Updates

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Open Access, Open Source, and the Battle to Defeat COVID-19

No legal development over the past decades has had a greater impact on the free flow of information and technology than the rise of the open access and open source movements. We recently looked at how.AI, machinelearning, blockchain, 3D printing, and other disruptive technologies are being employed in response to the coronavirus pandemic; we now turn to how two disruptive legal innovations, open access and open source, are being used to fight COVID-19. Although the pandemic is far from over, there are already promising signs that open access and open source solutions are allowing large groups of scientists, healthcare professionals, software developers, and innovators across many countries to mobilize quickly and effectively to combat and, hopefully, mitigate the impact of the coronavirus.

Quick Overview of Open Access and Open Source

<u>Open access</u> refers to the practice of making scholarly datasets, research, and literature freely available without legal, financial, or technical barriers. Open access materials may be provided either gratis (free of charge to read) or libre (free of charge to read, copy, distribute, and modify). Proponents of open access advocate for the movement as a means of empowering readers to find and make use of scientific research and increasing the visibility, readership, and impact of authors and their works.

Open source refers to releasing software or other works and products in a transparent manner that allows for open exchange and community development. As applied to software, this transparency is achieved by releasing programs not only in machine-readable object code format, but also in source code format, the human-readable instructions for a computer-executable application. Open exchange and community development are allowed for by permissive, non-negotiable open source licenses that impose few or no restrictions on how the applicable software may be used and modified. Open source initiatives are often self-perpetuating due to "copyleft" licenses that require any derivative works to be licensed under the same terms as the original work.

Sharing of Information

The widespread dissemination of information about COVID-19 is critical to the successful containment of the pandemic. For example, in an open letter dated March 13, 2020, the government science advisors of 12 countries, including the United States, called on scientific publishers to make their COVID-19-related articles and data freely accessible. Publishers, including *The Atlantic*, Elsevier, *The Lancet*, *The New York Times*, Oxford University Press, Springer Nature, *The Washington Post*, and *WIRED*, have responded by moving coronavirus-related content out from behind paywalls, despite severe economic challenges facing the publishing industry.

A number of platforms are being used by the research community to share information about COVID-19, such as bioRxiv, an open access preprint repository; GISAID, a German public-private partnership providing public access to genetic sequences of influenza viruses; and PubMed, a digital archive of peer-reviewed biomedical and life sciences literature maintained by the National Library of Medicine. These and similar platforms are being leveraged by research efforts, such as Folding@home, which have committed to providing free and open access to their findings.

The free sharing of information has also enabled crowdsourcing efforts to respond to the epidemic. For example, the *Journal of the American Medical Association* has sought to crowdsource ideas on how to maximize the use of personal protective equipment (PPE), to conserve the supply of PPE, and to identify new sources of PPE. Open access-fueled crowdsourcing has also played a critical role both in helping those in need of PPE to locate supplies and in assisting those with PPE to identify organizations in need of supplies.

At least one information sharing initiative, the <u>Internet Archive</u>'s <u>National Emergency Library</u>, has stirred <u>controversy</u>. The Internet Archive operates the Open Library, which allows users to "check out" digital copies of books; however, prior to the coronavirus outbreak, the Internet Archive limited the number of digital copies of a book that can be checked out at any particular time to the number of physical copies of such books owned by the Open Library. In the wake of the pandemic, these restrictions have been removed to create what the Internet Archive calls a National Emergency Library. While the open access projects highlighted above operate on an "opt in" basis (that is, participants determine whether and to what extent to contribute to a project), the National Emergency Library operates on an "opt out" model; authors who object to the lending of unlimited copies of their books, like <u>Colson Whitehead</u> and <u>N.K. Jemisin</u>, are required to contact the Internet Archive to request that their books be removed.

Sharing of Software

Open source software has also been embraced in the fight against the coronavirus. For example, <u>CHIME</u>, which is made available under <u>the MIT License</u>, allows hospitals to run models to project the number of new COVID-19-related admissions that can be expected each day. <u>Nextstrain</u>, an open source software project for real-time tracking of the evolution of viruses and bacteria, has released a collection of open-source tools under the <u>GNU</u> Affero General Public License.

Other open source software responses to the pandemic are coming, including from established *Fortune* 500 companies that have not been associated with the open source software movement in the past. For example, Pfizer, in its COVID-19 response plan, has stated it is committed to making tools it develops available to the broader scientific community via an open source platform.

Sharing of Plans for Medical Devices and Medical Supplies

With available medical devices and medical supplies expected to fall short of peak demand for COVID-19 patients, many people have begun sharing designs and mock-ups of quick-to-produce alternatives online. The Open Source COVID19 Medical Supplies (OSCMS) group, which attracted over 50,000 members in just over two weeks, allows members to exchange and peer-review designs. Similarly, endeavors like MIT E-Vent, OpenLung, and Open Source Ventilator (OSV) Ireland are volunteer efforts that have focused on inventing ventilator designs that can be rapidly deployed.

The Open COVID Pledge

A particularly exciting and innovative sharing initiative is the Open COVID Pledge, which provides:

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.

Although pledgors are free to adopt their own license agreement, the founding pledgors make available a model "Open COVID License" for use, and expressly permit participants "to modify this license to conform to the rules and regulations under which they operate." The model license covers the exploitation of "all patent, copyright and other intellectual and industrial property rights (other than trademarks and trade secrets)" that the licensor has "the right to license under these terms," but such exploitation must be "for the sole purpose of ending the COVID-19 [p]andemic." The license grant terminates one year after the World Health Organization declares the COVID-19 pandemic to have ended.

The Promise of Open Access and Open Source

By providing readily available, turnkey solutions for collaboration among large groups of people across many jurisdictions, open access and open source are proving to be essential tools for making possible rapid, coordinated, wide-scale responses to the coronavirus pandemic. By merely activating an existing set of open access/source contractual arrangements, a person or organization can enlist hundreds, thousands, and even millions of people to work on developing datasets or technology to address a healthcare or other need created by the pandemic.

In many ways, open access and open source make possible mass, concerted efforts to fight a pandemic, efforts that used to be possible only through national and state governments; they effectively supplement government initiatives to defeat an epidemic, and, at least in connection with COVID-19, allow for more seamless cooperation across jurisdictions than is the case with governmental actors.

One shudders to think of the crushing transaction costs and delays that collaborators would have had to overcome if the current epidemic had erupted prior to the open access/source revolution of the late 1990s and early 2000s; parties would have needed to painstakingly negotiate issues such as intellectual property ownership and rights, royalties, limitations of liability, choice of law, and attribution. Absent open access and open source mechanisms, many of the projects noted above would never have been initiated or, if initiated, would have been slow to launch and gain needed critical mass.

Potential Concerns

Although the exciting, sudden boom in pandemic-related open access and open source initiatives will undoubtedly accelerate our efforts to understand the coronavirus and mitigate its deadly impact, such open initiatives are not without serious risks.

For example, a high-profile open access/source initiative may attract amateurs who, although well intentioned, may make flawed or misleading contributions to the project. Similarly, the highly decentralized nature of many open initiatives, combined with the sense of urgency created by the pandemic, can lead to a lack of oversight or quality control, creating the risk of poorly designed, poorly executed, or even outright dangerous information or products being disseminated.

Of course, when open initiatives are used to develop, say, a <u>web browser</u> or design a <u>wind turbine</u>, the "<u>wisdom of crowds</u>" will, over time, root out product defects and create fixes; but this approach can be problematic when an initiative instead focuses on drug development or patient health. An undetected defect in an open design for a ventilator part may prove deadly; a crowdsourced mask that doesn't work may give wearers a false sense of security that leads to increased infection rates. And <u>the results of open initiatives rarely if ever undergo the rigorous peer-review process</u> that helps to weed out errors and misinformation from traditional medical and scientific publications.

A Legal Hurdle

For healthcare providers, the potential concerns raised by open access and open source solutions are compounded by the legal framework governing the use of such solutions. A traditional license agreement in the healthcare industry will typically contain protective representations, warranties, and indemnities that give the licensee the confidence to rely and build upon the licensed data or technology. In contrast, open access and open source offerings are usually offered with all representations and warranties disclaimed, and with no indemnities (for example, information and designs provided by the MIT E-Vent project are offered, as is typical for open access/source initiatives, on an "as is" and "as available" basis). For the contributors to an open initiative, this approach makes sense; after all, who would volunteer countless hours for no compensation on a crowdsourced project only to risk potential liability exposure in return? But risk-averse healthcare providers and their insurers may have little choice but to reject even the most promising open access/source licensing terms.

Although there exists a wide variety of open access/source agreements available for use on collaborative projects, the gap between the "as is" approach taken by these agreements and the understandable need for caution taken by doctors, nurses, and hospitals is a challenge that will need to be addressed before the next pandemic inevitably arrives. Perhaps this is a problem calling for its own crowdsourced, collaborate initiative to address?

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