‘THE PERFECT SHOULDN’T BE THE ENEMY OF THE GOOD’—WHAT CANADA CAN DO *TODAY, TOMORROW & NEXT WEEK* TO ENHANCE EQUITABLE ACCESS TO COVID-19 BIOPHARMACEUTICAL INTERVENTIONS

A Brief submitted to the House of Commons’ Standing Committee on Foreign Affairs and International Development (FAAE)

Matthew Herder, JSM LLM
Director, Health Law Institute, Schulich School of Law
Associate Professor, Department of Pharmacology
Dalhousie University

May 10, 2022

Re: Vaccine Equity and Intellectual Property Rights

Dear Honourable Members of the Committee:

There is overwhelming evidence of inequitable access to a range of COVID-19 targeting biopharmaceutical interventions, including not only vaccines but also anti-viral drug therapies, diagnostic tests, and various materials that are incorporated into these products.[1] As recently explained by Yamey et al. in the *British Medical Journal*, inequitable access is baked into every phase of the biopharmaceutical system—from production and allocation to affordability and deployment.[2] Yet, it is still possible to improve access to these critically important biopharmaceutical interventions in low and middle-income countries (LMICs).[3] Intellectual property (IP) rights are one crucial site where policy intervention can make an immediate and direct impact.[4]

In this Brief, I outline six IP-related policy actions that the federal government can take ***today*****,** ***tomorrow*****,** and ***next week***, which will enhance equitable access to COVID-19 biopharmaceutical interventions. The policy actions are to:

1. Disclose key information pursuant to section 21.1(3)(c) of the *Food and Drugs Act* in order to streamline the production of COVID-19 anti-virals and vaccines by manufacturers for populations in LMICs;
2. Remove section 19.4(9) of the *Patent Act* in order to override patent rights pertaining to COVID-19 interventions in the context of the ongoing public health emergency;
3. Add the phrase "COVID-19 drugs, biologics, and vaccines" to Schedule 1 of the *Patent Act* in order to make such interventions eligible for export under Canada's "Access to Medicines Regime;"
4. Increase Canada's financial support for the World Health Organization's "technology transfer hub" in South Africa;
5. Announce Canada's support for the "TRIPS waiver," to shield would-be manufacturers of COVID-19 drugs, biologics, vaccines, and other interventions from IP-related sanctions; and,
6. Require all agreements pertaining to the development of a federally funded patented invention to include one or more clauses that allow for "equitable access" licensing to manufacturers based in LMICs.

---

[1] Joseph E Stiglitz, "Vaccinating the world against COVID-19 is a no-brainer" (2022) 2:5 PLOS Global Public Health e0000427; Fatima Hassan, Gavin Yamey & Kamran Abbasi, "Profiteering from vaccine inequity: a crime against humanity?" (2021) 374 BMJ n2027.

[2] Gavin Yamey et al, "It is not too late to achieve global covid-19 vaccine equity" (2022) 376 BMJ e070650.

[3] *Ibid*.

[4] Priti Krishtel & Rohit Malpani, "Suspend intellectual property rights for covid-19 vaccines" (2021) 373 BMJ n1344.

The policy actions I recommend are evidence-based and derive from my legal expertise in the areas of IP and biopharmaceutical regulation. I am the Director of the Health Law Institute at Dalhousie University's Schulich School of Law and an Associate Professor in the Faculty of Medicine's Department of Pharmacology. I hold a Chair in Applied Public Health, funded jointly by the Canadian Institutes of Health Research and the Public Agency of Canada.[5] As Chair, I am investigating how to improve the laws, policies, and practices that shape infectious disease related innovations, including—but not limited to—vaccines, so that those innovations are available as a function of peoples' health needs rather than their wealth. Since 2018 I have also served as a member of the Patented Medicine Prices Review Board (PMPRB), Canada's drug pricing regulator. I therefore have real world insight into the challenges that can arise when trying to improve access and affordability of biopharmaceutical interventions.[6]

In sum, my expertise in law and professional experience is directly related to the topic under study by this Committee. I hope my submission will thus help to inform the Committee's deliberations and spur a series of policy actions that will—in both the immediate and longer term—support more equitable access to biopharmaceutical innovation.

One Policy Action Today:

Disclose key information held by Health Canada to streamline production of COVID-19 anti-virals and vaccines for LMIC populations

Inequitable access to COVID-19 interventions stems in part from high-income countries' aggressive procurement strategies combined with manufacturers' decision not to share their technologies with would-be manufacturers located in, or producing interventions for, LMIC populations.

In view of this challenge, multiple actors, including not-for-profit organizations, such as the Drugs for Neglected Diseases initiative (DNDi), and multi-lateral organizations such as the World Health Organization (WHO), have sought to create additional supplies of COVID-19 interventions. The WHO, for instance, created a "technology transfer hub" in South Africa to produce mRNA COVID-19 vaccines. Demonstrating the power of this approach, new suppliers of COVID-19 interventions are starting to come online. In February 2022 the South African-based company Afrigen Biologics produced its own version of an mRNA COVID-19 vaccine without assistance from Moderna, Pfizer, BioNTech, or any other companies involved in first bringing mRNA vaccines to market.[7]

This milestone could have been achieved far more efficiently if Afrigen Biologics had access to certain key technical information. In particular, Afrigen Biologics reportedly struggled to re-

[5] Canadian Institutes of Health Research Government of Canada, "Applied Public Health Chair Program - CIHR", (27 January 2021), online: <https://cihr-irsc.gc.ca/e/52313.html> Last Modified: 2022-01-19.

[6] It is important to note that I have written the present submission in my capacity as a university professor. No other members of the PMPRB were involved in the conception or drafting of this submission, and the views and recommendations offered herein are not intended to represent the views and recommendations of the PMPRB.

[7] Amy Maxmen, "The fight to manufacture COVID vaccines in lower-income countries" (2021) 597:7877 Nature 455–457; Amy Maxmen, "South African scientists copy Moderna's COVID vaccine" (2022) 602:7897 Nature 372–373.

engineer the "lipid nanoparticle" (LNP) delivery system that is embedded within the mRNA vaccine.[8] Two Canadian companies, with strong ties to the University of British Columbia, played key roles in developing the LNP delivery system. Yet they did not share their knowledge with the WHO, Afrigen Biologics, or other LMIC manufacturers.[9] Treated by the companies involved and regulators as proprietary data,[10] much of the technical information about how to make an mRNA vaccine, including the LNP component, is not available in the public domain.

This secrecy presents a major barrier to increasing the supply of mRNA vaccines. Compared to a drug, including COVID-19 anti-virals, mRNA vaccines are much more challenging to reproduce because of their novel and intricate make-up.[11] In the case of an anti-viral drug, reverse engineering the drug is more straightforward because the molecular structure of the drug is publicly available. What stops companies from doing so is the patents that apply to that molecular structure. In contrast, an mRNA vaccine is much more complex and a lot of the crucial technical details of its makeup and how to manufacture it have been kept confidential by its developers.

Fortunately, a great deal of technical information about COVID-19 vaccines is contained in the "Master Files" that a company submits to Health Canada when seeking market authorization for its product.[12] Most of this information is treated as "confidential business information" (CBI) by Health Canada and, in usual circumstances, kept confidential.[13]

---

[8] Nurith Aizenman, "Moderna won't share its vaccine recipe. WHO has hired an African startup to crack it", *NPR* (19 October 2021), online: <https://www.npr.org/sections/goatsandsoda/2021/10/19/1047411856/the-great-vaccine-bake-off-has-begun>.

[9] Matthew Herder & E Richard Gold and Srinivas Murthy, "University Technology Transfer Has Failed to Improve Access to Global Health Products during the COVID-19 Pandemic" (2022) Healthcare Policy, online: <https://www.longwoods.com/content/26724/healthcare-policy/university-technology-transfer-has-failed-to-improve-access-to-global-health-products-during-the-cov>.

[10] Most biopharmaceutical products that have reached the market (i.e., drugs, biologics, vaccines, and medical devices) have multiple types of IP associated with them. Typically, such a product has several patents pertaining to the product's active ingredient, the process used to make it, or minor variations of the drug, which may or may not enhance the drug's properties but nevertheless serve to extend the patent-holder's market advantage. *See* Amy Kapczynski, Chan Park & Bhaven Sampat, "Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents" (2012) 7:12 PLOS ONE e49470. But patents are not the only form of IP used by developers of biopharmaceuticals. A variety of information generated in the course of developing a product are protected as "trade secrets" or other forms of *quasi*-IP, such as "confidentiality business information," that together serve to limit access to knowledge, in turn, protecting the product developer's competitive advantage. In recent decades, a number of market protections have also been built into regulatory systems, such that when a drug receives regulatory approval, it may also receive some form of "data protection" (further delaying competition by generic drug manufacturers).

[11] Derek Lowe, "RNA Vaccines And Their Lipids", (11 January 2021), online: *In the Pipeline* <https://www.science.org/content/blog-post/rna-vaccines-and-their-lipids>.

[12] Health Canada, "Guidance Document: Master Files (MFs) - Procedures and Administrative Requirements", (24 April 2017), online: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/guidance-document-master-files-procedures-administrative-requirements.html> Last Modified: 2017-04-28.

[13] Under the Food and Drugs Act, CBI is defined as follows:

> *confidential business information*, in respect of a person to whose business or affairs the information relates, means — subject to the regulations — business information
> (a) that is not publicly available,

However, under the *Food and Drugs Act*, the Minister of Health has the power to disclose such CBI to a "person who carries out functions relating to the protection or promotion of human health or the safety of the public",[14] provided the person in question plans to use it to protect or promote human health or the safety of the public.[15] Disclosing this information to eligible persons, which according to Health Canada's guidance is not limited to human persons but also not-for-profit organizations,[16] will help streamline efforts by manufacturers in LMICs to produce COVID-19 vaccines.

Similarly, sharing the raw data generated through clinical trials of anti-virals, such as Paxlovid (nirmatrelvir/ritonavir) with organizations like DNDi could help answer key outstanding questions about the duration of protection against SARS-CoV-2 as well as the effectiveness of the anti-viral in specific sub-populations.

No change in law or policy is required to take this action. Also, the Federal Court has affirmed Health Canada's authority to disclose such information without imposing a term of confidentiality upon the recipient,[17] as long as the recipient provides a written undertaking "that no subsequent disclosure of the information will be made in a form that could reasonably be expected to identify the individual to whom it relates."[18] Once disclosed by Health Canada, an eligible person is therefore free to share the information with manufacturers willing to produce mRNA COVID-19 vaccines on a not-for-profit, i.e., non-commercial, basis.

This policy action of disclosure can occur today if requests were made to the federal Minister of Health by an eligible person. To facilitate the process, I have drafted two template letters that request key information pertaining to the two mRNA COVID-19 vaccines and the anti-viral drug Paxlovid. I attach these two template letters as **Appendix A** and **Appendix B**, respectively, and

---

(b) in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available, and

(c) that has actual or potential economic value to the person or their competitors because it is not publicly available and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors;

See *Food and Drugs Act,* R.S.C. 1985, c. F-27, s. 2.

[14] *Food and Drugs Act,* R.S.C. 1985, c. F-27, s. 21.1(3)(c).

[15] Health Canada, "Guidance Document - Disclosure of Confidential Business Information under Paragraph 21.1(3)(c) of the Food and Drugs Act", (9 March 2017), online: <https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/request-disclosure-confidential-business-information/disclosure-confidential-business-information/guidance.html> Last Modified: 2019-05-24.

[16] Health Canada's Guidance states: "Where disclosure of CBI has been requested by an organization, Health Canada expects that it would be a not-for-profit organization and that its mandate, as described in its articles of incorporation or other documentation, would include purposes relevant to the protection or promotion of human health or the safety of the public and the health or safety issue that is the subject of the request. In addition, it is expected that the designated representative of the organization identified in the request would have qualifications in a health profession or health research and demonstrated expertise in the topic of the research." *Ibid*.

[17] *Doshi v Canada (Attorney General)*, [2018] 1 FCR 157.

[18] This requirement is contained in the *Privacy Act,* R.S.C. 1985, c. P-21, s. 8(1)(j). Importantly, this same mechanism of a written undertaking was used to safeguard the privacy interests of clinical trial participants while sharing "raw data" from clinical trials to Dr. Peter Doshi following the Federal Court's ruling in favour of disclosure in the *Doshi* case.

encourage all eligible persons, including not-for-profit organizations such as DNDi and multilateral organizations such as the WHO technology transfer hub to take advantage of this existing flexibility in Canadian law to secure key information held by Health Canada in order to facilitate the production, and inform the most effective use of, COVID-19 interventions.

Two Policy Actions Tomorrow:

Change two lines in the Patent Act to facilitate generic manufacturing of COVID-19 interventions

Patents on COVID-19 interventions have proven to be a substantial contributor to inequitable access.[19] One vaccine manufacturer (Moderna) has promised not to enforce its patent rights in LMICS during the pandemic, but its patents are in dispute[20] and there are many other competing patents on the mRNA vaccines.[21] Moreover, numerous entities have used their patent rights to exercise firm control over who has access to a given intervention, when, and at what cost. Seeking to reduce patent related barriers, the United Nations' "Medicines Patent Pool" has struck deals with patent-holders in order to facilitate manufacturing in LMICs. But these deals exclude LMICs with the most domestic manufacturing capacity, such as Brazil, undercutting the value of these deals in terms of efficiently adding to the global supply.[22]

Importantly, though, patent rights are not absolute. Canada's *Patent Act* contains a number of checks and balances, including section 19.4(1), which mandates the Commissioner of Patents to "authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency."[23] Importantly, this is a mandatory power: if the Minister of Health makes the application, the Commissioner of Patents "shall" grant the authorization. COVID-19 clearly meets the threshold of a "public health emergency."

The *Patent Act* also provides that this override provision cannot be used after September 30, 2020.[24] Why this time limitation was included in the legislation is not clear.[25] Regardless, deleting

---

[19] Elizabeth F Peacocke et al, "Global access to COVID-19 vaccines: a scoping review of factors that may influence equitable access for low and middle-income countries" (2021) 11:9 BMJ Open e049505; Aisling McMahon, "Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance" (2021) 47:3 Journal of Medical Ethics 142–148.

[20] "Moderna loses key patent challenge" (2020) 38:9 Nature Biotechnology 1009–1009; Zachary Brennan, "Moderna loses latest battle in key vaccine delivery patent fight as federal appeal falls flat", (1 December 2021), online: *Endpoints News* <https://endpts.com/moderna-loses-latest-battle-in-key-vaccine-delivery-patent-fight-as-federal-appeal-falls-flat/>.

[21] Mario Gaviria & Burcu Kilic, "A network analysis of COVID-19 mRNA vaccine patents" (2021) 39:5 Nature Biotechnology 546–548.

[22] Luis Gil Abinader, "International landscape of molnupiravir patents", (20 October 2021), online: *Knowledge Ecology International* <https://www.keionline.org/36779>.

[23] *Patent Act,* R.S.C. 1985, c. P-4., s. 19.4(1).

[24] *Ibid*., s. 19.4(9).

[25] C B C Radio ·, "COVID-19 pandemic reveals the risks of relying on private sector for life-saving vaccines, says expert | CBC Radio", (8 May 2020), online: *CBC* <https://www.cbc.ca/radio/sunday/the-sunday-edition-for-may-10-2020-1.5554451/covid-19-pandemic-reveals-the-risks-of-relying-on-private-sector-for-life-saving-vaccines-says-

the time limitation from the legislation would allow this power to be used, provided a public health emergency exists, in turn, removing one the key barriers—potential liability for patent infringement in Canada—that generic manufacturers have faced during COVID-19.

Deleting this time limitation is a simple but powerful amendment to the *Patent Act* that could be introduced tomorrow and passed by Parliament within a matter of days.

A second change to the *Patent Act* that stands to improve equitable access is to add the phrase "COVID-19 drugs, biologics, and vaccines" to the list of products currently included within Schedule 1 of the legislation. Forty-one experts called for "COVID-19 vaccines" to be added to phrase in April 2021.[26] Given the importance of newly developed anti-viral therapies, such as Pfizer's Paxlovid (nirmatrelvir/ritonavir), this phrase should be expanded to include COVID-19 drugs and biologics in addition to COVID-19 vaccines. Adding this phrase to Schedule 1 of the *Patent Act* would make COVID-19 biopharmaceutical interventions part of Canada's "Access to Medicine Regime" (also known as "CAMR"), and permit manufacturers to make and export COVID-19 interventions to eligible LMICs. At least one Canadian manufacturer, Biolyse, has indicated that they have the requisite capacity and has consistently expressed its interest in doing so.[27] It is likely that other generic manufacturers would step up to produce COVID-19 anti-virals for LMICs if the prospect of being sued for patent infringement was removed from the equation. This is especially important for interventions like Paxlovid, where Pfizer's patent holdings globally are not fully transparent, creating considerable risk and uncertainty for generic manufacturers.[28]

Adding the above phrase to Schedule 1 of the *Patent Act* does not require Parliamentary approval. Rather, the amendment to Schedule 1 can be made by the Governor in Council upon an application from the Minister of Innovation, Science and Economic Development and the Minister of Health.[29]

Three Policy Actions Next Week:

Help create the conditions for capacity-building and the production of COVID-19 and other infectious disease interventions in LMICs

While the above policy actions can help enhance equitable access now, additional actions are needed to sustain equitable access to infectious disease related biopharmaceuticals in the longer term. If undertaken in the weeks ahead, the following three policy actions can help create the conditions for more equitable access to infectious disease related biopharmaceuticals, both in the context of COVID-19 as well as future infectious disease outbreaks.

---

expert-1.5554463>. Notably, this time limitation was not part of section 19.4 when it was originally drafted by Health Canada officials for incorporation into Canada's COVID-19 emergency response legislation. Rather, it was added to the *Patent Act* at the political level.

[26] Arianna Schouten, "41 Canadian Experts Request Amendment to Schedule 1 of the Patent Act to include COVID-19 vaccines", (30 April 2021), online: *Knowledge Ecology International* <https://www.keionline.org/36017>.

[27] James Crombie, "Intellectual property rights trump the right to health: Canada's Access to Medicines Regime and TRIPs flexibilities in the context of Bolivia's quest for vaccines" (2021) 17:3 Journal of Global Ethics 353–366.

[28] *Paxlovid Patent Landscape: Pfizer's path to building patent barriers in a global pandemic*, by Benjamin Wild (2022).

[29] Patent Act, *supra* note 23, s. 21.03(1)(a).

First, the federal government should significantly increase its financial support for two technology transfer hubs seeking to ramp up production of mRNA vaccines, including the WHO's technology transfer hub in South Africa and the regional hub established by the Pan American Health Organization (PAHO) in Argentina and Brazil.[30] To date, the government has provided a mere $15 million in support for the WHO hub[31] and zero funding for the PAHO hub. After demonstrating capacity to produce its own mRNA vaccine with the support of the WHO, Afrigen Biologics is now training scientists and companies from other LMICs to do the same.[32] If appropriately resourced, the WHO and PAHO hubs have tremendous potential to scale up the global supply of COVID-19 interventions. Canada should therefore increase its financing for these technology transfer hubs as soon as possible. These added resources will complement the first policy action of disclosing key technical information to help overcome the know-how related challenges to mRNA vaccine production.

Second, the federal government should announce its official support for the "TRIPS waiver" proposed by India and South Africa, as amended in May 2021, to include not only vaccines but also "therapeutics, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19."[33] Over one hundred countries have signed onto the waiver to date, and Canada should no longer be silent on the issue.

Third, the federal government should require that all agreements relating to the development of federally funded biopharmaceutical research include one or more clauses that promote equitable access. Such clauses have been drafted and, in select cases, incorporated into agreements between universities and industry.[34] But they appear to be the exception, not the rule. To ensure they become the norm, the federal government should make such clauses a standard term of all research agreements arising from federally funded research, and regularly audit such agreements to ensure they are incorporated and, when necessary, enforced.[35]

Conclusion

---

[30] "PAHO selects centers in Argentina, Brazil to develop COVID-19 mRNA vaccines - PAHO/WHO | Pan American Health Organization", online: <https://www.paho.org/en/news/21-9-2021-paho-selects-centers-argentina-brazil-develop-covid-19-mrna-vaccines>.

[31] Global Affairs Canada, "Canada's aid and development assistance in response to the COVID 19 pandemic", (9 March 2022), online: *GAC* <https://www.international.gc.ca/world-monde/issues_development-enjeux_developpement/global_health-sante_mondiale/response_covid-19_reponse.aspx?lang=eng> Last Modified: 2022-03-09.

[32] Sara Jerving, "Moderna's patents stand in way of mRNA vaccine hub's grand vision", (21 April 2022), online: *Devex* <https://www.devex.com/news/sponsored/moderna-s-patents-stand-in-way-of-mrna-vaccine-hub-s-grand-vision-103055>.

[33] "India and South Africa proposal for WTO waiver from IP protections for COVID-19-related medical technologies", (27 May 2021), online: *Médecins Sans Frontières Access Campaign* <https://msfaccess.org/india-and-south-africa-proposal-wto-waiver-ip-protections-covid-19-related-medical-technologies>.

[34] Samantha Chaifetz et al, "Closing the access gap for health innovations: an open licensing proposal for universities" (2007) 3:1 Globalization and Health 1; Kishor M Wasan et al, "The Global Access Initiative at The University of British Columbia (UBC): Availability of UBC Discoveries and Technologies to the Developing World" (2009) 98:3 J Pharm Sci 791–794.

[35] Herder, Gold & Murthy, *supra* note 7.

Although COVID-19 has presented unprecedented challenges, the core approach to infectious disease innovation has remained fundamentally the same during the pandemic. Despite providing massive amounts of funding in support of COVID-19 research and biopharmaceutical interventions, governments, including Canada, have failed at every turn to ensure that the resulting products would be available as a function of health need rather than privilege and wealth. Worse, by hoarding vaccines and other biopharmaceutical products, wealthy nations like Canada, have directly contributed to the inequities that have been observed.

Proponents of the status quo, including the companies that benefit from the current system, have actively opposed any IP related policy reforms. They argue that *any* changes to the current IP system will undermine the innovations *they* produce. However, this position is not grounded in evidence about who contributes to biopharmaceutical innovation, the relationship between IP and innovation, and the access constraints that IP imposes.

To begin, the position inaccurately implies that industry is the primary source of biopharmaceutical innovation. On the contrary, most biopharmaceutical interventions emerge from publicly funded research environments, such as universities and government laboratories.[36] Further, there is increasing evidence that publicly funded researchers contribute extensively not only to the discovery of promising innovations, but also their subsequent development.[37] It is well documented that many of the biopharmaceutical innovations that have been introduced since the advent of COVID-19 build upon decades of publicly funded science.[38] Several biopharmaceuticals targeting coronaviruses were in various stages of development before the pandemic. But until COVID-19 struck, and governments stepped in with massive injections of funding, industry was largely uninterested.

Secondly, the evidence to support the contention that IP is integral to innovation is, at best, mixed, especially in the context of infectious diseases.[39] IP can serve to structure partnerships and attract

[36] Ekaterina Galkina Cleary et al, "Contribution of NIH funding to new drug approvals 2010–2016" (2018) 115:10 PNAS 2329–2334; Matthew Herder, Janice E Graham & Richard Gold, "From discovery to delivery: public sector development of the rVSV-ZEBOV Ebola vaccine" (2020) 7:1 Journal of Law and the Biosciences, online: <https://doi.org/10.1093/jlb/lsz019>; Rahul K Nayak, Jerry Avorn & Aaron S Kesselheim, "Public sector financial support for late stage discovery of new drugs in the United States: cohort study" (2019) 367 BMJ, online: <http://www.bmj.com/content/367/bmj.l5766>; Ashley J Stevens et al, "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines." (2011) 364:6 N Engl J Med 535–541.

[37] Nayak, Avorn & Kesselheim, "Public sector financial support for late stage discovery of new drugs in the United States", *supra* note 35; Herder, Graham & Gold, "From discovery to delivery", *supra* note 35.

[38] Zain Rizvi, "Government Funds Coronavirus Research While Pharma Sits By", (19 February 2020), online: *Public Citizen* <https://www.citizen.org/article/blind-spot/>; Elie Dolgin, "The tangled history of mRNA vaccines" (2021) 597:7876 Nature 318–324 Bandiera_abtest: aCg_type: News Featurenumber: 7876publisher: Nature Publishing GroupSubject_term: SARS-CoV-2, History, Intellectual-property rights, Vaccines; Stiglitz, *supra* note 1.

[39] Amy Kapczynski, "Order without Intellectual Property Law : Open Science in Influenza" (2017) 102:6 Cornell Law Review 1539–1648; Amy Kapczynski & Talha Syed, "The Continuum of Excludability and the Limits of Patents" (2013) 122:7 Yale Law Journal 1900–1963; Trouiller et al, "Drugs for neglected diseases", *supra* note 10; Hong-Bo Weng, Hai-Xia Chen & Ming-Wei Wang, "Innovation in neglected tropical disease drug discovery and development" (2018) 7:1 Infect Dis Poverty 67.

investment. But it can also slow research down,[40] and precipitate expensive lawsuits that delay and take away from product development.[41] Further, there is no evidence to support the claim that, in the absence of multiple patents and other forms of IP protection, there would be less biopharmaceutical innovation. Companies seek multiple patents and other forms of IP to protect their competitive advantage and secure maximum profits over an extended period of time.[42]

Finally, proponents of the status quo claim that other barriers—including "vaccine hesitancy" and a lack of healthcare infrastructure and distribution capacity—are bigger impediments to equitable access than IP.[43] This is a red herring. It is true that there are other barriers,[44] but all of them, including those that are IP related, need to be resolved to improve equitable access to COVID-19 biopharmaceutical interventions. Efforts to produce an mRNA vaccine have been slowed by a lack of access to the underlying knowledge because that knowledge has been treated as confidential business information; the risk of being sued for patent infringement has prevented manufacturers in Canada and elsewhere from producing a range of COVID-19 biopharmaceutical interventions; and manufacturers have charged high prices for COVID-19 interventions in a number of countries, including some LMICs, because of the IP they own. These are all IP barriers to equitable access.

In short, the perfect must not be the enemy of the good. The six policy actions recommended in this Brief stand to improve equitable access to COVID-19 biopharmaceutical interventions. I urge the members of this Committee to act on them.

---

[40] Tania Bubela, Saurabh Vishnubhakat & Robert Cook-Deegan, "The mouse that trolled: the long and tortuous history of a gene mutation patent that became an expensive impediment to Alzheimer's research" (2015) J Law Biosci lsv011; Fiona Murray & Scott Stern, "Do formal intellectual property rights hinder the free flow of scientific knowledge?: An empirical test of the anti-commons hypothesis" (2007) 63:4 Journal of Economic Behavior & Organization 648–687; Kenneth G Huang & Fiona E Murray, "Does Patent Strategy Shape the Long-Run Supply of Public Knowledge? Evidence from Human Genetics" (2009) 52:6 ACAD MANAGE J 1193–1221; Heidi L Williams, "Intellectual Property Rights and Innovation: Evidence from the Human Genome" (2013) 121:1 Journal of Political Economy 1–27.

[41] The Canadian companies involved in developing the LNP delivery system that is embedded in the mRNA vaccines have, for instance, been embroiled in litigation for several years. It is far from clear whether the IP those companies hold accelerated or slowed the commercialization process. See Herder, Gold & Murthy, *supra* note 7.

[42] Amy Kapczynski, Chan Park & Bhaven Sampat, "Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents" (2012) 7:12 PLOS ONE e49470; The Editorial Board, "Opinion | Save America's Patent System", *The New York Times* (16 April 2022), online: <https://www.nytimes.com/2022/04/16/opinion/patents-reform-drug-prices.html>.

[43] Citing vaccine hesitancy as a reason not to change IP policy is deeply problematic. As noted by Hassan et al., "the mere existence of hesitancy in several parts of the global North, has never been invoked as a reason not to prioritise supplies to them." Fatima Hassan, Leslie London & Gregg Gonsalves, "Unequal global vaccine coverage is at the heart of the current covid-19 crisis" (2021) 375 BMJ n3074.

[44] Yamey et al, *supra* note 2.

Appendix A

May 9, 2022

The Honourable Jean-Yves Duclos, M.P.
Minister of Health
70 Colombine Driveway
Tunney's Pasture
Postal Location: 0906C
Ottawa, Ontario K1A 0K9

[INSERT RETURN ADDRESS]

Re: Request for information pursuant to the *Food and Drugs Act*, s. 21.1(3)(c), in order to protect and promote human health

Dear Minister,

I, [INSERT NAME OF PERSON/ORGANIZATION], am writing to formally request access to the master files and related information for two mRNA-based COVID-19 vaccines; namely, the mRNA vaccine known as "Comirnaty" manufactured by Pfizer/BioNTech, and the mRNA vaccine known as "Spikevax" manufactured by Moderna.

Canada's *Food and Drugs Act*, R.S.C. 1985, c. F-27 [hereinafter "the *Act*"] gives you the power to make these master files and other documented information related to vaccine manufacturing they contain, available upon request in certain circumstances.

Specifically, to disclose the master files and other information under section 21.1(3)(c) of the *Act*, two pre-conditions must be met. The first condition is that I must be "a person who carries out functions relating to the protection or promotion of human health or the safety of the public." I meet this condition because I: [DESCRIBE YOUR RELEVENT ROLES WHICH MIGHT INCLUDE USING THIS INFO TO TEST/DEVELOP HEALTH INTERVENTIONS FOR POPULATIONS IN LOW&MIDDLE INCOME COUNTRIES]

The second condition is that the purpose of disclosing the information must be "related to the protection or promotion of human health or the safety of the public". My request also satisfies this condition because the information contained in the master files and other documents I am requesting will help to increase the available supply of COVID-19 vaccines, which are essential to the protection and promotion of human health.

The reason being is that current efforts to make vaccines similar to Comirnaty and Spikevax, which offer the strongest protection against SARS-CoV-2, have been slowed by a lack of access to key technical information about how to manufacture an mRNA vaccine. This information is not in the public domain, however, the master files (and other information) submitted to Health

Canada by Pfizer/BioNTech and Moderna likely contain a great deal of this key technical information.

Further, I would like to emphasize that I am requesting this information on behalf of my organization, [INSERT PERSON/ORGANIZATION NAME]. Consistent with Health Canada's Guidance Document regarding section 21.1.(3)(c) of the *Food and Drugs Act*, [INSERT PERSON/ ORGANIZATION NAME] is a not-for-profit organization with a mandate to [DEVELOP/PRODUCE/DISTRIBUTE MEDICINES TO LMIC POPULATIONS].

To assist with processing my request, the information I am requesting for both Comirnaty and Spikevax should be contained within the following documentation:

- Master Files
- Active pharmaceutical ingredients (API) Master Files
- Material Safety Data Sheets
- Product development report
- Storage conditions Stability data
- Forced stability data
- Specifications
- Supplier qualification
- Formulation development reports
- Master formula
- Material compatibility/interaction studies
- Specifications for delivery devices
- Master of executed batch record
- Scale up information
- Risk assessment
- Critical process parameters
- In-process control specification
- Scale up protocol and report
- Process validation
- Packaging material specification
- Master of executed packaging record
- Validation
- Sampling plan
- Acceptance Quality Level (AQL) for products and defects
- Packaging validation
- Finished product specification
- Analytical test procedures
- Analytical procedure development
- Analytical procedure validation
- Standard test procedures
- Instrument specifications
- Quality control sampling procedures

- Stability testing protocol and procedures
- Release test analytical procedure validation E
- List of equipment and instruments
- Preventive maintenance information
- Overview of qualification

I trust that you will invoke your discretion pursuant to Canada's *Food and Drugs Act* to make the foregoing information available in a timely fashion.

Sincerely,

[INSERT NAME/TITLE/AFFILIATION]

Appendix B

May 9, 2022

The Honourable Jean-Yves Duclos, M.P.
Minister of Health
70 Colombine Driveway
Tunney's Pasture
Postal Location: 0906C
Ottawa, Ontario K1A 0K9

[INSERT RETURN ADDRESS]

Re: Request for information pursuant to the *Food and Drugs Act*, s. 21.1(3)(c), in order to protect and promote human health

Dear Minister,

I, [INSERT NAME OF PERSON/ORGANIZATION], am writing to formally request access to unpublished information, including clinical trials and other investigational studies for the anti-viral drug known as "Paxlovid" (nirmatrelvir/ritonavir).

Canada's *Food and Drugs Act*, R.S.C. 1985, c. F-27 [hereinafter "the *Act*"] gives you the authority to make this available upon request in certain circumstances.

Specifically, to disclose the information under section 21.1(3)(c) of the *Act*, two pre-conditions must be met. The first condition is that I must be "a person who carries out functions relating to the protection or promotion of human health or the safety of the public." I meet this condition because I: [DESCRIBE YOUR RELEVENT ROLES WHICH MIGHT INCLUDE USING THIS INFO TO TEST/DEVELOP HEALTH INTERVENTIONS FOR POPULATIONS IN LOW&MIDDLE INCOME COUNTRIES]

The second condition is that the purpose of disclosing the information must be "related to the protection or promotion of human health or the safety of the public". My request also satisfies this condition because the information I am requesting will help to answer critically important questions about the degree of protection conferred by Paxlovid against SARS-CoV-2 and its variants over time, as well as its effectiveness for particular sub-populations. In settings, such as low- and middle-income countries where access to this anti-viral remains limited, research into these questions stands to inform the extent to which the drug is helpful and how it can be most effectively allocated within the overall population.

Further, I would like to emphasize that I am requesting this information on behalf of my organization, [INSERT ORGANIZATION NAME]. Consistent with Health Canada's Guidance Document regarding section 21.1.(3)(c) of the *Food and Drugs Act*, [INSERT

ORGANIZATION NAME] is a not-for-profit organization with a mandate to [DEVELOP/PRODUCE/DISTRIBUTE MEDICINES TO LMIC POPULATIONS].

To assist with processing my request, the specific information I am requesting with respect to Paxlovid is as follows:

- Complete copies of all sections of all clinical study reports for all studies related to Paxlovid (nirmatrelvir/ritonavir) that are held by Health Canada. For clarity, I am also requesting the above for any studies of unapproved indications, not just marketed indications.
- All electronic datasets from these same trials, including participant level datasets.

Consistent with best research practices, standards of research ethics, and the *Privacy* Act, R.S.C., 1985, c. P-21, I hereby provide a written undertaking that, in the event that personally identifiable information is included within the scope of the information I have requested, that no subsequent disclosure of the information will be made in a form that could reasonably be expected to identify the individual to whom it relates.

I trust that you will invoke your discretion pursuant to Canada's *Food and Drugs Act* to make the foregoing information available in a timely fashion.

Sincerely,

[INSERT NAME/TITLE/AFFILIATION]