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Overcoming Market Failures in Pandemic Drug Discovery Through Open Science: A Canadian Solution

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Among the lessons learned from the COVID-19 pandemic is the need to develop antiviral drugs poised to treat the next pandemic. Unfortunately, traditional drug development economic models, centered principally on patents, are ineffective to induce private sector investment due to unpredictable timing and cause of the next pandemic. As a result, illustrated by the COVID-19 pandemic, it is the public and philanthropic sectors sectors that overwhelmingly fund the development of innovative vaccines and therapies. To meet the need for proactive antiviral medicines in advance of the next pandemic, new models of drug development are needed. Open science partnerships (OSPs) show promise in this regard. Rather than rely principally on patents and private investment, OSPs combine a variety of academic, philanthropic, governmental, and private sector incentives to share knowledge and develop and test antiviral drugs. Private sector investments are, within an OSP, not only leveraged against investments by other actors, but predicated on gaining regulatory data exclusivity, a known and secure form of commercial advantage. Building on domestic expertise in OSPs, Canadian leaders created the Viral Interruption Medicines Initiative, a not-for-profit OSP, to develop pandemic ready-antivirals and address other areas of market failure.

Keywords: pandemic, antimicrobial resistance, patents, open science, partnerships, regulatory data protection

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INTRODUCTION

The COVID-19 pandemic showcased both the best and worst of science. Collectively, the scientific world quickly shared the SARS-CoV-2 sequence, created vaccines, put those vaccines through clinical trials and delivered them in record time. At the same time, scientists promoted false treatments such as vitamin D, hydroxychloroquine, and firms exercised their proprietary positions over vaccines and drugs to leave low- and lower-middle income countries greatly under-vaccinated.

One important strand of the pandemic story is that, as of the date of writing, only three anti-viral pills have been approved for use—one new and two repurposed. Pfizer's Paxlovid is a derivative of a shelved drug lead developed 20 years ago for the original SARS virus while the other two—remdesivir and molnupiravir—are repurposed from legacy programs targeting other viruses. Many firms and university labs attempted to repurpose other types of drugs to identify those with antiviral activity, but none of these efforts proved fruitful (Edwards 2020). There are many antiviral antibody drugs approved, and dozens in development, although these must be administered in hospitals and are priced beyond the reach of most people. Broadly, the world simply had no advance plan to proactively develop simple drugs to treat pandemics—despite several epidemics since the Millennium (Edwards et al., 2022).

As night follows day, there will be another viral pandemic, for which we must prepare now. Unfortunately, existing models of drug discovery have not proven themselves suitable. Pandemic preparedness is an example of market failure where reliance on traditional forms of intellectual property simply do not provide the incentive to develop the vaccines and simple drugs needed (Outterson et al., 2007; Eccleston-Turner 2016; Jacobs 2019).

In this review, we investigate a novel intellectual property approach to drug development that promises to develop pandemic-ready drugs quickly and accessibly before the next pandemic hits. This approach, an open science partnership, has been put into practice for 2 decades in the health sciences. Specifically, we summarize how a Canadian not-for-profit corporation, the Virus Interruption Medicines Initiative (VIMI) and its international partners aim to develop an open science drug discovery ecosystem to develop pandemic-ready drugs without the use of patents.

MARKET FAILURES IN DRUG DISCOVERY

While debate continues, there is growing evidence that drug discovery is facing productivity declines (Gold 2021). Drug development costs increase and drugs are less novel, while patient costs increase and accessibility decreases. This tendency is exacerbated in addressing pandemics given the large uncertainty as to drug target and timing of the pandemic (Eccleston-Turner 2016, 583). In this field, the incentives provided by patents, relied on heavily by the pharmaceutical industry in relation to other disease areas (Hall 2022), become less effective. Eccleston-Turner (2016) notes, for example, that patents did not play a significant role in developing a vaccine against the 2009 H1N1 influenza pandemic. Sherkow et al. (2021) go further in respect of vaccine development against SARS-CoV-2:

> Patents are instead—surprisingly—something of a sideshow. To the extent that innovation policymakers are trying to figure out where to focus their efforts in improving vaccine development and distribution, they shouldn't focus on patents.

Despite the lack of significant incentive effect of patents, firms and universities have gone on a patenting extravaganza during the COVID-19 pandemic. The World Intellectual Property Organization reports that firms and universities filed over 5,000 patents in the period ending in September 2021 (World Intellectual Property Organization. 2022). This marks a significant increase over the 500 patents relating to influenza vaccines from 1941 to 2011. Around 80% of patents on drug candidates related to repurposed drugs (World Intellectual Property Organization. 2022).

The Pandemic Market Is Broken

The problem is that, while we know we will face future pandemics, we know neither its timing nor the virus involved. This uncertainty leads firms to underinvest in research and development prior to an outbreak (Eccleston-Turner 2016). Once a pandemic hits, it is government and philanthropic investments that dominate due to the enormous social and economic losses suffered by the public. These outweigh whatever profits the private sector would earn through ordinary market forces. Data to the end of June 2021 show that governments, philanthropies and international organizations invested the overwhelming portion of the over $45 billion put into vaccine research and delivery (Devex 2021). Private sector investments, while significant—Pfizer says it spent $2 billion beyond the German government's direct investments and government contracts—paled in comparison to these public investments (Lalani et al., 2022).

Without the pull of a known market, patents are insufficient to provide the incentive to invest. It is not surprising, for example, that it was the public and philanthropic sectors that not only developed but tested the Ebola vaccine while industry remained on the sidelines (Herder et al., 2020). The key components of the mRNA vaccines were developed through public funds, largely at universities and government laboratories (Herder et al., 2022; Lalani et al., 2022).

Although government spending dominated vaccine and antiviral drug markets, this did not prevent rent seeking behavior. As noted above, universities heavily invested in patenting everything they could even though government grants and spending, not patents, provided the incentive for development and commercialization. Both universities and firms sought to capitalize on government largesse to extract maximum individual benefit.

This rent-seeking behavior came with a substantial cost. According to former International President of Doctors without Borders, Dr. Joanne Liu, by March 2022, 23 countries had not been able to vaccinate even 10% of their population and 73 countries had not reached the 40% vaccination mark (Meloche-Holubowski 2022). The British Medical Journal reported how, when the World Health Organization set up a vaccine hub in Africa to address vaccine inequality, vaccine patent holders threatened patent infringement (Davies 2022). Two Canadian companies associated with a university—where researchers had conducted the basic research using public funds—did not share their critical lipid nanoparticle technology with the hub (Herder et al., 2022). While Afrigen Biologics developed its COVID-19 mRNA vaccine using publicly available information—delayed by the lack of active sharing—it still faces hurdles in getting to market because of a continued failure to share.

Because of these failures, developing countries brought forward proposals to temporarily waive compliance with intellectual property rules built into international trade agreements and to require active sharing. The United States and France joined in the call to waive compliance with trade agreements. Pressure mounted and soon after the British Medical Journal report, both Pfizer and Moderna, holding rights to the two approved mRNA vaccines, moved to build facilities in Africa (Khemlani 2022) and, in the case of Moderna, to permanently waive enforcement of its patents (Moderna Inc. 2022).

Unfortunately, none of the firms involved is sharing the know-how and data needed for Afrigen to bring its vaccine to market.

The inefficiencies caused by market failures in the vaccine and pandemic antiviral drug markets thus result in three interrelated problems: 1) underinvestment before health crises, leading to delays and increased costs; 2) lack of access to vaccines and drugs (Drugs for Neglected Diseases initiative 2022) in much of the world, leading to a prolongation of the health crisis and an environment hospitable to the emergence of variants and resistance; and 3) rent-seeking behavior not related, in any significant manner, to incentives.

OPEN SCIENCE DRUG DISCOVERY

Acknowledging the inefficiencies in the pandemic market, global public health experts called for a "reboot" of the global health research system. Critical among their recommendations was the need for "a change of rules and incentives", particularly around intellectual property, "to secure the rapid, open sharing of inputs, processes and outputs." (Swaminathan et al., 2022).

In fact, the innovation literature has increasing focused on, and found evidence for, inefficiencies in research and development system (Bloom et al., 2020; Gold 2021), including in the pharmaceutical industry. The combination of decreasing research and development productivity with market failure, calls for new approaches to pandemic preparedness.

The Efficiency of Open Science Partnerships

A new innovation model that seeks to increase the efficiency of innovation has been gaining attention: the open science partnership (OSP) (Gold 2021). These multi-sectoral partnerships leverage the incentives within academic, governmental, philanthropic, and industrial sectors to accelerate innovation from early to late stages of commercialization. OSPs build on the differential expertise of the various partners, with generally academic and governmental partners taking on a larger role in the earlier stages and firms leading in the later stages of product development, manufacturing, and distribution.

A defining feature of OSPs is their adherence to various forms of sharing within the partnership: open results, open publications (including pre-prints), open data, open tools, open materials and the lack of intellectual property—most particularly, patents—that limit these (Ali-Khan et al., 2018). Partners are free to use the results of the OSP to improve or develop their own proprietary products, but within the OSP sharing is paramount in order to decrease duplication, lower transaction costs, and facilitate knowledge development (Gold 2021).

In fields facing market failure, OSPs offer the greatest promise. These fields include pandemic and antimicrobial resistance (AMR) drug development (Rand Europe 2021), due to uncertainty in terms of timing and target, and rare and pediatric diseases, because of their small market sizes. In these fields, as noted, patents do not provide a significant or sufficient incentive to invest. Firms underinvest or, as the demise of two leading AMR drug firms illustrates, go under (Jacobs 2019).

OSPs offer four strategic advantages for these areas of market failure.

First, they rely on incentives other than patents to overcome uncertainties. Academic inducements, such as publishing in a novel area, philanthropic motivations, such as addressing a critical health need, government interest in preventing large-scale economic losses, and private sector market advantages combine to provide a broader and deeper set of incentives to engage in drug research and development.

Second, free-riding is not only not a concern, but a feature. The goal of the majority of actors investing in areas of market failure—university researchers, philanthropists, and governments—do so to encourage production of drugs in general rather than a single, proprietary drug. Thus, if their investment induces firms to jump in, all the better. In particular, governments do not seek, through their investments, any profit on the pandemic drugs developed, leaving these to the private sector.

Third, there remain strong private sector incentives to invest. Because of the breadth of actors in the OSP ecosystem, private firm investments are heavily leveraged by investments by governments and philanthropies, greatly reducing their risk and enabling them to hold off on the majority of funding until after proof of concept. Further, firms benefit from regulatory data exclusivity that, given the leverage of other investments, is sufficient to attract them (Morgan et al., 2018). In fact, because this exclusivity is not subject to the level of validity attacks as exist for patents and that it begins later in the life of drug development, it is often more attractive than are patents.

Fourth, OSPs accelerate information, data, and material flow, avoiding duplication of effort and investments but also speeding up drug development itself (Gold 2016). In one example, an open science partnership between the Structural Genomics Consortium (SGC), the Ontario Institute for Cancer Research (OICR), and academic laboratories around the world resulted in the largest pre-clinical deal in Canadian history when OICR's commercialization partner licensed a leukemia drug to Cellgene for $40 million upfront and up to $1 billion if the drug proved successful (Gold and Morgan 2019).

The Viral Interruption Medicines Initiative

In response to the COVID-19 pandemic, leaders in open science partnerships in Canada created an OSP focused on proactively developing simple molecule drugs for the next pandemic and beyond. Drawing on the experience of the SGC's largest campus in Toronto (Morgan Jones et al., 2014) and the open science policy of the 60-some laboratories at the Montreal Neurological Institute and Hospital (the Neuro) (Gold 2016), these leaders created the Viral Interruption Medicines Initiative (VIMI). VIMI brings together universities, SMEs, large pharmaceutical firms, philanthropies, and government to solve two problems.

First, VIMI aims to develop, in conjunction with an international consortium of actors, a stock of antiviral drugs to treat each of the major viral families responsible for pandemics. VIMI and its partners will develop drugs to the end of Phase 1 trials and put them on the shelf until the next

pandemic. With no patents, any firm or laboratory around the world could test, manufacture, distribute or improve the drug. Further, by licensing the preclinical regulatory data package, VIMI and its partners would position firms to move quickly into Phase 2/3 trials, as well as launch combination studies. Second, VIMI will develop new antibiotics up to the end of preclinical work to place on the shelf should the need arise due to antimicrobial resistance.

VIMI takes an ecosystem approach to drug development, identifying global leaders in virology, microbiology, computational drug development, chemistry, and strategy to bring not only drugs to market but the ancillary products and services needed to support drug development. Combining funding from multiple sectors—large firms, SMEs, universities, and government—VIMI operates through four pillars.

The first pillar is computational drug discovery. Housing the Critical Assessment of Computational Hit-finding Experiments (CACHE) initiative (Ackloo et al., 2022), VIMI will establish competitions for computational drug discovery firms to validate and improve their algorithms based on drug targets that fall within VIMI's mandate. While the firms retain all intellectual property rights over their algorithms, all molecules submitted to the competition will be patent free. This model is similar to that used by the COVID Moonshot team, which is crowd-sourcing the development of a new SARS-CovV-2 protease inhibitor (Consortium. 2020). CACHE researchers will openly disseminate the results of laboratory analyses and make the molecules available.

The second pillar is open science drug development. VIMI will work with firms or other non-profit initiatives, such as READDI (www.READDI.org), to pursue the development of molecules consistent with its open science principles of sharing and absence of patent rights. VIMI will provide strategic and management expertise and co-fund development of drugs falling within its mandate.

The third pillar is open science strategic support, ranging from education, to open science commercialization strategy, to policy assistance. Firms or universities that have decided to pursue an open science strategy will access advice on how to establish and manage OSPs, develop novel open science tools, and develop and implement an open science strategy based on regulatory data exclusivity and other means.

The last pillar is the ability to collaborate with other public and private sector efforts, such as the COVID Moonshot initiative now being led by DNDI ("COVID Moonshot | DNDi" n.d.), as well as any other global initiatives that aim to develop new medicines with a focus on equitable access, including repositories such as bioRxiv and medRxiv, provided they continue after the COVID-19 pandemic.

DISCUSSION

The COVID-19 pandemic highlighted the need for governments, universities and firms to develop antiviral medicines against the major pandemic viral families in advance of the next pandemic. Traditional intellectual property strategies, based on patenting and exclusive licensing, do not provide sufficient incentives given the uncertainty as to the virus responsible for the next pandemic and its timing. This has led to market failures, taking the form of too few medicines available to combat the pandemic when needed, and too little access to those medicines that exist.

While the pharmaceutical sector normally relies heavily on patents, patents come at a cost. They restrict use of knowledge, increase transaction costs, and, as the COVID-19 pandemic illustrated, create global access problems. With increased costs and decreased access, viruses have more time and opportunity to evolve, creating new variants. The health, social and economic cost is enormous. Given that patents are relatively weak incentives, especially in advance of a pandemic, their costs become unacceptable.

OSPs provide an alternative model of drug development that is particularly apt in areas of market failure. Based on open sharing of results, tools, materials, and publications, OSPs remove transaction costs involved with negotiating about patents by eschewing them (Gold 2021). OSPs leverage the different incentives that motivate academic, philanthropic, governmental, and industrial partners to achieve agreed upon goals. Drawing on the different forms of expertise—with academic researchers strongest at early stages of commercial development and firms at later stages—OSPs move technology through to delivery.

Rather than invest billions of dollars after a pandemic or health crisis, VIMI aims to develop drugs in advance of the next crisis at a much, much lower cost. Bringing together the research and development expertise of a broad group of actors, identifying gaps in the ecosystem and filling them, and providing education and strategic advice, VIMI is able to accelerate development while reducing transaction costs in proactively developing pandemic-ready drugs. VIMI will also pursue drug development in other areas of market failure: AMR, rare diseases, and pediatric diseases. With its focus on open science drug discovery in various areas of market failure, VIMI is unique.

While the use of OSPs to prepare for pandemics and other health crises is new, VIMI draws on the expertise of the SGC and of the Neuro to enter into this field. With its network and reputation within the national and international research and industrial communities, the SGC is jump-starting VIMI's activities.

The VIMI project raises several uncertainties. The first is whether it will successfully identify drugs with pandemic treatment potential. Even with access to global experts, there is no guarantee that VIMI will develop a portfolio of drugs that will be positioned to successfully treat the next pandemic or AMR crisis. The second is whether its partners will sustain their investments in open science once the COVID-19 pandemic is far in the rearview mirror. Experience from the SGC suggests that they will, but governments and firms have lost interest in preparing for pandemics in the past (Sirleaf and Clark 2021). Third, there remain questions about how VIMI will operationalize its commercial strategy during the next pandemic. For example, VIMI will need to quickly enable actors to acquire rights to the regulatory data package, encourage firms to conduct Phase II/III clinical studies, and enable those actors to manufacture and distribute drugs globally.

Beyond areas of market failure, the OSP model may provide an additional commercialization strategy, particularly in respect of technology that requires multiple sets of knowledge and skills not normally housed within a single entity, where the technology faces a

high technological risk of failure, where benefits are widespread rather than being able to be captured by a single entity, and where global access is important. With experiments such as VIMI, policy-makers and firms can learn how best to deploy this strategy.

AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

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