<https://fivethirtyeight.com/features/how-pharmas-lucrative-patent-system-is-complicating-the-pandemic/>

MAY 24, 2021, AT 3:14 PM

How Pharma’s Lucrative Patent System Is Complicating The Pandemic

By Anna Rothschild and Sinduja Srinivasan

Filed under Podcast-19

Anna Rothschild was FiveThirtyEight’s senior producer for video

There’s a worldwide shortage of vaccines but plenty of factories standing by to make them. Why is there such a gap between what we need and what we can make? On this week’s episode of PODCAST-19, we explore the surprisingly wild world of pharmaceutical patent law to understand how our system came to be and how it has shaped the pandemic. You can find the episode and a lightly edited transcript below.

By Anna Rothschild and Sinduja Srinivasan

Anna Rothschild: HIV was sweeping through Africa in the ’90s. South Africa was ground zero in this viral war: the HIV rate there was as high as 22 percent. At one point, 20,000 people a month were dying from AIDS.

Western pharmaceutical companies had developed really effective drugs against HIV. But the annual cost per person was more than $10,000, which South Africa couldn’t afford. So, to help fight the epidemic, the South African government wanted to import and make generic versions of the drugs, to save lives at a fraction of the original cost. So, they issued what’s called a “compulsory license” to local manufacturing plants to start producing HIV drugs on the continent. Seems straightforward enough, right? People were dying, so the government wanted to do something about it.

But when money is involved, nothing is ever that simple. The big pharmaceutical companies that owned patents on those drugs were not happy.

Ronald Labonté: They actually went to court to try to challenge and prevent the South African government from issuing a license to create lower cost generic versions of antiretroviral drugs.

Anna Rothschild That’s Ronald Labonté, a professor of globalization and health equity at the University of Ottawa.

Ronald Labonté: The outrage at that time, globally, around what the pharmaceutical companies were doing in the light of such a fatal pandemic sweeping the continent. Eventually the companies withdrew their court challenge, but they really suffered a lot of very bad press as a consequence.

Anna Rothschild The parallels to our current situation are clear to see.

Ronald Labonté: Some of us today kind of are wondering, are we entering another period of time where we’ve got the same sort of issue: a global pandemic, and pharmaceutical companies that don’t seem to be willing to share their technology, their know-how, their ability for other countries and other companies to be able to rapidly scale up production of these vaccines and other medical products.

As COVID-19 ebbs in the U.S., many countries are enduring new waves of the disease. That’s in part because of vaccine shortages in those countries. But some countries, like Canada, South Africa and Bangladesh, think they have a solution. They say they have factories just sitting around, waiting to make vaccines — all they need is the recipe.

The issue — just like it was in the late ’90s — is patents. Moderna, Pfizer, Johnson & Johnson and AstraZeneca all hold patents on their COVID vaccines. And those patents are lucrative. In 2021, Pfizer expects sales of over $15 billion dollars from its vaccine. Moderna? $19 billion.

Last year, there was a push to get pharmaceutical companies to share their COVID vaccine knowledge with the world. But none of the companies have voluntarily shared their expertise. So now, there’s a rising international debate about whether the World Trade Organization should temporarily waive COVID vaccine patents, to prioritize public health over profit. But some argue that if you remove the chance companies will get super rich off of vaccines they develop, they won’t bother developing vaccines at all.

Patents may not seem like the most exciting issue, but they are so, so important to how we got to this moment, when people need vaccines but there aren’t enough to go around. If the patent system were different, so would our approach to fighting COVID-19.

I’m Anna Rothschild and this is PODCAST-19 from FiveThirtyEight.

The international community has rules governing whether foreign countries have to honor patents from, say, the U.S. Those rules were written fairly recently, as part of a 1995 agreement on Trade-Related Aspects of Intellectual Property Rights — more commonly known as TRIPS. Again, here’s Labonté.

Ronald Labonté: And most of the rules that are written down in the TRIPS agreement are actually written by the pharmaceutical companies, Pfizer, in particular, and other intellectual-property-holding chemical manufacturers.

Anna Rothschild: So when it comes to international intellectual property rights, drug companies wrote the rules … literally. And once TRIPS was passed, it gave the pharmaceutical companies a guaranteed monopoly.

Rachel Silverman: It basically says that the person who produced this invention or the company or entity, whatever it is, they have the exclusive right to sell this invention for some period of time. And usually, the period of patent exclusivity is 20 years.

Anna Rothschild: Rachel Silverman is a policy fellow at the Center for Global Development, a nonpartisan think tank. She explained, from the companies’ perspective, that patent exclusivity …

Rachel Silverman: That’s going to allow us to make a profit, a pretty sizable profit, above what would exist in a competitive market. And that profit is what’s going to incentivize research and development. So that’s going to allow us to recoup our investment, it’s how we fund research and development in the U.S., in Europe.

Anna Rothschild: So, how can foreign manufacturers get access to patented COVID vaccine technologies? Well, they have to ask, through a process called voluntary licensing. The manufacturer pays the pharmaceutical company for use of their technology, with the understanding that they won’t use that technology for anything else. But just because a company asks for a voluntary license, doesn’t mean it will receive one. Labonté told me about a Bangladesh-based vaccine manufacturer called Incepta.

Ronald Labonté: It has a brand new manufacturing plant, where it’s basically imported all state of the art equipment from Europe — from Germany. And this particular vaccine manufacturer is 75 percent underused right now, it has a 75 percent capacity.

Anna Rothschild: Currently, Incepta has several production lines in disuse. And according to the company, any one of these lines could produce at least half a billion doses each year.

Ronald Labonté: So it went to Moderna and said, “We’d like to be able to get a license from you”. You know, they’ll pay for that license, right? So it’s not, it’s not that Moderna is giving it away for nothing.

Anna Rothschild: Incepta actually contacted Johnson & Johnson, Novovax and Moderna. None of those companies were moved. And the pharma companies aren’t just denying licenses to developing countries.

Ronald Labonté: There’s a, again, a very modern kind of manufacturing plant in Denmark called Bavarian Nordic. And it has the capacity to produce 200 million doses in very short order. And it is still trying to get a license with one of the vaccine producers.

Anna Rothschild: So why are COVID vaccine developers refusing to license their technology to foreign manufacturers?

They’re literally offering to pay for this intellectual property. I don’t understand exactly what the downside is to these companies.

Ameet Sarpatwari: Let’s take a company like Moderna, who was basing their sort of entire business on the long-term viability of mRNA technology.

Anna Rothschild: Ameet Sarpatwari is the assistant director of the Program on Regulation, Therapeutics and Law at Brigham and Women’s Hospital in Boston.

Ameet Sarpatwari: To share that know-how, even if it’s through a licensing that will assure protection of IP means that their trade secrets are now in the hands of other people. And we may say that’s great for society. But the company is saying, “Is that great for our shareholders for that know-how to be out there?” And I think that there’s a real fear that that is something that would take away a competitive edge in the marketplace for the long term, when the potential revenue earnings they’re talking already about using mRNA technology for all of these other types of conditions, not just for the COVID-19 pandemic.

Anna Rothschild: Most vaccine developers have rejected offers from foreign manufacturers to license their technology. In response, some countries want to issue those compulsory licenses we talked about at the top of the show. They’re sort of like a loophole in the TRIPS agreement. Silverman explains:

Rachel Silverman: Countries can, in certain situations for matters of public health, produce their own version of an invention, a health invention, without the permission of the patent holder, and then they would have to pay some sort of license, but they could actually decide what that license fee would be.

Anna Rothschild: This year, a Canadian company, Biolyse, attempted to get a voluntary license from Johnson & Johnson, but was turned down. Now, it hopes to produce the J&J vaccine for Bolivia through a compulsory license. They have some legal challenges ahead, but that’s not their only problem. Labonté told me that compulsory licenses don’t provide access to what’s called “undisclosed information.”

Ronald Labonté: And that’s the information that’s proprietary, that patent holding companies file when — in order to get their patent.

Anna Rothschild: That information gives manufacturers insights into how to make the vaccine. That’s why many countries, led by India and South Africa, are requesting a waiver to TRIPS, which would extend beyond patents, and cover all COVID-related intellectual property. The waiver would be temporary, until we achieve widespread global vaccination and most of the world’s population has developed immunity. But it would allow foreign manufacturers to make existing COVID vaccines without the threat of a trade dispute.

Recently, more and more countries have come out in favor of a TRIPS waiver, including the United States, France and China. But, as Labonté says, even if the World Trade Organization grants this waiver, all that means is,

Ronald Labonté: It removes the first hurdle.

Anna Rothschild: Meaning countries would not face any legal ramifications for manufacturing COVID vaccines. But some experts, like Silverman, think that alone isn’t worthwhile.

Rachel Silverman: It would not force someone from Pfizer to get on a plane, come over to India and show them how to make the vaccine.

Anna Rothschild: In other words, even though a company couldn’t sue you for making their vaccine, it would not force that company to reveal any trade secrets that weren’t in the patent application. And Silverman thinks that without that inside information, it would be really hard for foreign manufacturers to reverse engineer Covid vaccines.

Rachel Silverman: Vaccines are a complex biological product. There are sometimes hundreds of different components that go in. The exact steps to produce these vaccines are not something you can just figure out from looking at it.

Anna Rothschild: I might have flour and water and yeast, but that doesn’t mean that I’m gonna automatically know how to make the same type of bread that Paul Hollywood from the Great British Bake Off knows how to make.

Rachel Silverman: Yes. And even if you are separately a world class baker, if you’re just looking at the text, you’re not learning from him directly, you’re not seeing what he does step by step, he’s not coaching you. It’s not about you being a bad baker, it’s not about you having the recipe although, you know, all of that would be helpful. But even with all those things in place, it’s still not as simple as just copying it.

Ameet Sarpatwari: I want to push back a little bit on that point, because I think it’s been used as a scare tactic in saying why the waiver may not be effective.

Anna Rothschild: Here’s Sarpatwari.

Ameet Sarpatwari: My point is, those are challenges that are surmountable. The question is, are they surmountable in the timescale and in the sort of amount of product that’s needed in the immediate future?

Anna Rothschild: Regardless of whether it’s possible to reverse engineer these vaccines, Labonté thinks, like with the HIV drugs, optics may be a powerful incentive for pharmaceutical companies to share their knowledge.

Ronald Labonté: It’s gonna be extremely embarrassing for them, I think over the longer term, not to do so. I think politically it could also be kind of like, have a blowback on them.

Anna Rothschild: Especially since governments gave pharmaceutical companies billions of dollars for COVID vaccine research and development. But Silverman is worried that if the patents are waived, the companies might not be motivated to invest in global public health at all.

Rachel Silverman: I want to see pharmaceutical companies incentivized to solve the world’s big problems. I want them working on Covid vaccines and updates for new variants. I want them working on a cure or vaccine for HIV, a malaria vaccine, new TB cures — like we need all of this. What you don’t want is a situation where we’re telling pharma, you know, don’t focus on the most important issues of the day because if you do so, if you produce something really important, we’ll just take it. Spend all your time on the next Viagra, the next Botox, no one’s gonna come after you for that.

Anna Rothschild: But Sarpatwari told me pharmaceutical companies aren’t actually incentivized to solve the world’s biggest problems even now.

Ameet Sarpatwari: If you’re looking at what society needs, definitely there is a skew in terms of our system incentivizes the development of products that are less risky to make, and in which payers have an obligation to pay.

Anna Rothschild: In fact, the pharma companies are incentivized to keep making the same drug, just with a few small tweaks.

Ameet Sarpatwari: There’s also this sense that if I can make just a marginally better drug, or maybe it’s frankly not even marginally better, but has longer patents, longer market exclusivity associated with it, it’s worthwhile to make it because the payers have to cover it. So as long as I can convince physicians that they should prescribe this drug, then I’m going to invest in this, rather than investing in let’s say something extraordinarily risky, which has enormous potential upside from a public health standpoint. So you’ve seen a lot of companies over the past two decades shutter their portfolios for central nervous system diseases, so like Alzheimer’s. We want from a public health standpoint them to do the exact opposite. We want to ramp up drug development in this space, but it’s very difficult and so there is not the appropriate incentive to do that.

Anna Rothschild: Labonté thinks we need to rethink the incentive structure for pharmaceutical companies.

Ronald Labonté: So we have a system right now which is really based on kind of oligopolistic or monopolistic market models. And yes, it produces stuff. But is it producing the right stuff at the right time at the right price for the whole global population? Should we give prizes for people to do the R&D in terms of these companies? Should we kind of incentivize in different ways to make sure that the companies can still sort of do the research they want?

Anna Rothschild: In some ways, Operation Warp Speed used this prize model. The government gave Moderna nearly $1 billion to develop a COVID vaccine, and then pre-paid another $1.5 billion for 100 million doses before even knowing if they’d work. Yet the companies are still raking in the cash. And what happens if we can’t control COVID around the globe and it continues to mutate, so we need to get new booster shots each year? Well, Pfizer, Moderna and Johnson & Johnson have a plan for that. They’ve already told their investors that they’ll raise the price if COVID looks like it’ll be sticking around for a while.

A quick note: We reached out to Moderna, Pfizer and Johnson & Johnson for this episode. None agreed to an interview, but a rep from Pfizer directed us to a joint statement from international pharmaceutical trade organizations outlining five steps to increase COVID vaccine equity. Those include sharing excess doses, reducing trade barriers for raw materials, and prioritizing the development of new COVID vaccines. It did not support a TRIPS waiver.

That’s it for this episode of PODCAST-19.

If you have a question, you’d like us to answer on the show, email us a voice memo at askpodcast19@gmail.com. That’s “ask podcast one nine at gmail dot com.” I’m Anna Rothschild.

Our producer is Sinduja Srinivasan.

Chadwick Matlin is our executive producer.

Thanks for listening. See you next time.

Anna Rothschild was FiveThirtyEight’s senior producer for video. @anna\_rothschild

Sinduja Srinivasan was the producer for PODCAST-19.

Dit is een interessant verhaal over medicijnen en patenten.

Bedrijven menen via patenten het recht te hebben wel of geen opening van zaken te geven ook al gaat het om de volksgezondheid.

Dat is natuurlijk een onverkwikkelijke zaak.

Maar de valkuil is misschien nog meer onverkwikkelijk:

Het bovenstaande verhaal gaat ervan uit dat het gebruik van vaccins een noodzakelijk iets is. Het wordt beschreven als een noodzaak zonder dat de vraag gesteld wordt waar komen de ziektes überhaupt vandaan?

Kan het niet zo zijn dat de farmaceutische industrie ook de veroorzaker van de ziektes is?

Als er geen ziektes zijn kun je ook geen vaccins verkopen, zo simpel is het toch? De winsten die deze industrie maken zijn astronomisch.

Bovendien is de vraag: zijn de vaccins wel zo effectief als beweerd wordt?

Het wetenschappelijk onderzoek is zeer beperkt zo niet afwezig.

En de toelatingsregels en commissies worden betaald door de industrie zelf, dus hoezo betrouwbaar, veilig en effectief?

De wetenschappelijke basis ontbreekt en er is alleen sprake van een commerciële basis, het gouden kalf.

Voor zaken die met gezondheid te maken hebben is een absolute openbaarheid geboden. De rechten kunnen anders beschermd worden.

Geheimhouding is uit den boze omdat dat wetenschappelijke toetsing in de weg staat.