

WHY INTELLECTUAL PROPERTY RIGHTS MATTER FOR COVID-19

By *Philip Stevens and Mark Schultz*

■ SUMMARY

- At every step of the COVID-19 crisis, critics of intellectual property rights (IPRs) have called for their suspension, claiming IPRs will thwart research and development and make vaccines and treatments unaffordable.
- In reality IPRs have been crucial, promoting trust, knowledge-sharing and collaboration between organisations and individuals. They have underpinned the development of multiple effective vaccines in remarkably compressed timeframes and the mass scale-up of manufacturing.
- Now there are calls for the suspension of IP rights to keep prices low and to address supply shortages, particularly in low and middle-income countries.
- Such calls are mistaken. IP rights are mischaracterised as a “monopoly” when in fact they drive competition, resulting in multiple competing medicines and placing downward pressure on price. A highly competitive market in COVID-19 vaccines is unfolding right now.
- Far from being a barrier, IP is part of the solution. IP licensing allows the innovator to control which partners manufacture the product, ensuring high quality supplies, and to maximise low-cost access for low and middle-income countries. This model has a proven track record for infectious disease, notably with hepatitis C.
- There is no evidence that removing IPRs will achieve more than the licensing agreements currently being forged between innovators and reputable vaccine manufacturers in countries like India and Brazil; and the emergence of procurement mechanisms like COVAX.
- Instead of creating uncertainty and sowing division at venues such as the World Trade Organization, World Health Organization and other international organisations, opponents of IP should support current efforts to develop and distribute vaccines. The IP system has put us in a position to end the pandemic. We should allow it to continue doing its job.

■ INTRODUCTION

The development of COVID-19 vaccines and treatments over the past year has been nothing less than a triumph of innovation. The unprecedented speed with which researchers and life sciences companies have met this challenge is astounding.

Unfortunately, at every step on this path, some have sought to undermine the intellectual property rights that have underpinned this effort.

Perhaps the difficulty of achieving such advances is underappreciated, as they have become almost commonplace in recent decades. While the race to a COVID-19 vaccine is unprecedented, advances in medicine have made previously incurable diseases such as HIV manageable and hepatitis C curable.

In truth, progress in life science innovation is difficult and fraught with challenges. Today's cures are founded on a complex ecosystem, in which many individuals, public institutions, and private businesses play crucial roles. Huge sums must be chanced on funding clinical trials and regulatory approvals and building manufacturing and distribution capabilities.

At every step of drug development, intellectual property rights (IPRs) play a crucial role, supporting early research, bringing treatments through clinical trials, and getting them to patients. Each of these steps requires large investments of time, money and resources. Intellectual property rights support those investments by giving the opportunity of a return. They also create a basis for cooperation among organisations by encouraging trust.

And yet critics of intellectual property view it as an obstacle at every turn. Sceptics believe

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that since intellectual property owners may stop others from using their property, they will stop others from doing so.

This fundamental misunderstanding miscasts intellectual property rights as a roadblock. In reality, it's the vehicle that speeds progress, providing the investment and cooperation needed to achieve ambitious goals. This is certainly true in this crisis

Yet opponents of IP have called for the suspension of intellectual property rights at every stage in the effort to develop treatments to defeat COVID-19 – from early R&D, to bringing treatments to market, to ramping up manufacturing. This has culminated in proposals by South Africa and India at the World Trade Organisation to waive all IP rules for COVID-19 technologies.

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■ FEARS OF COVID-19 AND IP

As soon as the world began to realize the scale of the potential threat from COVID-19, certain academics and activists rolled out shopworn criticisms of intellectual property. While researchers and drug companies began work to develop the vaccines and therapeutics necessary to end the pandemic, scholars and health activists warned that intellectual property rights would thwart the effort.



Calls to override IPRs in the early stages of the pandemic were backed by respected global humanitarian NGOs and prominent political figures. But it is to the credit of the majority of governments that they ignored such calls.

Some [asserted](#) that intellectual property would inevitably hold up urgent research. They theorised that the “winner-takes-all” nature of intellectual property rights, especially patents, would [prevent](#) scientists from rapidly disclosing research results, and discourage the sharing of unpatentable insights that may potentially lead to patentable treatments with further work.

Members of Congress warned that IP would “put public health at risk”, while NGO Médecins Sans Frontières (MSF) called for “no patents or profiteering” on yet to be developed health technologies. A coalition of over [500 NGOs](#) claimed that IP rights were a “hindrance” to efforts to tackle the pandemic, calling for all COVID-19-related IP to be rescinded.

As events demonstrated, critics of IP were wrong by a wide margin. In January 2020 very little was known about COVID-19. By January 2021, three safe and highly efficacious vaccines had been authorised for use by

stringent regulatory authorities, with several others poised to follow.

As of 21st December 2020, there were [1052](#) COVID-19 vaccines, therapeutics and diagnostic tools under development or approved globally, of which 219 are vaccines. This major achievement is a testament to how well the IP system has worked during the pandemic.

Calls to override intellectual property rights in the early stages of the pandemic were seductive and were backed by respected global humanitarian NGOs and prominent political figures. But it is to the credit of the majority of governments that they held their nerve and ignored such calls, despite the growing urgency of the situation over 2020.

■ BUILDING ON EXISTING IP

IP is the bedrock upon which today's COVID-19 vaccines have been built. The technologies they are based on did not come out of thin air at the beginning of the pandemic, but had been under development for decades, with substantial research in academic labs followed by years of risky investment by commercial start-ups.

Consider the messenger RNA (mRNA) technology that is the basis for two of the first vaccines approved in Western countries. Scientists discovered in 1961 that mRNA could be used to “reprogram” cells to battle disease. It took decades of lab research and private sector-funded development by startups BioNTech and Moderna to overcome major difficulties and turn the technology into an effective vaccine that can be safely given to patients.

Both companies and their investors have [spent billions of dollars](#) on mRNA research prior to the pandemic.

While academic research is fundamental, the end result would not have been possible without the private sector, which depends on intellectual property rights.

Shortly before the pandemic started, we spoke to Dr. Derrick Rossi, the academic founder of Moderna. When asked whether the treatments could be brought from the academic lab to patients without the help of the private sector,

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Dr. Rossi's reply was categorical: “Not a chance. Academics are good at academia and fundamental science. They are not good at developing drugs for patients.”

Dr. Rossi explains that bringing a drug to market takes many professionals, sharing their labour and diverse expertise. “This industry of professionals is out there... The more people that are involved in the chain, post-academic discovery, the more you have pros involved – all the way from IP filings to VCs to due diligence to assembling a team,” the more likely you are to develop a viable treatment.

Developing a practical application for a great academic insight takes vast sums, and investors need some prospect of a return on that investment. As Dr. Rossi explains, “you can be working on the coolest thing, but investors need to know that there is some protection for their investment, plain and simple.”

■ IP HELPS NOT HINDERS R&D COLLABORATION

The other claim [frequently heard](#) at the beginning of the pandemic was that IP poses a barrier to collaboration and knowledge-sharing, so in a time of emergency any related IP should be open licensed or pooled.

In reality, the IP system encouraged the rapid establishment of dozens of partnerships around COVID-19-19, with even [commercial rivals](#) prepared to cooperate and share capital and proprietary intellectual resources such as compound libraries. Examples of consortia between the private sector and research centres include the [COVID-19-19 Therapeutics Accelerator](#) to evaluate new and repurposed drugs and biologics, the EU-backed [Swift COronavirus therapeutics REsponse](#), [Corona Accelerated R&D in Europe](#) (CARE) as well

as dozens of bilateral agreements between companies. Indeed, the Pfizer vaccine is the result of its collaboration with BioNtech, where partners shared and combined know-how and proprietary knowledge to create the first vaccine authorized in the U.S.

Far from being a barrier to collaboration, IP is fundamental

Far from being a barrier to such collaborations, IP is fundamental. Because patent rights require public disclosure, they enable drug developers to identify partners with the right intellectual assets such as know-how, platforms, compounds and technical expertise. Without patents most of this valuable proprietary knowledge would be kept hidden as trade secrets, making it impossible for researchers to know what is out there.

Second, the existence of laws protecting intellectual property helps rights-holders make the decision to collaborate in the first place. By allaying concerns about confidentiality, IP enables companies to open up their compound libraries, and to share platform technology and know-how without worrying they are going to sacrifice their wider business objectives or lose control of their valuable assets.

For instance, rights holders might contribute IP that is useful for entirely different diseases to COVID-19 collaborations. IP rights and licensing ensure those rights can only be used for the agreed reason, preventing competitors freeriding to gain an unfair advantage in other areas.

As the former Director General of WIPO noted in June 2020, the main challenge at the time

was “not access to vaccines, treatments or cures for COVID-19, but the absence of any approved vaccines, treatments or cures to have access to. The policy focus of governments at this stage should therefore be on supporting science and innovation”.

During this initial phase of the pandemic, the majority of governments followed this advice, especially by not threatening to remove IP of products yet to be invented. [No government](#) from a country with a significant life-science R&D industry, for instance, backed the WHO’s “[Solidarity Call to Action](#)” in which companies were asked to unilaterally cede IP and data related to COVID-19 to its new technology and IP pool, C-TAP. The WHO embarked on this initiative with no evidence that IP would stand in the way of R&D and access efforts, distracting efforts away from more practical initiatives that stood greater chance of success.

■ **WHAT ABOUT THE PRICE OF PATENTED VACCINES AND THERAPEUTICS?**

Nevertheless, the emergence of several competing vaccines has shifted the debate. There are [increasingly loud calls](#) to suspend IP rights in order to promote affordable prices for low and middle-income countries, and to mandate forced transfer of know-how and technology in order to scale up global manufacturing . These calls have culminated in proposals at the WTO to implement a temporary suspension of certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including obligations regarding patent rights and the protection of undisclosed information on all COVID-19-related technologies.



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Such extreme proposals are based on muddled thinking. Specifically, the political campaigns that underpin them [mischaracterise](#) IP rights as “monopolies” that allow companies to charge unaffordable prices.

One eminent scholar of patents, Prof. Edmund Kitch described the application of the term “monopoly” to patents as one of the “[elementary and persistent errors in the economic analysis of Intellectual Property](#)”. In reality, IP rights drive the emergence of competing products in the same category, putting a lid on the ability of manufacturers to charge premium prices.

Owning IP rarely gives control over a market and IP markets are often intensely competitive. In medicines, for instance, there are usually many substitutes and alternatives. For example, a patient needing a cholesterol drug has a host of statins from which to choose, both patented and generic. Similarly, patients with osteoporosis and their doctors can choose from Fosamax®, Actonel®, or Boniva®. Recent years have seen the

emergence of competing shingle vaccines, increased competition in the lung cancer therapeutic space, and a slew of promising clinical trials and new drug launches in the [under-served area of lung disease](#).

Each of the owners of patents in these products has a temporary exclusive right to their product; none of them has a monopoly over the market for this type of treatment.

The most spectacular demonstration of this point is the recent emergence of multiple competing hepatitis C cures, which have opened up a wide range of [treatment options](#) and placed downward pressure on [prices](#).

As Geoffrey Dusheiko and Charles Gore wrote in [The Lancet](#), “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”

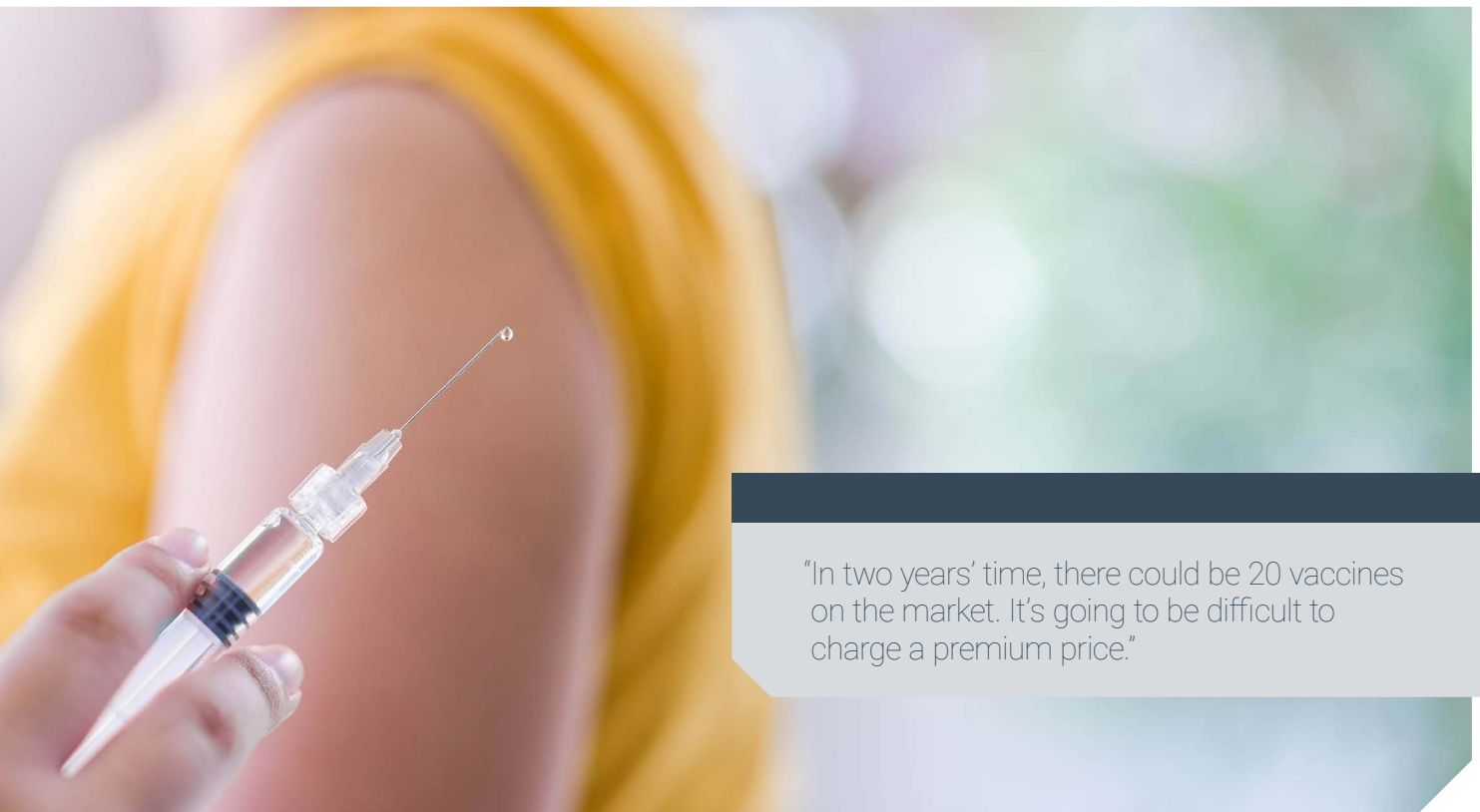
Every step of the development of this new market in hepatitis C cures was accompanied by [calls to override their IP](#) by civil society and certain intergovernmental organizations. Had those calls been heeded, it is doubtful such a competitive market would exist today.

A similar story is unfolding in the COVID-19 vaccine space. Pharmaceutical market analysts predict competition will hold COVID-19 vaccine prices down even in the unlikely scenario of rights holders declining to license their IP to other manufacturers. “In two years’ time, there could be 20 vaccines on the market,” Emily Field, head of European pharmaceutical research at Barclays told the BBC. [“It’s going to be difficult to charge a premium price.”](#)

■ THE REAL CHALLENGES

IP has underpinned the research and development that has led to the arrival of several game-changing vaccines. But the challenge does not end there. Perhaps the biggest hurdle is manufacturing billions of doses or new antibody treatments while maintaining the highest quality standards.

There’s more to it than starting a global manufacturing free for all by overriding or ignoring patents. A spokesperson for Regeneron, a manufacturer of a novel COVID-19 antibody treatment explained to [The Lancet](#): “Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months, as well as significant resources and skill. Unfortunately, it is not as simple as putting a recipe on the internet and committing to not sue other companies during the pandemic”.



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[John-Arne Røttingen](#), chair of the WHO COVID-19 Solidarity trial, explains that technology transfer will be crucial to scaling up production, but voluntary mechanisms are better: “If you want to establish a biological production line, you need a lot of additional information, expertise, processes, and biological samples, cell lines, or bacteria” to be able to document to regulatory agencies that you have an identical product, he explains.

The TRIPS waiver, he says, is the “wrong approach” because COVID-19 therapeutics and vaccines are complex biological products in which the main barriers are production facilities, infrastructure, and know-how. “IP is the least of the barriers”, [he says](#).


Then there is the problem of distributing the vaccines to billions of people in every country. Even with plentiful supplies, a [range of issues](#) need to be considered such as regulatory bottlenecks; supply chain, transport

and storage; maintenance of the cold chain; adequately trained staff; data tracking; and vaccine hesitancy amongst the population.

The costs of the vaccine itself is only a small component of the total cost of delivering doses to millions of people. The UK, for example, has spent around £2.9bn on procuring vaccines, far less than the official [estimate](#) of £8.8bn to be spent on distributing and delivering them. Comparable costs will exist for all other countries, even if they are subsidised by Overseas Development Assistance. Even then, the combined costs of vaccination are dwarfed by the other economic costs of the pandemic.



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It would make no sense for IP owners to use it to withhold access, when they can profit from supplying all demand. IP licensing is the way this is done.

■ IP IS PART OF THE SOLUTION

Far from being a problem, IP has repeatedly proven itself to be part of the solution in fighting disease. It allows innovators to manage production scale-up by selecting and licensing technology to partners who have the skills and capacity to reliably manufacture large quantities of high-quality products, which they distribute at scale in low and middle-income countries. It would make no sense for IP owners to use it to withhold access, when they can profit from supplying all demand. IP licensing is the way this is done.

This is the model unfolding for COVID-19, with new manufacturing licensing deals such as those between AstraZeneca and the Serum Institute in India (1bn doses), China's [BioKangtai](#) (200m doses), Brazil's FioCruz, Russia's R-Pharm and South Korea's SK Bioscience. Collectively, such deals will see the manufacture of [2 billion doses](#) by the end of 2021. The Serum Institute has also entered into manufacturing licenses with a number of developers of yet to be approved COVID-19 vaccines, as have several other [Indian vaccine manufacturers](#). Many of these doses will be procured on a non-profit basis by new collective procurement bodies such as COVAX, for distribution to low and middle-income countries.

IP is important because it allows the innovator to control which partners manufacture the product, ensuring the quality of supplies, while maximising low-cost access for low and middle-income countries. It also allows the innovator to preserve its ability to recoup costs from richer markets, meaning the preservation of incentives for future R&D investment.

Voluntary licensing has worked well in the past, particularly for low and middle-income countries. A recent academic analysis of hepatitis C voluntary licenses published by The [Lancet Global Health](#) concluded that they have increased access to medicines at a considerably faster pace than alternative access models, by avoiding the need for lengthy patent disputes and bringing to bear inter-company competition and economies of scale.

But again, these licenses model were [criticised](#) by public health NGOs and other stakeholders, who called for the confiscation of IP rights via compulsory licensing. Time has shown such calls to be mistaken.

■ CONCLUSION

As of January 2021, there are three vaccines approved by stringent regulatory authorities with several more likely to follow in the coming months. [Prices of COVID-19 vaccines vary](#) between more expensive but complex to manufacture, and cheaper ones based on existing technologies. Companies are offering their vaccines at cost, with pooled procurement mechanisms such as COVAX ready to leverage their enormous purchasing power to drive economies of scale and bring prices down further for developing countries, many of which will have the cost of vaccination subsidised by Overseas Development Assistance.

Forceable tech transfer and other forms of IP abrogation such as those proposed by India and South Africa at the WTO TRIPS Council would throw manufacturing supply chain planning, financing and distribution systems into chaos for little upside.

Meanwhile, the existence of multiple vaccines means there is no COVID-19 vaccine “monopoly”, and minimal risk of premium pricing. In fact, there is a competitive marketplace in which manufacturers are incentivised to refine and improve their vaccines – vital given the new strains of the virus which constantly emerge.

Providing COVID-19 vaccines rapidly at scale is a pressing challenge for all countries but there is no evidence that overriding intellectual property rights will achieve more than the licensing agreements currently being forged between innovators and reputable vaccine manufacturers in countries like India and Brazil.

Manufacturing of COVID-19 vaccines is continuing at speed, and mechanisms are gearing up to ensure a rapid global roll out. Forceable tech transfer and other forms of IP abrogation such as those proposed by India and South Africa at the WTO TRIPS Council would throw manufacturing supply chain planning, financing and distribution systems into chaos for little upside.

Instead of sowing division and creating major distractions at venues such as the WTO, opponents of IP should stop the rhetoric. The IP system has put us in a position to end the pandemic. We should allow it to continue doing its job.



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