American Innovation in Peril: Misuse of the Bayh-Dole Act and Section 1498 Could Be a Knockout Punch

April 4, 2024
Joe Allen (00:00:03):
Hi, I'm Joe Allen. I'm the Executive Director of the Bayh-Dole Coalition. And on behalf of the Bayh-Dole Coalition and the Licensing Executives Society, we want to welcome you to our webinar today. We're going to leave everybody about a one minute ... We saw people coming in and we have actually a good turnout today. So we're going to start at about one minute, and I think we're going to have an interesting discussion today, and we appreciate you being with us. By the way, if you want to ask questions, you can do that on the Q&A feature at the bottom of the Zoom, and we'll answer every question we possibly can. So if you have things that come up either during the discussion or that you want to ask now, just put them in there and we'll pose those to the panel, and I think we'll have good answers to probably anything that people want to ask.

Okay. So let's go ahead and get started. We just have an hour. We want to make sure that we maximize everyone's time, but again, we really appreciate everyone joining us today. As I said before, I'm Joe Allen, the executive director of the Bayh-Dole Coalition. And this is the joint webinar from the Coalition and also the Licensing Executive Society. For more than 20 years, opponents of the Bayh-Dole Act, which forms the foundation of the public and private sector R&D partnerships which have made the U.S. the leader in innovation, have argued that if the march-in rights provision of the law was misapplied so the government could force universities to license copiers, drug prices would be lowered. I staffed the Bayh-Dole Act for Senator Birch Bayh. I actually wrote this report to the Senate Judiciary Committee. And march-in rights were intended to be used to force universities to license other companies only in a couple specific instances.

One was which if good faith efforts were not being made to commercialize a technology, or if the university was trying to license it on unreasonable terms, or if the needs of a health or other public need was not being met, or if the licensee failed to make the product in the United States as they'd agreed to do. None of those apply to somebody saying they don't like the price of a commercialized product. And every administration, including the Biden administration, has uniformly rejected attempts to misuse march-in rights because someone doesn't like the price of a successfully commercialized product. Until suddenly in December last year, we had a draft guideline coming out from all the agencies opening the door to march in if a product isn't, “Reasonably priced,” and that's a completely undefined term. But faced with evidence that the misuse of march-in rights alone wouldn't lower drug costs because most patents that would need to be copied or funded by the private sector, the critics have added another demand, that the pending interagency framework not only include march-in rights, but also Section 1498, so copiers can also access privately funded inventions as well.

In their letter supporting the march-in framework, Senator Elizabeth Warren and a number of congressional progressives, "strongly urged the administration" to include a directive to agencies to review all federally funded inventions under their purview within six months and determine whether to use march-in rights either solely or in conjunction with Section 1498. So we're going to discuss what the implications of this really radical idea would be on U.S. innovation, and we really have an excellent panel with us this morning to go through these issues. Brian O'Shaughnessy chairs the IP Transaction Licensing Group of Dinsmore, an internationally recognized law firm and is also the past president of LES, and perhaps most importantly is my boss as he chairs the Bayh-Dole Coalition's Board of Directors. So we're going to be particularly deferential to Brian today. Adam Mossoff is a Professor of Law at Antonin Scalia Law School and chairs the Forum for Intellectual Property at the Hudson Institute. Professor Mossoff's writings have been cited by our federal courts, including the U.S. Supreme Court.

Jennifer Young is the CEO of the Technology Councils of North America TECNA, which represents more than 60 technology councils across the U.S. and Canada, and that includes more than 22,000 technology-related businesses. And Bob Schmidt founded and chairs companies including Cleveland Medical Devices, Orbital Research, and Great Lakes Neural Technologies. He also holds 56 US patents, led two companies into the Inc. 500 and is the only person to win the Inner City 100 award from Michael Porter at Harvard Business School and Inc. Magazine for the fastest growing companies seven times in the first seven years of the award.

So we really appreciate this panel being with us. These are people with hands-on expertise in the issues we're going to talk about. And as I said before, if you have any questions, please submit them to the Q&A feature on the Zoom.
link at the bottom. So to get things started, Professor Mossoff, maybe you could just explain to people, there's been a lot of talk about march-in rights, but I don't think many folks understand, what is Section 1498 and what is it supposed to do?

Adam Mossoff (00:05:10):
Thanks Joe, and thank you for having me on this panel. It’s a real honor to be on this panel. I know everyone here through lots of interactions, and it’s always good to be here for comedic relief as the academic, before we get to the real meat of the discussion. But I’m very happy to talk about my research and work on Section 1498 in addition to the Bayh-Dole, it’s not as well known statute by dint of the fact that it doesn’t even have a name. It’s just known by its section number. So it’s known well to lawyers, but not necessarily to the public. Section 1498 essentially achieves for patent owners as owners or property rights, the same rights that they have when they own their homes and they own buildings and their cars and other types of assets. And that is if the government comes and takes your home because it wants to build a military base or it wants to build a courthouse or build a road, it has to pay you.

And the reason why it has to pay you for taking your home for those public uses is because there’s a provision in the Constitution called the Takings Clause that prohibits the government from taking property for public use without paying just compensation. Now, patents are property rights. In fact, this was one of the unique American contributions to the history and development of patent law up into the modern day. And it was recognized very early on that this type of constitutional protection applied to patents. If the government used your invention without your permission, it was taking your property and it had to pay you. They had to pay you just compensation. And there are cases in the 19th century address the use of, for instance, patented tents by the Union Army during the Civil War and the U.S. Post Office using a patented stamping machine without authorization.

Well, at the beginning of the 20th century, there was some confusion in Congress about whether you could really sue as a patent owner. So they passed a statute that essentially says if an invention is used and the language in the statute is, “by and for the United States,” then the government must pay reasonable and just compensation to the patent owner for that unauthorized use of their patent. So what you can see is that the statute is what we call an eminent domain statute. When the government uses its power without your authorization to take your property, just like if it takes your home from you, if it uses your patent without your permission, it has to pay. And so this is what Section 1498 has achieved. It’s recognized as an eminent domain statute by courts, and it was enacted in 1910. It was amended in the First World War and again in the Second World War because government contractors or private companies working for and by the government to produce tanks and airplanes were sometimes sued for patent infringement.

And they said, “Well, we’re working for the government. We’re doing this for the government.” And so the government stepped in and said, “Yes, we’ll indemnify you. We’ll protect you. We will be the person responsible for paying for the patent infringement by you as a contractor.” But you can see it’s still for and by the government. And so that’s essentially what Section 1498 covers. When the government takes your invention for the use by the U.S. military, the U.S. Post Office, there’s an example in the 20th century involved the Veterans Bureau and the U.S. Veterans Affairs and other examples, then the government has to pay you for the same reason that it would have to pay if it took your house or your car from you. So it’s not meant to be a price control statute in the private market. It’s not designed in either its text or its purpose to control prices of products and services created by private companies and sold to private consumers, whether they’re patients or any other type of consumer in the marketplace.

Joe Allen (00:08:48):
That’s really helpful. Again, thank you very much, because these are kind of obscure issues, but now really front and center. And as we just heard from the letter by Senator Warren, while this is being done under the name of drug price control, this applies to any federally funded invention. This framework applies to any federal funded invention. So as we said before, this is being done under the guise of controlling drug prices, but it not only applies to research being done at universities and federal laboratories, it applies to inventions made by contractors, including small companies. So this is a really sweeping idea, and it also includes things like the CHIPS Act that we
just passed. So it really fundamentally changes 43 years of the Bayh-Dole Act, and I don’t know how many years of
1498 to really make people question, is the government really a reliable research partner?

So if somebody can file a march-in petition, and under the Bayh-Dole Act, anyone can file a march-in petition. It’s
not just done by the people who’ve made a cottage industry out of filings at NIH because they don’t like a drug
price. They can be filed by a competitor, by somebody who wants to shake down a small company, by foreign
entities who don’t wish us well, just to start this whole process. So Brian, if you don’t mind, I’d like you to kick
things off and we’ll have the whole panel jump in.

What are the implications for this? Is this a big deal, a small deal? What does this really mean if suddenly now,
if you have federal funding, you make a product, somebody doesn’t like the price, it’s undefined, it applies to
anything, potato chips or computer chips or anything else that comes out of it, a new lima bean model, whatever,
and somebody says, “I don’t think the price is reasonable.” And then you can go to the agency that funded it,
the Department of Agriculture and say, “I not only want you to march in, I also want you to take their privately
developed inventions under 1498 so we can copy them.” So what are the implications of that?

Brian O’Shaughnessy (00:11:00):
Well, Joe, to answer your question, you said, is this a big deal or a small deal? This is a huge deal. This framework
has the potential to completely undermine and undo the brilliance of the Bayh-Dole Act. And I think it’s very
important that we remember the Bayh-Dole Act, for example, was characterized by the Economist magazine as the
most inspired piece of legislation in the last 50 years of American legislation. It is truly a brilliant piece of legislation
because it decentralizes away from the federal government, the technology transfer of technologies that are borne
of basic research funded by the federal government, and it decentralizes it and puts it in the hands of people who
have skin in the game, the people who actually develop the technology. Now, in the case of university-developed
research, it is especially brilliant because it gives the universities the opportunity to effectively take ownership of
that IP and then license it out and earn the revenues that come from those licenses.

Those revenues are in some cases, very substantial. It can be millions if not hundreds of millions of dollars, all
of which goes back into America’s higher education system. As a result, we fund laboratories, we fund faculty
members, we fund graduate students, all of whom are able to do work because of the revenue that the university
receives under the Bayh-Dole Act from its licensees. The other thing I want to emphasize is that this applies to
government-funded research. Invariably, the government does not fund all of the research, it might fund only a
small portion. But nonetheless, the government, by and large is engaged in funding basic research. The real, I would
say, underpinnings of what might ultimately turn into a commercial product. Nobody knows whether or not it’s
going to turn into a commercial product until somebody comes along in the private sector, takes a license, puts the
time and money into development of that basic research to hopefully come up with a product that the consumer
actually likes and is willing to pay for.

Nobody knows whether or not that’s going to happen at the stage of basic research. So the licensee is invariably
taking a huge risk, is investing great sums of money and a great deal of time to find out whether or not that basic
research can actually yield fruit in the form of a consumer received or acceptable product. So oftentimes, we hear
critics talk about, “Well, Bayh-Dole gives things away to private industry, and notably, the pharmaceutical industry
of products.” They are not products when they are licensed. The products are many years down the pike. It’s basic
research. And turning basic research, as I said, into products is a very risky endeavor. So the main concern that we
have with this issue is by saying that the government can march-in because they arbitrarily don’t like the price puts
a cloud on the title of that IP. So the licensee now faces the prospect that after doing the years of research and taking
the risk, that the government’s going to step up and say, “Well, we don’t like the price that you’re charging, so we are
going to march-in on your IP rights.”

That means that all the time and money that private sector entity has invested could potentially disappear. So
what this means is if march-in is actually ever invoked as the framework suggests, then licensees will shun the
basic research that comes out of our universities and will not take a license to it, which means that taxpayer-funded
research and potentially very, very valuable research that might improve all of our lives sits on the shelf because the private sector won’t take the risk. So we want to avoid that, and the best way to do that is to ensure licensees that they have good title in the IP that they’ve licensed, and the use of march-in would put a huge cloud on that title. And licensees will unfortunately fall back on a phrase that existed prior to Bayh-Dole, which back on a phrase that existed prior to Bayh-Dole is, which is that research is tainted by federal funding. Therefore, we are not going to take the risk. So I'll stop there and let other panelists chime in, but I hope I've answered your question, Joe,

Joe Allen (00:16:17):
That’s excellent background. So Jennifer and Bob, do you disagree with that? What’s your thoughts? I mean, you’ve had people that are actually practitioners that actually are commercializing things. So is this a big deal, little deal, or what do you think about it?

Jennifer Young (00:16:33):
Yeah, well, I'll hop in. So as you mentioned, we represent 65 different members, member regional technology associations that through them serve 22,000 small to medium-sized innovators in North America. So we hear on the ground examples from these companies all the time about what it takes to commercialize a product, a life-saving product. And to use a metaphor, which we often do when we’re explaining this to other people, to put this in other terms, imagine you’re buying your first home. For those of you who are not innovators or company owners, if you’re buying your first home, you save up for a long time, you’re excited about it, you may not have enough money to purchase it, so you rely on potentially wedding gifts or family loans or anything like that to help make that down payment. So you’ve utilized some additional help to purchase that home, and the home is your dream and you’re so excited about it, but it needs some renovation.

And so you might be putting in a new paint job or redoing the hardwood floors. But then there’s also some necessary renovations that take place, perhaps a new HVAC system, some electrical work, and oftentimes things that also come up that are financially hard decisions to make, like plumbing that are emergencies. And so an entrepreneur lives a parallel life to a homeowner, but in a larger scale. So the emergencies come up. You have to make decisions when you are choosing to make emergency upgrades in your home on things like plumbing or HVAC systems, determining how you’re going to get that done. Sometimes you also have to solicit some additional assistance in doing so. You might ask a family friend, a neighbor to come and help you with the project, help to carry the new toilet into the house or help dig out a pipe in the yard.

And so someone’s helping you to do that. So all of that being said, those decisions are made are yours. And oftentimes you’re doing so under your financial restraints of your home, you know your home budget best, you know how to manage it best, and it is yours. You have invested your blood, sweat and tears. You’ve missed family outings working on some of these things because you have to maintain your house. You’ve missed children’s games and birthday parties. Well, that’s a parallel life to an innovator. An innovator invests blood, sweat, and tears in their product because they believe in the product. They believe it is something that may be life-changing and sometimes it isn’t commercially viable right away because people don’t totally understand what it’s going to do. And they need to solicit outside assistance like the federal government through a program to help get the product going.

Well, just like your home, you’ve spent all of this time and all of a sudden with your home, your neighbor decides, “You know what? I helped you with that project. I think you need a new roof. I’m going to petition the government to make sure you get a new roof put on that house. And by the way, you have to pay for it.” Okay, I don’t have the money to do that. Why would I ever buy a home if someone else can start to tell me where I need to do things or how I need to make upgrades? Well, the parallel life is happening with an entrepreneur and any small business owner that is working towards producing something that potentially could be life-changing, life-saving and had to help get it commercialized from the federal government. If the government could come in and say that price isn’t what we think it needs to be.

They have no idea what kind of commitment has gone into this, what you’ve had to pay your researchers, what you’ve had to invest, what you’ve had to miss. These innovators are pouring their blood, sweat and tears into these.
And if they can have to surrender their license or their product to the federal government, what’s in it for them? So we see downward to this huge impacts on the future of innovation in the United States. If this is to go into effect, why would any innovator ever want to start a company or start to work towards a life-changing product, vaccine, any medical device for that matter? Why would they ever want to do that? And so we’re constantly advocating for the small innovator because this is really important. They invest everything and they are disproportionately the contributors to the economy, far more than the large corporations that I think this is probably misdirected at.

Joe Allen (00:21:04):
Bob, you’re one of those strange people who actually has commercialized the technology. So how does this whole thing strike you? Or would you be willing to license a university or federal lab technology or an SBIR technology knowing that if somebody doesn’t like your price, they can ask the government to not only copy that one, but everything else you’ve done, your 56 patents that you have on your own?

Bob Schmidt (00:21:26):
Well, it’s clear this bill is not a small deal. It’s not a large deal. It’s a life and death deal. This bill or the NIST program is going to put every single little company out of business if they have anything successful, a Chinese company or a large company is going to come along and say, “I can make this for two cents cheaper in China.” Or, “We’ve got large manufacturing facilities. We can make this cheaper than the little company.” So we’re going to see this every time something is good, the little company is going to lose it. But let me spend a few minutes kind of describing how I got here and what our organization, the Small Business Technology Council does, because I’m a co-chair of the SBTC, Small Business Technology Council. That’s used by small companies for the SBIR program. So we are the advocates for SBIR, and we’re a council of the National Business Association.

It’s America’s oldest small business organization, with over 65,000 members. So that’s what we do is we advocate for SBIR and on behalf of America’s small inventing companies. So I’m also an inventor, an entrepreneur. So I use the term “inventorpreneur” in my own right. The SBIR program has created over 10,000 inventorpreneurs over the years, and about 6,000 of them are currently active. They have created over 150,000 patents. More than all the universities combined in most years. So patents are these small businesses. I personally have created about 60 patents on my companies and control over 300 patent assets. I provide a somewhat unique perspective as a professional engineer, attorney MBA, patent attorney, so I understand all the aspects of inventing products, founding the company, acquiring funding, developing commercial products and services, manufacturing goods, performing the marketing and growing the company. One of my companies, Cleveland Medical Devices, has taken an $1 million SBIR and developed a new diagnostic for sleep apnea for home testing that has saved U.S. payers over a half billion dollars.

SBTC strongly opposes the concept of including pricing as a rationale for allowing march-in rights to take over patents belonging to small businesses under the current law. We support many of the other organizations such as the Bayh-Dole Coalition, various bio-organizations and small business organizations such as US Inventor, who also oppose this rule change. One of the sayings about inventorpreneurs is they are poor until they are either rich, broke or dead. Being an inventorpreneur is extremely taxing in one’s personal family and financial life, expounding upon what Jennifer just said. It requires to focus to work a hundred-hour weeks and dedicate their entire financial resources, not for their personal enjoyment or for their family, but for their business, to keep it alive and hopefully grow. I’ve lost two good inventorpreneur friends who died prematurely because of the stress it brings. This is not easy.

Unfortunately, NIST’s proposal to include pricing as a factor to initiate march-in rights will not only remove all financial incentives to do research for the federal government in programs such as SBIR, it will ensure that the only outcome for SBIR participants is to end up broke or dead. There will be no more light at the end of the tunnel, no possibility of becoming rich. If an SBIR company shows signs of success, competitors particularly the Chinese, will be able to show that the small U.S. company’s price is not reasonable as it can be made and sold cheaper by a large or foreign company. So this is for all products, not just drug prices. This will have an effect of killing off SBIR companies and inventions. As one, no rational person will start to get into the government-sponsored invention
business. Two, those that are in the business will be strangled by bigger companies requesting march-in. And three, there will be no wealth creation by the inventors allowing them to start spin off or follow on companies.

The result of this “reasonable pricing policy” will not be lower drug prices as shown by the comments provided to NIST, but the decline of the American economy killing the golden goose. I hope that NIST will learn from the lessons of the NIH from their disastrous experiment of 1989 to 1995 discussed in the Bayh-Dole Coalition’s comments. You will not only drive industry away from collaborators, but you will perform infanticide on new potential small businesses. So this is a killer for us. I take this very personally. I’m the only one in this panel where they’re going after my wealth. Not somebody else’s, not our group. This is my wealth, and this is a disaster for all the people that are in our business, the 65,000 members of the National Small Business Association, and for all of the 6,000 participants of the SBIR program. So that’s my two cents, and I thank you for the time.

Joe Allen (00:27:03):
Well, it’s clear that obviously these are two different worldviews because Senator Warren says that when the government’s funding research at a university, that that’s in essence venture funding. And so therefore a licensee is getting a special benefit and the government should have a say in how the resulting product is licensed. So let’s go back again to that. Is that true? If that’s true, why is it so hard for universities, even for technology to win a Nobel Prize like immunotherapy and mRNA, universities can’t find a single licensee of... The search engine that became Google, Stanford couldn’t find a single licensee. So if this is a giveaway, if the government’s de-risking these technologies and companies are getting some special benefit, which they should then reflect in their pricing, why is it so hard to find companies to license technologies?

Or has the word not gotten out to them, that this is basically a goody bag? And once you license the technology from university or federal lab, you’re pretty much assured of making money. What’s the downside? So how would you respond to that worldview? Which was in the letter that a number of progressives sent to President Biden. And back to Bob’s point, it’s explicit in that letter. They want every government-funded invention reviewed. Not just drugs, every government invention reviewed to see if march-in rights and 1498 should be applied to them to lower prices across the board. So how do we explain the worldview that the government is in fact a venture capitalist? And if you license the technology, you’re getting a benefit.

Bob Schmidt (00:28:41):
Well, I’ve got several points from that. The data doesn’t support the supposition. If you go before 1980, when Joe you were wise enough to be able to help create this, the Bayh-Dole bill, you saw virtually no contracts being licensed from the universities. And then they tried again with the NIH in the 1989 to 1995 period. And then also all of the licensing dried up. And so we showed that that doesn’t work according to the facts. And as far as, “Gee, if I get a fifty or a hundred thousand dollar SBIR for a phase one, I’m guaranteed to make money.” If you want to make a box and just cut cardboard and fold it up and be able to produce the box, you’re talking $5 million of startup. So, “Gee, I got a hundred thousand from the NIH or from a government agency, and now where’s my other 4.9 million come from?”

Well, I’ll tell you where it comes from because anybody that’s not in California or Massachusetts is not going to be getting venture capital to the large extent. And so it’s coming out of my house, it’s coming out of my family, it’s coming out of my kids’ tuition funds. It’s coming out of anywhere that I can beg or borrow that money. And so there is no great big thing at the end of the line here. And there certainly will never be if I’m trying to license this to somebody else and finally get paid out or sell my company, they’re not going to buy it. They’re not going to license it. They’re not going to take it because it’s tainted. And so that’s what I said is that now my only options will be broke or dead and you know what they say about death and taxes. So the death is always a certainty, and the broke question is, will it come before I die or after I die? That’s what they want from us.

Brian O’Shaughnessy (00:30:40):
Joe, can I jump in with a clarification as well?
Joe Allen (00:30:42):
Absolutely.

Brian O'Shaughnessy (00:30:43):
Sure. Thank you. So I think this gets directly to the point that I was touching upon earlier, which is the basic research that's funded in America's universities is just that it's basic research funded by the federal government. That's a unique role for the federal government to take. But basic research is very speculative. Sometimes it's just a mechanism of action that might lead to a drug. So nobody really knows whether or not it's going to turn into a product. A lot of the critics are saying, “Well, the federal government has created a product.” Almost never has the federal government created a product.

They've created the results of some basic research that might be able to be developed. And so therein lies the rub, because the basic research then might be patented and often is, and that's what's covered by the Bayh-Dole Act. But the subsequent development work is privately developed. And so that's the result, or that produces oftentimes privately held patents and the patents cover the ultimate product. So the march-in is not going to be effective as a price control mechanism at all, because you're still not going to be able to make users sell the resulting product because that's covered by subsequently developed private research and privately patented. Now, the critics of the Bayh-Dole Act are trying to dovetail the Bayh-Dole Act's march-in provision by saying, “Well, okay, in those circumstances, let's use 1498. Because 1498 purportedly gives the federal government the opportunity to step in and take away private property.” But they don't get the right to take away private property. They only get to use the private property for the very limited circumstances that Adam identified. And that is for the government and by the government. And so even if the federal government were to use 1498 where Bayh-Dole's march-in provision doesn't work, then they're still going to have to resort to 1498, which requires the federal government to provide just compensation. So now, the federal government, even if they used 1498 and the march-in provision to take away or use those two together as a price... excuse me, price control mechanism, the federal government is still going to have to pay the patent donor just compensation.

So now, the federal government is still going to be on the hook for exactly what the pharmaceutical company would have made, for example, and they're going to have to pay the pharmaceutical company all of the profits that they would've otherwise made. So I don't mean to steal your line, Adam, but Adam is fond of saying, “Congress knows how to write price control legislation.” Neither of these bills are price control legislation. If they were, they would say so. But in both instances, the critics allege to have found mysteriously hidden within the bill some tool that allows them to implement a price control regime.

Nothing could be further from the truth. What these critics are attempting to do is usurp the authority of Congress and to do unilaterally what Congress has steadfastly refused to do. They are not authorized to do that. No matter how much the critics want to be able to take away the rights of people to charge what they think is a fair and reasonable price for their ultimate product, they are not entitled to do so and Congress has never sanctioned that.

Joe Allen (00:34:31):
Well, that's a great opportunity to bring Professor Mossoff back in because as Brian said, a lot of the comments, including those of the Bayh-Dole coalition is there's no legal authority for this framework because it's an attempt by the executive branch to change legislation without the consent of Congress. So Adam, first of all, you have your thoughts about that, but the other thing is we're either a nation of laws or we're not. If every administration can suddenly turn legislation into a pretzel to score a political talking point, what does that do to innovation? I mean, who's going to rely on a system where you have to take private sector risk if it looks like the government can pull the rug out from under you anytime they want to?

Adam Mossoff (00:35:13):
Yeah. Excellent points. In fact, to hit on the kind of as the academic here, the kind of classic academic or historical point, this was one of the United States's contributions again, in addition to securing patents as property rights, was to secure those property rights within a rule of law framework that had never been done before. It was always viewed through a kind of discretionary royal prerogative in England and another countries because it was viewed
as kind of an economic policy, generalized, this is what we’re doing to benefit the realm. And the United States said, “No, we’re going to treat these just like property rights and homes and in factories and regionally carriages and horses and then in cars.” And economists across the board have recognized that this was foundational to the industrial revolution shifting from England to the United States in the 19th century, the pharmaceutical revolution shifting from Germany to the United States in the 20th century, and then revolutions happening in the United States. The digital revolution, the computer revolution of the 20th century, the biotech revolution of the late 20th century and the mobile revolution of today.

So it’s exactly right Joe, and I appreciate that Brian stole my line. Luckily, I don’t have any intellectual property in it, so it’s perfectly okay. But one of my favorite examples is literally a law that Congress enacted in 1942 called the Price Control Act in 1942. I mean, Congress knows how to enact price control statutes when it wants to do so. And what you have here is a bunch of academics and activists for several decades now, kind of engaging in a Jedi mind trick. This is not the statute you think it is. This is actually a price control statute, even though there’s nothing in it that actually says that. And it’s not its purpose. Brian earlier mentioned the Economist recognized the Bayh-Dole Act as one of the most significant post-World War II pieces of legislation that the United States has ever enacted. And by the way, that’s a statement against interest by the Economist because the Economist for well over 150 years has been anti-patent. In fact, they were calling for the elimination of all patent systems 100 years ago.

So for them to recognize a patent statute as profoundly significant in driving economic growth and creating a flourishing society is tremendous. And as Joe, as you mentioned, and as others have already mentioned, it’s the statutes serve a particular function. Bayh-Dole removed this cloud on the title, this taint of government financing that occurred when you had the upstream government financing. And Section 1408, which is an entirely different statute, because it’s not about government financing. It applies to all property in a sense, all patents. Because it says when the government uses your patent for a government function or purpose, military, post office, then it has to pay you. That’s what the statute says. In fact, it’s a pro patent piece of legislation. It protects patent owners against what occurred in England. Because in England, the Crown claimed what was referred to as the Crown’s right, or the Crown’s privilege.

We granted you this patent. That means we can use it whenever we want and we don’t have to pay you. And again, the United States said: “No, this is property rights. This is protected under the Constitution just like any other piece of property right.” There’s due process requirements, there’s prohibitions on the government using your property without paying you, and that applies just as much to a home or to a farm or to a machine as it does to a patent because they’re all the same thing under the law in our country and adjudicated to the courts in the same way.

Joe Allen (00:38:54):
Well, listen, we’re getting some great questions in the audience. I want to get to those in a second. But let me just pose another fundamental question. Unlike every other country in the world, our system is driven by small companies as Bob and Jennifer said. Even 50% of our drugs come from small companies. So when those small companies either spin off of universities or start on their own as Bob did, a lot of them have to get venture funding. David Kappos, who was President Obama’s director of the patent office, was on a program with us, and he made the point that he would advise all of his venture capital people that government funding is toxic because this framework is retroactive. This applies to anything that’s been commercialized so far. This is not starting from now. Let me just throw out to the panel. Would a venture capitalist put money into long-risk technology, federally-funded technology or even privately funded?

Let’s talk federally funded so you’re under this guise. You’ve got a company that’s licensing a technology. It looks like it may have market, but it’s going to be 10 years down the road. You got to have to go through a series of fundings. And now you know that if you make it across the finish line, if somebody says, “I don’t think your price is reasonable,” and there’s no definition of that, would a venture capitalist put their own money, unlike the government, this is their money, not taxpayer money. If the government’s a venture capitalist, it’s a poor one because there’s no consequences if they make a bad bet. But in industry, there are consequences. So let me just throw out to
the panel. What impact, if any, would this framework and using 1,498 in margin rights for price control, what impact would that have on our venture capitalists and the ability to even form a small company?

**Bob Schmidt (00:40:42):**
That’s real clear. It ends that whole supposition, because no venture capitalist, no angel investor is ever going to invest in something where all a Chinese company needs to do is say, “I can make it cheaper and you’re out of business.” So this is just, it is devastating to our economy and to how our economy works. It’s a disaster, and this ought to be killed right away.

**Joe Allen (00:41:11):**
Jennifer?

**Jennifer Young (00:41:13):**
The American Edge Project just released a study on Tuesday studying venture capitalist investment in the last couple of years in the United States, in Canada. I’m sorry, United States, North America, Europe, and China, and have found that especially in China, with significant government backing, they witnessed notable growth in its venture capital ecosystem. And due to a growing wave of regulatory actions and proposals at the federal level and state levels in the United States that has severely threatened domestic tech industry growth and innovation, they’re running scared. They want a sure fire. This is their money, and they’re expecting a 10-time payout on venture capital investment, knowing that nine out of the 10 of them are going to fail. They know that going in.

So when the one hits the jackpot, they expect the 10-time payout. Well, if that’s at risk of being sacrificed or given to someone else, what’s their game in this? This system works because of everything that is involved with it. The venture capitalists invest, angel investors invest, a supportive regulatory system. When pieces of that start to fall apart, and we’ve been seeing that throughout the last year. The regulatory system supporting the innovation economy is starting to break down because of government encroachment. This is the true knockout punch. This would really decimate many other pieces of this. And why would people like Bob ever want to start or innovate in the United States? They’ll go somewhere else.

**Joe Allen (00:42:46):**
I think the other... Let me just one thing real quick before we lose that. The other thing people need to understand is when those nine out of 10 fail, somebody has to pay for that. That’s not free and it’s not paid for by the government.

**Jennifer Young (00:43:02):**
They paid out their pockets, and they paid from venture investment. And some of them had to give their homes up and they’ve lost valuable years of their lives and it’s gone.

**Joe Allen (00:43:11):**
Nobody in the government loses their job or university if a project fails, but people in industry do. So Brian, I’m sorry. Go ahead and make your point.

**Brian O’Shaughnessy (00:43:20):**
Yeah, just one minor point, Joe. And it’s just, I don’t want to put too fine a point on it, but we need to keep in mind for the critics that there is a huge distinction between a venture capitalist and the government. The government plays a role in funding basic research. It is no different than building roads and rail systems and what have you. They are providing the infrastructure. Now, many of us then drive our trucks and cars over those roads to make money, but that doesn’t mean that the federal government is responsible for those developments. The federal government does what the federal government is supposed to do, and that is provide basic infrastructure. And so that’s what they’ve done with basic research. Nobody knows how that basic research is going to be used until a private investor comes along and is willing to take the risk to put in the sometimes 10 to 15 years and billions of dollars in investment to find out whether or not that basic research can be turned into a product.

But that’s not known at the time. But that’s a fundamental purpose and a role for the federal government to play, is
to lay the basic infrastructure and let private enterprise come in and utilize that basic infrastructure and develop it into something that in fact works to the benefit of the populace. And that is the brilliance of what I call the virtuous cycle of Bayh-Dole, is that it allows the federal government to start the process and then private sector comes in. And if they make money, a lot of that money goes back into the pockets of our universities. And that works to the benefit of us all, because then we have much more viable universities that can employ better faculty and educate more graduate students. It’s a beautiful virtuous cycle.

**Joe Allen (00:45:18):**

Well, the other irony is this is all being proposed by people who are enemies of Bayh-Dole. So this is a poison pill. This kills the system. But we have some great questions to the audience. By the way, if you’re in the audience, you want to ask a question, go to the Q&A feature on Zoom. So let’s get into some of the questions from the audience, and I’ll throw this out to the whole panel. Would you approve of these march-in/1498 efforts if they were limited to just drug prices, or is that also unacceptable? Can the effort be redirected to apply only to drug prices?

**Brian O’Shaughnessy (00:45:50):**

Well, if I could—

**Adam Mossoff (00:45:51):**

It goes to your earlier comment, Joe, and the comments by the other panelists that it’s a myth that the government funds all biomedical research in this country. It’s not the case. The majority of the funding that produces the drugs that we receive as patients in the healthcare market are created through private venture capital funding or private investments by private companies. And this has shown repeatedly again and again, again, I think 2019 or 2020 is the last year we had some data on this. Private sector investments and R&D and biomedical research was approximately $139 billion as compared to the $40 billion that was issued by the NIH in grants. And as Brian has emphasized repeatedly, those grants are upstream basic research grants. They are not for the actual specific pill oftentimes that one is taking.

In fact, there’s a great study that was shown this. Someone finally looked at 23,230 NIH grants in the year 2000. And by the year 2020, of those 23,230 NIH grants, only 18 FDA approved medicines were linked to those 23,230 NIH grants, which reinforces the points that we constantly are hearing, that it is private capital, it is private investment by the companies that is doing the significant amount of research and development. The D in the development is the most significant part in creating the actual innovations, drugs, devices, and things of this sort that result in incredible medical treatments that we have today.

**Joe Allen (00:47:36):**

The short answer to the question is no, this can’t be limited to drugs because Bayh-Dole is a foreign policy applies to all agencies, not just NIH. So once you let this genie out of the bottle, it applies to every federally funded technology including SBIR technologies. So this is being done, as we mentioned in the beginning, under the guise of controlling drug prices. But it really can’t do that because most of the patents you need to copy are not federally funded, which is why they’ve added 1498. But once, if this formula is accepted, it applies to agriculture energy, DOD, you name your technology, this applies to them. And the other thing is, remember, there’s nothing in the Bayh-Dole Act defining what a reasonable price is because we didn’t intend that. There’s nothing in the guidelines defining it a reasonable price that’s completely arbitrary. So some GS-14 at the Department of Agriculture is going to decide whether they like the price of your new Lima bean. And if they don’t, then they can start this whole process.

**Brian O’Shaughnessy (00:48:38):**

And even if it were possible to limit it only to drugs, it’s still worthy of debate as to whether or not that’s a good policy. I mean, Senator Warren makes a point in her letter that says an unaffordable drug is an unavailable drug. Well, that’s a bit specious. First of all, unaffordable to whom? And then I’d have to ask the writer to say, tell me, would you rather have an expensive drug that cures your fatal illness today or no drug that cures your illness at all? That’s the difference. And the beauty of the Bayh-Dole system is it only lasts for the term of the patent. So it may be
an expensive drug today, but it won’t be an expensive drug tomorrow. And I’d rather have an expensive drug that turns inexpensive tomorrow than no drug at all.

Joe Allen (00:49:28):
Well, let’s also mention another thing which we haven’t talked about so far. If you’re the company commercializing technology, there is a specific process for marching rights. The government can’t just say, we want to march in and they do it. They have to have an administrative hearing. And then you can appeal to the court of claims. As Professor Mossoff said, there’s also a procedure for 1498, but this would be applied disproportionately to small companies, which license 70% of technologies, as Bob said also under SBIR. So what would be the impact now? Suppose I want to shake down Bob Schmidt and I know you need venture funding. So I say, Bob, I may have to file a march-in petition because I don’t like your price unless you make it worth my while to go away or let me infringe on it. So you have to choose between buying lawyers to go through administrative process, defend yourself in court on 1498 or paying somebody to go away.

What does that do to our innovation system? Remember, anyone can file a march-in petition. Your brother-in-law who hates you, a competitor or somebody wants to shake you down. Somebody says, hey Jennifer, I’d really be a shame if something happened to your nice little company now that you’re looking for venture funding. And if I publicize I have a march-in petition against you, who’s going to fund you? So let’s talk about that for a second. But let’s talk about the unintended consequences. Could this be misused by people who just want to shake you down? Is that happening in the patent system? Are people filing over there to say, hey, how long can you afford to do it? I can afford to do it for a long time, could you?

Bob Schmidt (00:51:02):
This isn’t something new. It’s been going on for a long time in the patent area. And this is not a surprise, I would argue against unintended consequences. I think this is fully intended. This is fully intended to be able to kill small businesses. The America Invents Act, I always call the “Google Executive Bonus Protection Program Act.” This is all about making sure that – this is first grade stuff. Build your clubhouse up in a tree so you can pull the ladder up to keep the little kids and the girls from coming up into the clubhouse. This is just an extension of everything we saw on the America Invents Act and a lot of the Mayo and eBay and other court cases of how do I make sure these little businesses can’t survive because their new invention is going to eat my lunch and I want to make sure that we keep it from them and I can continue to get my bonus as a big company guy. So I look at this as just one more nail that they’re trying to put in our coffin to make sure that we never come out of the coffin.

Joe Allen (00:52:19):
Jennifer, what would the impact of this be on your members? Are they well-financed enough that they don’t mind spending a lot of money on lawyers to go through administrative procedures that they have to defend themselves?

Jennifer Young (00:52:29):
No. I just had a conversation last week with an innovator who is currently in the litigation, very, very expensive litigation over a non-patented product that they have that a large company who is a potential competitor just decided that they need to put them out of business where we want to run this marketplace. So they’re going to be involved, the small company is going to be involved in defending their product for years, hundreds of thousands of dollars probably encroaching into the millions for a company that’s not, I mean, that’s a roth of their budget, their annual revenue that they’ll spend to defend their company because a large company has come in and said, we just think we need to put you out of business. So we can’t do it in the marketplace, we’re just going to do it in litigation. And the large company has fleets of attorneys. It’s an actual business practice for them to go in and do this. That’s how they operate.

And so doing this, like Bob said, it’s been going on a long time already. This is just yet another tool in the toolbox and companies that might be near acquisition. So let’s say this small company was potentially looking to be acquired or was potentially going through a round of investment, they’re backing off on that. No way, we’re not touching that. That’s good you guys, sorry, good luck. Investors won’t invest. And furthermore, their customers might start running scared too. Are they going to go out of business? Do we need to find another supplier? The pervasive effects
of just the litigation system that exists in the country and the way it’s manipulated now are bad. Adding another tool to the toolbox like this, just one more way to do it to put them out of business.

**Joe Allen (00:54:09):**
We actually have a couple good questions I want to finish up with. One says this is having a detrimental impact right now, that this hanging over the system, it’s making people reluctant to fund companies, they actually mentioned VC. So is there long-term damage being done? I mean, actually after we passed Bayh-Dole, it really took us a couple of years for companies to believe that government could be a reliable research partner. Now, I think people are starting to really wonder, and as Jennifer and Bob said, Bayh-Dole has been rock solid for 43 years.

You know what the rules are? Now it’s being turned on its head to be used as a club to beat down anybody who’s dumb enough to commercialize a government-funded technology. I mean, just to be blunt, that’s what you’re talking about. You have no idea what you’re getting into. And at the very least, you may be looking at who knows how much in legal fees, trying to defend yourself against something that was never intended. So do you think this is doing long-term damage to the U.S. innovation system? And what do you think the Chinese reaction to this is? Seeing us shoot ourselves in the foot like this for no particular reason.

**Brian O’Shaughnessy (00:55:14):**
They’re viewing it as a gift. But yes, the short answer to your question, Joe is absolutely this is doing harm right now, companies are thinking very long and hard about whether or not they’re going to license technology from universities where the federal government has funded any part of the basic research and it’s going to dampen the amount of licensing and development of federally-funded basic research.

**Joe Allen (00:55:46):**
Anybody else? Well, listen, one thing I wanted to close with, this has been a great discussion. I knew getting this panel on here would be a lot of fun. Somebody asked another great question, okay, this is bad. We realize this. What can we do about it? One thing that we’re doing, that’s where we’re doing this webinar is we’re really trying to get the word out so that well-meaning people that really don’t understand these issues and think, well, maybe the public’s being ripped off, get a sense of how serious this is. But what can people do now with this thing pending to really try to send a message back about what a disaster this is? And the irony is it’s not going to lower drug prices. That’s the real shame is what it’s being intended to do.

We can’t possibly do for the reasons we talked about in the beginning. But for other fields of technology, your government-funded inventions may be your key technologies which are susceptible to march-in rights or anything susceptible to 1498. So what would you recommend? What can people do now that really want to get a signal out to, hey, this is something that need to be removed and get back to having the laws work the way they were written. So give me some closing thoughts about what you think people can do that around the audience are getting alarmed about this.

**Bob Schmidt (00:57:03):**
Well, Joe, I know you mentioned that you wanted to be able to post this whole webinar on the Bayh-Dole Coalition website. I would also suggest that the letter signed by the seventy-some congressional representatives that wanted to support this also be posted because they’re frequently small business congressional visits days. The IEEE is having one next week, and so there’s going to be hundreds of small businesses coming into Washington. And having that list is then the target list of who we need to go see. So that would be very helpful that we can go to these congressional people and try and educate them on just how disastrous their proposal is.

**Joe Allen (00:57:46):**
Bob, you can rely on a small businessperson to be practical and pragmatic and get right to the bottom line.

**Jennifer Young (00:57:53):**
Call your Members of Congress, call your Senators, tell them this isn’t going to lower drug pricing. This is going to make it worse. You’re actually potentially limiting what you can get if you’re starting to eliminate companies.
So definitely call your members of Congress, call your senators. And I'll leave you also with a quote from Ronald Reagan, “The nine most terrifying words in the English language are, I'm here from the government and I'm here to help.” It's bad.

**Brian O'Shaughnessy (00:58:21):**
Yeah, I would echo that sentiment and I would say it's axiomatic in DC that if you're an organization like the Bayh-Dole Coalition, you're everybody's constituent and therefore you're nobody's constituent. So those of you who are out there who are members of companies, members of universities, please reach out to your specific representatives and senators and tell them of your concern. Tell them how this is going to restrict your business, restrict your funding. Let them know that this is very serious and it's very damaging to the innovation ecosystem.

**Joe Allen (00:59:00):**
Adam?

**Adam Mossoff (00:59:01):**
Yes. Just to add a little flavor more to everything everyone said, which is exactly right, to speak up and to call your representative, call your senator, let them know that this is a serious issue to you and to follow the issue. This is being pushed through, not through Congress because this is being pushed through in the executive branch and the agencies. And so also we went through what was called a notice and comment period. And people should kind of follow these issues and get on the Bayh-Dole Coalition's mailing list or other listservs where they can be notified of these things because you have an opportunity also to speak up and to file a statement to someone saying, don't do this. This is wrong. And to build upon Brian's point a little bit, what speaks very loudly in DC is not just an individual voice, but a group of voices, but also institutions and companies and organizations.

So speak up within your organization or your company that you work in. Let them know that this isn't about drug prices. This is about all patented innovation that underlies every single business plan and model in this country. And in fact, the proposed regulations actually go through and identify. There might be patents on street signs and patents on your 5G telecommunications software that you use in your smartphones and things of this sort. If there was any government funds used at any point in the time in the creation of that invention, that falls within the vital margin. And we can impose price controls through this new guidelines. And so let your company know that you work at, you need to speak up as a company and let the Congressman and Senator in your jurisdiction, in your district know this is a problem to us. This will hurt us. It'll hurt our ability to thrive. It'll hurt our ability to hire people and have jobs and hurt our ability to grow the economy.

**Joe Allen (01:01:00):**
Well, when we started off, Brian quoted from the Economist about the importance of Bayh-Dole. But there's another part of that quote that also said, more than anything, the Bayh-Dole Act helped reverse America's precipitous slide into industrial irrelevance in the seventies. We can go right down that slide again, and unfortunately, this is taking us back to the pre-Bayh-Dole era where government funding is toxic. I'm old enough to, I was around then. You don't want to go back to that slide again, believe me. So anyway, thank you very much for the panel. Thank you for the great questions we had here. This will be posted on our website, and again, we deeply appreciate the time that our panel has given. Thank you also for the excellent questions we have, and we'll see you down the road.

**Jennifer Young (01:01:44):**
Thank you, Joe.

**Brian O'Shaughnessy (01:01:45):**
Thank you, Joe.

**Adam Mossoff (01:01:46):**
Thank you, Joe. Really great discussion. Appreciate it. Honored to be here.
Joe Allen (01:01:49):
Thank you.

Bob Schmidt (01:01:51):
Bye Joe.