Does Section 1498 Really Allow the Government to Ignore Patent Protections?

April 17, 2023

Frank Cullen (00:00:00):
Hello, and thank you all for joining us today. My name is Frank Cullen. I'm the Executive Director for the Council for Innovation Promotion or C4IP. The Council for Innovation Promotion is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. Today it's my privilege to serve as the moderator on a panel discussing an important issue in the world of intellectual property. As I'm sure many of you know, this has been very topical and very much a focus for folks in the IP community. Recently, some members of Congress have urged the Secretary of Health and Human Services to misuse a little-known statute, which is Section 1498(a) of the U.S. Code, by inducing generic drug companies who are directly contracted with them to infringe on patents issued by the United States Patent and Trademark Office.

Frank Cullen (00:01:09):
Of equal concern, just last month, the Department of Justice told a federal district court judge in a patent infringement case between two private companies that to invoke the statute, a party only needed to establish that the government authorized or consented to infringement. This potentially requires the American taxpayer to foot the bill for multimillion-dollar damages. Now to understand why the positions taken by the legislators and the Department of Justice are legally incorrect, and they're flawed as policy initiatives, and actually threaten our innovative sectors and innovation generally, we have several expert speakers in this field joining us today to discuss these very important and troubling developments. First, I'm delighted to welcome Judge Susan Braden (retired). It's great to have you with us, and thank you so much for taking time from your very busy schedule to share your expertise today. I think many folks already know that Judge Braden has served on the U.S. Court of Federal Claims and was designated Chief Judge in 2017.

Frank Cullen (00:02:28):
She served from 2003 to 2019 and has extensive experience on these issues. She's also been appointed as a public member of the Administrative Conference of the United States and by the Secretary of the Department of Commerce to the USPTO's Private Patent Advisory Committee. She's also a member of the advisory committee of The Bayh-Dole Coalition and an arbitrator, mediator, and special masters for FEDARB and AAA in complex, i.e. in commercial cases. Judge Braden, I'm looking forward to hearing more about some of the things you're working on currently, and thanks again for joining us.

Judge Susan G. Braden (00:03:08):
My pleasure.

Frank Cullen (00:03:10):
It's now my distinct pleasure to welcome Eb Bright. Thank you so much for taking time from your schedule to join us and for partnering with us last week on another C4IP event. As a patent attorney, Eb serves as president and general counsel of ExploraMed, a venture-backed medical device incubator dedicated to developing patient-driven solutions for unmet health needs. He's also the policy director of the Stanford University Byers Center for Biodesign Innovation Policy Fellowship and is a co-founder of and serves on the advisory committee of the Alliance for U.S. Startups and Inventors for Jobs or USIJ. Obviously, Eb has a lot of expertise in these issues as

well. I want to thank him again for doing such a great job serving as moderator for our event at Stanford last week. Eb, it is a real pleasure to have you with us.

Eb Bright (00:04:10):

Yeah, thank you for having me to talk about something very important.

Frank Cullen (00:04:14):

Terrific!! Now I'd like to introduce Professor Adam Mossoff. Adam is someone I've known for a long time and highly respect. He has great expertise in these fields, and his research is some of the most important and compelling data-driven, fact-based material that covers some of these complex IP issues. So, having an expert like Adam on today's panel is also a terrific pleasure. He currently is a professor at the Antonin Scalia Law School and chair of the Forum for Intellectual Property at the Hudson Institute. As I said before, his research in intellectual property and patent law has been extremely valuable. It has been cited by the U.S. Supreme Court, the Court of Appeals for the Federal Circuit, and countless federal agencies. Adam, we'd love to hear more about that from you in a few moments when we ask you to talk about your work. So, thank you and welcome, Adam. Great to have you with us.

Adam Mossoff (00:05:11):

Thanks, Frank. Looking forward to the discussion.

Frank Cullen (00:05:14):

Last but not least, my friend Brian O'Shaughnessy. Brian also has a wealth of experience in these issues. Brian is chair of the IP Transactions and Licensing Group at Dinsmore, a national full-service law firm with one of the nation's most prolific IP groups, and board chair of The Bayh-Dole coalition. He's a past president of the Licensing Executive Society in the United States and Canada and continues to serve LES as a Senior Vice President for public policy. Brian, thanks so much for joining us, and maybe I could start with you for just a moment to just share a few thoughts about your current work and just expand a little bit about your experience in these areas.

Brian O'Shaughnessy (00:06:03):

Thanks, Frank. As past president of the Licensing Executive Society, these sorts of issues involving the use of intellectual property, whether by the government or by private enterprises, is a very important topic. It's become the forefront of people's minds and forefront of policy debates. So, both in my work at Dinsmore, but also of LES and The Bayh-Dole Coalition. These are pressing issues that really affect innovation going forward. I'm delighted to be here, Frank.

Frank Cullen (00:06:38):

Thank you, Brian. Adam, if I could just ask you to share for a moment why it is so important that we have fact-based data-driven research into the materials to share, particularly with policymakers who often don't understand the complexity of these issues?

Adam Mossoff (00:06:55):

Sure thing, Frank. It's incredibly important because the patent system has been the principal driver of the U.S. innovation economy and has been the basis for U.S. global leadership and technological innovation now for well over two centuries. The extent to which Congress or any

policymakers or courts are considering changes to that system, they really implicate not only our future economic growth and our flourishing society that follows from, that but also even as recognized today, our national security concerns given that we exist in a global economy and have global competitors both economic and military.

Frank Cullen (00:07:34):

Yeah, well said. Eb, as someone who's out in the wild doing things in the industry, perhaps you could share a little bit of your thoughts as somebody who sees this intersection in your daily work between the important IP policies and how innovation actually gets brought to market.

Eb Bright (00:07:54):

I work in medical devices, and we're constantly looking at new opportunities to make investments in, to put hard R&D time into. Knowing that that's going to typically take somewhere around 6 to 10 years on average to get a product even to market well before you even begin to make any money on it and knowing that it's going to take tens of millions if not over $100 million to do the preclinical testing and then the clinical testing. Having strong intellectual property rights and certainty around the intellectual property rights is very, very important before you start into that exercise and go down that long and expensive path.

Frank Cullen (00:08:40):

Yeah. Thanks, Eb. Well said. Judge Braden, obviously, the federal judiciary handles these IP cases. It's tremendously important they get it right and that policymakers don't become swayed by perhaps misguided judgments or decisions that influence how some of these policies play out. Judge Braden, could I actually ask you to share a little bit about why you're particularly concerned about these issues? Why is it so important that the judiciary understands these issues and gets some right?

Judge Susan G. Braden (00:09:50):

The most important thing to remember is our Constitution, when the principal issues in the Founding Fathers' concerns were the concerns about private property rights. Why? Because there were not honored by the Crown in England. So, they embedded property rights, the protection of them, including those with patents, in our constitutional system, and that's the job of the courts to enforce those rights.

Frank Cullen (00:10:26):

Yeah, tremendously important and one of the few actual, actually the only right articulated in the Constitution until we had the Bill of Rights, so thank you, judge, tremendously important. Now that we have all of our panelists on camera, I'm going to invite them to remain on camera as we jump into our discussion. I'd also like to encourage everyone attending today, including journalists, to submit questions using the Q&A feature at the bottom of your screens, and we'll do our best to try to answer as many as we can. If your question is not answered during today's webinar, we invite you to please follow up with us via email at media@C4IP.org. Finally, I want to flag the recording of this webinar will be available on the C4IP website, and we appreciate all of you taking time to be with us.

Frank Cullen (00:11:18):

Let's go ahead and jump right into the discussion because you don't want to hear too much from me; you want to hear from our experts. I'd like to kick off our discussion on Section 1498 by asking

our panelists to share their insights on the history and the historical background of this statute. Now, specifically, I think it'd be helpful if we could hear from you to get a deeper understanding of what the original intent behind Section 1498 was and shed some light on its impact on U.S. intellectual property and U.S. intellectual property policy. I think perhaps I could ask Professor Mossoff to give us a little bit of information regarding the text of the law, legislative history, and perhaps some of the case law. Adam.

Adam Mossoff (00:12:02):

Excellent. It's always fantastic to start a conversation about these issues with the facts of what the law actually says and what it means, and where it came from. For those who don't know, Section 1498, it doesn't have a name, so we just refer to it as Section 1498, is a century-old statute that was enacted first by Congress in 1910, amended again in 1918 and 1941 but has remained essentially the same since then. It's primarily a statute that implements and authorizes for patent owners their ability to obtain compensation from when the government uses their patents without authorization. Why would you need a statute on that? As already discussed, patents are in the Constitution, and we also have in the Constitution the Fifth Amendment Takings Clause that says the government shall not use private property for public use without paying just compensation.

Adam Mossoff (00:13:06):

In fact, that was the approach that was taken originally by courts in the 19th century when in various instances involving military, involving the uses of patents on tents and cartridge containers holding bullets, and even the U.S. Postal Service, used without authorization patents, and patent owners sued the federal government for compensation. The courts applied the Fifth Amendment Takings Clause recognizing patents as private property rights, which has been a key feature of the U.S. patent system from the very beginning, and therefore authorized the payment, or mandated, the payment as required by the Constitution for the unauthorized use or infringement of any property right, including patents. Unfortunately, the Supreme Court showed some uncertainty and some confusion about the scope of the protection of this key constitutional protection under the Taking Clause for patents in the late 19th century in a few decisions.

Adam Mossoff (00:14:03):

At the start of the 20th century, it became unsettled as to whether patent owners actually had protection under the Constitution under the Fifth Amendment Takings Clause for when the government and government agents and use patented inventions for governmental purposes and therefore receive the types of protections that all property owners received when the government did that for land or other types of property interests. To resolve this confusion, Congress stepped in and enacted Section 1498, or at least the predecessor version of this statute, in 1910. The statute is very clear and straightforward. It essentially says that when the government uses, without authorization, a patented invention, the patent owner may sue for entire and reasonable compensation. So, kind of following some of the language of the just compensation requirement you have in the Fifth Amendment.

Adam Mossoff (00:14:58):

When the government has used that patent, for and by the United States, again reflecting its classic concerns that were in the cases in the 19th century and in all eminent domain cases, when the government uses property, whether it's a patent or land or any type of asset for a

government purpose and by the government, that effectuates a taking and that's where it triggers the compensation requirement. Congress amended it in 1918 given World War II, I mean World War I, I apologize, and then again right before the start of World War II to provide the same type of protection of payment of compensation when contractors, so private companies providing services and products such as tanks, jets, airplanes, and other types of materials to the government that therefore patent owners must sue the government for compensation because this is for and by classic government activity and purpose, military hardware and military protection as it would if the government had done it directly.

Adam Mossoff (00:16:13):

It's a classic eminent domain provision authorizing the courts to hear what has long been recognized as an eminent domain claim and a claim for takings or compensation for the unauthorized use of property. This is very important to understand because this framing helps us understand exactly why courts have applied it in the way they have, as I think our panel will be discussing in a few moments. I think that effectively provides history, and I'm happy to turn it over now to lawyers and judges who will talk about the more immediate, practical concerns today.

Frank Cullen (00:16:49):

Thanks, Adam, and that's terrific. Before we go to our second question for the rest of the panel, I would like to offer any of you who have any thoughts again on the intent of the original law, particularly being distorted, if you have any quick thoughts you want to share on that. Otherwise, we can move on to talk about some specific aspects of how this has actually been applied and also interpreted in real practice and certainly setting dangerous, perhaps precedents if we don't follow what the intent of Congress was when this was originally enacted. With that, I just invite Judge Braden or any of the other members of the panel, if you have any quick thoughts on that before going to our second question, feel free to jump in. If not, I'll more than happily ask our next question. Judge Braden, you're muted. I'm sorry.

Judge Susan G. Braden (00:17:46):

Professor Mossoff gave an accurate description of the history, and that's really important in the context.

Frank Cullen (00:17:52):

Absolutely. Appreciate that. All right. Let's jump to our second question. Now we do have a little bit of a better understanding of the context surrounding Section 1498. But the interpretation and application of Section 1498 in practice. How have we seen this statute applied in the past, and how did the recent position taken by different legislators who are focused on perhaps getting legislation enacted or even the actions of the Department of Justice align with or contradict established precedent? With that, maybe I'd ask first Judge Braden, who has written extensively on this, to provide perhaps her perspective on this.

Judge Susan G. Braden (00:18:41):

First of all, I served on the court for over 17 years, and I was probably the leading adjudicator of many of these cases that arose under 1498(a), and every one of them concerned what I would call traditional military or government use cases. There was never anything that even closely resembled the suggestions of how the statute should be used by certain members of Congress.

When I retired, I was fortunate to ask to be the jurist-in-residence for the Center for Intellectual Property Protection at George Mason, the Antonin Scalia Law School, which was very important to me for a number of reasons since I knew the justice and his family quite well for many, many years, long before he went on the Supreme Court. I was looking for something to write about, and I happened to stumble across the Yale Law Review, the article that talked about 1498(a).

Judge Susan G. Braden (00:19:40):

From that, I began to realize that law review article cited absolutely no data, history was wrong, the suggestions that they made about the use of the statute were wrong, and worse than that, several legislators, primarily Senator Sanders and Warren, had taken that article out of context and it appears lo and behold in the Washington Post and the New York Times as a suggestion that the government could use 1498(a) to lower the price of pharmaceutical drugs, which is absolutely absurd. First of all, they can't use the statute as a matter of law, and second of all, there's no data to support that even if they did, it would lower drug prices. What it would do is impose a tax on the American public.

Judge Susan G. Braden (00:20:34):

I didn't realize this until I started doing a lot of research, but the price of generics is much higher than pharmaceuticals that are used widely by Americans, many of which are covered by Obamacare and other programs. There are a very few, limited number of pharmaceutical drugs, however, which have a very high price, and the reason for that is there are a very small number of people that really use that drug. By the time the drug companies have a chance to market the product the life of a patent, people don't realize, is 15 years. And that goes from the date that you receive a patent from the patent office, but then you must go through the FDA process, you have to go through manufacturing and marketing. So, there's only a very few years left on the patent.

Judge Susan G. Braden (00:21:22):

We'll hear from someone who does investing, but the investors that put the money behind some of these blockbuster drugs, which took years to develop, result in they only have a very short period of time to obtain returns on that money. Now, there are many issues that arise out of that, one of which is perhaps we need to begin the life of the patent at some other time so that the patent is extended longer and therefore, the prices of drugs could be lower, but that's not the subject of this seminar. But, this statute is not the way to, nor will it from every empirical study that I've looked at, lower pharmaceutical drug prices.

Frank Cullen (00:22:07):

Thank you, judge; really very helpful perspective. Brian, I know that you have some experience here that I think is particularly relevant to today's conversation. Could you discuss the claims court procedures in the BIT management case and following up on the judge's comments?

Brian O'Shaughnessy (00:22:26):

Yeah, sure. Thank you, Frank. I think following up on both what Adam said and what Judge Braden said, this is a very specific statute with a very specific purpose. Over the past several years, a particular case, the proper implementation of Section 1498, was Bitmanagement Software versus the U.S. In that case, it was the application of Section 1498(b) as opposed to (a), which is the copyright corollary of the patent provision of section (a). But nonetheless,

this was a case where bid management entered into a license agreement with the Navy for some 3D visualization software that was being used by the Navy in simulators and whatnot for training purposes. So, it was clearly being used by and for the U.S. government for purposes of national security. In that case, the courts, of course, the lower court, the Court of Federal Claims, determined that there was not a proper license covering the infringement that took place.

Brian O'Shaughnessy (00:23:39):

The Court of Appeals for the Federal Circuit revisited that and said that, in fact, there was an implied license between the two entities and sent it back down, and on further reconsideration, the Court of Federal Claims determined that yes, indeed, there was an implied license. Yes, the Navy had breached the implied license, and so, therefore, the Navy was liable for the infringement that took place. In that case, I think it was a classic example where the U.S. government, in the form of the Navy went beyond the terms of a license agreement, effectively breached the license agreement, and infringed the copyrights of Bitmanagement Software. As a result, they were held liable for damages. So, I think that's precisely what 1498 is there for and what it's supposed to be used for. We can talk a little bit more later on the implications of what the DOJ is proposing, but I think to the points earlier made, this is an example of the very confined, limited purpose of Section 1498. It was properly applied.

Frank Cullen (00:24:54):

Thanks, Brian. You raise a very important issue and one that I'd like to bring Eb into the conversation to discuss. What are the implications of an incorrect interpretation of a very narrow provision in the law? One thing we all know is that industry, the business community wants certainty. They may not always agree with the position taken by a court or with laws that are passed by Congress, but when they know what the rules of the road are, they're able to plan and deal with them in a much more practical fashion. But when you have uncertainty or you have misguided decisions that create confusion in terms of the legal framework in which we all have to operate, it's going to affect our domestic innovation ecosystem and our ability to continue to be competitive in the global marketplace. Eb, perhaps you could share some thoughts on specifically what might be the potential impact from the standpoint of an investor.

Frank Cullen (00:26:04):

None of these cutting-edge, new developments in medicine or other technologies happen without investment in cutting-edge research and development initiatives that happen across a whole range of IP-intensive sectors but are particularly important in the biopharma sector, which has a very low percentage of products actually achieving the ability to come to market and the judge already mentioned how lengthy the process is to bring some of these lifesaving new drugs and treatments and devices to market. Eb, perhaps you can share your perspective both as somebody who's dealing with this as a businessman, but also on trying to attract investment.

Eb Bright (00:26:51):

Okay. I'll also speak to, from a national security standpoint, when I originally started my career as a design engineer working for Lockheed, a defense contractor. When I step back and I think about this statute and the Takings Clause and why this was established, the government has certain fundamental things that it wants to carry out or encourage, and they don't want to be a manufacturer themselves. So, they need to rely on private industry to supply them with the

materials they need in order to carry out their public function of keeping the public safe as well as improving the life and quality of life for patients. So, they created this statute so that there would be an encouragement and a balance in intellectual property rights and in encouraging private industry to provide these products to them.

Eb Bright (00:27:52):

If the government took the position that they're just going to step in and take intellectual property from a private industry who has developed something that's very important to them, they will discourage any future investment in new fundamental technologies. Whether or not you're talking about defense systems which take decades to develop and are extremely cutting edge, high technology, or you're talking about pharmaceuticals or medical devices, all these things are very risky undertakings. If you think about the human body just simply for a second, we are a mechanical system, we're a biologic system, we're a chemical system, and we're an electrical system. When you have that many systems all working together in concert and they start to go a little bit out of balance, to step in and try to do an intervention, whether it be a pharmaceutical intervention, a biologic, an electrical or mechanical intervention, you are working in a very uncertain area, and you're working in an area that requires extreme safety and caution as you move through the development phase so that you don't do more harm than good.

Eb Bright (00:29:19):

So, many, many times, a small company or even a university lab will start down that path and they won't know what is going to be the ultimate outcome. There's a lot of people who are happy to sit on the sidelines and watch them go through that development process, spend all that time and money to develop something. And once they've proven that it works, then the people who've been sitting on the sideline are more than happy to then step in and try to duplicate what has been proven to work after many, many years.

Eb Bright (00:29:54):

Just for example, on average, for a pharmaceutical product, it generally takes about 10 years and close to $2 billion in investment in order to get that product to market and that's just to get it to market. That doesn't then cover all the time and investments that need it in order to get insurance companies in CMS to recognize that it brings enough value for them to pay for it. Medical devices typically, it's anywhere from six to 10 years to bring a medical device to the market, and somewhere in the neighborhood of 60 million to 120 million dollars on average. So, investors need to know that if they're going to go down that long path, that at the end of it they're going to be able to get a return on their investment. So, upsetting the balance by changing laws midway through the way that they've been established will discourage any of that future investment.

Frank Cullen (00:30:57):

Thanks, Eb. Before we go to the next question, I'd just like to ask the panelists if anyone else would have any perspectives they'd like to share on this. Happy to move on, but I think it's such an important point that Eb has made. This does go beyond just the interest of an individual company, an individual inventor, or an individual industry sector. This has, as Eb pointed out, even national security implications, which very often folks don't think about in the context of IP policy. But these

are very, very serious and consequential actions that are being proposed. I saw that Brian was nodding his head. Brian, can I perhaps have you share a few of your thoughts?

Brian O'Shaughnessy (00:31:43):

Yeah, sure. Just quickly, Frank, thank you. I think the thing to revisit just briefly here is the case that brought us to address this topic, which is the Arbutus versus Moderna decision or case, I should say. In that case, the Department of Justice stepped in and filed a statement of interest saying that, in fact, 1498 immunized Moderna from some of the infringement that allegedly took place in manufacturing vaccines under a contract for the government. There, the DOJ was saying, it was done under a government contract. Therefore it was done with the consent and authorization of the U.S. government, and therefore it's immunized from normal infringement and you have to sue the federal government in the Court of Federal Claims. I can tell you, as a practicing patent attorney that that's the sort of thing that gives any client a great deal of cause for concern.

Brian O'Shaughnessy (00:32:43):

If the government can step in and, in fact, just order or put in place a contract for any patented item for any purpose, even though it's ultimately for private use, then it puts the private sector at the mercy of the federal government, and there are no patent police. So, the private sector would then have to sue the federal government. What would be created is effectively a compulsory licensing regime that would be, in effect, an exception that would swallow the purpose of 1498. You'd have to sue the U.S. government for every infringement that they ordered under a contract, which of course, most innovation takes place in small to medium-sized enterprises. They don't have enough money to sue the federal government. They're never going to do it, and they're never going to be able to withstand the costs that would get them to the end of the day.

Brian O'Shaughnessy (00:33:41):

If we were to take the DOJ's position in its statement of interest in the Arbutus case, we would be creating this enormous, compulsory licensing regime that I think would, to Eb's point, dramatically frustrate and diminish innovation within America. We need to keep 1498 in the very narrow confines in which Congress intended it, as Adam very eloquently explained. I think that these are the things that we have to watch out for. These are the things we have to guard against.

Frank Cullen (00:34:17):

Absolutely, Brian. I think I would be remiss if I did not encourage all those who are joining us today for this webinar and discussion to read Judge Braden's writings on this topic. It does clearly lay out the case that this is absolutely inconsistent with what this provision of law was originally intended for and goes well beyond the scope of how it was anticipated to be utilized. So, Judge?

Judge Susan G. Braden (00:34:53):

Frank, I think there is something important for us to add here, which is there are a lot of members of Congress who have signed onto these dear colleague letters urging this. I doubt that they really know anything about the law. They're well-meaning; they want to help their constituents with a problem. I share their concerns, but this is not the way to do it, and frankly, it's a bit embarrassing. I don't think their staff have had the opportunity to learn about the history and the importance of the section, nor have they thought about the consequences of this. Let's say that you do have a pharmaceutical drug company where the government contracts with, say,

a generic to infringe that pharmaceutical big company's patent. They're entitled in my court to entire and reasonable compensation. What is the entire compensation? That would mean the cost of developing the drug from the very beginning all the way through the steps we've talked about, which can take up to 13, 14 years sometimes, and the FDA process itself. That's just to get there, then to the marketing aspect of things before you even get to the reasonable royalty.

Judge Susan G. Braden (00:36:29):

The amount of money that these members of Congress are basically setting up for the taxpayers to pay for is enormous, and they don't know it. They have not had the opportunity to learn about this. To the extent some of the staff may have an opportunity to see this webinar, please take a look at the materials that are attached to this website. Look at the scholarship that has been done here, read the footnotes, which will provide the backup data. Which Professor Mossoff… has cited the importance of. This is no small thing. This is a big deal.

Frank Cullen (00:37:22):

Thanks, judge. I'm going to turn to Adam for one second, see if he has a comment. But I want to follow up on what you said. Too often, we see particularly members of Congress who don't have expertise in these issues getting involved in very complex policy matters with good intention. At the end of the day, C4IP is trying to help do the kind of education for folks, particularly outside of the judiciary committees, and the House and the Senate, where there are more folks who have expertise in these issues. But even within those committees there is a misunderstanding sometimes or misappreciation for what the original intent was or the scope of the statute. With that, Adam, I'll give you the final word on this before we go to the next question.

Adam Mossoff (00:38:06):

Oh, thank you. I just really wanted to quickly point out that, in addition, I think the excellent points being made at the policy level of the dangers of what would happen to the biopharmaceutical industry and the innovation industries more generally. I just want to return back to the classic academic point that the argument that Moderna made and that the Department of Justice has made and that academics have made that Section 1498 can be used to control prices, regulate prices, or set prices of products and services being sold in the marketplace, does violence to the statutory text and to the function and purpose of the statute. Congress knows how to enact price control statutes if it wants to do so. It has done so many times, like the Price Control Act of 1942. It's in the very title; it knows how to do that.

Adam Mossoff (00:38:59):

It knows how to enact regulatory regimes to regulate prices if it wants to do so as well. That is not what Section 1498 does, and this is why its text is very explicitly clear that it only is applicable in the narrow sphere of an eminent domain type action. All of the cases involve eminent domain style uses of patent inventions by and for the government and or its agencies and officials. Some academics have misrepresented the history and have tried to claim that it's been used for price control purposes in the past and I've looked at the history, and so those Judge Braden and others, and those are actually false claims. They involve the Veterans Administration, which is a government agency, and other instances where it's been government officials, government agencies, and government in the government itself which is using the inventions for the government purposes and by the government.

Frank Cullen (00:39:56):
Yeah, great points, Adam. I think we've talked very specifically about some of the impacts, but let's broaden the conversation for a minute. What we all know, who have been working in this field for a while, is that there are folks who either legitimately don't understand the important role that IP plays or actually willfully try to characterize it incorrectly or, in fact, try to weaken intellectual property policies and do that for their own purposes or for perhaps economic benefit in different countries. There's a whole slew of reasons why different folks, not just here in the United States but also globally, are working actively to undermine IP rights. That's a serious concern for our innovation ecosystem and certainly America's competitiveness and our innovation economy.

Frank Cullen (00:40:49):
So, I'm very interested in hearing from all of you who have so much expertise in these matters. What would the potential global implications be if we, again, much as we did when we changed decades of bipartisan U.S. policy to support a TRIPS waiver through the WTO, what would it be like if these flawed domestic pursuits were creating precedence that could cause disruptions on the international stage? How might that impact the broader landscape of innovation and intellectual property protection around the world? That's a question to all the panelists, but I'm particularly interested in hearing from Eb as an investor because, truly, we work in a global marketplace now. We have to be able to compete with not only companies here domestically, but from around the world. Eb, maybe I'll start with you.

Eb Bright (00:41:50):
Yeah. One of the first things that I think about is that investment is very fluid, and it can flow to many different geographies. It doesn't have to be, there's nothing that mandates that it has to be here in the United States. So, if you end up with a very uncertain intellectual property regime, you're not going to make huge investments in that particular geography. Instead, you are going to focus your attention on certainty and markets in terms of intellectual property stability and then also market size. So, a lot of the innovations or investment would shift from the United States to Europe, for example, where you would have a greater certainty with respect, stability of intellectual property rights. They're actually improving intellectual property enforcement by establishing the Unified Patent Court, which allows you to have a more larger area of enforcement for your patent, for the relative same cost, and develop certainty with respect to your investment.

Eb Bright (00:43:10):
We've seen countries like China who are making a similar move with respect to their intellectual property systems. They understand that as they move up through the economy from being originally just an agrarian-based economy to then being just a manufacturing-based economy to now being an innovator economy. In order to continue to move through that progression, you have to have strong and stable intellectual property rights. It's quite confounding to me that the United States who helped establish that and prove that it was the case from the foundation of our Constitution all the way through the last 250 years that other people recognize that and other governments recognize that, but United States itself somehow and another seems to be blind to that development.

Frank Cullen (00:44:07):

Thanks, Eb. A really important perspective. Brian, you've had a lot of experiencing experience with LES in terms of the licensing and the legal framework that allows for us to see support within the innovation economy, the opportunity for folks to work together through a legal framework. And at the end of the day, when we start disrespecting how things should be applied correctly, or we start putting out misguided policies that are going to undermine confidence, to Eb's point, in the ability to bring new products to market or get a return on investment, it's very troubling. And I agree 100% with Eb's point that it's perplexing, concerning, and at the end of the day, it has serious consequences. So, I'd love to hear your perspective a little bit as someone who's dealt with this environment so much during your career, so welcome your thoughts.

Brian O'Shaughnessy (00:45:09):

Thanks, Frank. Yeah, I think the flawed premise of the TRIPS waiver and the anti-IP rhetoric, in general, is that if we just take away property rights, then everything will become readily available, and innovation will continue to fall from the skies like manna from heaven, and the technology will bubble up into the marketplace spontaneously. But, as other commentators have said, particularly in the pharma space, a great deal of risk, great deal of investment, great deal of time required to bring those things to market and the most effective way to bring those things to market is to allow the market to focus on specialization where different enterprises do different things and therefore they trade their resources very effectively and reliably.

Brian O'Shaughnessy (00:46:00):

The way to do that and to create an effective supply chain for innovation, the best way to do that is to have firm, reliable, and dependable assets that enterprises can exchange with the expectation that they know they're going to be able to rely on the others and they're going to be able to rely on their own investment and their own expertise and get an effective return on investment. Because as Eb rightly points out, investment is very mobile. And ideally, we want most of it to be here, funding American innovation. Whether we're talking about licensing in general or the preservation of rights under the Bayh-Dole Act, we've run the experiment with regard to the Bayh-Dole Act. Prior to the Bayh-Dole Act, when the universities could not take title to their inventions simply because there was a modest amount of federal funding, there were absolutely no drugs, zero drugs that came out of university labs.

Brian O'Shaughnessy (00:47:09):

Since the Bayh-Dole Act has been implemented, there have been over 300 FDA-approved drugs. Clearly, the ability to rely on intellectual property protections to incentivize investment and to take risk has paid benefits. I like to say it over and over again. We've run this experiment; let's not reinvent the wheel. We know what good IP laws can do for the benefit of society as a whole. So, let's stick to that plan and continue to preserve strong, reliable, dependable intellectual property rights.

Frank Cullen (00:47:51):

Yeah, well said. Adam, I know you must get so frustrated with some of the bumper sticker slogans that the anti-IP crowd sometimes runs out that are not based so much in any kind of fact, but in an emotional appeal or a catchy slogan type politicking or policymaking. From your perspective,

I know you have some thoughts on this, but it has to be pretty galling for somebody who does such excellent research and spends a lot of time making sure we have fact-based arguments to see some of this stuff is really based on either incorrect information, misinterpretation or just flat out wrong argument. With that, I didn't mean to derail from your point on this specific topic, but it's interesting to me that so much of what goes on in the IP space is not necessarily rooted in the correct factual data.

Adam Mossoff (00:48:48):

Correct. Brian, Eb, and Judge Braden have eloquently explained all of the incredible benefits that have flown from our evidence-based policymaking in having a patent system that has secured reliable and effective property rights to innovators, that they can go into the marketplace and distribute new technological innovations, new drugs. Not just to people in the United States, but ultimately throughout the entire world. More people have smartphones now than have access to potable water, and that was something that has been entirely facilitated by one of the most patent-intensive sectors of the innovation economy, the mobile sector, in history. You're exactly right. The arguments here are so dominated by rhetoric. I saw, and people sent photos to me of the posters that went up around Washington D.C. and cities around the world over the original debate over the vaccine waiver on patents that said patents kill with a picture of a cadaver.

Adam Mossoff (00:49:59):

That is such false rhetoric. Patents have actually facilitated and made possible what was an historically unprecedented response by the biopharmaceutical sector to a pandemic, and we did not repeat the pandemic of 1918, where tens of millions of people died around the world. An estimated 50 million people died at a time when world population was 15% what it is today. To give a sense of the comparative numbers, that would be effectively about 300 million people today dying in two years from COVID-19. That did not happen because of the biopharmaceutical sector and their ability to develop the mRNA platform, Remdesivir and the tests, and all the other incredible innovations that they have been building and creating and developing through licensing and other infrastructure that they've developed over the past couple decades on the basis of reliable and effective patent rights.

Adam Mossoff (00:51:01):

It's very frustrating to hear rhetoric dominate the discussions the patents kill, patents prevent access, or patents prevent people from obtaining new technologies or new medicines when the exact opposite is true. It's very important that we have evidence-based policymaking and not, as so well stated by a former eco chief economist of the USPTO, policy-based evidence-making, which is what happens too often in the patent policy discussions.

Frank Cullen (00:51:32):

Absolutely. To your point, IP was not the problem. IP was the solution. I know that Eb had a quick point he wanted to make before I turn to Judge Braden to share her thoughts, but I'm not sure if Eb was able to stay with us. So, Eb, if you're no longer on the line, I apologize for not getting to you quickly and also for not being able to thank you if you had to jump. But let me go ahead and turn it to Judge Braden to have the final word on this.

Judge Susan G. Braden (00:52:04):

I think this is just endemic of a larger discussion we're having in the country about property rights. Let's just come back and talk about that just for a second. I'm actually related to somebody who signed the Magna Carta. Those people were landowners, and at some point, they said, "Hello, King John, I know that God appointed you, but you want to come and take my crops and my horses and my cattle and the farmers that work in our community to provide food for our community, you want all of us to go over to France to fight with somebody else? I'm not getting anything out of this." From that came to Magna Carta. The Magna Carta was the foundation for property rights and the concern that the founders had in the Constitution.

Judge Susan G. Braden (00:53:04):

This is a much bigger discussion, and we need to remember it in that context. The reason we have the world-class medicines and pharmaceuticals and support systems that people come to the United States for from around the world is because of our patent system and our understanding and appreciation of the role of private property rights. Why, oh why, do we think that's not a bad idea to continue? There's no place in the world that offers what we have. We should work hard to keep it, improve it and be cheerleaders for the innovations that are going to save our children, our grandchildren, and our great-great-grandchildren. Our lives are on this world for a very short time, but I have two grandsons, and I know they're going to benefit from all of this, and I'm working hard for that purpose.

Frank Cullen (00:54:17):

Thank you, judge. Appreciate that.

Judge Susan G. Braden (00:54:19):

We all need to.

Frank Cullen (00:54:20):

We do. Eb, perhaps a closing word from you?

Eb Bright (00:54:25):

I just wanted to also point out that in addition to what Brian was saying in terms of the Bayh-Dole Act, unleashing all of these new pharmaceuticals by securing intellectual property rights, we've also seen the empirical data on the other side of the equation, which is over the last 15 years, the percentage of investment going into IP-intensive industries like pharmaceuticals, medical devices, computer networking and everything as a percentage of investment is actually declining, and it started declining at the same amount of time that the courts and the legislature started changing the intellectual property rights to make them either weaker or more uncertain. We know by facts what this impact is. This isn't just theoretical; there's actual evidence.

Frank Cullen (00:55:16):

Yeah, that's a great point, Eb, and I think the other thing we have to remember, we're talking about a very specific proposal when it comes to 1498 in the context of the biopharma sector today. We've seen certainly the slippery slope issues around how decisions can impact other industries. It's important to remember that something like the Bayh-Dole Act spurred innovation across broad industry sectors. We know that even the founders of Google credited the Bayh-Dole

Act with helping bring them to market. So, we're not talking just about life-saving drugs or life-saving treatments. This is something that could impact all of our innovative industries. I'm going to now… ask one last question of our panel very quickly because we only have a couple of minutes to wrap up, and I do want to get a real quick sense of what we can do to respond to this threat.

Frank Cullen (00:56:07):

But, Lisa Kilday had a question in the chat and asked about specific examples of how 1498 had been used when it should not have been actually used. I think the judge has already talked a little bit about this, and I would also recommend to Lisa that she read the very good scholarship that the judge has done to provide some specific examples of the history here along with Adam's, Professor Mossoff's work. Real quickly, does anyone just want to provide quick commentary to Lisa, and then we'll switch the remaining minute or so to just talk about what we can do?

Judge Susan G. Braden (00:56:44):

I think there's a lot of material on the website that'll be very helpful to her.

Frank Cullen (00:56:48):

Absolutely, judge, I concur. Lisa, I encourage you to take a look at the resources that have been provided as a companion piece to this webinar. There are a number of links to some very excellent materials to help answer your question, and a lot more detail than we have time to go into at the moment. With that, what can we do? C4IP stands ready to be a partner. We're certainly going to be educating policymakers, speaking to staff, trying to encourage folks to look at fact evidence-based arguments as opposed to Adam's point about emotional sloganeering. Perhaps I can start with Adam. What are your thoughts? What can we do?

Adam Mossoff (00:57:31):

Excuse me. Yes, and the problem of emotional sloganeering and rhetoric is an old one, even from the patent troll debate today. In the 19th century, they were called patent sharks. And you had similar types of attacks on innovators. As Judge Braden mentioned earlier, this is a long-standing debate, and it's one that goes beyond the patent system. It's a debate also about property rights and the market and whether what are the avenues for securing economic growth and flourishing societies and flourishing lives of individuals. So, I really think that the thing that is best advanced by us are the facts. We have the facts on our side, the economic evidence, the history, the data, and to the extent that we can ensure that that information is in front of policymakers, in front of legislators, then we will prevail over the long run. I'm optimistic and hopeful, although some might think that that is an example of irrational exuberance.

Frank Cullen (00:58:34):

Brian?

Brian O'Shaughnessy (00:58:35):

I would say that it's been wisely said by more wise observers than me that a problem with IP is that we are a war and peace industry in a bumper sticker world. In Washington, the joke is if you're explaining, you're losing. So, the challenge is education. We have to educate policymakers. But I would also offer one other observation. I would say that, certainly, since the birth of the Court of Appeals for the Federal Circuit and in modern history, the beauty of the

IP system is that people generally respected the IP rights of others. And there wasn't a lot of haggling. There wasn't a lot of gamesmanship going on. It greased the wheels of industry. When you knew that you could license your IP, you could rely on the IP that the PTO had granted, and it was dependable. That, for some reason, seems to have disappeared, and I think our economy has suffered as a result.

Frank Cullen (00:59:42):

Thanks, Brian. I know we're over time, but very quickly, Eb, perhaps thoughts from you. You work an awful lot with folks in these fields, and every day they're confronted with having to sometimes just explain what they actually do for a living. But, your thoughts on how we can respond to this current threat?

Eb Bright (01:00:00):

That's really it. It's to talk to people that are in the trenches, that are actually doing the R&D work, that are the investors that are backing those people, and understand what each of them has to contribute and why they're doing what they do. Also, to understand that it takes many different parties with specialization in different areas in order to bring forth fundamental technology, particularly in the life science space. The university lab can't manufacture and produce products, but companies can bring forth R&D. Large companies are really good at distributing them, and investors are good at backing up each of those different people depending on what their investment risk tolerance is at any particular stage. It takes a very important coordinated ecosystem, and it's fundamental that you learn each one of those members' viewpoints and where they operate in the system.

Frank Cullen (01:01:02):

Thanks, we're going to have to wrap up, but if you have any last brief comments, I'd welcome the opportunity to hear your thoughts.

Judge Susan G. Braden (01:01:10):

Make a difference. Talk about these issues.

Frank Cullen (01:01:14):

Absolutely. Well said. Thanks to this great panel. It's been really an amazing discussion about the serious dangers of the Department of Justice's interpretation of Section 1498 and misguided legislative proposals coming out of Congress that are really threatening our innovation ecosystem and economy and American competitiveness. Thank you to our panelists. Thank you also to our audience members. Please email us with any additional questions at media@c4ip.org. And we look forward to having further discussion on this very, very important issue. As a reminder, a recording of this webinar will be made available on the C4IP website in the coming days and, with that, once again, thank you to the panelists. Great discussion. I hope everyone has a great day. Thanks for being here and to the judge's comments, make a difference.