the electronic design files associated with a particular ventilator model and authorized others to use those files and accompanying software to manufacture and sell ventilator products on a royalty-free basis.

Medtronic requires any user that wishes to download its design files to register on its website. It then grants users a nonexclusive license that extends until the end of the WHO-declared public health emergency of international concern (PHEIC) or October 1, 2024, whichever is later. 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 (that is, a share-alike or copyleft-style requirement reminiscent of similar requirements imposed under open source code software licensing agreements).

The Smiths pledge is not publicly available and appears to have been extended only to other members of the UK government's Ventilator Challenge Consortium.

(D) UNIVERSITY OF CALIFORNIA BERKELEY INNOVATIVE GENOMICS INSTITUTE The Innovative Genomics Institute (IGI) at the University of California Berkeley is a

[38] Press Release, Wellcome, *Sharing Research Data and Findings Relevant to the Novel Coronavirus (Covid-19) Outbreak* (Jan. 31, 2020), https://perma.cc/H4KZ-VMKD (last visited Dec. 5, 2023).

[39] Press Release, Wellcome, *Statement on Data Sharing in Public Health Emergencies* (Jan. 31, 2016), https://perma.cc/U436-KPME (last visited Dec. 5, 2023); Press Release, Wellcome, *Sharing Research Findings and Data Relevant to the Ebola Outbreak in the Democratic Republic of Congo* (May 21, 2018), https://perma.cc/MWE6-JSP4 (last visited Dec. 5, 2023).

[40] *See UK's Smiths Makes Ventilator Available to Other Producers*, REUTERS (Mar. 21, 2020), https://perma.cc/F4T2-J7EJ (last visited Dec. 5, 2023).

[41] *See* Press Release, Medtronic, *Medtronic Shares Ventilation Design Specifications to Accelerate Efforts to Increase Global Ventilator Production* (Mar. 30, 2020), https://perma.cc/NWU5-KGKR (last visited Dec. 5, 2023).

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, shared the Nobel Prize in Chemistry for 2020). On March 23, 2020, IGI released an "Emergency Covid-19 Technology Pledge" in which it committed to make technology that its researchers developed after March 13, 2020 (the date of a pivotal, multiparty meeting convened by Doudna), available on a royalty-free basis to any entity conducting research on the diagnosis or treatment of COVID-19.[42] 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.

(E) HARVARD–MIT–STANFORD (HMS) On April 7, 2020 (the same day that the OCP was launched), Harvard University, the Massachusetts Institute of Technology (MIT), and Stanford University announced a "Covid-19 Technology Access Framework" (HMS Framework) that would make available nonexclusive, royalty-free licenses for the purpose of making and distributing products to prevent, diagnose, and treat COVID-19 infection.[43]

As of January 2021, twenty additional US research institutions and one non-US university had also "signed" this commitment. 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 nonexclusive and royalty-free, features designed to ensure broad access. The term of the licenses is the COVID-19 pandemic plus "a short period thereafter."

One important feature of the HMS Framework is the 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."[44] 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, if any, and with respect to what IP, as this information does not appear to be publicly available.

(F) OXFORD AND ASTRAZENECA Approximately two weeks after the announcement of the HMS Framework, Oxford University unveiled a similar program that

[42] Press Release, Innovative Genomics Institute, *Our Pledge to Share Covid-19 IP* (Mar. 29, 2020), https://perma.cc/J6X9-5L33 (last visited Dec. 5, 2023). The meeting and the circumstances leading up to the IGI pledge are described in WALTER ISAACSON, THE CODE BREAKER: JENNIFER DOUDNA, GENE EDITING, AND THE FUTURE OF THE HUMAN RACE 405 (2021).

[43] *Covid-19 Technology Access Framework*, Stanford Office of Technology Licensing, https://otl.stanford.edu/covid-19-technology-access-framework (last visited Dec. 5, 2023).

[44] *Id.*

also included the express expectation of downstream pricing constraints.[45] But in August 2020, Oxford is reported to have granted pharmaceutical giant AstraZeneca an exclusive license to the university's COVID-19 vaccine technology with no pricing constraints.[46] Oxford's apparent abandonment of its earlier pledge attracted criticism,[47] but has also been justified based on the large number of vaccine doses distributed to low-income countries at a modest cost.[48]

(G) ABBVIE – KALETRA 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.[49] Two days later, AbbVie announced that it would no longer enforce patents relating to Kaletra anywhere in the world.[50] AbbVie's pledge was widely viewed as a response to Israel's action, and was possibly an attempt to deter compulsory licensing orders by other governments.

(H) 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.[51] The pledge, administered by biotechnology firm GenoConcierge, quickly attracted major Japanese industrial participants from the automotive, electronics, and healthcare sectors. Pledgors included LSI Medience and SRL Inc., which provide COVID-19 diagnostic testing, Mitsubishi Chemical, which operates in the healthcare sector, and Teijin, a pharmaceutical manufacturer.[52] The Japanese program reported that over 100 organizations pledged nearly 1 million patents toward "any activities whose sole purpose is stopping the

[45] *Expedited Access for Covid-19 Related IP*, Oxford University Innovation, https://perma.cc/NGX3-6UZM (last visited Dec. 5, 2023).

[46] Jay Hancock, Kaiser Health News, *Oxford's Covid Vaccine Deal with AstraZeneca Raises Concerns about Access and Pricing*, FORTUNE (Aug. 24, 2020), https://perma.cc/37Y5-PR8V (last visited Dec. 5, 2023).

[47] See Luke McDonagh, *Could University Patents Stand in the Way of Universal Global Access to a Covid-19 Vaccine?*, LSETHINKS (Sep. 10, 2020) https://perma.cc/3GL7-7UGT (last visited Dec. 5, 2023).

[48] See Jorge L. Contreras & Kenneth C. Shadlen, *Contrasting Academic Approaches to COVID-19 Vaccine Production and Distribution*, 2(2) HEALTH AFFAIRS SCHOLAR qxae012 (2024).

[49] *See Israel Approves Import of Generic of AbbVie's HIV Drug for Covid-19*, PHARM. TECH. (Mar. 20, 2020), https://perma.cc/MN5K-U3ZY (last visited Dec. 5, 2023).

[50] *See* Donato Paolo Mancini & Hannah Kuchler, *AbbVie Drops Patent Rights for Kaletra Antiviral Treatment*, FINANCIAL TIMES (Mar. 23, 2020), https://perma.cc/9F3N-CG9G (last visited Dec. 5, 2023); Ed Silverman, *AbbVie Will Allow Generic Copies of Its HIV Pill in Israel after the Government Approved a License*, STAT (Mar. 20, 2020), https://perma.cc/E34Z-6YCD (last visited Dec. 5, 2023).

[51] *See* Jacob Schindler & Bing Zhao, *Top Japanese Corporates Pledge Patent Non-Assertion to Speed Virus Fight*, INTELL. ASSET MGMT. (May 7, 2020) https://perma.cc/2N63-WVNA (last visited Dec. 5, 2023).

[52] GenoConcierge Kyoto, *Open Covid-19 Declaration* (Apr. 3, 2020), https://www.gckyoto.com/covid-2-1 (last visited Dec. 5, 2023).

spread of Covid-19, including diagnosis, prevention, containment and treatment."[53] In addition to patents, the pledge covers utility models, designs, and copyrights.

Like the OCP, the Japanese pledge permitted firms to modify the terms on which they were willing to make their IP available to users. As reported by one press account, eighteen pledgors had modified these terms by late May 2020.[54] The modifications included requirements that users notify pledgors of their activities and the patents that they intended to use, and potential limitations to the term of the license extended.[55] In addition, concerns were raised regarding the scope of the Japanese pledge, which extended only to activities whose "sole" purpose related to COVID-19.[56]

(i) Gilead – Remdesivir In May 2020, amidst calls for foreign governments to impose compulsory licenses on Gilead's patented drug remdesivir,[57] Gilead granted nonexclusive licenses to, and committed to share manufacturing technology with, five generic pharmaceutical manufacturers based in Egypt, India, and Pakistan for distribution in 127 low-income countries.[58] The licenses were to remain royalty-free until the WHO declared the end of the COVID-19 PHIC, or until a pharmaceutical product other than remdesivir or a vaccine was approved to treat or prevent COVID-19.

(j) Moderna – mRNA Vaccine On October 8, 2020, mRNA vaccine maker Moderna, Inc. publicly pledged not to enforce its COVID-19-related patents during the pandemic against "those making vaccines intended to combat the pandemic."[59] 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." The reasons for Moderna's pledge were not publicly disclosed, but some have speculated that the company sought to defuse a brewing ownership dispute over the patents with the NIH.[60] In addition, one watchdog group alleged that Moderna

[53] *Id.*

[54] Jacob Schindler, *Japanese Covid-19 Patent Pledge Triples Membership, but Users Must Read Fine Print*, Intell. Asset Mgt. (May 25, 2020) https://perma.cc/VJA5-XNAH (last visited Dec. 5, 2023).

[55] *Id.*

[56] *Id.* (discussing possible interpretations of "sole purpose").

[57] See Zeba Siddiqui, *Health Groups Ask India to Rescind Gilead's Patents for Covid-19 Drug Remdesivir*, Reuters (May 14, 2020), https://perma.cc/5DS5-7MXF (last visited Dec. 5, 2023).

[58] *Voluntary Licensing Agreements for Remdesivir*, Gilead Scis., https://perma.cc/6W5Q-7MRT (last visited Dec. 5, 2023); Ed Silverman, *Gilead Signs Licenses for Generic Companies to Make and Sell Remdesivir in 127 Countries*, STAT (May 12, 2020), https://perma.cc/ZE77-4HEH (last visited Dec. 5, 2023).

[59] Press Release, Moderna, *Statement by Moderna on Intellectual Property Matters during the Covid-19 Pandemic* (Oct. 8, 2020), https://perma.cc/A3TW-ZD4K (last visited Dec. 5, 2023).

[60] See Jorge L. Contreras, *Deconstructing Moderna's Covid-19 Patent Pledge*, Bill of Health (Oct. 21, 2020), https://perma.cc/6NHE-526S (last visited Dec. 5, 2023). Unfortunately, Moderna's dispute with NIH flared up again a year after Moderna made its pledge. See Jorge L. Contreras, *Will NIH Learn from Myriad when Settling Its mRNA Inventorship*

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).[61]

In March 2022, Moderna issued an "update" to its pledge, making the pledge perpetual with respect to vaccine producers in low-income countries.[62] It is not clear, however, whether Moderna, by this update, intended to terminate its pledge for producers outside of low-income countries and, even if this was its intent, whether it could legally terminate the commitment that it made in 2020.[63] In August 2022, Moderna sued rival vaccine manufacturers Pfizer and BioNTech in the United States and Germany, asserting that it was no longer bound by its pledge,[64] a position that could be challenged in the litigation, which is ongoing.

Table 12.1 summarizes the principal terms of the pledges made and royalty-free licenses granted in response to COVID-19 and situates the OCP chronologically within this group.

3 THE OPEN COVID PLEDGE

This section describes the genesis and evolution of the OCP and details some of the considerations that went into its design, drafting, and implementation, as well as its adoption in the market.

A *The Impetus for a New COVID-19 Pledge Community*

The designers of the OCP believed that a generalized platform for IP contributions could facilitate pledges by organizations that did not wish to reinvent 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 (that is, while vaccines and therapeutics received significant attention in international

Dispute with Moderna? Bill of Health (Jan. 6, 2022), https://blog.petrieflom.law.harvard.edu/2022/01/06/nih-moderna-mrna-covid-vaccine-patent/ (last visited Dec. 5, 2023).

[61] Luis Gil Abinader, *Moderna Failures to Disclose DARPA Funding in Patented Inventions* (Knowledge Ecology International, Research Note 2020:3, Aug. 27, 2020), https://perma.cc/HD9S-UPQ6 (last visited Dec. 5, 2023).

[62] Press Release, Moderna, *Moderna's Updated Patent Pledge* (May 7, 2022), https://investors.modernatx.com/Statements–Perspectives/Statements–Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/default.aspx (last visited Dec. 5, 2023).

[63] See Jorge L. Contreras, *No Take-Backs: Moderna's Attempt to Renege on its Vaccine Patent Pledge*, Bill of Health (Aug. 29, 2022), https://blog.petrieflom.law.harvard.edu/2022/08/29/no-take-backs-modernas-attempt-to-renege-on-its-vaccine-patent-pledge/ (last visited Dec. 5, 2023).

[64] *See id.* (analyzing the permissibility of Moderna's lawsuit given its earlier pledge).

TABLE 12.1 *Intellectual property pledges for COVID-19*

Pledge	Date	Duration	IP	Restrictions and limitations
Wellcome Trust Publishers' Group	1/31/20	Duration of outbreak	Publications relating to COVID-19	n/a
Fortress/ Labrador	3/17/20	?	Diagnostic patents relating to COVID-19	n/a
AbbVie	3/19/20	?	Kaletra/ Aluvia patents	n/a
Smiths	3/21/20	?	Ventilator designs, software, patents	Only offered to members of UK Ventilator Challenge Consortium
UC Berkeley Innovative Genomics Inst.	3/23/20	Term of patents	Specified patents	Only covers technology invented after 3/13/20
Medtronic	3/30/20	PHEIC[a] or 12/1/24	Designs, software, patents	Sharealike for modifications; User registration/ identification
Open Covid Pledge	4/7/20	Pandemic[b] + 1 year or 1/ 1/23	Patents, copyrights	Defensive suspension
Harvard–MIT–Stanford	4/7/20	Pandemic[b] + short period	Unspecified	Licensed products must be distributed at low cost
Oxford–AstraZeneca	4/8/20	Pandemic[b]	Unspecified	Licensed products must be distributed free of charge, at-cost or cost + limited margin
Open COVID-19 Declaration (Japan)	5/7/20	PHEIC[a]	Patents, utility models, designs, copyrights	Applies to activities whose "sole purpose" is addressing COVID-19 Add'l restrictions may be added by pledgors
Gilead Sciences	5/12/20	PHEIC[a] or approval of alternate drug	Remdesivir patents, know-how	Licensed to five generic drug makers for sale in low-income countries
Moderna	10/8/20	Pandemic	mRNA vaccine patents	Pledge "updated" in March 2022 to cover post-pandemic period for low-income countries

[a] Duration of WHO-declared PHIC.
[b] Duration of WHO-declared COVID-19 pandemic.

pooling proposals, medical equipment and software applications did not). 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 response to COVID-19.

B *Design Requirements*

A number of fundamental design requirements were recognized early during the process of creating the OPC. These included:

1. *Legal enforceability*: Any commitment made by IP holders had to be legally enforceable. Mere aspirational statements and expressions of intent were not sufficient. 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 needed to ensure the broadest possible use of the committed IP. 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 induce them to incur 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 pledging IP could not be so burdensome or punitive to IP holders that it would dissuade them from participating. That is, the requirements on IP holders needed to be as reasonable as possible within the constraints established by requirements 1 and 2.
4. *Limited scope*: In order to attract large enterprises with significant patent portfolios, it was necessary to design the OCP so that it did not extend beyond the scope of the immediate emergency: the COVID-19 pandemic. Accordingly, the scope of the pledge was limited to diagnosis, prevention, containment, and treatment of COVID-19 and related research, and was limited in duration to the pandemic as defined by the WHO or January 1, 2023, whichever occurred first.

C *Adoption of the Open COVID Pledge*

The OCP was "launched" on April 7, 2020 via the public website opencovidpledge.org. It consisted of a short statement of intent linked to a more formal public

licensing agreement – a model derived from open-source software licensing and Creative Commons.

The first major pledgor was Intel, followed within two weeks by Amazon, Facebook, Hewlett Packard Enterprise, IBM, Microsoft, and Sandia National Laboratories. More large IP holders joined the pledge in subsequent weeks.

In May 2020, 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.[65]

By mid-June 2020, the OCP had attracted more than thirty pledgors with an estimated 500,000 pledged patents. These included twenty-six corporate entities, four nonprofit entities (universities or research institutes), and two US national laboratories. Twenty-six pledgors were based in the United States, four in Europe, and two in Japan. The following section analyzes the adoption patterns of the OCP and assesses its value in fields in which adoption has been high and low.

D *Pledged IP*

Frank Tietze and colleagues have identified five categories of product innovation that are critical when responding to a major infectious disease outbreak such as COVID-19 ("crisis-critical products").[66] These categories include:

- Vaccines and treatments;
- Diagnostic tests;
- Medical equipment (especially hospital/intensive-care 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 and understand the spread and development of the virus across populations."

Intellectual property in each of these crisis-critical product categories was pledged to the COVID-19 response under the OCP. The following discussion summarizes and offers examples of pledges in each of these categories.[67]

[65] WHO, *Solidarity Call to Action*, *supra* note 19.

[66] Tietze et al., *supra* note 4, at 3.

[67] A more complete description of the patents pledged under the OCP can be found in Jorge L. Contreras, *The Open Covid Pledge: Design, Implementation and Preliminary Assessment of an Intellectual Property Commons*, 2021 Utah Rev. 833 (2021).

Biopharmaceuticals (Vaccines and Cures)

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 affected this sector from an early date. As a result, repeated calls have been made by government officials for open access to vaccine-related patents and other IP.

Yet compared to other market sectors, there was 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 and Moderna, discussed earlier, and pledges by a number of Japanese firms in the biomedical sector). Firms in the biopharmaceutical sector likewise avoided participation in the WHO's C-TAP pool.

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. This economic logic underlies the vaccine industry; as Ana Santos Rutschman describes it, "patents have permeated the ethos of vaccine R&D."[68] And, more generally, scholars have long observed the high value placed on patents and exclusivity within the biopharma sector.[69] These longstanding attitudes pose a substantial barrier to participation in arrangements that tend to limit the enforceability of IP rights – more so than in industries, such as information technology, in which patents have traditionally played a smaller role in innovation and product development.[70]

In addition, biopharmaceutical firms point to legitimate concerns about the quality and safety of products that may be manufactured under open licensing regimes.[71] For 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.[72]

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, sought the "rapid development, testing, and

[68] Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. REV. 728 (2019).

[69] *See* DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (2009).

[70] *See id.* (patents contribute little to firm value in electronics industry).

[71] Adam Houldsworth, *WHO Covid-19 IP Pool Launches This Week Without Strong Pharma Support*, INTELL. ASSET MGMT. (May 26, 2020), https://perma.cc/L8RL-G7JX (last visited Dec. 5, 2023) (quoting Corey Salsberg, head of IP affairs for Novartis).

[72] This being said, a number of vaccine manufacturers made other public commitments relating to product access and pricing during the COVID-19 pandemic. *See* Adam Houldsworth, *Your Guide to Covid-19 Vaccine Stakeholders' IP Strategies*, INTELL. ASSET MGMT. (Nov. 19, 2020), https://perma.cc/MAS7-FLVW (last visited Dec. 5, 2023).

free and open-source sharing of vaccine designs and essential protocols."[73] RaDVaC freely shares all information on its vaccine designs, production, self-administration, and testing on its website under the OCP.

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. Moreover, numerous firms have pledged IP covering artificial intelligence and computational methods for enhancing drug discovery, design, testing, manufacture, and administration.

UNIVERSITIES A significant amount of biomedical innovation in the United States and elsewhere originates in academic research institutions, much of which is funded by governments and charitable foundations. Yet no major research institution 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.

Twenty-four academic research institutions committed to use the Harvard–MIT–Stanford COVID-19 Technology Access Framework described in Section 2.B (HMS Framework). This Framework, announced on the same day as the OCP, shares many of the OCP's fundamental design features, including royalty-free licensing of IP related to the COVID-19 response. The HMS Framework is more administratively burdensome than the OCP, in that it appears to require bilateral, signed licensing agreements between participating universities and licensees. It also imposes downstream pricing constraints on licensees, as do programs such as the Medicines Patent Pool. It is not known how many, if any, licenses were executed under the HMS Framework.

But even with these programs, the vast majority of academic research institutions worldwide declined to make any pledge whatsoever with respect to their IP. 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.

Alternatively, like private firms, universities may wish to maximize revenue generation from their IP portfolios. While such a profit-seeking motive may seem incongruous with the public missions of many universities, it has been well documented over the past several decades.[74]

[73] RaDVaC, https://radvac.org; https://perma.cc/MPY7-HWU4 (last visited Feb. 17, 2021).

[74] *See, e.g.*, Daniel S. Greenberg, Science for Sale: The Perils, Rewards, and Delusions of Campus Capitalism (2007); Jennifer Washburn, University, Inc.: The Corporate

Diagnostics

Early efforts to develop diagnostic tests for the SARS-CoV-2 virus were led by research groups at the University of California Berkeley and the Broad Institute, which avoided seeking patent protection on these developments.[75] Patents covering COVID-19 diagnostic tests gained prominence early in March 2020, when Labrador Diagnostics asserted patents, which its parent Fortress Investments acquired from defunct blood-testing firm Theranos, against diagnostic test makers. As discussed in Section 2.B, 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. IBM pledged several relevant patents, including one claiming a method for detecting a nucleic acid (for example, DNA or RNA) sequence using a cellular phone, and a pending patent application claiming a microfluidic device with programmable verification features – a technology similar to that allegedly developed by Theranos. Sandia National Laboratory, which holds a number of patents covering the detection of proteins and other organic molecules, 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." Together, these pledges represent a meaningful body of technology that could 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, all with reduced concerns of patent infringement.

Medical Equipment

As noted in Section 1, 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 Oxygen and Ventilator System Initiative (OVSI), an OCP participant, is a UK-based project that designed a portable and affordable ventilator device for deployment in low- and middle-income countries. With these pledges, significant access was granted in the area of hospital ventilator equipment, and numerous open-source ventilator projects have since emerged around the world.[76]

Corruption of American Higher Education (2005); Jorge L. Contreras, *In the Public Interest: University Technology Transfer and the Nine Points Document – An Empirical Assessment*, 13 U. Cal. Irvine L. Rev. 435 (2023).

[75] Isaacson, *supra* note 42, at 430.

[76] *See* Joanna Goodrich, *Iranian Engineers Invent Resilient Open-Source Ventilator*, IEEE Spectrum TI-6, TI-6 (Sep. 2020); Ravinder Dahiya & Andrew Hart, *Why DIY Ventilators Are Still a Vital Stopgap*, IEEE Spectrum TI-8, TI-10 (Sep. 2020).

Intellectual property covering a number of other medical products and devices relevant to COVID-19 was also pledged. These products include simple yet innovative devices such as a nasal forceps swab for sample collection and a plastic device for spiking intravenous bags. 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.

Personal Protective Equipment (PPE)

Personal protective equipment (PPE) such as masks and face shields are essential to preventing the spread of airborne infectious agents, in both public places and healthcare facilities, but also at vaccine and drug manufacturing facilities where contagious agents may be concentrated. Shortages of PPE became acute during the early months of the pandemic and continued to plague hospitals, clinics and testing sites. Both Sandia National Laboratory and the NASA Jet Propulsion Laboratory (JPL) were early contributors of PPE IP 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. The JPL published the digital design files for four different 3D-printed respirators. One small business, ProBuccal, pledged its IP in an oral bioaerosol shield for dental applications. And Leonardo, an Italian industrial conglomerate, pledged a patent for monitoring PPE usage in the workplace.

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 attracted significant attention during the COVID-19 pandemic.[77] 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 (avoiding the need for direct contact between an individual and a device). Technologies such as these were utilized with increasing frequency during the pandemic due to concern over contamination and the spread of contagion through human touch.

Digital Innovation

In terms of both number of pledgors and number of patents, the greatest uptake of the OCP was in the information technology sector. Large multinational firms such as Intel, IBM, Microsoft, Facebook, Fujitsu, Uber, Mitsubishi Electric, Amazon, and SAP each made thousands or tens of thousands of patents available through the OCP. Any accurate inventory of the close to half a million patents pledged in this

[77] *See* Mark Anderson, *The Ultra-Violet Offense*, 57 IEEE Spectrum 50, 51–52 (Oct. 2020).

area is impossible. However, some of the industry subsectors 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) were pledged under the OCP by firms including Microsoft and Fujitsu. One 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. And a recent IBM patent claims methods for identifying clinical trial site locations based on epidemiological and demographic factors.

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

(b) CONTACT TRACING AND EPIDEMIOLOGY The rapid spread of COVID-19, its long latency period, and the uncertainty surrounding its precise vectors of transmission, led to a need for reliable and pervasive methods of modeling, predicting, and tracing the spread of contagion. So-called contact tracing applications, which allow users to track the individuals with whom they have had contact, helped epidemiologists to understand the nature of the disease and its spread.

Numerous patents claiming contact tracing methods and technologies, as well as epidemiological modeling techniques, were issued and asserted during the pandemic.[78] Nevertheless, a significant number of patents, patent applications, and other IP relating to contract tracing and epidemiological modeling were pledged under the OCP by firms including apheris AI, IBM, Mitsubishi Electric, and Microsoft. These contributions, together with the prior art identified by Unified Patents, provided significantly enhanced freedom to operate in the area of contract tracing technology.

(c) INFRASTRUCTURE AND LOGISTICS Though seldom making headlines, the COVID-19 pandemic placed unexpected strains on global network infrastructures,

[78] *See* $2,000 *for Blyncsy Prior Art*, Unified Patents (Oct. 21, 2020), https://perma.cc/N6TS-D864 (last visited Dec. 5, 2023).

supply chains, and transportation systems. As governments and institutions struggled to cope with aging systems, new technologies were deployed to ensure the rapid, safe, and efficient allocation of resources across physical spaces. In many cases, these technologies were covered by IP pledged through the OCP.

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

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. 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.

(D) INFORMATION RELIABILITY One highly publicized development that 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 developed methods for automatically generating and collecting contextual information about posts, including credibility indicators, additional content, and statistical information, and for displaying this information for users. Microsoft, another pledgor, also developed methods for using credibility-related data in conjunction with servicing web requests such as search queries. And IBM pledged patents covering methods for aggregating data from multiple sources to validate incidents reported via social media, and also for measuring a recipient's perceived degree of trust in an online message. The patents and patent applications underlying these and many other technologies for increasing the accuracy and reliability of public information were pledged under the OCP.

E *Pledges in Support of an Open Innovation Landscape*

Table 12.2 offers an assessment of the adoption of the OCP by providers of the five crisis-critical product categories, based on a subjective three-tier assessment (low, medium, high) of the quantity of IP pledged in each category. In addition, the table 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 above.

TABLE 12.2 *Pledges of crisis-critical product IP*

Product category	Pledged through OCP	Pledged through all pledges
Biopharma	Low	Low–medium
Diagnostics	Low	Medium
Medical equipment	Low–medium	Medium
Personal protective equipment (PPE)	Medium	Medium
Digital innovation	High	High

As shown in Table 12.2, there was wide variation in pledging activity among product categories. The lowest degree of activity occurred with respect to biopharmaceutical products such as vaccines and treatments, most likely due to the substantial economic windfalls at stake. 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 was 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 with immediate potential benefit to society.

Few pledges of any kind can assure a user of complete freedom from patent risks when it produces a commercial product. In the high-technology sector, many products are covered by thousands of patents held by multiple firms, and even biotechnology and pharmaceutical products, once viewed largely as single-patent products, are covered by an increasing number of diversely held patents.[79] 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. Finally, there may always be "outsiders" who are not bound by the patent nonassertion commitments of others, but whose patents cover an otherwise pledged technology.[80] 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.

[79] *See generally* Lisa Larrimore Ouellette, *Note, How Many Patents Does It Take to Make a Drug: Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299 (2010).

[80] *See* Jorge L. Contreras, *When a Stranger Calls: Standards Outsiders and Unencumbered Patents*, 12 J. COMPETITION L. & ECON. 507, 509–510 (2016); Michael Mattioli, *Patent Pool Outsiders*, 33 BERKELEY TECH. L.J. 225 (2018).

That said, it is not essential that complete clearance exist in order for 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 risks exist from outsiders.

Likewise, numerous categories of digital innovation appear to be substantially "opened" to innovation and product development through the OCP and other 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 might have been attractive to innovators in this area. Moreover, even if innovators are unaware of specific pledged IP, or the existence of such pledges, the resulting lack of IP enforcement in these market segments should, itself, have encouraged further development and innovation that might otherwise have been chilled in an atmosphere of active IP enforcement.

The broad nature of most OCP pledges, and the public licensing structure of the OCP, further contributed to the open innovation landscape. That is, within fields in which OCP (and related) pledge coverage was 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 Section 2. Such an identification exercise is both time consuming and technically difficult, requiring 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 eliminated 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 with limited legal resources.

Thus, while quantitative measurement of the precise impact of IP pledges on markets is difficult, there is cause to be optimistic that such pledges may had an effect, direct or indirect, on the willingness of innovators to invest in the development of products relevant to pandemic response. This "opening" of fields to innovation and new market entry is among the principal benefits of the OCP.

F *Extension of the OCP Model beyond COVID-19*

While the OCP was developed as a direct response to the COVID-19 pandemic, the IP pledging framework that it established is not unique to COVID. The OCP provides a lightweight, legally enforceable mechanism for the coordinated pledging of IP 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 IP rights may constrain research, development, or the supply of crisis-critical products.

It is important to note that these benefits can be achieved even without the participation of biopharmaceutical firms. For example, with sufficient public notice, pledges of technologies relating to pathogen detection, manufacturing processes,

cold storage and transport, disease modeling, contact tracing, and the like (all of which were pledged as part of the OCP) could accelerate the response to future disease outbreaks. It is also possible that the successful "test run" of the OCP during the COVID-19 pandemic will demonstrate to IP holders that there are few risks or adverse consequences to participating in such a program, thereby increasing participation in future efforts.

Of course, pledge mechanisms alone may not be sufficient to address many aspects of a new disease outbreak. The COVID-19 pandemic made apparent the criticality of trade secrets and know-how to the manufacturing and distribution of drugs and vaccines.[81] Nevertheless, IP pledges may represent a first step toward transferring knowledge necessary for effective disease response, as they could signal a firm's willingness to assist in the global response, potentially with compensation from governmental or philanthropic funders.

In addition, IP-sharing frameworks may not 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. Intellectual property sharing can help to alleviate bottlenecks in the supply chain by authorizing additional producers to enter the market in order 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 to increase the supply of critical products may not be the ideal solution for these public health issues.

Another looming health crisis is posed by climate change. Limited IP pledging efforts such as the EcoPatent Commons, which ran from 2008 to 2016, have previously been undertaken in this area, yet none has made available significant amounts of IP.[82] Climate change poses many daunting challenges – technological, social, and political – and it is not clear whether IP is currently blocking or promoting progress toward their solution.[83] Moreover, it is not clear that a generalized pledging framework would achieve meaningful gains when issues are tied to local conditions (sea-level rise, drought, storms), require substantial services, know-

[81] See W. Nicholson Price II, Arti K. Rai & Timo Minssen, *Knowledge Transfer for Large-Scale Vaccine Manufacturing*, 369 SCIENCE 912 (2020).

[82] Jorge L. Contreras, Bronwyn H. Hall & Christian Helmers, *Pledging Patents for the Public Good: Rise and Fall of the Eco-Patent Commons*, 57 HOUST. REV. 61 (2019).

[83] *See* Joshua D. Sarnoff, *Government Choices in Innovation Funding (with Reference to Climate Change)*, 62 EMORY LAW J. 1087, 1089 (2013); Joy Y. Xiang, *Addressing Climate Change: Domestic Innovation, International Aid and Collaboration*, 5 N.Y.U. J. INTELL. PROP. & ENT. L. 196, 199–201 (2015).

how, and technical expertise to address, and do not lend themselves to commoditized solutions that are usable by large segments of the affected populations. 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.[84] 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.

4 CONCLUSION

Intellectual property concerns characterized the COVID-19 pandemic from its outset. In addition to various governmental and international efforts to address these concerns, private sector organizations made a number of voluntary pledges in an effort to facilitate the pandemic response. One such effort was the Open COVID Pledge, which was modeled on successful public licensing structures previously developed by the open-source software community and Creative Commons. An estimated 500,000 patents 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 gains that awaited 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 was pledged in the areas of PPE and digital innovation, and to a lesser degree in diagnostics and medical devices. Pledges made through the OCP and other pledging mechanisms enabled the development and manufacture of hospital ventilators and replacement parts, respirators, and a variety of other medical tools and devices. In addition, large quantities of IP covering digital innovation were 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 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 the existence of such pledges, the resulting lack of IP enforcement in these market

[84] One such effort that was recently launched is the Low Carbon Patent Pledge, a pledging framework created by several participants in the OCP which is directed to technologies relating to sustainable energy sources. See https://lowcarbonpatentpledge.org (last visited Dec. 5, 2023).

segments should, itself, encourage further development and innovation that might otherwise be chilled in an atmosphere of active IP enforcement.

Thus, while 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 may contribute to the pandemic response. This "opening" of fields to innovation and new market entry is among the principal benefits of the OCP.

Regrettably, 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 even greater demand for access to innovative, lifesaving technologies. It is hoped that the OCP, which was 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.