



Unpacking the Proposed TRIPS Waiver Expansion: A Conversation with Gary Locke

December 1, 2022



Andrei Iancu (00:00:01):

Hello, everybody, and thank you for joining us today. My name is Andrei Iancu. I'm a partner at the Irell & Manella law firm. And from 2018 to 2021, I was the under secretary of commerce for intellectual property and the director of the United States Patent and Trademark Office. In September of this year, my friend and predecessor, Dave Kappos, and I launched the Council for Innovation Promotion or C4IP. And the two of us are co-chairing this organization. This bipartisan coalition is dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. A strong intellectual property system is a necessary component for a strong innovation economy. One simply cannot happen without the other. And C4IP works to ensure that the public and decision-makers understand that innovation and IP are inextricably linked. Today, I am thrilled that C4IP is hosting a conversation between Dave and Ambassador Gary Locke on the efforts to suspend global IP protections for Covid-19 diagnostics and therapeutics.

Andrei Iancu (00:01:29):

The two additional proposals would be an expansion on the current waiver of the TRIPS Agreement with respect to Covid-19 vaccine technologies. Now let me turn it over to Dave and Ambassador Locke. But before that, I want to introduce the two of them. Very good. There they are. Ambassador Locke has had an illustrious career in public service. From 1997 to 2005, he served as the Governor of Washington State. From 2009 to 2011, he served as the Secretary of Commerce during President Obama's administration. From 2011 to 2014, he was the U.S. Ambassador to China. And since 2020, he has been the interim president of Bellevue College.

Andrei Iancu (00:02:37):

Meanwhile, David Kappos, as I said, my fellow board chairman at C4IP, he was the under secretary of commerce and director of the USPTO when Ambassador Locke was Secretary of Commerce. So now we hope, and I very much hope, that this webinar will illustrate the widespread bipartisan opposition to expanding the TRIPS waiver. I worked in the Trump administration, while Ambassador Locke and David were colleagues in the Obama administration. But these are bipartisan issues. All of us agree that the waiver would be doing considerable damage to intellectual property in the United States and around the world, as well as the innovation economy. So with that in mind, let me turn it over to David for some opening remarks. David?

David Kappos (00:03:30):

Yeah, thanks, Andrei, and great to be working with you. And thank you all who've joined. Really an opportunity to have a great discussion. And Secretary Locke, absolutely great to see you and to be working with you again on this super important issue of the various TRIPS waivers that we're going to talk about. I have great memories of our days in Commerce with you as my boss working on what became the America Invents Act, riding the ship at the USPTO. And your leadership there remains an inspiration to me today. So thank you for your willingness to be involved and be a part of intellectual property issues in addition to just everything else you're doing. Look, let me start with the Covid-19 diplomacy issue.

David Kappos (00:04:27):

Last year, we worked together, jointly publishing a white paper on Covid-19 diplomacy and the TRIPS, at the time, vaccine waiver/IP waiver, through the Center for Strategic and International

Studies. Going from there, Ambassador Locke, I thought perhaps a place to begin is for you to talk a bit about why you've become involved in this effort to combat these TRIPS IP waivers for Covid-19 vaccines and now therapeutics and diagnostics.

Gary Locke (00:05:03):

Well, thanks a lot, David. And I'll also want to thank Andrei for kicking off this event. It's really great to know that we have bipartisan views and support in opposition to the next proposed TRIPS waiver. TRIPS — for many of you who don't know--is an acronym for really the worldwide agreement protecting intellectual property among all the countries of the world. And these waivers that we're talking about to deal with Covid-19, first the vaccines themselves, and now therapeutics and testing protocols or testing kits and things like that. But it's really also great to be with you, David. And I remember our days at the Commerce Department and you heading up the Patent Office. I remember the time I introduced you to all the employees in the Patent Office. We were in the square outside the Patent Office, and I made a comment at that point that our mission was to dramatically reduce the backlog of cases, applications wanting a patent. And also to streamline the patent application and approval process.

Gary Locke (00:06:16):

And I think I said that if people want to get a patent within one year, we're going to enable them to do so. And I remember so many people just closing their eyes and tilting their heads down, saying, "What does this guy know about the patent application process and how backlogged they are?" But under your great leadership and the committed dedication and efforts of the employees and the staff, and the examiners of the Patent and Trademark Office, you were able to substantially reduce the backlog. And with the legislation that was passed, working with Democrats and Republicans, the most comprehensive reform of our patent laws in several decades. And I think it really has positioned American industries and inventors and innovators to move forward. And that's why I guess I'm really concerned about these TRIPS waivers — first for the vaccine, as well as now for therapeutics and testing.

Gary Locke (00:07:13):

It will do nothing to prevent people from getting ill or do nothing in terms of the treatment of people who become ill. And I think that it sets a very bad precedent in terms of weakening our American economy and the innovation that occurs in our country and in innovation and inventions all across the world — if there's a constant rush to waive these intellectual property protections, which companies and innovators, inventors, and researchers, whether in the private sector or in our colleges and universities, that they depend on when they invest their blood, sweat, and tears — and in cases of companies and startup companies, millions and millions, if not billions, of dollars. Let me just say that my mom suffered from Parkinson's, and our whole family longed for a cure for Parkinson's. And I think so many of us know of friends and neighbors and relatives who are afflicted with either Lou Gehrig's disease or Alzheimer's, or cancer.

Gary Locke (00:08:28):

We want incentives for our innovators to put in their blood, sweat, and tears to come up with life-saving cures. And I think that by granting these waivers, we're lessening the incentives that people will have, and companies will have to invest hard-earned time, energy, and money, if they know that the secret sauce that they come up with might easily be copied and taken

advantage of by other people. And so, why would they invest? Why would they invest? And with respect to the TRIPS waivers, with respect to Covid-19, the evidence is overwhelming that intellectual property protections have not impeded people's access to treatment. It did not in any way impede the development of vaccines. Drug companies have been voluntarily licensing their technology to accelerate global manufacturing and distribution of treatments of medicines to treat people who come down with Covid. In fact, our two main companies, Pfizer and Merck, have signed hundreds of agreements to allow generic versions of their medicines to be manufactured all around the world.

Gary Locke (00:09:54):

They've worked with the United Nations, the United Nations Medicines Patent Pool, to allow generic versions to be manufactured by approximately 200 companies worldwide. And many other companies have entered into these voluntary licensing agreements, making it available to people, basically half the population of the world. And what's interesting is that in just the year 2022, governments and NGOs received some 80 million doses of these treatments, but they only gave out — administered — 18 million. So it's not a question of lack of supply, but it's really the supply chain. How do you get it to people? Even the vaccines? How do you get into the arms of people? What we found out with respect to the vaccines, for instance, is that the two main countries that were advocating for the waiver of intellectual property protections, South Africa and India, India alone, the largest worldwide manufacturer of generics and of drugs, the Serum Institute, they actually threw out over a hundred million doses of vaccines that had expired because of no demand all around the world.

Gary Locke (00:11:15):

South Africa, which had a contract to buy at a very low cost, vaccines from Johnson and Johnson, South Africa is trying to cancel that contract for over 10 million doses of the vaccine. And so, not a single country took advantage of the waiver of intellectual property protections, which would've enabled South Africa, China, [and] India to produce copycat Moderna, Pfizer vaccines, and so forth. Not a single country used that waiver to increase the supply of vaccines. And why? Because so many generic companies from around the world, including India and South Africa, had agreements with companies like Moderna and Pfizer to produce generic versions. But the problem in many of these developing countries was they couldn't refrigerate it. They could not get it out into the hinterlands. They didn't have the personnel; they had distribution problems.

Gary Locke (00:12:25):

And so all these vaccines have expired, and they're being thrown away. And again, there's no evidence to show that there's a problem with getting access to the medicines to treat people who come down with Covid. So I guess I fear that we're creating a precedent that will eventually weaken the U.S. economy, the innovation economy, which is so important if we want to look at developing cures and medicines for some of the most dreaded diseases out there.

David Kappos (00:12:57):

Yeah. Thank you very much, Secretary Locke. That's just a wonderful summary. So as I reflect on what you've already shared, number one: There are literally hundreds of agreements in place between the manufacturers of both the vaccines and the treatments. The world is awash in the vaccines and the treatments, so much so that some of them are going bad and having to be

thrown out. The problems with moving vaccines and treatments around have nothing to do with intellectual property. As you've explained, their infrastructure, refrigeration, roads, those kinds of things. There has been not a single case, and thank you for pointing that out, not a single case of a country that's used to actually use the vaccine waiver. So it's kind of crazy, actually. All the evidence points in the direction towards this was a terrible idea in the first place, and we should not repeat the mistake and go any further with it.

David Kappos (00:13:57):

And then, as you point out, we're frankly playing fast and loose as a country with the goose that lays the golden egg, if you will, our intellectual property system that undergirds the biopharma research for the next cures, as you mentioned. Parkinson's and Alzheimer's, et cetera. So it does seem rather ill-fated what's going on here. But there are proponents, as you've pointed out, a few of them. And I wonder if you could just talk a bit more about who are the proponents and what countries are there that want these waivers to proceed anyway?

Gary Locke (00:14:46):

Well, the waivers were first proposed by India and South Africa. And what's interesting to note, as I indicated earlier, is that, for instance, the Serum Institute in India has been producing through licensing agreements with the U.S. and European manufacturers of Moderna and Pfizer vaccines, they've been producing generic versions of it, and now they're throwing them away. So nobody has really needed the waiver to increase their supply by copying the formula, et cetera. They've been able to do that using these agreements with Pfizer and Moderna that protect the intellectual property, the secret sauce, so to speak, of our innovators. But now joining the call for the waivers for at least treatments and testing kits are China, Pakistan, Tanzania, Egypt, and Indonesia. And what's really at stake is they want to be able to understand the technology, the secret sauce, the secret recipe, like the Coca-Cola formula.

Gary Locke (00:16:00):

People understand the essential science behind the new technologies that have given us the Pfizer and the Moderna vaccines. But they want the actual formulas that they can then use to build upon and look for future advancements and discoveries, tackling many other diseases and problems of the world. And so, they really want a head start. China has made no bones about how they want to be world-class, a world leader in biotechnology along with artificial intelligence and semiconductors and things like that. So the ability to gain a head start to jumpstart their intellectual capabilities, to develop medicines and vaccines for many other dreaded diseases or illnesses or viruses, is an economic boost to them. They want to piggyback off of the hard-earned blood, sweat, and tears, and labor of American and other innovators from around the world. And if you're able to do that, if we give them the secret sauce, why should American companies continue to spend billions of dollars doing clinical trials and coming up with trying to come up with cures?

Gary Locke (00:17:23):

Because we know that oftentimes, these advancements, these discoveries don't work. They're promising in the lab, and they spend billions and billions of dollars on clinical trials, further R&D, and then they have to say it's not going to work. And they move on to something else. We need to create that incentive for innovation, which is really the secret sauce of our dynamism as a country, our innovation as a country. And that's why I fear the precedent that providing a waiver

for Covid treatments and testing equipment and protocols would have, especially since there's really no need for it.

Gary Locke (00:18:13):

There was no need to give a waiver for the intellectual property protections with respect to the vaccine itself, and nobody used it. We are awash in vaccines. There's vaccine hesitancy all around the world, and in those areas that need the vaccine, the problem is not supply. It's personnel — that go out into the countryside to administer the vaccines, to store the vaccines, to transport the vaccines. Those have been the bottlenecks to getting more people vaccinated. And in China alone, with all the lockdowns that they have imposed, it's because of the low vaccination rate in China and because their vaccines are not very effective. And even China has not taken advantage of the waiver to produce their versions of Moderna or Pfizer vaccines.

David Kappos (00:19:08):

Yeah, thank you, Secretary Locke. Really great points. So this is really, when you unpack it, this isn't an issue of access to vaccines or access to treatments. It's about industrial policy, and it's about countries that didn't innovate wanting to get free access to the, as you say, hard-won fruits of the innovation of countries that did innovate, of wanting to get what — I mean, I'll characterize this myself — what I think could be the biggest free giveaway of the outputs of innovation ever in the history of the world. We're talking about the mRNA platform, as you correctly point out. It's not just some single specific thing. It's the platform that enables the creation of new mRNA-based treatments in the future. That was created by, as you mentioned, Moderna, Pfizer, et cetera. And the question is, frankly, not treating people for Covid. We've got that down, as we've pointed out.

David Kappos (00:20:28):

We've totally got that and the access to the treatments for people who have the disease. We've got that down. The real issue is industrial policy, and it's great that we can have a conversation where we just honestly point that out. And you also mentioned: It's recently been discussed that in the case of China, in particular, there is a company that had all the approvals in place very early on, including the contractual rights, the license rights, to move the really effective mRNA-based treatments to China. And it was denied access to the market there in favor of the less effective Chinese treatments. That's a decision that's certainly within the rights of the Chinese decision-makers to make.

David Kappos (00:21:22):

But it clearly shows you that the issue there, just like everywhere else, isn't about Covid treatment. It's about industrial policy. So great to point that out. Secretary Locke, I wonder if we could just move back to the U.S. for a minute now and talk a little bit about so what's the U.S. done to respond? What have we done as a country to come to grips with what you and I have been talking about here, the fact that we invented the vaccines, we invented the treatments, other countries want them as an issue of industrial policy. The issue isn't at all access to the vaccines or treatments. It's an issue of industrial policy. What's the U.S. doing about this?

Gary Locke (00:22:10):

Well, what's interesting is that just within the last year, the Congress has passed a whole host of laws to increase our competitiveness, to bring high-tech manufacturing back to the United States. And also, the administration has tried to restrict the export of high-technology materials to other

countries, namely specifically China. And so if we're really trying to stimulate high technology in the United States, whether it's on solar, whether it's advanced manufacturing, whether it's in semiconductors, that ought to include our pharmaceutical industry as well. We're here to stimulate innovation and manufacturing and creation of jobs, good paying jobs in America. So why would we then turn around and support giving away our intellectual property, especially around medicines and take away, almost negate what we're trying to do in terms of building that innovative economy here in the United States? On the one hand, we're saying, "Yes, we want innovation. We want high-tech development, both R&D and manufacturing, in the United States."

Gary Locke (00:23:45):

But on the other hand, we're going to waive these intellectual property protections with respect to medicines and biopharmaceuticals, et cetera, and allow other countries to basically take our secret sauce and develop it on our own and compete against us. Our pharmaceutical industry alone spent billions of dollars on clinical trials for the treatments for Covid, the medicines to help people who come down with Covid, supporting hundreds of thousands of jobs in the United States. And so, why would we now turn around and say, "It's okay that we're going to let other countries compete against us." And not on a fair basis, but we're going to give them all the technology, the secret sauce, so they can actually move ahead and compete against us?"

David Kappos (00:24:42):

Yeah, crazy. It's one thing to offer licenses on a royalty-bearing basis or those kinds of things, but to just give the technology away seems crazy. Another area that I think is really interesting is the role that the labor unions are starting to play. As you've pointed out for the biopharma industry, clearly, this is a huge problem, and you can understand that very directly. But what if we could just talk for a minute about how labor unions are coming into the discussion here because they are, as I understand it, strongly opposed to these waivers also. Naturally, you think about jobs when you think about labor unions and good-paying jobs. And as I understand it, there are literally hundreds of thousands of labor union jobs, workers, who stand to lose their employment. I wonder if you could just comment a little bit on what's going on there that is impacting this discussion.

Gary Locke (00:25:50):

Well, you actually summarized it perfectly. Labor understands the job implications of a strong, innovative economy, innovation economy in the United States in all aspects, whether it's semiconductors, whether it's artificial intelligence, whether it's electric automobiles, to solar and clean energy. But certainly, our pharmaceutical industry and our biotech industries, because all the equipment, very sophisticated equipment, it has to be very precise, exacting standards. And that's where American companies excel in terms of advanced manufacturing. And so these are jobs for American companies and American workers, to build the laboratories where the R&D occurs, and then, of course, the manufacturing facilities, which are up to where the standards are so exacting. And we saw, earlier in the year, some problems with one of the laboratories in Maryland where there was some sanitation issues, and it took a long time to really make sure that the equipment was meeting the highest standards in producing vaccines.

Gary Locke (00:27:08):

So there are a lot of jobs at stake. And just as we want to increase job opportunities, good family wage jobs for American workers, we should not be so nonchalant and saying, "Well, hey, we're

going to give away the secret sauce so that all these other companies around the world can now compete against us, and we're going to turn over our hard-earned blood, sweat, and tears, and efforts." And some of these technologies that companies invest in are years and years and years in the making. It's not discovered overnight. A lot of trial and error over decades and building upon that knowledge and that foundational information. And now, just to say, "Hey, I'm going to give it to someone else," and they can immediately compete against us. That's not a level playing field. And so the labor unions understand what's at stake. It's not just the development of the material itself, the vaccine, the medicine, but all the requirements going into the physical infrastructure, into R&D labs, the equipment, the manufacturing facilities. And that's good paying jobs for the American people.

David Kappos (00:28:24):

Yeah, that's tremendously helpful. Thank you. So interesting also: You mentioned a little bit before about some of the other countries that are on the side of being proponents. It turns out there's also quite a few countries that stand to lose, like the U.S., and that know they stand to lose and that are starting to ask the hard questions that our country needs to ask. So for the audience, WTO member countries were supposed to be deciding on December 17th, so just a little bit later this month in a couple of weeks, whether or not to expand the Covid-19 vaccine IP waiver to include therapeutics and diagnostics. As I understand it, given the rising opposition, that folks are starting to wake up, and other countries are starting to raise their hands. Unfortunately, the U.S. hasn't yet will come back to that, but other countries are starting to raise their hands. It's seeming it may be likely the WTO will defer its decision until the new year.

David Kappos (00:29:37):

So some specific instances that seem to be leading to this slowing down of the decision-making process, Mexico, along with Switzerland, recently sent an official communication to WTO members questioning the need for the waivers because, as you've pointed out, Secretary Locke, supply isn't an issue. They've honestly pointed out, "Hey, what's going on here?" You're giving away Mexican and Swiss jobs and intellectual property for no good reason. The UK, the EU, Japan, Korea, [and] Singapore all want to see proof. They're standing up and saying, "We want to know that IP is actually hindering access to therapeutics before we're willing to vote for the waiver expansion." And obviously, they're asking this question not out of naivete. They're asking it because they know, like we know, there isn't any proof. In fact, the proof all goes in the opposite direction, as we've discussed. So I find myself wondering if the U.S., America, should be leading on this issue.

David Kappos (00:30:51):

We need to be the voice. We need to be the adults who are standing up, being honest, accurate about the data, what's going on. It's totally in our country's best interest, and it's in the best interest of the world generally to be having fact-based discussions about these important points of public health. These WTO decisions are made by consensus. If the U.S. says no, gets involved in a discussion in a fact-based and candid way, it's pretty clear the expanded waiver is going to fail. So Secretary Locke, coming back, where do you feel like this leaves us? What's going to happen next in terms of decision-making? You've been on the inside of this apparatus at the very top of the government. Can you give us a sense for who in the executive branch usually would be involved in a decision like this at this point?

Gary Locke (00:31:51):

Well, I think that obviously, the Department of Commerce needs to be involved, needs to weigh in, along representing American industry and understanding and presenting the implications to job creation, as well as continued R&D by our companies. And the implications in terms of not just jobs and the health of our biotech industry but also what's going to happen in terms of discoveries down the road. How does our medical community feel about the United States taking a backseat or slowing down its progress in terms of innovation and discovery, looking for cures for some of the most dreaded diseases and illnesses afflicting the world? The U.S. Trade Representative's office also needs to be involved along with, for instance, Health and Human Services because, obviously, they are focused on the health of the American people. And if policymakers were to understand that the continuation of these waivers — the continuation of waiving intellectual property protections when there's clearly no need for it — that we're creating a precedent, and that will serve as a disincentive for continued innovation R&D with respect to finding cures for these dreaded diseases ... that's going to be of a major implication to the health of the American people. And so I think that all branches of government need to weigh in and understand from their own constituencies and the people that they work with, understanding the implications and presenting that to the White House. I also think members of Congress need to weigh in because, obviously, members of Congress are focused on jobs in their communities. Whether you're a mayor, a state legislator, a senator, or a member of the House of Representatives, you're always concerned about job creation and good-paying jobs for your constituents. And so we need to have those members of Congress looking at this issue and weighing in and offering their voices, giving their voices to the administration. We've already had a letter, a bipartisan letter, opposing this expansion by members of the United States Senate on a very bipartisan basis. And so I think more need to get involved.

David Kappos (00:34:13):

Yeah. Thanks. That's all super helpful. And let's just focus a little bit on Commerce. So when I was running USPTO, you were my boss, the Secretary of Commerce. I remember vividly you calling the whole senior team together in the beautiful oak-lined Secretary's conference room on the fifth floor of the Commerce building across from the Secretary's office there, the so-called blue carpet area. And expecting us as your leadership team, myself and all the other heads that were relevant, to advise you so that you could advise the president so that you could interface, like you said, with the USTR. I don't think it would change much from the administration. Maybe you could comment from the Secretary's viewpoint about how you would've been thinking about this if you were there, and who you'd be looking to for advice, and who you'd be going out and trying to influence to make a good decision here.

Gary Locke (00:35:25):

Well, certainly, the Secretary of Commerce has great influence within the administration because it's the voice of representing not just the manufacturers and companies, and not just employers, but also workers. We had a motto in the Commerce Department that we wanted to create more jobs for the American people, and we wanted American companies to succeed because we knew that, for instance, if they were able to export more, they would manufacture more. The more they manufacture, the more workers they need. And that means jobs for the American people. So the Commerce Department is well situated and well positioned to really advance the interest of American companies and American workers — and to understand the implications down the road and the impact of an expansion of these waivers, of intellectual property protection

and the implications it would have on job creation and innovation and investment by American companies. So the Commerce Department is well situated, well positioned, highly respected within the administration to advance these concerns. And I think the Commerce Department, they should be working with U.S. Trade Representative's office as well because the position at the WTO would be conveyed by the USTR'S office.

David Kappos (00:36:45):

Yeah, and for folks to understand, there's also the interagency review process at the Secretary level. I would think the Commerce Secretary like you said, would be meeting with USTR and Health and Human Services and others. This is a really important issue. This is not just national but global health, innovation, leadership. All these things we've talked about. You're not going to delegate this down deeply into the organization. Would you hope that the interagency review process is bubbling up these issues like we're talking about to the secretaries, the Health and Human Services, Commerce, et cetera?

Gary Locke (00:37:27):

Well, I'm sure many of the relevant agencies are getting feedback from the different organizations within the departments. But it's important that stakeholders, business leaders, labor representatives, scientists, researchers — that they all use whatever bodies they are on in each of these departments to convey their concerns. And if they're not even part of an advisory committee, just to contact the Secretary's office directly and let those secretaries, whether it's HHS, the U.S. trade representative or the commerce secretary, a small business administration, to help them understand the impact on a very discrete basis, on a company by company basis or university basis or research entity basis, what this means. What an expansion of waving intellectual property protections would mean to them and how they would view it.

David Kappos (00:38:31):

Yeah, great. That is great advice and for everyone watching listening. This is the time to do it. This is the time, and Secretary Locke has just given you pretty clear thoughts on how to make a difference. Also, for myself, when I was running the USPTO, you certainly would've called on us at the PTO as the expert advisors. This is an intellectual property matter, after all. The statutory job of the director of the USPTO is to advise the secretary of commerce, the administration, and through the secretary of commerce, the president of the United States on intellectual property issues. So I would've been saying, and I would've been saying, "Wait a minute, this is my job. I've got a responsibility to weigh in here and to call balls and strikes and honestly explain what's going on." So I would hope that same thing is happening now. So a lot of very difficult issues that we're dealing with clearly. Andrei, I feel like we've had a tremendous discussion here. I want to bring you back in and just ask: do you have other questions that we haven't covered yet?

Gary Locke (00:39:48):

Or actually, we'd love to hear from Andrei in terms of his perspective on how stakeholders can be involved in this process and how they can weigh in, and what he feels would be effective as well.

Andrei Iancu (00:40:01):

Yeah, sure. Well, thanks, Ambassador Locke and Dave. First of all, tremendous conversation here. Really good points. I do want to pick up just briefly on the last point you guys were talking about, the interagency process. I do think that every administration works a little bit differently.

Obviously, the department, the agencies are still there. There's the same USPTO, same Department of Commerce, but still, the interactions between various heads and so on is a little bit different. But on an issue as important as this, I don't think there would be too much variance. And it's hard to imagine. It's certainly true when I was there in the Trump administration, and it sounds like it was the same in your administration. It's really hard to imagine that a decision like this that impacts the intellectual property system would be made without, frankly, not just the involvement of the under secretary for IP and the secretary of commerce, but also their approval.

Andrei Iancu (00:41:12):

And I'll ask you this and comment to the extent you're comfortable: But is it possible that a decision like this can be made without the approval of the Secretary of Commerce, and if the Secretary is adamantly opposed, what's the next step? How does that get resolved? Ultimately, it's a presidential-level decision in the end.

Gary Locke (00:41:40):

Well, I think what happens is that if a Cabinet member is firmly opposed to a possible policy decision or a certain proposed policy, that will be heard within the White House, and there'll probably be a convening of some of the leading people within the White House and perhaps even all the way up to the President. But certainly top staff. And to hear out these voices, which is why it's so important that each of the Cabinet members hear from their constituents and their advisors and industry people and the constituent groups that they interact with — because if industry is loud and clear in opposition to expanding weakening intellectual property protections, Cabinet members are not going to ignore that. And then they will then present those views. Hopefully, it helps them formulate their position, which they then advance to the White House.

Gary Locke (00:42:41):

So each administration is different, but the cabinet secretaries do have great influence in the final decisions. But the cabinet secretaries and the under secretaries, whether it's the head of the patent office to someone over in Health and Human Services dealing with innovation and illnesses and things like that, if they really hear from constituent groups and researchers, they will pass that information on. But if people are silent, then the implication as well, American businesses, American researchers, American innovators, our scientists, and researchers don't really care about it, then they'll make their decision in a vacuum.

Andrei Iancu (00:43:26):

So true, and what I think is critically important is for members of various industries in the circumstance, if they care about IP and innovation, to speak up. Frankly, this is an issue that, in my view, doesn't just affect the healthcare industries. Sure enough, the immediate decision impacts these particular Covid-19-related technologies. But the precedent that's being set, as you've mentioned a bit earlier, is much broader. So if we are waiving IP for this particular crisis, who knows what other crisis comes down the line? And similar decisions could be made at that point. As just one example, climate change technologies that can be of critical importance to humanity. Maybe already, frankly, there are folks advocating for waivers in some of those industries. So speaking to stakeholders, if you care about the issue, irrespective of the industry you're in, the government officials need to hear from you. The universities that play such an important role in American innovation, your voice needs to be heard as well. So as Secretary Locke says, please all speak up.

Gary Locke (00:45:02):

And I can understand the feelings of the administration and the rationale of the administration when they supported the original proposal to waive intellectual property protections for the development of vaccines. Because this was a worldwide crisis and everybody was, quite frankly, alarmed and freaking out. And we needed to make sure that all countries had access to the vaccine. Although many of us pointed out early on that with all the voluntary agreements and licensing to generic companies to produce generic versions, there was no need for the waiver. But nonetheless, the countries around the world agreed to give the waiver against protections for intellectual property for the development of the vaccine. But we have since seen that nobody used it. There was no need for it. And that we are awash in vaccines around the world, and that some of the leading and some of the companies in the countries that were the most vocal advocating for the waiver of intellectual property rights, South Africa, India, they're canceling orders for vaccines.

Gary Locke (00:46:12):

They're throwing away a hundred million doses of vaccines that were produced on a generic basis with agreements with our pharmaceutical companies because nobody wanted them. They cannot get them into the arms of the people who need them. And so, given that background, why would we want to waive intellectual property protections with respect to treatments or testing equipment for Covid, especially when, again, all these agreements have been made, and the doses and treatments and the medicines that have been made available around the world have not really been used at all? And so, you're right, Andrei. It's about the precedent that this would create with respect to: "Are we now creating a pathway, setting a precedent for more and more waivers against protections of intellectual property, and what will be the impact and the message it sends to American innovators and researchers, colleges, universities who are looking at cures and treatments for many other diseases and illnesses around the world?" And even, as you said, just innovation in general. Innovation in general.

David Kappos (00:47:34):

Yeah. Andrei, one other point that we haven't touched on yet that enters my mind listening to Secretary Locke is while WTO is, and I'll use a pointed word here, wasting its time discussing non-issues, intellectual property, it's not doing what we need it to do, which is to discuss the real issues involving whether it's Covid-19, or the vaccines or treatments or other health-related issues and trade-related issues. We've got all kinds of trade problems in this world on a national and international level. And we need our WTO officials dealing with them on an honest and fact-driven basis and not squandering their time and resources, and energy of many others, including ourselves, on having to discuss what we now know are truly non-issues. So my view, there's a lost opportunity component to this too. Not to mention the fact that what we're really playing with here is human health. So all the time that's spent discussing and toiling over non-issues and negotiating for waivers that clearly aren't needed is time that's not spent dealing with the real inhibitors to the human health crisis.

Andrei Iancu (00:48:55):

And on top of that, it provides, unfortunately, political cover for leaders around the world to simply say, "Hey, we are working on this. We don't need to bother with anything else because we're handling." But the fact is that what they're working on doesn't have much of an impact on

addressing real-world issues that need to be addressed. But on that point, I did want to follow up Dave on the international aspects of this. The United States historically has been a leader on the international stage when it comes to intellectual property and innovation policy.

Andrei Iancu (00:49:35):

Could the two of you speak a little bit to the role the U.S. administration or, and in particular, the secretary of commerce, the under secretary for IP, what role does the administration have, the United States in general, to persuade other countries about the role here of IP and how it should be handled? Because the truth is that there is, in fact, significant international pressure on this issue. Various countries are applying pressure in international bodies, at the WTO and WHO and elsewhere, for something to be done. I think the administration was trying to be responsive to that. But what more can be done, and what are the actual mechanisms for doing it?

Gary Locke (00:50:32):

Well, I really think that the United States should be taking the lead in terms of trying to address future pandemics and how we have systems in place to deliver the medicines and the vaccines. As we've seen from this recent pandemic with Covid, the problem was not the supply of vaccines or even the treatments, it's the infrastructure of getting the medicines, the vaccines into the arms of people. And perhaps in the future, it will not be a vaccine. It might be a pill or something that can be taken. But again, how do we remove the barriers and sometimes these restrictions on exports, ensuring that there are public health capacities within countries, nurses and technicians and others who can go out into the villages and into the cities, into the neighborhoods, to ensure that people take advantage of whatever medicines are available? I think we've seen that the response of the world was slow. Even here in America, we were not equipped to respond quickly to the pandemic.

Gary Locke (00:51:43):

And so, I think that the effort should really be focused on each country developing their internal mechanisms to respond to huge pandemics. But also coordination among countries around the world to ensure that there's assistance available, whether it's UN peacekeeping forces helping deliver the supply of vaccines, ensuring that if refrigeration is necessary, that countries around the world have the capability. And if they don't have the capability, there ought to be sharing of personnel and technical assistance and equipment, the same way that countries respond jointly in terms of natural disasters around the world. That's the type of energy and focus that the United States should help promote.

David Kappos (00:52:33):

That's a great point. Just reflecting on the role of intellectual property in that, the role there, if you're talking about preparing for the next pandemic, the role has got to support and champion a strong, effective intellectual property system for the whole world, for the U.S. and by extension everywhere else, so that the incentives will be in place for scientists to continue to invest. Says Secretary Locke, you've pointed out in the very risky failure-prone business of creating new drugs for the future, delivery platforms, and specific therapeutics and getting them through the regulatory process.

David Kappos (00:53:13):

And the only way that happens is if there is an economic incentive to make those investments. And

the only way there's an economic incentive is if there's a strong and effective intellectual property system. So I find myself coming back to the beginning of the discussion and feeling like, Secretary Locke, to answer your call, for better preparedness for the future, we need all of these things. We need better refrigeration. We need more cooperation. We need UN peacekeepers to be able to go into countries and help. We need international collaboration. We need a strong and effective global intellectual property system. And the U.S. really needs to step up again and start leading in putting that call out.

Andrei Iancu (00:53:57):

Yeah.

Gary Locke (00:53:59):

Absolutely.

Andrei Iancu (00:54:00):

To tie some of these things together that both of you said, these are not short-term issues. These are long-term. People need to have a long-term perspective here because it takes a long time. One of the best things that we can do in the world, to the Secretary's point, is to build capacity for the local governments, for local countries to be able to develop their own technologies, their own manufacturing capabilities for vaccines and medicines and refrigeration, all of that. But this takes a long time. The United States can play a unique role here to help the countries of the world to develop their capacities.

Andrei Iancu (00:54:43):

But this again takes a long time, and it cannot be done by government alone. This requires a public-private partnership both in the United States and across the world. And the only way to get the private industries to participate is to ensure, to Dave's point, that there are strong intellectual property regimes around the world. It is virtually impossible to convince private industry to make heavy investments to help other countries develop their own technologies if they are not secure that the rule of law will be respected in those foreign jurisdictions and that their IP will be protected. If IP protections are in place in those foreign jurisdictions and the U.S. government is working with the U.S. companies to help build capacities overseas, then we can have some hope that, in the long run, various countries will become self-sufficient, in my view.

Andrei Iancu (00:55:42):

We're almost out of time. I do want to ask the Secretary because he's got the unique role. I don't think I know anybody else who's been in the highest levels of government, both in the federal and at the state level. Is there something, Secretary, that the states can do at the state level to help along these issues?

Gary Locke (00:56:01):

Well, obviously, the states want to promote their own industries, and they need to create a climate that enables R&D and innovation to occur within their borders. Now, that means really investing in their education system, K through 12 science and technology, math courses, and having a robust university system because that's where so much of the innovation occurs. We in government from the state and the national level support so much R&D at our colleges, universities, and through government-funded laboratories. But that's still just a very small

piece of the equation. So much of the real innovation occurs among private individuals in small little startup companies in our respective states. And if we want those companies to grow from something in the basement of someone's house or the garage, becoming a Microsoft or a huge development of cures for dreaded diseases, the states have to be very much protective of intellectual property as well.

Gary Locke (00:57:04):

And that's why, getting to your point of both David and Andrei, America needs to help other countries develop an intellectual property system and to enforce intellectual properties. As much as, for instance, China wants to be able to steal our secret sauce and have access to our secret sauce. And we know that there are a lot of concerns about how China's trying to obtain our technology, whether it's biotech to advance manufacturing to semiconductors and the list goes on and on. Nonetheless, China also recognizes that it needs to have a strong intellectual property protection system because if they want their own people to invest huge sums of money and to innovate, they don't want to discourage that to occur, if they know that someone else in another part of China or around the world can suddenly steal that intellectual property, take that intellectual property, because they know that will be a disincentive discouragement to their own people to innovate.

Gary Locke (00:58:12):

So actually, it's ironic that, for instance, the United States Patent and Trademark Office has been advising the Chinese on how to set up a robust IP protection system. And in many ways, they're trying to copy some of our legal courts and our framework of our legal system on how to have faster adjudications of cases involving intellectual property. But at the same time, while they're trying to develop their own internal mechanisms for enforcement of intellectual property, we cannot just turn around and give it away to other countries, including China, especially when they're openly trying to compete against the United States and overtake the United States in many of these facets.

Gary Locke (00:58:54):

And so that's why we need to have policies to protect our intellectual property, especially in areas that's going to create good paying jobs for the American people and where in fact, waiving these intellectual property protections have no basis. There's no reason for it. And what is the precedent and the message that we send to our innovators, to our companies, to our workers if, in fact, we're so freely giving away technology and the secret sauce that many companies, researchers, and laboratories have spent years and years and years developing?

Andrei Iancu (00:59:36):

Well, thank you so much, Ambassador Locke, for a great summation. Thank you, Dave Kappos. Thank you both for a phenomenal conversation today. And thank you to our audience for joining us. I would invite everyone, including journalists, to email us with any additional questions. You can just send us a note at media@c4ip.org. And all three of us are happy to talk to you about these issues at any time. And with that, I'd like to wish everyone a very good rest of the day and thank you again for being with us.