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Public lies and public goods: ten lessons from when
patents and pandemics meet.

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Abstract

The paper examines three decades of the history of patents and pandemics that begins with the HIV/AIDS pandemic and TRIPS. This history demonstrates that the patent system is itself a huge source of risk when it comes to managing the risks of pandemics. From this history ten core lessons are extracted. The central message of the paper is that developing countries will have to focus on collaborations among themselves with the aim of building a wide base of rich manufacturing experience in the production of medicines and therapies. They can expect no priority of treatment under the present patent-mediated response to pandemics.

Keywords

COVID-19, Pandemic Risk, Patents, TRIPS, Vaccines, Waiver

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Table of contents

INTRODUCTION.....	1
COMPETITORS FROM EVOLUTION’S PAST	1
H5NI.....	2
TRIPS AND HIV/AIDS.....	3
COVID-19	5
TEN LESSONS FROM PATENTS AND PANDEMICS	7
FINAL REFLECTIONS: LABORATORIES OF OPENNESS AND HOPE.....	8

Introduction

In this essay I examine three decades of the history of patents and pandemics. This history, I argue, demonstrates that the patent system is itself a huge source of risk when it comes to managing the risks of pandemics. In the field of health, patents exist to commodify human suffering. Commodification is the point of patents. Global circuits of capital accumulation are not built on providing life-saving knowledge as a pure public good. Sadly, and dangerously, the patent system is here to stay, growing ever stronger because the US and EU support the elite networks of pharmaceutical executives, patent lawyers, investors and entrepreneurial scientists that profit from its commodified logic.

From the recent history of patents and pandemics I extract ten core lessons. For developing countries these ten lessons can be reduced to two basic messages. First, formal negotiations by coalitions of developing countries to modify the rules of a globalized intellectual property paradigm in order to improve access to knowledge and technology, while important, needs the backing of an even longer term informal networking strategy. Second, this informal networking strategy needs to focus on collaborations among developing countries with the aim of building a wide base of rich manufacturing experience in the production of medicines and therapies. Developing countries cannot roll back the global intellectual property system, but they can find ways to bypass it in order to better manage pandemic risk.

Competitors from evolution's past

In the first 15 years of the 21st century there were five cases of clear pandemic threat: SARS, (severe acute respiratory syndrome) H5N1 (avian influenza), H1N1 (swine flu), Ebola, and MERS (Middle East respiratory syndrome).¹ Climate change may bring significant changes to the current range of infectious diseases.² Unsurprisingly, suffering from the health effects of climate change is likely to be deepest in low-income countries.

In order to understand the grave shortcomings of the patent system as a tool for managing pandemic risk, one has to understand the risks posed by bacteria and viruses within an evolutionary framework in which contestation among species is a fact. Microbes are tiny but terrifying competitors. They “outnumber us by a factor of 10^{22} , ... outweigh us by a factor of 10^8 , ... can undergo as many as 500,000 generations during 1 of our generations”.³ This speed of reproduction creates many more opportunities for adaptation, as the rapid emergence of antibiotic resistant bacteria illustrates. The human immunodeficiency virus (HIV), first discovered in 1984, has proved to have a remarkable rate of both reproduction and mutation, evolving approximately a million times faster than humans.⁴ More than 35 years and some 38 million deaths from HIV/AIDS later, there is still no effective vaccine.

Any system for managing pandemic risk has to be responsive, as best it can, to the fast-mutating and exponentially-scaling nature of microorganisms and viruses. Pandemics on the scale of Spanish

¹ GHRF Commission (Commission on a Global Health Risk Framework for the Future), The neglected dimension of global security: A framework to counter infectious disease crises, 2016 <http://nam.edu/GHRFreport> (doi: 10.17226/21891), 19.

² Confalonieri, U., B. Menne, R. Akhtar, K.L. Ebi, M. Hauengue, R.S. Kovats, B. Revich and A. Woodward, Human health.ClimateChange 2007: Impacts, Adaptation and Vulnerability. Contribution of Working Group II to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change, M.L. Parry, O.F. Canziani, J.P. Palutikof, P.J. van der Linden and C.E. Hanson, Eds., 2007, Cambridge University Press, Cambridge, UK, 391-431.

³ Spellberg B, Guidos R, Gilbert D, Bradley J, Boucher HW, Scheld M, Bartlett JG, Edwards J Jr., The Epidemic of Antibiotic-Resistant Infections: A Call to Action for the Medical Community from the Infectious Diseases Society of America, *Clinical Infectious Diseases*, 2008, 46: 155-164, 157.

⁴ W.D. Wick and O.O. Yang, War in the Body: The evolutionary arms race between HIV and the human immune system and the implication for vaccines, 2013, New York, Springer, v.

influenza, HIV/AIDS or COVID 19 turn us into globally networked communities of shared fate. The failure to distribute treatments or cures to one community in the network creates a weak link, another opportunity for a pathogen to play for a win in evolution's replication game. It can do so with overwhelming speed.

In the next three sections I briefly sketch three histories of when patents and pandemics have met. From there the paper moves to synthesizing ten lessons from these three histories and then offering some final reflections on the role of craft knowledge in managing pandemic risk. Before moving on, I need to make clear a conventional but important distinction on which the paper relies. Knowledge of, for example, the DNA structure of a virus can be either a pure or impure public good. It is an impure public good when some means are used to exclude people from using the knowledge. A vaccine is a private good. The vaccine dose that I receive is the dose that you do not. That said, the vaccine is different from many other private goods in the way it creates positive network externalities, both for those in the network as well as for those outside of the network if the network of the vaccinated is sufficiently large. From the perspective of the global risk management of a pandemic, the challenge is to supply private goods (vaccines) at sufficient speed to create the network externalities needed to reduce the risk that an attacking virus poses to us as networked communities of shared fate. Our success in meeting this challenge depends on the speed with which we can translate our knowledge of the virus and possible therapeutic responses into the manufacturing of medical treatments. Surge capacity in manufacturing is everything in dealing with an attacking and exponentially-scaling virus.

H5NI

In 2004 the World Health Organization (WHO) sent a team from its global response network to a village in Viet Nam. A dangerous strain of the avian influenza virus, H5NI, was killing poultry populations in large numbers and had jumped to humans. For the WHO, H5NI was a pandemic in waiting. As it turned out, the dice of mutation rolled in favour of humanity and the pandemic never eventuated.

There was no vaccine for avian influenza, but at the time two anti-viral agents were thought to be effective as a treatment if administered early – oseltamivir (Tamiflu) and zanamivir (Relenza). States rushed to stockpile oseltamivir, a strategy encouraged by the WHO. The stockpiling of oseltamivir, the preferred treatment, was affected by the fact that Roche held an exclusive patent licence for its production. This led to supply shortages. Given the global shortage of supply, a rational global public health strategy would have been to help build a stockpile in those countries in which the risk of the global pandemic beginning was the highest. These were countries such as China, Cambodia, Indonesia, Laos, Viet Nam and Thailand, which in any case could not afford Roche's prices for oseltamivir. Precisely the opposite occurred.⁵ Countries scrambled to look after themselves. The ones with biggest sticks and deepest pockets did the best in terms of stockpiles. In the shadow of the US government power to issue a compulsory licence, Roche established a supply chain for oseltamivir in the US, allowing the US to meet its strategic national stockpile target.⁶ The poorest countries ended up with almost no stockpile.

The case of oseltamivir also shows how difficult it is to meet urgent and global demand for a medicine when technical details of manufacturing are not shared among potential manufacturers. Roche claimed that the fermentation process for the making of shikimic acid, the starting ingredient for oseltamivir, was too complex for other firms to handle. However, other manufacturers eventually reverse-engineered the process. A chemist at Harvard University, Elias Corey, found a way to synthesize the active ingredient, bypassing the need for shikimic acid altogether, a process that was placed into the public

⁵ For details of the stockpiles see B. Lokuge, P. Drahos and W. Neville, 'Pandemics, antiviral stockpiles and biosecurity in Australia: what about the generic option?', *Medical Journal of Australia*, (2006) 184(1), 16-20.

⁶ FDA News, Roche established U.S.-Based Supply Chain for Tamiflu, September 15, 2006, <https://www.fdanews.com/articles/62534-roche-establishes-u-s-based-supply-chain-for-tamiflu>.

domain.⁷ Roche's claims about the complexity of manufacture were tested through a process of open science and found wanting.

The oseltamivir story has a much darker side. The clinical trial evidence for the benefits of oseltamivir included a reduction in risk of secondary complications from influenza, as well as reducing the risk of person-to-person transmission. But this evidence came from a small number of trials funded by Roche. When all the evidence about oseltamivir was assembled, a very different picture emerged. Beginning in 2009, a Cochrane review team took almost 4 years to assemble around 150,000 pages of clinical trial data, most of which had never been made public.⁸ Cochrane reviews are systematic and transparent reviews by independent researchers of all the scientific evidence for a given problem. The Cochrane analysis of the data showed evidence of harms from oseltamivir such as nausea, vomiting and psychiatric events. It did not support the claims of efficacy made by Roche. Governments had paid billions of dollars to stockpile a treatment that was 'no more effective than aspirin'.⁹

TRIPS and HIV/AIDS

The origins of the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS), its implications for intellectual property, for innovation and development and its effects on access to medicines have been much written about.¹⁰ In this section I simply want to highlight the speed of patent rule evolution in the TRIPS Council. But first we need to remind ourselves about the speed and spread of HIV.

HIV was discovered in 1984, although clinical observations that a new disease was afoot had been made for three or so years earlier.¹¹ The search for an effective vaccine was launched soon afterwards. Some 37 years later the search continues. Drug treatments to prevent AIDS came onto the market quite quickly. The first to gain FDA approval was zidovudine (AZT) in 1987. However the drug investigators following the patients involved in the trials found that after 6 months those on AZT were getting the disease.¹² HIV had mutated. From these beginnings researchers moved on to develop other classes of drug treatments that could be administered in combination (known as triple combination or highly active antiretroviral therapy (HAART)). By 1996 HAART was being widely used in the US. The impact on the number of people dying each year from AIDS in the US was dramatic. In 1995 the estimated number of deaths was 51,670. The estimated number in 2001 was 15,603.¹³

The situation was rather different in low income countries. By the end of the 1990s UNAIDS (2000) was describing the HIV/AIDS pandemic as a development crisis, pointing out that almost 20 million people had died with around 4 million of those being children.¹⁴ One of the first attempts to document

⁷ D. Mackenzie, 'Way to mass produce key bird flu drug revealed', 4 May 2006, <https://www.newscientist.com/article/dn9107-way-to-mass-produce-key-bird-flu-drug-revealed/>

⁸ Jefferson T, Jones MA, Doshi P, Del Mar CB, Hama R, Thompson MJ, Spencer EA, Onakpoya IJ, Mahtani KR, Nunan D, Howick J, Heneghan CJ. Neuraminidase inhibitors for preventing and treating influenza in adults and children. *Cochrane Database of Systematic Reviews* 2014, Issue 4. Art. No.: CD008965. DOI: 10.1002/14651858.CD008965.pub4.

⁹ P. Doshi and T. Jefferson, Drug data shouldn't be secret, April 10, 2012 <https://www.nytimes.com/2012/04/11/opinion/drug-data-shouldnt-be-secret.html>

¹⁰ For a volume that draws much of this literature together see Hanns Ullrich, Reto M. Hilty, Matthias Lamping, Josef Drexler (eds), *TRIPS plus 20: From Trade Rules to Market Principles*, 2016, Springer.

¹¹ W.D. Wick and O.O. Yang, *War in the Body: The evolutionary arms race between HIV and the human immune system and the implication for vaccines*, 2013, New York, Springer, 1.

¹² W.D. Wick and O.O. Yang, *War in the Body: The evolutionary arms race between HIV and the human immune system and the implication for vaccines*, 2013, New York, Springer, 9.

¹³ Centers for Disease Control and Prevention, *HIV/AIDS Surveillance Report*, 2001;13(No. 2) 1-44, 38.

¹⁴ UNAIDS, *Report on the Global HIV/AIDS Epidemic*, 2000 Geneva.

the patents around antiretrovirals for HIV, as well as for AIDS (for example, antibiotics to treat the disease) revealed HIV/AIDS-related patents or patent applications for 80 countries.¹⁵ At that time reliable data for other countries was unavailable.

In the 1990s TRIPS became a focal point for public dissatisfaction with the hidden processes of global rulemaking by private elites. Of course, patent barriers to treatment depend on much more than TRIPS. Treaties such as the Patent Cooperation Treaty provided easy and low cost means for patent owners to globalize their patent portfolios.¹⁶ But TRIPS does one crucial thing for the brand pharmaceutical industry. Article 27.1 of TRIPS obliges all Members of the WTO to recognize patents on products in all fields of technology. Before TRIPS many countries did not recognize patents on pharmaceutical products, India being one prominent and well-known case. No other single rule matters as much to the structure and future of pharmaceutical markets as the product patent rule. If, for example, one only has a process patent rule in place, then a generic company is likely to be able to find a different process for the manufacture of a compound. Trying to patent every conceivable process for the manufacture of a compound is very difficult. TRIPS does contain a deeming rule that places the burden of proof on the defendant in the case of an alleged infringement of a process patent (see Article 34). But this reversal rule is not of much value in the wide world of the chemical process industry, where sufficiently different processes to the patented process can almost always be developed (as Elias Corey and others showed with shikimic acid).

It is the product patent rule that represents the keys to the global pharmaceutical kingdom. The actual drafting of product patent claims is a technical art that has seen patent offices allow claims to, for example, a theoretical antibody i.e. not one actually produced by the patentee.¹⁷ Aside from product claims, there is a range of other ways in which one might obtain protection including second medical use or formulation claims. By globalizing product patent protection for pharmaceuticals, TRIPS has released a wave of change in pharmaceutical markets that will be felt for decades to come.

A globalized product patent rule that is entrenched in an international agreement generates huge risk when it comes to pandemic management because it may allow the response time of states to a pandemic threat to be affected by a patent monopolist. In effect, systems of patent rules at the national and international levels become the medium through which states have to respond.

During the 1990s the cost of patented antiviral drugs for treating a patient with HIV/AIDS was somewhere between US\$10,000 to US\$15,000 per year.¹⁸ In November in 2001, some 6 years after TRIPS came into operation, a coalition of developing states and civil society actors secured the Declaration on the TRIPS Agreement and Public Health (Doha Declaration).¹⁹ Amongst other things, the Doha Declaration affirmed the right of states to use, under certain conditions, patented technology without the permission of the patent owner. TRIPS has not altered this fundamental regulatory power of states. The Doha Declaration was a document of hope that over time helped to steer the production of high quality low cost generic antivirals. Treatment for AIDS became a reality for millions of poor people.

The Doha Declaration had left the TRIPS Council with a task that was defined in Paragraph 6 of the Declaration. The Council had to find a solution to the problem of how developing countries that lacked

¹⁵ P Boulet, J. Perriens and F. Renaud-Thery, Patent situation of HIV/AIDS-related drugs in 80 countries, January 2000, UNAIDS/WHO, Geneva, 1-16.

¹⁶ P. Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients*, 2010, Cambridge, Cambridge University Press, 183-187.

¹⁷ U. Storz, *IP Issues of Therapeutic Antibodies* in U. Storz, W. Flasche and J. Driehaus, *Intellectual Property Issues: Therapeutics, Vaccines and Molecular Diagnostics*, 2012, Heidelberg, Springer, 1, 4.

¹⁸ Hoen Ellen 't, Berger J, Calmy A, et al. . Driving a decade of change: HIV/AIDS, patents and access to medicines for all. *J Int AIDS Soc* 2011;14:15.

¹⁹ See WT/MIN(01)/DEC/W/2, 14 November 2001.

manufacturing capacity in the pharmaceutical sector could make use of the flexibilities of TRIPS, when TRIPS itself imposed a limit on export under compulsory licence. Essentially, where a patented good had been manufactured under a compulsory licence in a country, the use of that good had to be “predominantly for the supply of the domestic market”.²⁰ As a result of this restriction the export capacity of generic producers would be left underutilized - obviously a problem, especially in a pandemic situation.

The solution that was adopted by the WTO General Council on August 30 of 2003 took the form of waivers of the obligations in Article 31 of TRIPS.²¹ The Paragraph 6 system (the negotiated solution to the problem identified by Paragraph 6) was encased in rule complexity, leading to questions about its workability.²² Use of the Paragraph 6 system requires compulsory licences in both countries to cover the import/export transaction, as well as compliance with a variety of conditions, including those relating to eligibility of import, quantity, labelling, and trade diversion. In annual reviews of the Paragraph 6 system by the TRIPS Council, WTO members have continued to debate its usefulness.²³ According to the WTO notification website, the system has been used once.²⁴

COVID-19

Cases of what would become known as COVID-19 were first reported in December of 2019 in Wuhan, China. Around three months later the WHO, in one of its situation reports for March 2020, reported that there were over 500,000 cases of COVID-19 in around 200 countries, territories and areas of the world.²⁵ One back of the envelope calculation suggested that if people did not change their behavior the virus could go from one infected person to a million in two months and one billion in three months.²⁶ Like other viruses, SARS-CoV-2 has demonstrated speed; speed of entry into a cell, speed of replication in a cell, speed in spread and, while it is by no means the fastest virus, it is, compared to humans, fast in terms of mutation and evolution rates.

What has been our patent-mediated response to the ever-materializing risks of COVID-19? Many of the important technologies related to vaccine development and treatment technologies more broadly have entered the globally networked national and regional patent systems of the world. For example, a preliminary patent landscape analysis for mRNA vaccine technology relevant to COVID-19 reveals a web of licensing and sublicensing of patents among academic labs, biotech companies and large

²⁰ See Article 31(f). This condition does not apply where the compulsory licence is issued as part of an anti-competitive remedy. See Article 31(k).

²¹ Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003, WT/L/540, 1 September 2003.

²² Brook K. Baker, ‘Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health’, *Indiana International & Comparative Law Review*, 2004, 14, 613.

²³ The system is now incorporated by protocol into TRIPS as Article 36*bis* and an Annex and Appendix.

²⁴ See [https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=\(%20@Symbol=%20ip/n/10/*%20\)&Language=ENGLISH&Context=FomerScriptedSearch&languageUICchanged=true#](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(%20@Symbol=%20ip/n/10/*%20)&Language=ENGLISH&Context=FomerScriptedSearch&languageUICchanged=true#)

In 2007 Canada notified the WTO that one of its generic companies, Apotex would use the system to export a fixed dose combination antiretroviral to Rwanda. See Canada, Notification under Paragraph 2(C) of the decision of 30 August 2003 on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, 8 October 2007, IP/N/10/CAN/1.

²⁵ WHO, Coronavirus Disease 2019 (COVID-19) Situation Report-67, March 2020 available at https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200327-sitrep-67-covid-19.pdf?sfvrsn=b65f68eb_4

²⁶ Bar-On YM, Flamholz A, Phillips R, Milo R. SARS-CoV-2 (COVID-19) by the numbers. *Elife*. 2020;9:e57309. Published 2020 Apr 2. doi:10.7554/eLife.57309

companies that has been evolving for a couple of decades.²⁷ Well before the arrival of COVID-19 many vaccine technologies were under patent protection.²⁸ The World Intellectual Property Organization (WIPO), a key node in propagating global webs of intellectual property protection, released a special COVID-19 search facility in relation to its PATENTSCOPE database, a database containing some 83 million patent-related documents.²⁹ In reality the specially curated searches WIPO's experts have put together would be of little practical use to researchers needing to know whether they were free of patent restrictions when it came to researching, for example, vaccines. Mapping patent landscapes requires access to fee-charging databases (for example, those accessible through Derwent Innovation) and specialist expertise. No serious player in this field would rely on PATENTSCOPE's COVID-19 search facility. In the world of high stakes patent litigation this would be suicide. PATENTSCOPE is a nice place for amateurs to have a go. The more important message of PATENTSCOPE is the one to be found blaring in its title; researchers have to scope patents before they begin researching. We have created a world in which scientists have to wander legal labyrinths in order to find out their degree of research freedom. For an exponentially reproducing virus looking for new hosts to infect, this (politically manufactured) slow response is a replication opportunity.

In October of 2020 developing countries once again began a Sisyphus-like trudge up the negotiating hill of intellectual property. A communication from India and South Africa requested a waiver from key sections of the TRIPS agreement.³⁰ The communication makes the critical point that if the world is to have any chance of a response in real time 'the unhindered global sharing of technology and know-how' is required. Earlier in the year Costa Rica had asked the WHO to set up a global mechanism for sharing technology and knowledge in relation to COVID-19. Launched formally in May 2020, one of the express goals of the COVID-19 Technology Access Pool is to encourage holders of manufacturing know-how to release it into a common knowledge pool. This is crucial to harnessing the surge manufacturing capacity that exists globally for the production of treatments and therapies.³¹ For the time being the major manufacturers of existing vaccines such as Moderna and Pfizer have not joined this multilateral mechanism.³² Generally speaking, major pharmaceutical companies have little to no interest in open source approaches to manufacturing, even though, as has been shown, open source in biotechnology is highly feasible.³³ Voluntary licensing is the preferred option for monopolists because they can shape the terms of the contract.

The matter of the waiver of intellectual property rights has continued to be debated in the TRIPS Council. The same pattern of distribution of medicines that occurred with HIV/AIDS and H5N1 has repeated itself with COVID-19 vaccines, with the Head of the WHO pointing out that 75% of vaccines

²⁷ Gaviria, M., Kilic, B. A network analysis of COVID-19 mRNA vaccine patents. *Nat Biotechnol* 39, 546–548 (2021). <https://doi.org/10.1038/s41587-021-00912-9>.

²⁸ See, for example, the patent landscape report for prophylactic vaccines by WIPO showing almost 12,000 patent families. *Patent Landscape Report on Vaccines for Selected Infectious Diseases, 2012*, WIPO, Switzerland, https://www.wipo.int/edocs/pubdocs/en/patents/946/wipo_pub_946_3.pdf.

²⁹ See WIPO Launches New Search Facility For PATENTSCOPE Database to Support COVID-19 Innovation Efforts April 21 2020 https://www.wipo.int/pressroom/en/articles/2020/article_0008.html.

³⁰ Communication from India and South Africa, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/W/669, 2 October 2020.

³¹ Operationalising the COVID-19 Technology Access Pool (C-TAP), available at <https://www.who.int/publications/m/item/c-tap-a-concept-paper>

³² See E. Baumgaertner, Vaccine companies and the U.S. government snubbed WHO initiative to scale up global manufacturing, *Los Angeles Times*, April 30, 2021, <https://www.latimes.com/world-nation/story/2021-04-30/vaccine-companies-and-the-u-s-government-snubbed-who-initiative-to-scale-up-global-manufacturing>.

³³ J. Hope, *Biobazaar: The Open Source Revolution and Biotechnology*, 2008, Cambridge, Mass.: Harvard University Press.

have been administered in just ten countries.³⁴ In May of 2021, the TRIPS waiver proposal had 62 WTO members as co-sponsors.³⁵ The US, the primary state architect of the product patent rule in TRIPS, indicated that it would be willing to participate in text-based negotiations.

Ten Lessons from Patents and Pandemics

1. Pharmaceutical companies are not to be trusted when it comes to claims around their products. The Cochrane Review established breathtaking data manipulation by Roche. Unfortunately this is unexceptional for this industry. Scholars for decades have been drawing attention to crime and deception in the pharmaceutical industry.³⁶
2. Pharmaceutical companies keep crucial manufacturing knowledge secret. In a pandemic this secrecy costs lives. Roche's secrecy about how to manufacture shininic acid did slow the supply of oseltamivir. As it turned out, Roche's claims about the complexity of the manufacturing process were shown to be exaggerated and in the hands of open science better alternatives were found and made public.
3. The HIV/AIDS pandemic and the oseltamivir story clearly demonstrate how the patent system enables rich countries to secure treatment for themselves first. Rich countries gain priority because they can pay the patent price. Because they pay the patent price they create an incentive for companies to keep charging the patent price. Under the present system the best that developing countries can expect are secret patent licensing deals or donations of treatment that will not meet their real needs. In both cases this reinforces the position of the patent monopolist. Issued pharmaceutical patents are often death warrants for many poor people.
4. The stockpiling of oseltamivir reveals how the patent system itself has become a source of pandemic risk. As a result of the patent price rich countries, where the risk of H5NI was the lowest, had the largest stockpiles of oseltamivir, while poor countries, where the risk of H5NI was the highest, had the lowest. Had oseltamivir been an effective treatment its stockpiles should have been the highest in high-risk countries. The same high-risk stockpiling has occurred with COVID-19 vaccines.
5. The three case studies show how slow TRIPS Council negotiations move in comparison to a virus. During the almost eight months of TRIP Council discussions over the possibility of a negotiating the text of a waiver from TRIPS obligations, an additional 2,300,000 deaths have been reported to the WHO.³⁷ Negotiations over global intellectual property rules can be seen as linear functions competing against exponential functions of growth (the virus) and decline (the death of people).
6. The rule complexity of intellectual property is the enemy of public health and saving lives. A critical lesson from the waivers in the Paragraph 6 system of TRIPS is to avoid procedural and

³⁴ Director-General's opening remarks at the World Health Assembly, 24 May 2021, <https://www.who.int/director-general/speeches/detail/director-general-s-opening-remarks-at-the-world-health-assembly---24-may-2021>.

³⁵ Communication from the African Group et al, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 – Joint Statement of Co-sponsors, Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/W/677, 17 May 2021.

³⁶ See J. Braithwaite, *Corporate Crime in the Pharmaceutical Industry*, 1980, London, Routledge & Kegan Paul; P. Gotzsche, *Deadly Medicines and Organised Crime: How Big Pharma has Corrupted Healthcare*, 2013, London, Radcliffe Publishing, G. Dukes, J. Braithwaite and J.P. Moloney, *Pharmaceuticals, Corporate Crime and Public Health*, 2014, Cheltenham, Edward Elgar.

³⁷ At the beginning of October 2020, when India and South Africa issued their communication the world had just gone past a million deaths from COVID-19. By the middle of May, as WTO members have begun preparing for a text negotiation the WHO has reported over 3,300,000 deaths.

substantive complexity. Creating complex systems that do not in practice serve global public health is to give patent monopolists important symbolic victories.

7. The three case studies show that rich countries have, despite pandemic crises, continued to support the patent system. They do so because it allows them to prioritize their own health and industrial interests in the life sciences. There is no reason to think that rich countries will support significant reforms to the patent system.
8. The HIV/AIDS crisis demonstrated that developing countries such as Brazil and Thailand that established their own manufacturing capability for antiretrovirals were able to lower the costs of treatment for their citizens.
9. Multilateral mechanisms for the sharing of know-how work slowly, if at all. The WHO's COVID-19 Technology Access Pool is the latest example of this historical truth.
10. Negotiations in the TRIPS Council, while important for developing countries, incur costs of time, coalition building and compromise. It is slow but important work. A well-drafted TRIPS waiver with a clear objects clause will do more for COVID vaccines development than multiple and uncertain national compulsory licensing procedures at the national level ever could. Such negotiations have to be accompanied by a parallel and informal track of practical initiatives, especially ones aimed at increasing manufacturing know-how.

Final Reflections: Laboratories of Openness and Hope

The importance of the spread of manufacturing know-how to increasing the capacity and quality in all industries is profound. Making something as opposed to scientifically theorizing the possibility of making it creates, one might say, craft knowledge, a label appropriate even to the world of high technology medicines manufacture. Keeping craft knowledge secret is an old practice that connects modern medicine manufacturers to the secrecy of medieval craft guilds, as well as the guilds of Roman times. Industrial espionage has been one way in which states have gained access to craft knowledge.³⁸

States can invest in building up their own manufacturing know-how. Brazil, for example, was able to underpin its policy of free access to antiretrovirals for HIV/AIDS by investing in the 1990s in state-run laboratories that produced those treatments for a fraction of the cost available from international brand companies.³⁹ States can also choose to share their manufacturing know-how. In 2003 under President Lula's leadership Brazil agreed to help Mozambique build a public pharmaceutical factory for the production of antiretrovirals.⁴⁰ Brazil agreed to the transfer of technical dossiers to enable the production of specific drugs, with the production of a small number of drugs beginning in 2013.

The diffusion of craft knowledge from US or European companies to developing countries is unusual. Secrecy is by far the dominant norm. US or European brand companies do outsource production of pharmaceuticals to generic companies in developing countries to take advantage of costs of production, but they also hold back the most technologically sensitive information in order not to lose control of their high value products.⁴¹ The importance of sharing craft knowledge in order to increase manufacturing capacity and supply is illustrated by the agreement between Russia's sovereign wealth fund, the Russian Direct Investment Fund, and three Chinese pharmaceutical companies to manufacture Russia's Sputnik-V vaccine. Russia was not in a position to meet global demand for its vaccine and so

³⁸ D.S. Ben-Atar, *Trade Secrets: Intellectual Piracy and the Origins of American Industrial Power*, 2004, Yale University Press.

³⁹ Jane Galvao, *Access to antiretroviral drugs in Brazil*, *The Lancet*, published online, November 5, 2002, 1-4, 3.

⁴⁰ Russo G, de Oliveira L, Shankland A, Siteo T. *On the margins of aid orthodoxy: the Brazil-Mozambique collaboration to produce essential medicines in Africa*, *Global Health*, 2014; 10:70. Published 2014 Sep 25. doi:10.1186/s12992-014-0070-z

⁴¹ World Health Organization, *Trends in local production of medicines and related technology transfer*, 2011, 17.

entered into manufacturing deals with Chinese companies. As one report of the deal makes clear, the shift from lab technologies to large-scale manufacturing of hundreds of millions of doses requires “stringent production management and rich manufacturing experience to be accumulated”.⁴²

Historically, US and European pharmaceutical manufacturers have always had this stock of ‘rich manufacturing experience’ and for the most part have clung to it like misers. In the case of the COVID-19 pandemic, the redacted advance purchase agreements for vaccines from brand manufacturers that have been published make it clear that the manufacturers own the know-how.⁴³

The collaboration between Russia and China on the production of Sputnik-V is a good example of the type of informal tracks that have to be pursued in parallel with any formal negotiations over the rules of the global intellectual property regime. Russia’s Sputnik-V vaccine came out of the Gamaleya National Research Institute of Epidemiology and Microbiology, an Institute with well over 100 years of experience in vaccine development.⁴⁴ China’s pharmaceutical companies look set to provide the surge manufacturing capacity that is needed to meet global demand for COVID-19 vaccines. For developing countries the informal track must be centred on building their own networks of innovation, networks that are anchored in key nodes of research excellence and which offer the possibility of building affordable life-saving products and processes. The alternative is to continue to rely on a metastasized patent system run by the US and EU to favour their own competitiveness, trade and health priorities. Under the current global patent regime developing countries cannot expect to be given any priority in the times of pandemics.

The manufacturing capacities of developing countries are almost certainly deeper and broader than in the early 1990s when only five developing countries had innovative capabilities in the pharmaceutical sector (Argentina, China, India, Korea and Mexico).⁴⁵ Networks of collaboration among developing country manufacturers have emerged, creating more opportunities for the exchange of craft knowledge. For example, the Developing Countries Vaccine Manufacturers Network, which was founded in 2000 with ten members, has grown to 43 members, 15 of which provide WHO pre-qualified vaccines.⁴⁶ Motivated by values of open science and open source, some biotech companies may help to transfer mRNA technology to developing countries.⁴⁷ The mRNA technology which is currently locked up in vaccine plants in the US and EU could diffuse much more quickly than patent monopolists are calculating. There are already reports of locally developed mRNA vaccines undergoing trials in China and Thailand.⁴⁸

Clearly the US and the EU will, through their universities, start-ups, and large manufacturers, remain powerhouses of advanced manufacturing knowledge for medicines and therapies. While some of this knowledge may over time be transferred or leak out, the history I have set out above suggests that developing countries should continue to build networks of collaboration among themselves. This networking strategy will, of course, take time. Governments will have to invest in laboratories of

⁴² Chinese companies to produce 260m doses of Russian Sputnik-V COVID-19 vaccine in rising OEM trend, April 21, 2021, <https://www.globaltimes.cn/page/202104/1221733.shtml>

⁴³ See, for example, the redacted agreement between the European Commission and the AstraZeneca available at https://ec.europa.eu/info/sites/default/files/apa_astrazeneca.pdf and the agreement between the European Commission and Curevac, https://ec.europa.eu/info/sites/default/files/curevac_-_redacted_advance_purchase_agreement_0.pdf.

⁴⁴ <https://sputnikvaccine.com/about-us/>

⁴⁵ Robert Balance, Janos Progany and Helmet Forstener, *The World’s Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy*, 1992, UNIDO.

⁴⁶ <https://www.dcvmn.org/Our-History>

⁴⁷ See, for example, the proposal by Biosciences to build a network of seven mRNA factories at the cost of US\$200 million each. Available at <https://www.greenlightbiosciences.com/blog/a-blueprint-to-vaccinate-the-world/>.

⁴⁸ S. Mallapaty, *The COVID vaccine pioneer behind southeast Asia’s first mRNA shot*, *Nature*, 26 May 2021, <https://www.nature.com/articles/d41586-021-01426-9>.

excellence and openness and help to build systematic links between those laboratories and manufacturing partners capable of turning the public good of knowledge into affordable life-saving treatments.⁴⁹ Without a manufacturing knowledge base, developing countries will find it hard to escape the deadly consequences of a patent-mediated response to pandemics. Perhaps vaccine hoarding by rich countries will cause developing countries to rethink their commitment to the patent system and focus more on laboratories of openness and hope.

⁴⁹ On the vital role of government in developing an integrated approach to vaccine innovation see K. Hoyt, *Long Shot: Vaccines for National Defense*, 2012, Cambridge, Mass., Harvard University Press.

