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How intellectual property rights helped America fight COVID-19

James Pooley
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The Mercury News

When COVID-19 came ashore, glaring gaps in the government's pandemic preparedness became painfully obvious. Everything from inadequate stockpiles of personal protective equipment to confusing and uncoordinated guidance regarding closures hampered our early response.

But while the government floundered, America's research scientists sprang into action. Moderna actually invented its vaccine mere weeks after the virus was genetically sequenced in January — though of course, it took months of clinical trials to prove the vaccine was safe and 94% effective.

Now, tens of millions of Americans have been vaccinated, and the end of the pandemic is in sight. The credit belongs to strong intellectual property protections, as they enabled scientists to move quickly and raise ample funding for vaccine research.

As a post-pandemic world nears — and we begin to prepare for future pandemics — bolstering America's IP infrastructure will help equip us for whatever challenges lie ahead.

Decades of expensive and risky research projects have paved the way for today's breakthroughs. Over the last 10 years alone, drug companies invested more than $1.5 trillion on global pharmaceutical research. And some of that went toward developing the technologies underpinning the leading COVID-19 vaccines.

Notably, that includes mRNA technology. mRNA directs our bodies to produce proteins. And for nearly three decades, researchers have posited that they could use synthetic mRNA to guide the production of proteins that help treat specific diseases.

When COVID-19 started spreading, pharmaceutical company researchers were actively working on mRNA vaccines for the flu, rabies, and Zika. The pandemic necessitated a shift in priorities — and within weeks, Moderna, a small biotech in Massachusetts, and BioNTech, a small biotech in Germany that had partnered with Pfizer a few years prior, began working on mRNA vaccines that essentially instruct cells to create a harmless version of the "spike" protein found on the surface of the coronavirus.

This, in turn, triggers an immune response, which produces antibodies and teaches our body how to fight off future infection. The FDA granted emergency use authorization to the mRNA vaccines from BioNTech/Pfizer and Moderna in December.

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Fortunately for us, America remains at the forefront of the global biopharmaceutical landscape. America is home to less than 5% of the world's population but roughly half of all international pharmaceutical R&D spending.

That's largely because of strong IP protections. These protections, including patents, give innovators a fair opportunity to recoup their investment costs before generics firms can manufacture copycat medicines. It takes years to develop a new medicine, conduct clinical studies, and navigate regulatory review. And it costs $2.6 billion, on average, to bring a new drug to market.

Patent protections make it possible for companies to chase state-of-the-art ideas. Ultimately, if a drug maker wants to stay in business, it's imperative they manufacture innovative products that provide considerable benefit to patients. Those are the types of products that end up changing the world for the better — just like mRNA vaccines are doing right now.

Yet, inexplicably, some have proposed weakening — or outright dismantling — these critical protections. On the home front, these attacks have come from Sen. Bernie Sanders, I-Vt., and Rep. Jan Schakowsky, D-Ill.

It’s not an accident that the overwhelming majority of drugs are developed in countries with strong IP rights. Quite simply, there would be no COVID-19 vaccines without them. America’s pharmaceutical companies delivered the greatest breakthroughs in modern history precisely because our ecosystem incentivizes firms to pursue cutting-edge research.

When the next pandemic arrives, we will have no hope of defeating it if we weaken the one industry that’s best prepared to develop innovative treatments.

James Pooley is a former deputy director general of the World Intellectual Property Organization and a member of the Center for Intellectual Property Understanding.

Covid Vaccine Shakedown at the WTO

James Pooley
December 16th, 2021
The Wall Street Journal

Mercantile interests are behind India's and South Africa's high-minded talk about helping the poor.

The World Trade Organization will decide on Thursday whether to approve an Indian and South African proposal that would allow countries to disregard intellectual-property protections on Covid vaccines and therapeutics. Proponents claim the move would increase patients' access to vaccines, especially in the developing world, by enabling companies to mass-manufacture generic copies of those drugs. In reality, suspending intellectual-property rights would make things much worse. The proposal is cynical—designed to benefit India's and South Africa's domestic drug industries at the expense of patients around the world.

India is the world's largest manufacturer of generic drugs, and South Africa is another big producer. They lament that the U.S. and Europe have blocked intellectual-property rights suspension, even though a greater number of WTO member countries are in favor.

I've heard this line of attack before, and it is fraught with danger.

From 2010-15, I ran the international patent system for the World Intellectual Property Organization, a United Nations agency in Geneva. WIPO administers the global systems for patent, copyright and trademark protection, and its member countries include all those in the WTO. I helped conduct meetings designed to improve intellectual-property laws around the world and thereby create incentives for private innovation that benefits people world-wide.

At those meetings, India consistently questioned the need for patent laws, repeatedly pointing to the failure of pharmaceutical companies to recognize and respond to the AIDS crisis of the 1980s. Indian delegates harped on this outdated criticism, even though manufacturers have made AIDS medicines available in developing countries at a fraction of their domestic prices.

Vaccines and most other medications couldn't exist without private industry investing in the risky research and development that yields new discoveries. The patent system has been carefully designed to preserve the balance that keeps new treatments coming while allowing for broad public access. Under current WTO rules, for example, the world's least-developed countries are exempt from certain critical patent-law obligations.

It would be hard to accuse the brand-name drug companies of profiteering from the Covid-19 crisis. AstraZeneca has promised not to make any profit while the pandemic lasts, and all of the vaccine producers have allowed manufacturers to license their patents for no cost.

So what's the real issue? The dirty little secret is that the WTO proposal is about more than patents. India also demands that vaccine developers release information about their confidential processes for producing drugs, which would reduce their ability to invest in future research. It would be a huge gift to the generic industries in India, South Africa and elsewhere.

Covid won't be the last disease humans need to fight. If we expect private companies to create treatments—and experience shows that they do it better than governments—countries need to protect the incentive to spend billions of dollars on a yearslong R&D process.

To be sure, governments have the power to remove patent protections for anything. But that power comes with grave costs.

If governments gave up on intellectual property rights for treatments, they would have to negotiate a framework to fund pharmaceutical research publicly and distribute drugs around the world. Given the divisions within the U.N., this is hopelessly unrealistic.

Private industry already has the capacity to produce and distribute drugs to combat new sources of infection. Why reinvent the wheel?

The vaccines from Pfizer, Moderna and AstraZeneca are medical marvels that will save millions of lives. Dismantling the system that enabled these breakthroughs is a disastrous idea.

Mr. Pooley is a former deputy director general of the World Intellectual Property Organization and a member of the Center for Intellectual Property Understanding.

Opinion: Waving vaccine patents would imperil public health

Adam Mossoff
April 13th, 2021
The Virginian-Pilot

The most far-reaching healthcare policy decision of 2021 won't be made in Congress or the White House. It will be made at the World Trade Organization, which is considering a petition to waive all patent rights on COVID-19 vaccines.

If the petition is approved, Pfizer, Moderna and dozens of other companies that raced to develop inoculations will be stripped of their intellectual property protections. The fruits of their productive labors, including massive financial investments made before and after the pandemic was officially declared a year ago, will be expropriated. They'll be forced to hand over hard-won knowledge to companies that didn't invest time or money into creating vaccines.

Supporters of the patent waiver — some U.S. lawmakers among them — say it will somehow speed up global vaccine distribution. There is zero evidence to support this claim. A Government Accountability Office report published in February found vaccine distribution was held up by manufacturing bottlenecks, supply chain issues and lack of a skilled workforce. One factor noticeably absent in the GAO report on vaccine delays: patents.

It is no surprise that India and South Africa are leading the waiver petition. India is known as the "pharmacy of the world" given its massive generic drug industry, which would profit even more handsomely from "free" access to cutting-edge medical patents it didn't create. South Africa is also a major producer of generic drugs.

It is unsurprising that countries that lead in biopharmaceutical research and development, such as the United States, Great Britain, Switzerland and the European Union, oppose the patent waiver petition. Their robust intellectual property rights support thriving industries and have fueled countless medical breakthroughs that have saved millions of lives over the decades.

Unfortunately, leading congressional Democrats have sided with India and South Africa, and are lobbying President Joe Biden to do the same. Anti-patent activists hope that if they can turn the U.S. government, this will influence other members of the WTO, which decides by consensus, to join their side.

The current patent system is a roaring success. Before 2020, no vaccine had ever been developed from start to finish in under four years. In response to COVID-19, companies developed, tested and delivered shots in less than 12 months.

This medical miracle was made possible by decades of previous research at pharmaceutical companies supported by strong patent laws. By securing reliable property rights in the fruits of their innovative labors, drug companies built a massive foundation of technical knowledge, research infrastructure and, even more importantly, commercial agreements.

These patents facilitated substantial commercial collaboration. This continued through the COVID-19 pandemic with Novartis and Sanofi making Pfizer-BioNTech inoculations, Merck

producing on behalf of Johnson & Johnson, and AstraZeneca entering a licensing deal with the Serum Institute of India. Drug developers wouldn't share their savvy without patent protections.

Yet Democrats in Congress are pressuring the White House to back the patent waiver petition, using stale populist rhetoric. Sen. Bernie Sanders of Vermont delivered a video message in which he said, "We need a people's vaccine, not a profit vaccine."

Hundreds of millions of people are vaccinated, thanks to patents. Sanders fails to understand that without patents, there would simply be no vaccine.

Cancer and heart disease remain the leading causes of death in the United States. Alzheimer's disease hasn't gone anywhere. And we are bound to face another viral pandemic in our lifetimes.

The only things standing between patients and new cures are the time, labor, and resources scientists need to discover them. That R&D costs hundreds of billions of dollars. In 2018, private industry investments in new drug development were $129.5 billion.

Without property rights securing the fruits of these high-risk, high-cost labors, medical miracles won't happen.

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Act Now to Prevent an American Epidemic

Luciana Borio and Scott Gottlieb
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The Wall Street Journal

Quarantines, flu vaccines and other steps to take before the Wuhan virus becomes widespread.

The novel coronavirus now epidemic in China has features that may make it very difficult to control. If public-health authorities don't interrupt the spread soon, the virus could infect many thousands more around the globe, disrupt air travel, overwhelm health-care systems, and, worst of all, claim more lives. The good news: There's still an opening to prevent a grim outcome.

China failed to contain the virus early. More cases in the U.S. are inevitable. Experience with the 2009 H1N1 flu pandemic suggests that emergency measures such as school closures and border screening—in place at 20 U.S. airports—can at most buy time. Several traits of the virus make border surveillance less effective. It results in a respiratory illness that looks like many other diseases. Some infected people won't show symptoms while they're traveling. Checkpoints don't have tests that can diagnose the virus rapidly.

The U.S. government's actions to prevent the virus from entering the country are valuable, and there aren't many good options in such early stages of crisis response. But it's time for additional measures. As more U.S. cases develop, the strategy needs to incorporate another goal: preventing transmission of the coronavirus within the U.S. Four important steps now could help.

First, the most important public-health tool for containment is the identification and isolation of cases to break the chain of spread. Public-health authorities and health-care systems are on high alert for potential cases. But authorities can't act quickly without a test that can diagnose the condition rapidly.

Health-care providers are relying on a polymerase chain reaction, or PCR, test conducted only at the Centers for Disease Control and Prevention. This test can be very accurate. But the procedure currently requires sending patient samples out to the CDC. It takes at least a couple of days to receive test results. Meanwhile, patients must be kept in isolation.

If the number of cases increases, experience from the 2009 swine flu pandemic and the 2015 Zika epidemic suggests that the CDC will struggle to keep up with the volume of screening. Government should focus on working with private industry to develop easy-to-use, rapid diagnostic tests that can be made available to providers.

Second, focus on the flu. The incidence of flu and other respiratory viral infection cases is high right now in the U.S. It isn't too late to boost flu vaccination efforts, which would reduce the burden that influenza puts on doctors and hospitals. It could also reduce the number of patients showing up at the emergency room with a respiratory illness that requires testing to rule out the novel coronavirus.

Third, hospitals need to prepare for an influx of patients who will need to be isolated. It isn't well understood how this virus is transmitted. There are reports of hospital staff in China coming down with the virus despite wearing protective gowns and masks.

One of the highest priorities should be determining and implementing the infection-control procedures necessary to stopping the spread. CDC recommendations for infection control include using airborne and contact precautions such as specially engineered rooms and masks known as respirators, as well as eye protection. This level of precaution is resource-intensive but may be required to protect health-care workers. It will take time to increase the number of beds in hospitals that can adopt these protocols.

In addition, many medical supplies that help prevent the spread of infection—gloves, gowns and respirator masks—are produced overseas. More outbreaks will strain global supplies. It is critical to begin limiting needless use of these products and prevent hoarding so that gowns and gloves are available where they're needed most.

Finally, government agencies, medical product developers, and public-private partnerships such as the Coalition for Epidemic Preparedness Innovations have started to develop vaccines and therapies. The available technologies and development processes are more innovative than ever. The demand for investigational vaccines and therapies will be very high. But it is hard to assemble the resources and expertise to run clinical trials during an outbreak, and they're important for determining whether treatments are safe and effective. It would help to start planning for these studies now.

Public-health professionals and policy makers have warned about outbreaks like this one—with the potential for global spread and the loss of many lives—for years. It appears such a threat may be at hand. Even if this novel coronavirus is brought under control, it is only a matter of time before another pandemic threat.

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No evidence that patents slow access to vaccines

Andrei Iancu
April 13th, 2021
STAT News

At this point in the exhausting and deadly Covid-19 pandemic, people around the globe are giving thanks for the multiple vaccines that have been produced and authorized in record time. All governments now share the goal of quick and worldwide vaccination.

To reach this goal, many are latching onto the idea of suspending intellectual property rights for Covid-19 vaccines and medicines, including more than 400 health, labor, religious, and other groups. Late last year, the governments of India and South Africa petitioned the World Trade Organization to waive patent protections for Covid-19 therapies.

To take effect, that proposal would have to be approved by member countries and, so far, the United States, the United Kingdom, the European Union, Japan, and others have withheld their approval. But international organizations, like Doctors Without Borders, as well as a number of U.S. lawmakers, support the call to strip away patent rights for Covid-19 vaccines and therapies. President Biden is reportedly weighing whether to back the waiver.

Proponents of the idea say it would boost vaccine supply and access. The problem is, there is no evidence for this claim.

In fact, the push by India and South Africa appears to be disingenuous, aimed not at curbing the pandemic but at allowing domestic companies to make money off of others' intellectual property.

Gutting patent rights is a dangerous prospect. Drug invention is highly risky: Fewer than 12% of new molecular entities that make it to the clinical trial stage get to the marketplace. The endeavor depends on $100 billion in annual private-sector investment, on top of billions in taxpayer money. Kill the patents taken out on these advances and you kill the incentive to invest. That would mean even worse trouble when the next pandemic comes around, in five, 10, or 20 years.

So before governments take the risk of waiving patents, they should evaluate whether intellectual property rights are really standing in the way of vaccine manufacturing and distribution. To do that, they need to answer two questions:

- Is there evidence that a broad range of Covid-19 vaccine developers have been asked for, and unreasonably refused, licenses to their IP?
- Are there more facilities that could manufacture a vaccine in short order if they just had the intellectual property?

The answers are no and no.

The issues about making more vaccines and distributing them to every country are far more complex than those proposing to waive intellectual property rights on these vaccines would

have us believe. Manufacturing and distributing these vaccines is extremely complicated, posing issues well beyond patents.

Almost every factory on the planet that can make these vaccines is already doing so. One of the biggest, the Serum Institute in India, has contracts with AstraZeneca and others to make millions of doses. Under deals like these, manufacturing plants in India will produce 3.6 billion doses of vaccine this year, second only to the United States.

Other companies have licensed their manufacturing process to subcontractors, and even to competitors. Johnson & Johnson and Merck are teaming up to expand manufacturing capacity of the J&J vaccine. Novartis and Sanofi are using their facilities to help increase the production of the Pfizer/BioNTech vaccine.

In short, there's robust collaboration and cooperation within the industry to ensure that vaccines are made quickly and safely. And patents actually facilitate such cooperation, because each entity can rest assured that its proprietary technology is protected in the long run.

So before rushing to disrupt the world's intellectual property systems, governments need to identify specific evidence that intellectual property protection is actually a problem. Adar Poonawalla, CEO of the Serum Institute of India, told The Guardian that insufficient license-granting by patent holders is not an impediment to speedy vaccine rollout and that "it just takes time to scale up," pointing to the complexity of the manufacturing process.

And Bill Gates, the mega-philanthropist whose foundation spearheads many global vaccination efforts, recently told the "Sway" podcast, "Believe me, IP did not limit anything."

On the contrary, intellectual property rights made it possible for research scientists to make the decades of investments required to develop and deliver safe and effective Covid-19 vaccines in record time. Companies would not share such critical technology with competitors if the law didn't protect their investments.

Some of those advocating for patent waivers have their hearts in the right place: They want to end the pandemic.

But the evidence that setting aside patent protection will do anything to boost access or expand supply just isn't there. Removing intellectual property protections on medicines will only ensure that we have fewer of them in the future. This is not a risk worth taking, especially when the evidence suggests we don't need to.

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