



*Innovation Under Siege:
A Conversation on the Potential
WTO TRIPS Waiver*

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Bayh-Dole
COALITION

Joseph P. Allen (00:00:00):

Well, as we mentioned, we appreciate you joining our webinar this morning. We called it Innovation Under Siege: a Conversation On The Potential TRIPS Waiver. As you all know, the global Covid-19 pandemic sent the world into a tailspin as there were no viable treatments available. In response to our companies, universities, and federal laboratories came together in an extraordinary partnership to develop desperately needed vaccines and therapies. Breakthroughs like mRNA were made under the Bayh-Dole Act, which allows universities and federal laboratories to license their inventions for commercialization. The result was the development of vaccines and therapies in record time as our researchers worked around the clock, as most of the world was shut down to get these products to market. It took time for them to be produced. And some claim that developing nations are being harmed because of patent rights. As a result, the agreement on trade-related aspects of intellectual property, or TRIPS, that was established to create minimal patent rights internationally, adopted a waiver with U.S. support so that developing nations could ignore IP rights on Covid-19 vaccines.

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China and India are included in the definition of developing nations. However, once production kicked into high gear, the world was soon awash in vaccines. Global demand has also dropped for Covid diagnostics and therapies. It was agreed at the time of the initial waiver to consider extending it to diagnostics and therapeutics. And whether to do so is now being considered. The Biden administration is weighing which way to come down. Excuse me. The U.S. Trade Representative, which supported the initial waiver, TRIPS waiver, for vaccines, asked the U.S. International Trade Commission to review the issue. The resulting report came out in October and pretty much summarized all points of view without making any recommendations. The U.S. led the world in developing vaccines, therapeutics, and diagnostics to fight the pandemic. Many were created under public-private sector partnerships where patent protection provided developers with the confidence needed to justify the around-the-clock efforts to create critically needed therapies.

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Many were licensed to small companies. Now that the world is seemingly awash in Covid vaccines and demand is receding, it seems like an odd time to be considering an extension of the TRIPS waiver. Concerns about the extension is shared on both sides of the aisle. Representative Darrell Issa, who chairs the House Subcommittee on Courts, Intellectual Property and the Internet, said, "Any extension of the TRIPS waiver agreement will undermine the very innovation and record-breaking rapid development that we saw for Covid-19. And for that reason, we are here today to talk not just about the risk of helping China, but the very risk to the innovation that we all enjoy here in the United States." The ranking Democrat on the subcommittee, Congressman Hank Johnson added, "I do not dismiss the concerns of those who oppose the TRIPS waiver, particularly those who fear that the Chinese government will take advantage of the waiver to access American technology and use this technology to compete with American companies."

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On the other hand, waiver advocates, like Public Citizen, argue that the price of Covid tests and treatments is still a problem. The extension will not harm U.S. jobs or the economy, and that voluntary licenses need to be strengthened with compulsory licenses to ensure access to needed treatments and diagnostics. Today, we'll discuss the underlying issue with three experts with extensive experience in the public sector, venture capital, and the private sector to consider these issues and the impact it could have on U.S. innovation, particularly on our entrepreneurial small companies, which drive our system. Rather than having theorists propound their ideas, we have hands-on experts representing the academic licensing, startup, and venture capital communities. Erik Iverson is the CEO of the Wisconsin Alumni Research Foundation, the granddaddy of all university technology management organizations. Before that, Erik worked with the Bill and Melinda Gates Foundation to found the first biotech startup company in Africa.

(00:03:58):

Jennifer Cheng is the CEO and Co-founder of PTM Therapeutics, a pre-clinical stage startup, developing antibody therapeutics for bowel disease and oncology applications. She also held positions as a patent attorney

for several major companies. Jennifer Androski chairs the Board of Directors for Incubate, an organization of life-science investors, and is also President and CEO of Roivant Social Ventures, which she helped found to promote partnering between innovative companies, institutes, and organizations to promote systematic, sustained improvements to the way healthcare is accessed and delivered. I also want to mention before we get started asking the panel questions that anybody in our audience that wants to can submit a question; just put it in the Q&A at the bottom of the screen, and we'll be happy to discuss that with our panel. So we have a limited amount of time.

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So let's get started. And what we're going to do is we're going to pose questions to the whole panel, and anybody can weigh in as you choose, and we're happy to have the panel raise additional issues as we go along. So let's start with this. A fundamental premise of those supporting the initial TRIPS waiver for vaccines and its extension is that patents create barriers of access to desperately needed technologies in poor countries. Opponents counter that without patents, high-risk breakthroughs won't be made. Last week, the administration released its long-awaited guidelines for agencies to use on march-in rights under the Bayh-Dole Act, which says that, "if someone believes that a product isn't recently priced," the government should consider licensing to rival companies. What impact, if any, do such policies have on U.S. innovation and entrepreneurial small companies? Somebody want to kick it off? Hopefully you will, because otherwise it's going to be a really long, long program.

Erik Iverson (00:05:45):

That's a long pause. Sure, I'll take the initial shot at that. Thanks for that, Joe, and thanks for the invitation to join this panel. And it is a very important issue. And of course the issues arising not just in the WTO march-in, not march-in, but the waiver, but we're also seeing it with Bayh-Dole and the new march-in issues that are arising as well as with the WHO, and some issues that are being badgered around certainly within that institution. With the Gates Foundation, with my time at IDRI, Infectious Disease Research Institute, and founding Afrigen down in Africa, which is really, was an altruistic effort to move vaccine technologies and biologics into Africans' hands and have them develop it. Certainly, I've played this game for a long time. I'm fully aware of the issues. Patents are not the problem.

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Patents themselves are not the problem. It is the way that one manages technologies and how they build relationships and provide access to technologies. I think the harm on the system and the incentives to develop new technologies, if people believe that they could simply be taken, will most definitely stifle new innovation. It will stifle innovation across the world, most certainly in the United States. What we really need to do is identify how we can best partner and incentivize the partners to develop relationships in other geographic regions, but we really need to identify the right incentives to do so.

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And what we have learned is that a lot of the essential medicines with the WHO are not on patent, but they're not made. The Covid vaccine waiver really produced no good technology transfer and production of new vaccines. And patent pools that have been created, have proven largely to be ineffective. And so the proof is in existence, and the data exists. What there's also proof of is strong relationships, building the right incentives, providing the right training, is really what's needed to address these kinds of issues, not simply attacking a very narrow aspect of patents, which in my opinion is a quite naive approach in a very complex set of issues.

Lindsay Androski (00:08:10):

I agree with Erik, and with some of our work with Roivant Social Ventures, we've seen in practice a lot of what Erik saw in the past with his experience in Africa. In particular, one of our areas of focus is simplified manufacturing technology that can actually be brought to Africa to enable these countries to locally manufacture so many of the drugs that are off-patent; that they don't have easy access to. And even there, it's not an easy sell, necessarily. The companies that we've been working with, there's a lot of negotiation with the governments, and it's not even an easy road to get the technology in there up and running and administered by locals. But certainly, that is an excellent

first step where we're spending a lot of our time and energy because there are so many treatments that would be available off-patent that could help patients there a lot if it was just brought there.

Joseph P. Allen (00:09:18):

All right. Jennifer, you have any thoughts about that?

Jennifer Cheng (00:09:21):

I do, and this is more from the perspective of small startups and innovative companies here in the United States. It's long been believed that our patent system, the way that it works and the strength of our patent system, is a bedrock for the innovation that we're seeing. And I think this affects more than just small companies. It also affects large companies that are looking to smaller innovative companies to do the riskier, the high-risk early research to bring these innovations to a point where they're ready to be partnered off and beyond. So without the strong IP protection that we currently enjoy in this country, I think that there is really even less of a guarantee of founders really taking that risk and starting new companies to explore these innovations that will hopefully eventually become therapies and part of the larger ecosystem. With these two things, with the TRIPS waiver extension and also with the Bayh-Dole Act's march-in rights, it's erosion of our IP system, the strength of our IP system, and I think it's going to have a chilling effect on innovation here in this country.

Joseph P. Allen (00:10:41):

Yeah, we really want to focus on what the impact is, of this, on innovation, and obviously we want to talk about how we can help the whole world because I think all of us feel that we have a social, moral, and even economic obligation to make sure we get products out that can help people. But before we get into that, one issue that we mentioned in the introduction is the timing of this. As Erik said, the first waiver wasn't used. I think the Chinese have agreed they will use the second waiver.

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So at a time when it looks like the world is awash in vaccines, in fact, some African countries are saying, "Please don't send us any more vaccines. Some of them are wasting before we even get them to the people." Why would we be thinking about actually making an additional waiver to therapeutics? And now you are into things which actually were made by small companies. Now you're into things where the focus is going to be more on the small companies than on big pharma. So why would we be thinking about doing this at a time when it looks like the problem is really receding?

Lindsay Androski (00:11:40):

I have a cynical answer to that, which is, I don't think it's by accident. If your view is that we should be chipping away at IP protections because the pharma industry charges too much, whatever your rationale is, this is a really great path to get there. Because this is no longer an emergency situation., There's not outrage that you would expect. There aren't Americans that will be deprived of booster shots or therapeutics if this is to go through. And so it's actually a really great time if your end goal is to use this later in the future and have a precedent in place. So, like I said, that's a cynical answer, but I think it probably has some validity to it.

Joseph P. Allen (00:12:30):

Erik or Jennifer, any thoughts about that?

Erik Iverson (00:12:32):

Sure, lots of thoughts. I think particularly with Covid vaccines, we better be careful because, as we saw with the pandemic and particularly on the vaccine side, we're tempting society to really struggle against the integrity of good science, and we cannot allow that to happen. But we saw the proliferation of vaccines, which really did not go through the safety and efficacy studies that we all expect as citizens. And now what we're asking is to waive any patents on this, pass it over to a bunch of geographic regions that don't have a lot of, they either don't have a lot of capacity or experience in developing vaccines, or they have very strong generics industries such as China, or India, or Indonesia, or Brazil, or otherwise. And we're saying, go ahead and take these vaccines that we are still asking a lot of excellent scientific questions around, saying, go ahead and produce those.

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And the transfer of patent rights is woefully insufficient in the world of biologics, where you really need training, you need know-how; it's an art. And that's why there is really no such thing as generic vaccines because it is incredibly difficult in the biologic space. And I have experienced, for example, while I was at IDRI, when we had a lot of work in the leishmaniasis space, we did vaccine development, but we did companion diagnostics, and we had diagnostics in the world, and we elected not to patent those leishmaniasis diagnostics. And there was an endemic disease within the Horn of Africa. It was elsewhere in the world, but particularly in the Horn of Africa. And I remember receiving an email from a clinic that said, "Hey, folks, please come over and enforce your patent rights to get these what were really", I suppose you could say pirated, but there were no patents, so you're not pirating anything, you're just creating and using trade names and those kinds of things.

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But they were saying, "Please come over and force your patent rights because the stuff that we're dealing with in these diagnostics are giving us wrong readings. And it's literally killing people." We could not, we didn't have any patents. We had to write back and say, "Talk to your local government people because we have no ability to enforce patent rights to stop these diagnostics that were really literally killing people." And I tell you, that was incredibly painful because we made the decision in the interest of global health not to patent. And lo and behold, it came back to bite us in a way that was 100% counter to what we were trying to achieve. Anyway, those are my thoughts. A little long-winded. Sorry about that, Joe.

Joseph P. Allen (00:15:34):

No, listen, that's why we have you on here because we wanted somebody who's been there. And I think those are the kind of stories that really illustrate that this is not some theory. There really are real-life implications of this, and some of them are really unexpected, and I guess it could be expected, but they're really not talked about. We actually got a question from the audience just to build on what we just talked about, which I'm going to bring up now, and then we'll go on to some other issues. The question says --

Joseph P. Allen (00:16:03):

I've heard this refrain regularly that African countries and companies have been given resources over time globally, and none of it has come to fruition. Do you have more insight as to why? What specifically needs to change to successfully implement tech transfer and local production? So that comes back to what you're talking about. So what really needs to happen so you really could get some of these things actually either developed in developing countries, or even more importantly, bring developing countries into the circle of actually making things and developing things? I know South Africa has actually adopted a Bayh-Dole Act because they said, "We don't want to be wards all the time. We want to actually be tapping into our university." So what are some creative or positive things that could be done that really could make developing nations part of the solution and not just all the time running around helping that somebody's going to give them something?

Erik Iverson (00:16:51):

Yeah. I hate to monopolize, but I'll describe very, very briefly how I created, with Steve Reed at IDRI, Afrigen, which has been now designated as a hub and a hub-spoke system of producing and providing access to RNA vaccines for the continent of Africa. Little old Afrigen, a startup company. I think we did it in 2014 or so. What I could have done in the U.S. in setting up a company, could have done it in three to six months, and it took really three to five years to set up. Because although we provided well-established technology, in this case it was adjuvants, which are needed to modulate the immune system, that you can couple with antigens to create a vaccine. We transferred that well-established technologies, waived all patent rights to that, hired all Africans to build and run Afrigen, did it altruistically because we were a global health organization, but it took years and years to do it, because there was insufficient training of the scientists. There was insufficient capital to build the company.

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There was insufficient regulatory environment because we were asking them to come in and help establish a regulatory framework, but they had no experience to do that. And so really, the patents or the rights to the

technology were the least of our worries. We flew scientists back and forth from the U.S. and South Africa, back and forth to do some training. We sent business people and financial people back and forth to do some of that training. And then we worked with the South African government to put money in without controlling the institutions so we wouldn't be beholden to bureaucracy, the bureaucratic hiring processes. That played well. We had to work our way through the banking system down there. They then had to go out and hire and build capacity. It's taken years and years and years to do.

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But my point is it's an extraordinary complex environment that we were willing to take the time and work through. One could argue that, "Well, wait a minute. You're a nonprofit doing this, so why would a company do it?" What we didn't add was financial incentives. IDRI's rights was picked up by a pan-African medical health institution that saw the economics in it. So if we were a for-profit company, I would've still done that, but I would've asked for some remuneration. Why am I using a difficult word on a panel? I have no idea. But we could have designed the right incentives within that, that we would've all been happy to play along. What nobody responds well to is a fiat or a dictate to transfer their rights to something. So it's really a matter of being patient with the right incentives and building the right partnership to make this happen. Afrigen's proof positive that it can be done.

Lindsay Androski (00:19:56):

I have one thing to add based on our experience working there with the manufacturing companies, which is that I did not appreciate the extent to which brands matter in Africa. So there is actually a very strong aversion to having generics, and there is not a system like there is in the U.S. where you get routed to the generic first and then have to jump through some hoops if you want the brand. And so that is part of why we have seen, even if it's possible to manufacture the generics locally, the demand just isn't there as much. And ironically, why is the brand so strong? Because of the strong IP protections back in the U.S. and the investment that has been made to build a strong brand.

Joseph P. Allen (00:20:43):

Jennifer, do you have any thoughts before we move on to something else?

Jennifer Cheng (00:20:48):

I think the other panelists have touched on all the points that I can make. My thoughts are purely, I think, theoretical. I think that it's just beyond the therapeutic. You have the regulatory industries, you have everything else that is surrounding the IP and the protection around the therapeutic itself. And that needs to be created in many of these nations, as Eric has pointed out in a real-world example. And I think that would be the bulk of the hurdles, and that's not an easy thing to overcome, even establishing hubs and centers in the United States. There's a reason why a lot of the companies are being founded at these hubs and it's just a creation of an ecosystem where you support all of that activity and expertise, and that needs to be created basically from scratch in some of these nations.

Joseph P. Allen (00:21:57):

One thing I'd like to do now is the title of this program is Innovation Under Siege, and I want to now focus about what this does to the U.S. And again, we're happy to have other questions. If people want to submit them, we'll certainly take them. But one thing that struck me was before we passed the Bayh-Dole Act in 1980, government-funded research was tainted because what happened was, before 1980, if you made something with government funding, the government would take it away from you and license it to basically anybody that wanted it. And so not much was developed. Bayh-Dole came in, changed that, and said, "Universities and federal laboratories can license technologies. You put patent incentives in there," and that's one of the things that's actually driving our economy.

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One thing that really struck me when Covid hit was seamlessly, overnight, when everybody else was hunkering down and putting a pillow over their head and was afraid to go outside, go to school, do anything -- companies, universities, federal laboratory, and venture funding came together overnight with public-private sector partnerships, and we literally developed these vaccines and therapies in record time. Operation Warp Speed was a

miracle to me. It was like World War II kind of conditions and people came through. Now, almost as soon as that was over, the administration came in and supported a waiver, basically saying anybody in a developing nation can copy our Covid vaccines. Now we're thinking about an additional waiver for diagnostics and therapeutics. We just had the administration last week saying, "If you commercialize a federally funded invention and somebody doesn't like the price, they can petition the government and maybe we'll license a copier." So what does that do to competence in the government as a partner in high-risk research?

Lindsay Androski (00:23:41):

This is going to be devastating in the venture capital industry. When it comes down to it, the science needs to be strong, the potential for patients needs to be strong, but whether to invest is a financial model. And if your financial model indicates that you can't rely on a reasonable price or there's high variability, a low percentage of confidence, and whether you'll be able to get that price, then you're going to pass on an investment. I'm very worried that whether federal dollars were used could just become a binary screening question for investors. If yes, take a pass. Look at something that didn't take federal dollars.

Joseph P. Allen (00:24:20):

Jennifer, you're actually doing this right now. I think your company is commercializing something. So if you come out and actually get a product across the finish line, and we hope you do, if any of your rivals or a foreign company or somebody wants to take a shot at you and say, "Hey, we think Jennifer's charging too much money, you should license a competitor," does that have an impact on your ability to run your company? Or what does that do to you?

Jennifer Cheng (00:24:45):

Yeah, I absolutely agree with Lindsay. On the other side. I think most of the tiny startups that I have talked to, and certainly myself, we've taken licenses to federally funded IP. And if there's high risk that it just won't work financially in business models of VCs and the way that they're deploying money, basically, my business is over before it even starts. And like many other tiny companies, we have built our companies on core technology that we license from someone, and it's usually a university or a federally-funded institution. And if we cannot rely on the strength of that or the protection that it can offer, we cannot find funding. The chance of finding funding is very, very slim to none. And basically, I think that you won't see small startups starting up anymore, which would be devastating to not only the pharmaceutical industries, but other innovative industries as well.

Joseph P. Allen (00:25:57):

Erik, some people seem to think that people like WARF just have people lined up around the street looking to take a license and that everyone recognizes what great technology this is, and it's just that hard to do. So is that the reality? Do you have people outside your door right now taking a number and hoping they can bid on a license?

Erik Iverson (00:26:14):

Yeah, it's kind of like being a bakery. Just take the number, and I'll call your number when we get around to it. I so wish that was the case. That is so far from the case. I can appreciate in the Covid context, the U.S. government put billions of dollars to work very, very fast. And we saw vaccines come about. Again, we bypassed a lot of that safety and efficacy studies and those things in response to what we were all grappling with. So I can appreciate that people point to Covid as a unique situation. What that then argues is then let's leave it as a unique situation, particularly the inventions that occurred back in the day when a lot of money was pouring out. But as you pointed out at the very beginning, we're no longer in that the earth's on fire, we need to run lightning fast.

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Let's now get back to what we recognize and appreciate as a rational scientific approach of development that relies on high-risk capital of the venture community, private equity, even mom and pops in seed rounds of these companies, which they're willing to put a lot of money at risk. Covid is not the norm. Far from it. And University of Wisconsin is such a prolific inventor. We got 400 inventions a year. We patent on 200 of those. Every one of those, it's such incremental funding. Even though there's a lot of federal funding that goes into research, when it comes down to an invention, it's really incremental. And we're relying on the venture community, the companies, the mom

and pops to put dollars to risk, which so overshadow ultimately the incremental funding that the government puts into it to really be a catalyst of some of those early inventions.

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There is any number of examples I can point to where if there's not a lot of patent life on a given invention, nobody wants it. There's no way I can license that invention. And there's one example of a biologic cell therapy actually, that the medical outcomes are really super cool, super promising, but there's only a few years of patent life. There's just no way we can find anybody to pick that up, even though scientifically and from a healthcare perspective, it could be amazing if enough research is done. I have to point one other thing out that we're struggling with as a tech transfer office is on one hand, there's a recent growing statements across both sides of the aisle of invent it in the U.S., make it in the U.S.

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The problem is there's a real lack of capacity to manufacture in the U.S., so we have spent every tech transfer office, and quite frankly, a lot of small companies rely on international partners to get things made. But if we're being told we can't license things internationally, how does it reconcile against march-in rights or waivers and then taking technology invented in the United States and handing it over to folks in China or India or Africa or wherever? How in the world are policymakers going to try to reconcile those two really, quite frankly, competing philosophical perspectives and laws that are being passed and funding provided? So I put that on the table as something that we're just really beginning to struggle with right now.

Joseph P. Allen (00:29:42):

And the problem... I'm sorry, go ahead.

Lindsay Androski (00:29:45):

Oh, no. I was just going to say I think it's worth restating, I'm guessing this is an audience educated about how drug development works, but it's worth restating how early the research is that government funds, and everything that needs to be done in between to turn that into something that can be used by patients. And we don't want this early research to die on the vine. We need the biotech industry to build on that work, and it's very expensive. That's the reason Erik's having trouble licensing something that's very promising, but only has a few years of patent life left. Because usually, something comes out of federal research or federal dollars, it's not even ready to start being tested in humans. There's a bunch of other preclinical work, like in Jennifer's company, that needs to be done. And then you get to the really expensive part of all the clinical trials, and that's where the bulk of the risk is. That's where the bulk of the money goes in. And all of that has to be successful for it to reach patients, and it requires a significant return on the backend when it succeeds.

Joseph P. Allen (00:30:51):

Jennifer, do you have any thoughts about that as actually somebody who's actually running one of those companies?

Jennifer Cheng (00:30:55):

Absolutely, and Lindsay is absolutely right. When the technology that we have licensed is very early and we are taking it through, we have proof of concept data, and usually this is something that's in-vitro, so not even in an animal. We then have to test it. Maybe we have to reformulate it or retool the molecule. All of this preclinical work, it costs money and time, and a lot of work is being put into it, even to a level where we feel comfortable that it is safe and effective and that we would even think about putting it into patients. And then the clinical work where you're testing it in patients, that's just a lot more for money, financial-wise, how much it costs. And it takes years, because of the necessary regulatory process that we have put into place in this country.

Jennifer Cheng (00:32:03):

So the IP creation that we're getting from universities, it's really just the beginning. And this doesn't even talk about... So the TRIPS waiver would apply to all patents, not just the federally-funded ones. And if you're creating things from scratch, and you're investing in an IP portfolio from scratch, in-house, in the private sectors, that is a lot of financial commitments. And the payoff and why people do it is because you can secure those rights and have the

protection so you can move forward, so you can get funding. And it takes a lot of money to get it to a place where maybe you can realize it on the back end. And if you take away from that, and you have the TRIPS waiver put in place, that affects all patent rights. I can't imagine any sane person investing in IP and in companies without IP, because these rights can just be thrown away at the end. And the money, that financial infrastructure that you have put into it, just wasted.

Joseph P. Allen (00:33:20):

Lindsay actually mentioned something at the very beginning of the program I want to go back and pick up on is, what we're really talking about is an assault on the patent system. And the same people pushing the TRIPS waiver are also pushing using march-in rights inappropriately for the government to micromanage pricing. I was on Birch Bayh's staff, I staffed the bill through, I wrote the report of the Senate Judiciary Committee, I oversaw the law at the Department of Commerce. And as both Senator Bayh and Dole said, the purpose of Bayh-Dole is to make their things are commercialized. It gives the government no right to second guess your business decisions if you've got something across the finish line. But the critics argue that the government is funding research and development. So the implication is, if you license something from a university or federal laboratory, you're getting some kind of special benefit.

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And sort of like taking a loan from the mob. If you have that special benefit, then you have a new partner suddenly telling you how to run your company. And that partner can either give your rights away under international agreements, or tell you what your price should be. So I think the other thing that Lindsay mentioned is, people don't understand that even our drug development system is largely driven by small companies like Jennifer's. 50% of our new drugs come from small companies. 70% of academic licenses go to small companies. So are these small companies, is Jennifer getting away with some special benefit, the fact that she's licensed a government-funded invention that justifies the government now coming in and saying, "Hey, we don't like the price of this, or you should license somebody else, or maybe we're just going to give your technology away because it makes people happy"?

Jennifer Cheng (00:34:56):

I wish I was getting a special benefit. I certainly am not. But I mean, again, it's not that... I'm not getting it for free, right? There are terms on the back end. And if we're all successful, then we all win. Right? And I do recognize that universities, they put in as much time and financial commitment in generating this IP. And just because the science comes from federally-funded dollars, it doesn't... I mean, there's every stop along the way it costs money and time and expertise. And yeah. There's no special benefits except for that it's the government's instead of some other third party. And it comes with actually a non-benefit that a third party can't just march in and take something away from you for no compensation. And I think that it's actually a detriment, but you're willing to do that bargain because it makes sense and you want to see these scientific innovations exploited and developed, and hopefully can be a benefit to patients sometime in the end, right?

Joseph P. Allen (00:36:17):

Right.

Lindsay Androski (00:36:18):

The biotech industry is full of heroes like Jennifer. You're not going to meet a founder or a member of a team there that isn't passionately trying to improve the lives of patients. And it is an indispensable part of the ecosystem. And you don't hear about most of these companies. This is where most of the failures occur. And for most of those that succeed in getting through clinical trials, they're going to be acquired, or have commercial rights licensed to one of the big pharma companies that you know about. Because it's a whole different world when you start building a commercial team, compliance, so most biotechs don't go that route. They stay in the development, research and development stage. And it's going to be really, really detrimental, I mean that's an understatement, if that dries up because IP becomes unpredictable.

Erik Iverson (00:37:16):

Mm-hmm.

Joseph P. Allen (00:37:17):

So Eric, when people license your technology, are you giving them a guarantee they're going to make money and they just walk out the door and everything is hunky-dory?

Erik Iverson (00:37:25):

I'm going to take that as a rhetorical attempt at humor, Joe.

Erik Iverson (00:37:30):

I'm totally teasing you. But I think really where we should continue to focus our efforts is on the incentive side. Because what we're talking about here, whether it's Bayh-Dole march-in, whether it's WTO, whether WHO, and all the things that are going on. We're talking about the sticks, we're not talking about carrots. And I think we're fundamentally risking losing our way by not focusing on the carrot side of the equation. And that is so many of our laws. And we should all absolutely celebrate the Bayh-Dole Act, Joe, that you're so dead center. You're such a hero, honestly, to this country, and to me, for what you did, and what Bayh-Dole did. We should celebrate Bayh-Dole, we should celebrate the patent system, because it was doing what it was set out to do, which was create new technologies, create new companies, create more jobs. And the largess that that law itself created for the U.S., but for the world, and the better health, the better communication systems, the better energies that Bayh-Dole has allowed to be fostered, is just truly amazing.

(00:38:44):

What we don't see, because nobody tracks it, is how much money and failure technologically occurred during the same period of time. It was a monumental amount of money that was put at risk and lost in that process. Thank goodness we've got so many great technologies, new jobs, new businesses. So why would we attack that system that has created really the greatest lifestyle the world has ever seen across the entire world? So let's then, if we identify those areas where we could do better, and we can always do better, then let's target those areas and figure out, what are the incentives to help make those situations better? Let's not harm the system that's created the greatness that Bayh-Dole and the PAP system has created, and attack that and tear it down. Let's leave that in place and just focus on those things that we need to get better at, and focus on the incentives. Because those incentives, whether it's money, whether it's childcare, whether it's healthcare, whether it's better communications, we can address all those. But let's address those in incentives, not as sticks.

Joseph P. Allen (00:39:50):

That's a great point. We have another great question. And audience, you're doing a really nice job giving us some thoughtful questions here. One of the questions is, do the panelists want to comment on the impacts of these waivers on the ability to respond to the next pandemic? We just had a hundred-year pandemic. Because of Bayh-Dole, companies were comfortable that government was a reliable research partner. And as Eric said, they put a huge amount of money at risk. Not all companies that got into the pandemic made money. Some of them lost their shirts. And a lot of them were small companies. So we've done this once, and now after it was over, the U.S. government says, "Hey, we're going to let our competitors copy your technologies. In fact, we may extend that." And now they've come back and said, "Hey, if you are successful in this system, if anybody thinks your price is too high, we'll think about that and maybe license your competitors."

(00:40:40):

So what impact does that have? Suppose we have, God forbid, another crisis, not that we're running out of crises, are companies going to walk in again and say, "Hey, we trust you as a partner"? Or now are people really concerned about, again, how reliable are you? If the politics change or something, some whim comes in, are you going to give away my technology and attack me?

Lindsay Androski (00:41:03):

Well, thanks to that listener for injecting a doomsday scenario that I hadn't thought about yet. I mean, I think, yeah,

obviously people will think twice, and maybe the government's got to double the carrot that it offers to make up for that on the front end. But I would also refer people to the International Trade Commission report, Joe, that you mentioned in your introductory remarks. Because they took a comprehensive analysis of, what were the roadblocks to addressing this on a global scale. And none of them had anything to do with IP. And an extended TRIPS waiver isn't going to help anyone globally during the next pandemic. Because the issues that stopped medicines and vaccines from getting there are not IP-related.

Joseph P. Allen (00:41:55):

Jennifer, Erik, any thoughts about that?

Jennifer Cheng (00:41:59):

If you agree with the kind of thesis that erosion of the IP system would stifle innovation, I would think that the results would be... For the pandemic, RNA vaccine technology existed before the pandemic. Antivirals existed before the pandemic. All of these things were built on innovative ideas and backed by IP protection. And I think one of the reasons why we were able to respond so quickly as we did was that these innovations existed before we even had the pandemic. So it was easier. We had just a jumping-off point. We didn't have to start from scratch to make these therapies and vaccines.

(00:42:48):

So if you stifle innovation because you erode the patent system of patent protection and incentives for companies to put in dollars into innovations, then for the next pandemic, I'm afraid that we will be woefully behind the start line in even developing other vaccines or treatments for the next pandemic that nobody can really anticipate what that will be. So, I think it's really important that, looking forward, if we don't have the innovation, and we don't have the engine that drives that, we are really on the back foot in preparing for any other major world disasters.

Joseph P. Allen (00:43:33):

Erik, do you have any thoughts?

Erik Iverson (00:43:38):

Yeah. I'll take it down a little tiny different path, and that is, I was reflecting on Afrigen. And when we transferred rights down there, one of the things that was really fundamentally important to Afrigen was to create its own innovation, and patent its own innovation. And one could say, well wait a minute. What we're struggling with right now is, how do we get rid of patents? I mean, this is the issue on the table. How do we get rid of patents? Because that seems to be the problem. It's not the problem. It's so hyper-complicated, as Lindsay pointed out too, and Jennifer has said. The overall recipe to make the really good soup, it doesn't take one ingredient. If you take one out, it doesn't destroy the soup, but it also doesn't make the soup. But it's an important piece of the overall ingredients that we need.

(00:44:29):

But it's just that patents happen to be an easy target for people to latch onto. I fundamentally disagree that patents are the problem. But I do find it interesting that when we partner with folks in other countries, particularly whether it's developing countries, or China or India, which quite frankly aren't developing countries anymore, they strive for their own strong patents within their companies and within their societies. Amen. I agree with that. But when we do our transaction with them, we want some rights to their inventions too, because we should all, let's just do the horse-trading, let's do the transactions.

(00:45:07):

So if you're going to say, "Hey, U.S. developers, we're going to take your patents away", then you better be taking everybody's patents away. Well, that's just, we're all going to take our bat and balls and go home and nobody's going to play the game. And that's just fundamentally wrong.

Joseph P. Allen (00:45:28):

Well, here's another great question we got from the audience. Because we've talked a lot about the things that came from federal funding, but these waivers also... The TRIPS waiver also applies to things that companies did on their

own dime. So here's the next question. What are your thoughts about the impact of patent waivers, under TRIPS again, where you're saying people can copy it, if the product resulted from 100% private funding, i.e. no federal government funding? So what does this do to folks that, hey, I developed this on my own, I'm out here, and now suddenly I wake up and the U.S. government has agreed that people in China and India can now copy it? Or any other developing country?

Erik Iverson (00:46:09):

Well, there are people in society who don't believe in private property rights at all. Okay. I mean, that is a philosophy that one can hold. All of us on this panel, I'll guarantee it, disagree with that wholeheartedly. But it would be a taking of private property. And there are plenty of laws against that for very, very good reason. But it's also shallow and naive, in the sense of... Patents, again, are a legal construct that represents science, which is incredibly complicated, that takes art and know-how and ingenuity and all the real-life physicality that goes into creating something new. A patent is just, again, it's a piece of paper construct that says, hey, that person who spends all her money on this and creates it, gets some monopoly to get some return on it. And so the idea that, again, you take patents away from people, is dismissive of the fact that nothing will get done with that if you don't have the right partnership, the right scientific training, the right resources to get things done, and all that goes into the beautiful nature of successful technology.

Joseph P. Allen (00:47:28):

Okay. Here's a question that actually came from somebody who's asking about potential benefits from the TRIPS waiver. So we want to consider all points of view. So let me just read this. People have heard the argument that because developing nations lack the technological capability to develop these complex mRNA vaccines, the TRIPS waiver will not help them produce vaccines. What are your thoughts on the counterargument that certain developing countries have been able to develop these vaccines in a time-bound manner, so the TRIPS waiver may help to globalize manufacturing? Anybody want to comment on that?

Erik Iverson (00:48:05):

I'm not sure how Afrigen success in figuring out how to make an RNA vaccine results in global manufacturing. I mean that's good on Afrigen and South Africans for trying to develop it, but that's a presumption that the entire world operates cohesively and in a uniform manner, which is a big leap to make.

Joseph P. Allen (00:48:31):

Any other thoughts about that? The other thing we mentioned in the introduction was we're also setting a precedent. When the U.S. agrees to these waivers people can come back and make the same arguments. We have an environmental crisis. We have a global climate crisis. We have an energy crisis. We're not running out of crises anytime soon. Why can't they? The UN has already said that energy technologies, environmental technology should be the common property of humanity.

(00:48:59):

Once you start going down the slope, how do you say, "Well, yeah, we'll do this for Covid therapies and diagnostics, but why aren't you doing the same thing with battery technologies or any kind of environmental remediation?" In other words, how does the U.S. remain a competitive country developing cutting-edge technologies if every time we have one, somebody can come back to an international agreement and say, "Hey, you should give this to us because we want to copy it?"

Lindsay Androski (00:49:29):

I worry about that slippery slope all the time. I'm going to get lawyerly for a minute and nerdy and actually remind folks that the patent system comes from Article 1 of the Constitution and that our founding fathers gave Congress the right, I'm going to quote it, "To promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." If we get rid of this exclusive right, we're going to get rid of the progress. I think it's as simple as that.

Joseph P. Allen (00:50:02):

Do you know of any innovative countries that don't have strong intellectual property protection? Are there any socialist countries that give everything away that are actually on the cutting edge of developing anything? Certainly, China doesn't give their things away. Can you think of anybody who in the pandemic came up with a great idea of technology they developed without any patent protection and really helped meet the needs of the global pandemic or any other technology? Venezuela, is that a dynamo of innovation?

Erik Iverson (00:50:38):

No, but we can point endlessly to I would say big companies, small startup companies, and a whole lot of academic researchers that provide access to technologies information and otherwise to people around the world whether it's a specific conference, whether it's a collaboration. It happens all the time. It happens constantly.

Joseph P. Allen (00:51:03):

Patents are public documents. You're disclosing how to make and use this. It's not a secret. This is the opposite of trade secrets.

Erik Iverson (00:51:10):

That's right and, by the way, a whole lot of NIH money, a whole lot of U.S. government money, U.S. aid and otherwise flows to research institutions all over the world, including South Africa, University of Cape Town and others. They receive a ton of U.S. dollars to help further research. Those are getting patented in the countries in which those are being done. Those are U.S. taxpayer dollars. What are we asking for there? I believe in the system that exists now.

(00:51:39):

I'm not asking for anything, but let's not target U.S. citizens and institutions in using U.S. dollars. U.S. supports much of the globe's research enterprise, including with the European Union as well as Wellcome Trust and some others, but the U.S. government for sure funds a ton of new innovation globally that winds up being patented in other countries.

Lindsay Androski (00:52:09):

Joe, your point about trade secrets and patents being published is an important one because, in recent years, we've come across more and more biotechs that are choosing not to file patents and that are instead holding information or inventions close as a trade secret instead. The world suffers ultimately when that information is not disclosed publicly. I think that we could be seeing more and more of that if the patent rights continue to be eroded.

Joseph P. Allen (00:52:43):

Listen, go ahead. Go ahead, Jennifer, please.

Jennifer Cheng (00:52:46):

I'm also going to be a little lawyerly and a little nerdy. Getting back to why TRIPS was adopted in the first place, I think there were safeguards in place. There was a recognition on patent rights and it's just intrinsically hooked up to innovation. One of the reasons why TRIPS was actually put in place was the concessions to that. There were safeguards that were put in place that you had to negotiate for a private license first before you can even apply for a government license, giving away your technology.

(00:53:29):

That's only in very limited circumstances of emergencies, right? There were safeguards put in place for TRIPS. I think that we shouldn't lose sight of just the fundamental nature of why TRIPS was put in place in the first place and to come in later in an arguably non-emergency state to just do away with all of that is really ignoring the genesis of the agreement.

(00:54:06):

If you have erosion, I mean the really short answer to your original question is you won't see companies putting in dollars and innovating and people will be holding trade secrets closer and electing not to patent things. I think

at the heart of it we're all scientists. These companies are made up mostly of scientists and researchers who come from academia first and you have this climate of sharing of ideas in science. I don't think the patent system is a deterrent against that.

(00:54:50):

I think it actually encourages the sharing of ideas because it's all publicly available information and it's the bargain that you strike, right? You get this limited monopoly in exchange for this free flowing of ideas and communication. Why do away with something that is working and that we've built not only in the pharmaceutical industry, but also other high tech and environmental discoveries? All these industries are built on innovation and science.

Joseph P. Allen (00:55:24):

Hey, listen, you guys have been great. We've got one more question I'm going to try to sneak in here before we end. It says, "I've read that there's a lot of risk in R&D for the private sector because most drugs don't make it all the way through clinical trials. At the university R&D level, I imagine there's even more risk that research may not result in a product. Inappropriate use of march-in rights would hamper research at the university level."

(00:55:46):

They're asking that as a question. If people want to speculate real quick, again we've got a high risk system already. It's leading the world and made the U.S. a leader in innovation. What happens now if you introduce even more risk, for example saying the government could march-in if somebody doesn't like the price of a product that made it across a finish line?

Erik Iverson (00:56:05):

I don't think that the march-in concept would stifle university innovation all that much, I mean as long as there's federal grants. The researchers who are really not driven on the most part by the commercialization, they are in science for science's sake. I really think there'll be a lot of research even in the absence of really exercise march-in rights.

(00:56:32):

A tiny fraction of technologies that come out of even this massive research institution called University of Wisconsin-Madison, incredibly prolific across energy and life sciences and animal products and agriculture, a tiny fraction winds up getting patented and gets licensed and into products. It is a very, very small amount. What that would do is, thank goodness we have, because it takes an enormous amount of money. The early-stage research that happens on campus is really just extraordinarily early-stage.

(00:57:10):

That really isn't a product certainly. It's not even really a technology. It's an idea that was proven out in a lab somewhere. Now we're asking the people like Lindsey and Jennifer to invest money into it and take it off a campus and spend a whole bunch of money and convert it into a product and then asking society to buy it. That is a monumental leap. I don't think it would stifle university research, but it sure would stifle what ultimately gets the society to better society.

Joseph P. Allen (00:57:45):

Jennifer or Lindsey, any last thoughts you want to share?

Jennifer Cheng (00:57:52):

I mean certainly it would be less attractive to license university technology or technology that comes from federal funding and it just wouldn't happen. I would imagine because of less demand, the university would elect not to patent inventions that come out of the research labs.

(00:58:14):

Then, I think it's just less innovation and small companies either wouldn't be formed or we would have to look for technology and innovation elsewhere. Either develop it ourselves, which would just be super capital-intensive and

really high-risk. I think it's just bad for the ecosystem in general, and the end result is we would see less therapies and benefits to society.

Lindsay Androski (00:58:50):

I just want to thank you for hosting this. We named it the TRIPS waiver and in between that and the event happening, the march-in rights thing happened. The big takeaway is this is a real attack on IP. It is coming from multiple angles and it's so important for people to cover this and bring attention to it. Thanks to the audience, too, for caring and tuning in.

Joseph P. Allen (00:59:18):

Listen, this has been a great panel. It's been a lot of fun. This hour has gone by very quickly. Also, the Bayh-Dole Coalition is actually having, we're calling it a fireside chat on Thursday at 2:30 on march-in rights. We invite anybody who wants to participate on that because, this just happened last week, but these are serious issues and I really appreciate your thoughts. I think this has really been an educational discussion and a lot of fun.

(00:59:43):

Thank you very much for taking your time. You're all busy people, and I really appreciate it. Also, on behalf of the Bayh-Dole Coalition, we thank everybody for joining us today. We hope you can join us again on Thursday at 2:30. If you go on our website, you can see how to register for free. Thank you very much for your attention, and we'll look forward to working with you down the road. Have a good day.

Erik Iverson (01:00:03):

Thanks for all you do, Joe.

Joseph P. Allen (01:00:05):

Thank you, sir.

Jennifer Cheng (01:00:05):

Thank you.