

Commentary: University Technology Transfer Has Made a Significant Contribution to Fighting COVID-19 while Ensuring Global Access

Commentaire : Le transfert de technologie universitaire a apporté une importante contribution à la lutte contre la COVID-19 tout en garantissant l'accès universel

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Abstract

This paper reviews the response by public sector research organizations and their technology transfer offices to the COVID-19 pandemic. It shows that leading universities and technology transfer associations quickly enacted licensing principles for the duration of the pandemic to maximize availability and minimize delays in translating public sector research institutes' (PSRIs') COVID-19 inventions to the public – in both the developed and the developing world – while waiving payment of royalties. It discusses examples of vaccines, drugs, diagnostics and personal protective equipment that were developed in PSRIs and swiftly deployed throughout the world on socially responsible terms. It reviews the case cited by Herder et al. (2022) and concludes that their proposed mandates are unnecessary and may inhibit the free flow of healthcare innovation from bench to bedside.

Résumé

Cet article passe en revue la réaction à la pandémie de la COVID-19 de la part des organismes de recherche du secteur public et de leurs bureaux de transfert de technologie. Il montre que les principales universités et associations de transfert de technologie ont rapidement adopté des principes d'octroi de licences pour la durée de la pandémie afin de maximiser la disponibilité et de minimiser les retards dans la transposition des inventions des instituts de recherche publics (IRP) vers les populations – dans les pays développés comme dans ceux en développement – tout en renonçant au paiement des redevances. Il présente des exemples de

vaccins, de médicaments, de tests diagnostiques et d'équipements de protection individuelle qui ont été développés dans des IRP et rapidement déployés dans le monde, et ce, dans des conditions socialement responsables. Il passe en revue le cas cité par Herder et al. (2022) et conclut que les mandats qu'ils proposent sont inutiles et pourraient entraver la libre circulation des innovations en soins de santé du laboratoire au chevet du patient.

Background

Herder and colleagues' (2022) article "University Technology Transfer Has Failed to Improve Access to Global Health Products during the COVID-19 Pandemic" is a severe indictment of academic technology transfer, and one would hope that the authors base their conclusion on a comprehensive survey and detailed analysis of academia's response to the pandemic. It appears that this is not the case. The authors do not seem to have surveyed the landscape of the responses to the pandemic by universities in Canada, the UK and the US – thereby failing to identify numerous cases and examples that contradict their thesis – and seem to have reached their conclusion by extrapolating from a single, complex technology development effort. This effort, which centred on lipid nanoparticle delivery (LNP) technology, spanned over 20 years and moved back and forth between companies and universities, has been characterized by Herder et al. (2022) as having been "developed in and around the University of British Columbia in Vancouver, BC, and incorporated into the Pfizer/BioNTech COVID-19 vaccine" (p. 16). Finally, they recommend "remedies" that would very likely inhibit the free flow of academic healthcare technologies to the bedside.

Response to the Pandemic by the Academic Technology Transfer Community

Contrary to Herder and colleagues' (2022) assertion, the response of universities in both North America and Europe to the pandemic has been both heroic and exemplary. By April 7, 2020, less than a month after the pandemic started to spread in the US, Harvard, MIT and Stanford universities published (Stanford Office of Technology Licensing n.d.) a "COVID-19 Technology Access Framework" in which they pledged to license any COVID-19-related technologies "quickly, non-exclusively and royalty-free for the duration of the pandemic and for a short period thereafter." Twenty additional institutions also signed on to this framework. Ten days later, on April 17, AUTM (formerly the Association of University Technology Managers), the leading association for technology transfer professionals globally, released its "COVID-19 Licensing Guidelines" (AUTM n.d.), which were essentially identical to the Harvard/MIT/Stanford framework. Ninety-five institutions (some of which also signed the Harvard/MIT/Stanford framework) have signed the AUTM guidelines, including some outside the US, specifically including McGill University with which E. Richard Gold is affiliated, and the University of British Columbia (UBC), with which Srinivas Murthy is affiliated.

The generic drug industry has shown that the key to making drugs accessible is to have multiple suppliers competing (Stevens and Effort 2008), instead of a single company whose sales are protected by patents. So by licensing technology non-exclusively and royalty-free,

signatories of these pledges are ensuring affordable access in both the developed and the developing world. Making technologies available royalty-free lowers production costs and increases affordability.

These are voluntary licensing approaches. By contrast, the World Trade Organization has been debating a proposal to waive patent rights on COVID-19 vaccines, which has been proposed by India and South Africa (World Trade Organization 2020) since early in the pandemic and has got nowhere (Farge 2021). International treaties are slow and cumbersome to change; licensing decisions are business decisions and can be made overnight. Later, I show how a voluntary licensing decision has obviated Herder and colleagues' (2022) complaint about UBC.

Some Specific Academic Contributions to Fighting the Pandemic

Turning to specific academic technologies to fight the pandemic, one of the major contributions has been the AstraZeneca vaccine, which was created by the University of Oxford and co-developed by Oxford and AstraZeneca. According to the *Wall Street Journal* (Strasburg and Woo 2020), after contentious negotiations involving Oxford and a university spin out, Vaccitech – which co-invented the technology with Oxford and will receive around 24% of Oxford's revenues from the vaccine (see Vaccitech S-1 prospectus filed with SEC, April 9, 2021, page 16: <https://www.sec.gov/edgar/searchedgar/companysearch.html>) – AstraZeneca agreed to pay Oxford \$10 million upfront and another \$80 million in regulatory and sales milestone payments. Oxford agreed to suspend all royalties for the duration of the pandemic and a royalty rate of 6% in the developed world thereafter, and insisted on stringent protections for the developing world with regard to the licence, requiring AstraZeneca to make the vaccine available to low- and middle-income countries (LMICs) at no profit *in perpetuity*. Although not approved in the US, Vaxzevria is one of the most important vaccines globally. AstraZeneca was the first company to start shipping doses of the COVID-19 vaccine to COVAX, the non-profit set up to co-ordinate the supply of COVID-19 vaccines to some 142 lower income countries (AstraZeneca 2021). As of December 2021, 65% of the COVID-19 vaccine doses supplied via COVAX had come from AstraZeneca, and over half a billion doses of the Oxford–AstraZeneca vaccine have been delivered at a non-profit price globally, with two-thirds going to LMICs (British High Commission Dhaka 2021). AstraZeneca has contracted with Serum Institute of India to manufacture Vaxzevria. It is also being jointly produced under licence in Latin America by Argentina's mAbxience, which reproduces the active pharmaceutical ingredient, and Mexico's Laboratorios Liomont, which formulates, fills and finishes the product for distribution. The Latin American product has received WHO Emergency Use Authorization (PAHO 2021).

Baylor College of Medicine (BCM) and Texas Children's Hospital Center for Vaccine Development developed a protein subunit vaccine called CORBEVAX based on unpatentable, older "tried and true" vaccine technology (Hotez and Bottazzi 2021). The resulting

vaccine is stable and does not require storage under low-temperature conditions. BCM is non-exclusively licensing the vaccine to vaccine manufacturers in the developing world. They have targeted manufacturers in countries where the vaccine can have the most impact:

- India through a licence to Biological E Ltd.;
- Indonesia through a licence to Bio Farma;
- Bangladesh through a licence to Incepta Pharmaceuticals; and
- Africa through a licence to ImmunityBio.

Emory University, a powerhouse in antiviral research, originally discovered Lagevrio (molnupiravir), one of the two orally administered small molecules that have been shown to be effective in treating COVID-19, as a potential treatment for influenza. Emory licensed molnupiravir to DRIVE, a limited liability company specialized in drug development wholly owned by Emory and funded by the royalties from Emory's earlier successes in discovering effective antiretrovirals to treat HIV. At the outset of the pandemic, DRIVE recognized molnupiravir's potential to treat COVID-19, developed it to the point of submitting an Investigational New Drug Application and licensed it to Ridgeback Therapeutics, which had been set up to treat Ebola. Ridgeback got molnupiravir into Phase 1 and was very quickly able to strike a partnership with Merck to co-develop molnupiravir. Emory – which has a well-established set of global health principles (Emory University Office of Technology Transfer n.d.) – Merck and Ridgeback granted a licence to the Medicines Patent Pool (MPP), which has already granted non-exclusive licences to manufacturers for around a hundred LMICs. The licences will be royalty-free for the duration of the pandemic (Merck 2021). Thirty generic drug companies have already signed on to obtain licences (Guarascio 2022).

Pfizer, which both discovered and developed the second oral small molecule shown to be effective against COVID-19 – Paxlovid (ritonavir-boosted nirmatrelvir) – has also licensed it to the MPP. MPP can license Paxlovid to multiple licensees to supply LMICs, again illustrating sensitivity to global health needs during the pandemic in the corporate sector as well as in academia (Pfizer 2021).

Academic institutions were also very active in developing COVID-19 tests.

The University of California, Berkeley, which started incorporating global health provisions in its licence agreements as early as 2003 (Mimura et al. 2011) to facilitate affordable access to its innovations in LMICs, discovered a new implementation of CRISPR (the gene editing technology), involving the enzyme Cas12 and licensed it including global health protection terms to Mammoth Biosciences – a company co-founded by CRISPR Nobel Laureate Jennifer Doudna. As part of a National Institutes of Health (NIH n.d.) program called Rapid Acceleration of Diagnostics, Mammoth used the technology to develop a high throughput COVID-19 test called DETECTR BOOST (WebWire 2020), which received

a United States Food and Drug Administration (FDA) Emergency Use Authorization in January 2022 (Hale 2022). Mammoth is continuing to develop the use of the DETECTR assay in different diagnostic formats for different uses, including under the Department of Defense's Defense Advanced Research Projects Agency program, "Detect It with Gene Editing Technologies" (WebWire 2021).

Yale University and the National Basketball Association (Poitras 2020) developed the SalivaDirect COVID test. The test received Emergency Use Authorization from the FDA in August 2020 and has been deployed to hundreds of labs in dozens of states, provinces and countries free of charge, with weekly webinars that share experiences and improvements with the user community (Yale School of Public Health n.d.).

Academic institutions even started making and testing COVID-19 supplies in the very early days of the pandemic. Herder's institution, Dalhousie University, tested personal protective equipment supplies being imported into Canada (Layne and Palmetter 2020). Columbia University used various 3D printing machines and, eventually, contract manufacturing facilities to turn out first thousands and then millions of face shields in the earliest days of the pandemic (Evarts 2020). The University of Calgary started manufacturing ventilators (Platt 2020).

AUTM has collected other examples of technologies developed to fight the pandemic at universities (AUTM n.d.).

The University of British Columbia and Lipid Nanoparticles

As noted, Herder and colleagues' (2022) entire indictment of academic technology transfer rests on the case of UBC and the LNP delivery technology used by both the Moderna and Pfizer COVID-19 vaccines. The authors document the complex history of the technology and the extensive litigation, which they state appears to have been driven by intercompany rivalries between Arbutus, UBC's spin-off company, and its predecessors and Acuitas.

UBC was a pioneer in developing liposome technology starting in the early 1980s and had spun out several companies in the space prior to the LNP technology, including Northern Lipids, The Canadian Liposome Company and Lipex.

Using the BioScience Advisors database (<https://www.biosciadvisors.com/>), I was able to identify that UBC signed a licence with Tekmira, which became Arbutus, effective July 1, 1998, that was amended effective July 11, 2006, and amended again effective January 8, 2007. I was not able to access a copy of this licence. This licence and its amendments are the only vehicles through which UBC could have exerted any influence on the development of the LNP technology and the financial terms for its use in LMICs. All of the subsequent technology development appears to have been done in these companies: Acuitas, Arbutus and its predecessors and Alnylam.

Blaming UBC for not including global health provisions in the licence is inappropriate on multiple levels:

- UBC could potentially have exerted an influence on the LNP technology development when it negotiated the licence with Tekmira in July 1998. As Herder et al. (2022) acknowledge, the global health implications of academic licences were not on anybody's radar screen until the Yale/Zerit case in 2001 (Michaelson 2002). UBC would have had additional opportunities to include global health provisions in the renegotiations in 2006 and 2007, but generally speaking, only minor changes are usually made to the original deal terms in later amendments. Even in 2007, the mechanisms to include global health protections in academic licences were only just beginning to be identified, formulated and adopted.
- The LNP technology is only a delivery technology and by itself does not enable an mRNA vaccine. Even had the UBC licence included global health protections, it is most unlikely that UBC would have been able to negotiate provisions that would have required companies licensing the LNP technology to include their downstream vaccine know-how in the global health provisions. Even if UBC had included onerous reach-through provisions, companies may have sought an alternative formulation technology.
- Any UBC patents and the associated licence would have expired by the time that the LNP's importance in delivering an mRNA COVID-19 vaccine had become apparent, and I am informed that neither the Pfizer nor the Moderna vaccines are royalty-bearing to UBC.
- Arbutus sued Moderna for infringing its LNP patents on February 28, 2022. In the complaint (*Arbutus Biopharma Corporation and Genevant Sciences GmbH, Plaintiffs v. Moderna, Inc. and Modernatx, Inc., Defendants* 2022), the patents Arbutus asserts are wholly owned either by Protiva, a company Arbutus acquired in 2008, or by Arbutus itself. The complaint's account of the development of the LNP technology nowhere mentions UBC.

Interestingly, BioNTech has just announced that it will establish mobile manufacturing units that will make Comirnaty (the trade name for its COVID vaccine) for sale at no profit (Pancevski 2022) in LMICs. The first three units will be located in the African countries of Ghana, Rwanda and Senegal.

In addition, early in the pandemic, Moderna announced it would not assert its COVID-19 vaccine patents during the pandemic (Sagonowsky 2020), and on March 8, 2022, it announced that it is permanently waiving its COVID-19 vaccine-related patents in the 92 countries that are members of COVAX (Cullinan 2022).

In other words, *voluntary* licensing decisions by BioNTech and Moderna have achieved what Herder et al. (2022) criticize UBC for not achieving, while the World Trade Organization has made no progress on a proposal to allow patent waivers, which would not have included the necessary knowledge for making a finished vaccine.

Herder and Colleagues' Proposed Remedies

Herder et al. (2022) use the LNP technology case to justify a series of public policy responses that the Canadian government should implement.

Mandatory Licensing Provisions

They propose that the Canadian government develop a set of standardized terms and conditions that *must* be included in any and all intellectual property (IP) agreements that flow from federally funded research and propose as a model those developed by Kapczynski et al. (2005). Kapczynski's proposed model was developed in response to the Yale/South Africa/d4T access issue, an episode in which Kapczynski, at the time a Yale undergraduate, was a prime actor (Kapczynski et al. 2005).

Academic technology transfer itself was active in response to this episode. Ten US universities and the Association of American Medical Colleges developed tech transfer's ethical guidelines, the *Nine Points to Consider*, of which point nine states:

Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world (*"In the Public Interest: Nine Points"* 2007: 8)

However, the *Nine Points* document did not provide specific licensing mechanisms to achieve this.

Stevens and Effort (2008) filled this gap by identifying a number of different licensing mechanisms and corresponding implementing language that would protect global health needs in academic licences. AUTM subsequently incorporated these in a *Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies* ("Statement of Principles and Strategies" 2004). A number of universities signed on to these principles and have included them in their standard forms of licence agreement ("Boston University EZ Start" 2012).

Such voluntary approaches are very different from a mandatory approach. Licence negotiations *always* involve a give and take and the changing of language. Were there a single, legally mandated mechanism, any language change that a prospective licensee insisted on would have to be agreed to by the government, inevitably delaying, and thereby threatening, the completion of the licence. Nor can we be sure that the Canadian government would come up with a practical or acceptable approach. Canada is notable for being the only country to have established a compulsory licensing mechanism in response to Paragraph 6 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)* and on July 17, 2007, authorized Apotex to export to Rwanda a fixed-dose combination AIDS medication, TriAvir (lamivudine+nevirapine+zidovudine), without licences from the patent holders

(World Trade Organization 2007). The procedure for receiving authorization was so complex that no other company has applied for a Paragraph 6 authorization since (Cotter 2008).

Agreement Transparency

Herder et al. (2022) propose that an unredacted copy of all agreements granting rights to the results of federally funded research be provided to a government body, whereby legal scholars and ethicists would be charged with ensuring compliance with the above-mentioned mandate, and that copies redacted for pricing information and IP previously held by the private party be placed in the public domain.

In the US, the Securities and Exchange Commission (SEC) requires that publicly traded companies and companies filing to go public file copies of all their material agreements, including their licence agreements. These are publicly accessible through the EDGAR system. Commercially sensitive information can be redacted, but the redaction is only available for five years. Database companies, such as the earlier referenced BioScience Advisors, are adept at filing *Freedom of Information Act* (US Securities and Exchange Commission 2021) requests for the unredacted versions at the end of the five-year process and would undoubtedly welcome the additional availability of additional transactions from this source. The Canadian Securities Commission has a requirement similar to the SEC.

The problem would come from the first part of the proposal: the review of the agreements by legal scholars and ethicists and its potential to delay and deter deal completion.

Support IP-Free Open Science

The authors propose that the Canadian government provide incentives for open science approaches to drug and vaccine development. While it is not clear how attractive such programs would be to scientists, the current IP-based approach that facilitates the transfer of rights from researchers to companies that wish to develop the technology has been extraordinarily successful in getting academic healthcare discoveries into the hands of the public (Stevens et al. 2011). Governments should be extremely cautious about changing it without evidence that any alternative system would be as successful.

McGill Research and Innovation (n.d.) and UBC (University–Industry Liaison Office n.d) have both adopted Global Access Principles that appear to be very similar to the open science approach that Herder et al. (2022) advocate. It is important to note, however, that open science is not synonymous with no-IP science, as Herder et al. (2022) seem to think.

Conflict of Interest

Ashley J. Stevens discloses the following relationships with the entities mentioned in his response:

1. He has provided assistance to 10X Genomics in a legal dispute with Harvard University and OneCell Bio, Inc., for which he was compensated.

2. He is a past president of AUTM and has previously received compensation for consulting services from it.
3. He is an alumnus of Oxford University and is a past president of the Oxford and Cambridge Society of New England.
4. He has provided assistance to AstraZeneca in a legal dispute with Her Majesty's Commissioners of Revenue, for which he was compensated.
5. He has provided assistance to MedImmune, a subsidiary of AstraZeneca, in a legal dispute with the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., Board of Trustees of the University of Massachusetts and Third Sector New England, Inc., for which he was compensated.
6. He has provided assistance to Emory University in a legal dispute with Glaxo, Inc. and BioChem Pharma, for which he was compensated.
7. He has provided assistance to Pfizer in a legal dispute with Brigham Young University and Daniel L. Simmonds, for which he was compensated.
8. He has provided assistance to Caribou Biosciences, Inc., a company working in CRISPR founded by Jennifer Doudna in a legal dispute with Intellia Therapeutics, for which he was compensated.

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