



*Attacks on Bayh-Dole are Attacks
on Small Business*

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Bayh-Dole
COALITION

Joe Allen (00:00:00):

Welcome to our webinar “Attacks on Bayh-Dole are Attacks on Small Businesses” presented by the Bayh-Dole Coalition. I’m Joe Allen, the Executive Director. The coalition’s mission is simple, we want to explain in as plain language as possible that R&D alliances between our public and private sectors are critical to both our economy and our wellbeing. Those partnerships are based on the Bayh-Dole Act, which allows universities and small companies making federally funded inventions to own and develop them. The very first lines of the Bayh-Dole Act state, “It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions, arising from federally supported R&D.” That statement makes it very appropriate that we are holding this webinar on World Intellectual Property Day for a strong, dependable patent system is the very foundation of Bayh-Dole. So happy World IP Day to everyone and thanks for joining us.

Joe Allen (00:00:59):

Despite overwhelming evidence from the past 42 years that Bayh-Dole works, we now find ourselves under unprecedented attempts to undo our system. Today, we want to consider the victims if these efforts were ever to succeed would be the entrepreneurial small companies, which drive innovation. Of course, the ultimate victims would be the American people and those around the world whose lives have been made better by Bayh-Dole. We don’t have speakers presenting theories, but invited leaders with hands-on experience and commercialization to share their views with us today. We invite you to submit questions for our panelists, which you can do by clicking on Zoom’s Q&A feature. We’re going to kick off our program by asking each of our speakers to give us a quick overview of how our interview nation system works from their perspective.

Joe Allen (00:01:49):

Our first speaker is Karen Kerrigan. Karen’s the president and CEO of the Small Business and Entrepreneurial Council. She regularly testifies before Congress on key issues impacting entrepreneurs in the economy. She engages with the President’s cabinet and key advisors and has been appointed to numerous federal advisory boards. Karen shares a small business round table, is a founding member of the World Entrepreneurship Forum. She serves on the board of the Center for International Private Enterprise. And I’m proud to say she’s on the board of the Bayh-Dole Coalition as well. So Karen, please kick things off.

Karen Kerrigan (00:02:26):

Well, great. It is a real pleasure to be with you all today with this esteemed group of presenters. And of course, with the Bayh-Dole Coalition on this really important day, which is World Intellectual Property Day, World IP Day. So I join Joe in wishing everyone a very happy World IP Day and real quickly just about SBE Council, the Small Business and Entrepreneurship Council. We’re an advocacy research and education organization dedicated to protecting small business, promoting entrepreneurship. And for 28 years now, we have worked on a range of policy initiatives, private sector initiatives, all aimed at strengthening the environment, the ecosystem, for strong startup activity and small business growth. And obviously, we’re big believers in entrepreneurship and small business and the role that they play in our economy and its competitiveness and its innovative capacity.

Karen Kerrigan (00:03:33):

And Joe asked me just really quickly, if I could touch on some general thoughts about the role of small business in our innovation system. And obviously, it’s extraordinary. This is not only documented by well established research on patenting across sectors, and particularly in emerging sectors and clusters. But also in the data that shows that small businesses and entrepreneurial firms dominate every industry in the United States. So if we look at the big picture, the data we see that small to midsize businesses represent a massive share of American businesses, firms with fewer than a 100 employees account for 98.1% of all firms. Those with fewer than 20 employees make up 89% of all firms and firms with fewer than 10 employees account for 78.5% of all firms, small businesses represent about 96% of employer firms in high-patenting manufacturing industries.

Karen Kerrigan (00:04:41):

A percentage that has remained constant from 2007 to 2012, according to research documented by the SBA’s Office of Advocacy. In other specific industries where innovation is considered to be more rampant, small firms play an outsize critical role as well. For example, among software publishers, 92% of firms have less than a 100 employees. 67% have less than 10 employees. Within the pharmaceutical and medicine manufacturing industry, 78.9% of firms have fewer than a 100 workers, 47.6% have fewer than 10 employees. The story is the same in the energy industry and across all sectors of our economies. Startups and small firms really are the drivers of competition and vibrancy, fueling innovative new technologies, practices, business models, and goods and services. This is what keeps our economy competitive, dynamic and more productive and why we need to be continually encouraging more startup activity.

Karen Kerrigan (00:05:54):

And this is something at least for as long as I have been doing this now in the small business space for 28 years, that policymakers, Congress and administrations have worked to support and much on a bipartisan basis. Whether that be incentives to encourage investment in small firms and their innovations, access to capital to help innovative startups launch and grow or training in education programs that connect entrepreneurs to the resources and the technical support that they need to succeed. This policy drive to support small businesses and upstarts has fueled extraordinary innovations and success. Bayh-Dole alone, for example, has supported the creation of more than 15,000 startups, most of which are true small businesses that have contributed an estimated 1.3 trillion to the US economy.

Karen Kerrigan (00:06:54):

I will also add that the US startup and innovation ecosystem is a phenomenon that other countries have tried or are trying to emulate. And many are doing this with great success. In fact, as I have traveled all over the world, doing missions with the State Department across administrations, this has been the reason behind these missions to work and help government and business leaders in these countries I visit to create policies and environments that encourage entrepreneurship, innovative startups, investments, et cetera, through incentives and common sense tax, regulatory, trade, property rights, and IP rights policies.

Karen Kerrigan (00:07:39):

So many other countries have caught up to the US, especially big competitors like China, which is why it is really quite the head scratcher for groups like SBE Council and many others as to why some in Congress and policy officials in the administration are moving to undermine or destroy the very incentives and frameworks that have proven successful in spurring and incentivizing innovative startups. Actually on this World IP Day, we believe Congress and the White House need to be recommitting to the principles and rationale behind Bayh-Dole and IP protections and rights, not weakening or undermining them. Again, it is small businesses and individual entrepreneurs who are the driving force behind innovation. And if policies or actions weaken or emasculate proven programs like Bayh-Dole, these will only weaken America's small business economy and the innovative solutions and technologies that we derive from them that keep our economy competitive and vibrant.

Karen Kerrigan (00:08:49):

And I'll just end by saying, this is particularly important now during this very uncertain economic period for our country and for the world where we are working to recover from the pandemic economy. But at the same time, there is an opportunity, I think, to rebuild this economy in a very strong way. If you look at some of the data and some of the numbers coming out of the Census Bureau, there may be an entrepreneurial boom going on. In terms of business applications in 2021 alone, there are 5.4 million of them, which is 50% higher, 53% higher, than business applications in 2019. But not all these business applications will turn into actual businesses. And I have to say, these are across all sectors of the economy.

Karen Kerrigan (00:09:41):

So the policies that both Congress and the administration need to be focusing on should be incentivizing these individuals to start their businesses. And once they launch their businesses, to grow their businesses successfully because this is the innovation for tomorrow. This is what's going to keep our economy vibrant and strong and growing and competitive. And again, Bayh-Dole is one of those important pieces that has worked well and Congress and the administration need to be doing all. They can, again, particularly on this World IP Day to recommit to those principles. So with that, Joe, I'll turn it back to you for the next speaker.

Joe Allen (00:10:26):

Well, thank you very much. That was an excellent introduction. Our next speaker is John Stanford. John is the Executive Director of the Incubate Coalition. John is an advocate for the early-stage life science ecosystem, as Executive Director of Incubate, the voice of the life science venture capital. He works with key stakeholders in government and industry to ensure that American biopharmaceutical innovation remains a cornerstone of our economy. John is also the host of the new Making Medicine podcast. For the past decade, John has advised Fortune 500 companies, leading trade associations, and breakthrough startups on navigating through governmental systems and developing business strategy for highly regulated industries. So John, we'll turn it over to you.

John Stanford (00:11:09):

Well, thanks and thanks for having me. It is a tough act to follow because when Karen Kerrigan says something about small business, we all should listen. And I want to echo from the venture capital perspective exactly what she alluded to

and that the conversation we're having today is really a small business and entrepreneurship conversation. Incubate was formed five years ago to give voice to a missing part of the equation of what drives America's incredible biopharmaceutical innovation ecosystem. And that's the role that private venture capital plays. At the time, it was clear that there was a lot of misunderstanding by policy makers about not just the drug development cycle, but the entire medical innovation life cycle. And so we represent the major venture capital organizations around the country, and we do a lot of work to bring their voice to Washington and to state governments.

John Stanford (00:12:10):

At the time when we started, there was a lot of conversation within hearings and in Congress about who develops drugs. And we noticed that some policy makers were sort of misinformed that a drug might come ready out of the NIH and the incredible basic research work that they do. But that completely overlooks the role of small businesses and entrepreneurs and scientists that are in Karen's universe. And that rely on the capital of folks like Incubate's members in order to move their mission and vision forward. So Incubate has spent its time working in a nonpartisan way to really make sure that policy makers understand not just the complexity, but the interrelated roles of entrepreneur, capital, large companies, name brand companies that we're all familiar with in order to bring deserving and much needed treatments and cures to patients. So I thought I'd try to level-set with why venture capital is needed in this space because not every industry has a venture capital. And the answer is why isn't it that these incredible research universities or our incredible government institutions that do so much basic research, why can't they take drug development from beginning to end?

John Stanford (00:13:31):

And the one word that comes to mind is simply the risk. It is an extraordinarily risky proposition to try to develop what could be a possible drug from a molecule or some discovery. We know that nine out of ten drugs that begin the process of FDA approval through clinical trials will fail and will learn a great deal from those failures. But it's an expensive proposition to lose 200, 300 million dollars at a time. And so what venture capital does is it aggregates that risk across an entire portfolio so that in some, there can be a reasonable return on investment. But there's no way to bet on any one single job or any one single drug. And that's why research institutions, gladly, enable the tech transfer process to allow an entrepreneur to bring a drug development forward.

John Stanford (00:14:28):

Another important aspect of this is then, where does our capital come from as venture capitalists? There's a lot of misconception about where venture capital comes from, but most of it comes from institutional investors like American retirement funds, pensions, or university endowments or foundations. And so it's sort of we are a small sliver of the greater public's investment that wants to be in this very niche area of life science investment. And what that means as stewards of the public's money, of stewards of your retirement dollars is that we can't take unproven leaps. And that's why venture capitalists in the life science space bring together a unique blend of business expertise, as well as deep scientific knowledge. And when we're considering an investment in a promising product, we're really looking at three things. The first is how much money is needed today to move a product forward, whether that is to enter clinical, whether that's to move clinical trials further forward, or whether that's even earlier in the process where simply it's giving an entrepreneur their first, second and third employee.

John Stanford (00:15:42):

So we'll look at how much money is needed today. Second, we'll look at the likelihood of success and that's where the scientific background of life science venture capital really steers smart dollars towards an investment. Because there are a lot of great ideas out there and great innovation out there, but it's not all proven science. And so life science, venture capitalists play this role of helping entrepreneurs move a great idea, whether it came from private industry, a research university, or even a government institution, there's a special set of knowledge to move that forward. And it's not just capital that we impart. It's also that technical assistance that allows Karen's members to go on to start that incredible biotech company. And third and most critically, as I said, sort of the fiduciary responsible for billions of dollars every year. And so there's certainly an aspect of, what is the reasonable reality of return?

John Stanford (00:16:43):

And that's one of the key reasons we're here today because we're very concerned by some of the steps being proposed that would make that return so uncertain for venture capital, that it would be unrealistic that we could invest any further. Because, again, our responsibility is to those whose capital we steward and we can't simply be pursuing science only for science's sake. And so that's an important role that venture capital plays in defining where we can take innovation next. And it is World IP Day, and so I joined Joe and Karen in celebrating World IP Day. And so I'll close my opening remarks with why is intellectual

property so critical? Well, if you think about all of biotech has on day one, when it's first looking for investment, they probably have a shiny PowerPoint deck about the promise of immuno-oncology or some breakthrough small molecule that they dusted off a shelf.

John Stanford (00:17:49):

But in actuality, the only investable asset is the intellectual property protections that lay behind that. And that is the only thing that gives venture capital one of the unique parts of the secret success of America's biopharmaceutical leadership. It is the only thing that gives us the confidence to deploy 20 billion a year into this incredibly risky space, where as I said 9 out of 10 will fail. And so I joined Karen in saying now is not the time to retreat on our strong intellectual property protection. We need to be celebrating that Bayh-Dole and its successors enabled four decades of unique leadership, but the rest of the world is playing catch up. We've seen a similar organization, some good colleagues of ours in Europe come together to make the same case about IP and venture capital in Europe. We know that China is on the rise and has changed some of its own IP standards to make it more attractive.

John Stanford (00:18:49):

And so I echo Karen in saying, now's not the time to go backwards on our IP system. It is time to double down on it because it has provided a unique return on investment for patients and investors alike. So thanks Joe, for having me really excited for today's conversation and glad to be here.

Joe Allen (00:19:08):

Well, thank you. That was an excellent presentation. Now we have Joy Goswami. Joy is the Assistant Director of the Office of Economic Innovation and Partnerships where he oversees and manages tech transfer activities and corporate partnerships for the University of Delaware. Among his other roles, Joy is actively involved in managing intellectual property, assisting and establishing startup spinoff companies and developing university industry collaborations and partnerships. So Joy, it's all yours.

Joy Goswami (00:19:38):

Thanks so much, Joe. And thank you Bayh-Dole Coalition and Joe for inviting me for this session. I'm greatly impressed to see such a wonderful panel and hearing Karen and John speak a little while ago. Of course, many of the important points have been touched upon. I do want to begin, of course, by wishing everyone a happy World IP Day and mention how important intellectual property and technology transfer has been in the past few years. The representation that I would do in this particular session is going to be mostly in terms of my contributions as an academic technology transfer professional. So many of you may or may not know what academic tech transfer is, but I will just go ahead and begin my talk by defining what technology transfer is. And I'm sure all of you have been impacted by tech transfer, for sure.

Joy Goswami (00:20:38):

But to just define tech transfer and only saying it from the perspective of an academic tech transfer professional, being that the transfer definitions can vary depending on what part of the world you are, is that it is the process of translating knowledge and research into impact for society and the economy. And boy, if it wasn't for Bayh-Dole, it probably would be that I wouldn't have my job or nobody in the university would be able to do what they're doing today. So with the passage of about 40 years of this Act, one of the primary Acts that has been the stimulus for innovation for the country and many others that have eventually ended up adopting, I think it is a critical time for us to discuss the impacts of Bayh-Dole and what we have done or at least, academic tech transfer professionals have achieved in due course.

Joy Goswami (00:21:31):

So I'm not going to take a whole lot of time at the risk of mentioning what Karen and John have already spoken, but just give you a general spiel about what my take has been about academic tech transfer and how Bayh-Dole has actually assisted with academic tech transfer professionals, doing what they're doing at this point in time and bringing innovations coming out of academic laboratories and institutions into the forefront, into the commercial pipeline. And by mentioning that I wish to obviously begin with a little background of myself.

Joy Goswami (00:22:08):

So I've been in this profession for about 15 years now. And then, like I mentioned, if it wasn't for Bayh-Dole, maybe I'd be struggling for another job because that has been the key for me to even get the job. And of course, the fact that Bayh-Dole is currently around is attributing to the fact that it has been able to contribute to the number of innovations that have eventually ended up being in the hands of the commercial folks that have been able to harbor the innovation coming out of some of

the research that's happening from the universities and mediated through funding that has come from the federal sources. So in the 15 years of my journey, I have been able to successfully bring together a lot of thoughts in this Act. And I've also been privileged for being able to commercialize several innovations in chemical engineering, agriculture, biotechnology, pharmaceuticals, electronic space as well.

Joy Goswami (00:23:14):

And in doing so obviously feel that I've been able to contribute in the best way that I could because prior to Bayh-Dole, as you all know, there really wasn't any mechanism for some of the best and the brightest innovation that come out of the university to get into the hands of consumers. There was a big gaping hole between where the innovation ended and where it could actually be put into the commercial pipeline, such that it could be taken to the consumers. And so by actually providing that kind of structure mediating the innovations to actually get to the marketplace. So for many that once again, don't appreciate tech transfer enough, just wanted to emphasize the fact that... I should probably put it in perspective that if you have used an N95 mask, for instance, to go thank University of Tennessee. Or if you have the COVID-19 immunization done, it's because of the University of Oxford -- and the booster dose also has been developed through universities.

Joy Goswami (00:24:18):

If you've had Honeycrisp apples for lunch today, you can attribute that to the University of Minnesota, or if you're sitting and having the privilege of using the internet on planes, University of Maryland should be attributed to that. And from my personal perspective...I hail from the University of Delaware where I've worked in the tech transfer professional for about 10 years, the touch screen technology, the technology that you have ubiquitous now, actually hails from here. And innovators have been prolific in developing many, many research, which I have been blessed to have had the privilege of taking from its earliest incipient stages to the stages where it has been in the hands of commercial entities that have taken on. So on an average, as you all know, based on the fact that Bayh-Dole is active on an annual basis, nearly 800 plus products are generated from academic tech transfer that go into the commercial pipeline.

Joy Goswami (00:25:17):

And there are various vehicles that eventually assist, including obviously the vehicle of startups, which are the subject of our discussion today. And on and again, on an average on an annual basis, there are more than 1000 startups created every year coming from academic tech transfer. So there's a lot that has happened in the last 40 years since the passage of Bayh-Dole and the mechanism has been very clearly something that has been successful in spurring economic development for the state from where the academic institution hails, and of course the nation and on a global platform as well.

Joy Goswami (00:25:56):

So just to give you a general spiel, the way academic tech transfer works is from a functional standpoint. So we at the Tech Transfer Office are recipients of innovations that happen at the university. And they basically happen by virtue of serendipitous inventions that faculty members eventually end up getting into at the time when they're using federal grants for the research. And these inventions then are turned into invention disclosures when faculty members knock at the door of the Tech Transfer Office of the respective universities. And the Tech Transfer Office then receives them, reviews them and looks for appropriate ways and means to commercialize it.

Joy Goswami (00:26:40):

The first thing, of course, that they do is to file intellectual property protection around it. So be it patents or copyrights or trademarks, they would eventually do the protection. And then they would look for appropriate vehicles to make sure that this technology gets into the hands of the consumers, because universities by principle are not commercial entities that can manufacture these goods and sell them. So in doing so there are basically two kinds of vehicles we look for, one is of course pre-established companies that we tend to assist with trying and getting collaborations and licenses done. But the more important one and the subject of discussion is when the faculty member decides to end up starting their own company. So startup is one of the most important vehicles for all these new innovations to reach the commercial pipeline. And these startups are oftentimes created by the faculty members that then wears two hats, or they're created by some entity in the laboratory, like a postdoc or graduate student that is interested to eventually go ahead and begin business.

Joy Goswami (00:27:47):

And you may be surprised that at a national scale, nearly 70% of these disclosures actually end up getting into the hands of the startup. And then it is upon the Tech Transfer Office to assist with these startup companies to take these technologies to the next level. And so any kind of support that these Tech Transfer Offices can provide in the academic space, where these innovations can get to the next level we do. And that's where we struggle a bit only because of the fact that these startup

companies are obviously very early, they're immature, they need a lot of assistance. And the one thing that we try to mitigate at the very least, given that we are really not always aware of what the best optimized course of direction is for them, is to assist them with making sure that they encounter a minimum amount of uncertainty.

Joy Goswami (00:28:42):

And so Bayh-Dole has been one of those prolific acts that has been a key for us to eventually make sure that the technology that they get into their hands is under some level of structure. And that the uncertainty is minimized. And just, again, as a course of discussion, as we will go and talk. If there is any attack done to the Bayh-Dole Act at this point in time, it would only eventually cause more of an uncertainty being introduced into these startup companies who themselves obviously struggle for not just the IP and the innovation to eventually be de-risked and taken to the commercial marketplace, but they actually end up playing a lot of other variables that have in their minds to eventually get, to make sure that they have the technology into the commercial pipeline. So any attack on the Bayh-Dole would eventually be an attack on small businesses.

Joy Goswami (00:29:41):

And that is a very accurate statement from the standpoint of academic tech transfer professionals. And having said that I'm going to actually open up for any questions. Anybody has to talk about specifics or anything that you would want to know and learn as to why we feel that is the way for us to go. But we have always considered Bayh-Dole as the pillar for the commercialization of innovation through startups. So I'm going to end here and give it back to Joe for the question answer session, where I'll be more than happy to discuss more in detail about any of these attributes.

Joe Allen (00:30:18):

Thank you very much, Joy. We really appreciate it. Great job. Our final speaker on the panel today is Peter Falzon. Peter is the CEO of Ripple Science, a 2017 University of Michigan spin-out. That is leading the digital transformation and clinical trials with a direct to patient software platform built by researchers for researchers. Prior to Ripple Science, Peter spent 20 years as a serial entrepreneur in San Francisco and Silicon Valley, and also spent 10 years learning and living and working in Japan. So Peter, we'd like to have you talk now from the perspective of the entrepreneur.

Peter Falzon (00:30:56):

Thank you, Joe, and to the organization for inviting me in to present an example of a company that is actually benefiting, and to some extent, in existence because of the Bayh-Dole Act. So let me start though, by just giving you a little bit of my perspective, which is I'm a serial entrepreneur, as Joe said, I spent time in Silicon Valley. I'm originally from the Midwest and Ripple, which is a spin-out of the University of Michigan, is my eighth startup. And of the previous seven, six are still operating and employ about 1200 people each. So I've seen lots of different examples of how a small business grows and raises money and gets traction and takes technology from bench to bedside. So the one thing that's been common across all eight of the startups that I've been involved with is that they, to some extent and some more than others, have relied upon university license agreements.

Peter Falzon (00:32:29):

And therefore it's been critical for all of them, that the technology is available, is unencumbered and is provided in the form of an agreement that allows us to go out there and be competitive in raising the money and taking it from bench to bedside. So I think both Karen, John, Joy have talked about the importance of small business. I think John said something that I think is incredibly important and that is drugs or technology, whether it's devices or in the case of Ripple Science, software, doesn't come out of the university ready for the market. There is a long and expensive process to take technology that is patented at a university and bring it to market. Let me give you an example of what that process looks like. So my background is in devices and software. So if we're talking about drugs, you can multiply all these numbers by probably five. But in my experience, it typically takes a company three to five years and five to 20 million dollars in funding to take a licensed technology from bench to bedside.

Peter Falzon (00:34:03):

And so my job is to identify very early on which technologies have promise. And it's very much like an analysis that a VC would do. Some of it is just based on your experience. Some of it is analysis. Some of it is gut, some of it is learned through the diligence process, but basically we have to look and see if there's a real need for this technology. And there's a problem that the technology can solve and how big that problem is. And from there, we build a business plan and we build a team. And most importantly, we raise capital. So looking specifically at Ripple, my current startup, the company was started in 2016. Since that time I've raised eight million dollars from friends, family, angels, and VCs. And the only way that I'm able to do that is if I actually have a competitive offering to put in front of the potential investors. Because even though I have licensed University of Michigan technology, I am vying for dollars with all kinds of small business organizations that don't have tech transfer license agreements.

Peter Falzon (00:35:35):

And so it's really important. I think one of the great things about Bayh-Dole is, Bayh-Dole has set up a system that allows the university to license their technology and allows the companies that license that technology to still be competitive and go out and marry, right, the grant funded investment that went into the tech technology initially with the venture and other forms of private capital that take it from a university setting out into the marketplace. And I want to also underline... Joy is a tech transfer professional, I'm sure he can vouch for this. Tech Transfer Offices are not gift offices. Tech Transfer Offices are revenue generators. So they also are licensing their technology in a competitive environment and they're able to share in the company's success. So in my company, Ripple, for example, our agreement, which is standard, includes two components, equity and royalties.

Peter Falzon (00:36:50):

So the more successful Ripple is the more royalties we pay back to the University of Michigan, go right back into the whole research program. So it becomes a self-funding process. And then there is a small equity component. So when there's a unicorn that gets acquired for \$2 billion, it happened to one of the University of Michigan companies last year. The university is also a partial winner in that. So all of those components together, add up to the creation of an ecosystem that actually really works. And I'll just close by saying, in summary, right, there are three components that are required in order for a technology to become a successful company. And those are technologies that the university holds. Talents, so attracting people who have experience in business to come and run these companies and capital.

Peter Falzon (00:38:06):

And the Bayh-Dole Act has created the system that is actually the envy of the world. And has created really healthy ecosystems, the early ones out in Silicon valley in the Northeast quarter around Boston. And now, wherever there are large research institutions and sometimes not even that large research institutions, they become kind of the nexus for the creation of a small business ecosystem and protecting and celebrating what we've created, I think is really important. And therefore I really commend the work that this group is doing.

Joe Allen (00:39:00):

Well, thank you very much. We're going to bring everybody back in now and we're going to spend the rest of our time on a panel discussion. So if everybody can unmute themselves and let us see you again, that'd be great. And we actually had our first question from the audience, which is a perfect question, because they said, "Well, can you discuss some of the issues that are confronting Bayh-Dole?" And we wanted to start with this panel, which has done an excellent job talking about how the system works right now. And the emphasis is, which I hope you got is, predictability is essential for this system. And companies are taking a high risk. It's not a given that if you license the technology, you're going to walk out the door and make money. In fact, it's more likely you're going to walk out the door and lose money.

Joe Allen (00:39:44):

So let's start with the first question to the panel and getting back into the issues facing Bayh-Dole, "Opponents of Bayh-Dole have launched a full scale attack, seeking to have the law turned on its head so the government can march in to ensure prices of resulting products are, quote-unquote, reasonable. A completely undefined term, which runs counter to the statute that is not in Bayh-Dole, but people are trying to misread Bayh-Dole, to allow the government to have that power. While ostensibly aimed at drugs, if this genie were ever released from the bottle, any Bayh-Dole product would be subjected to claims that a price isn't reasonable. And the government could march in, so that rival companies could copy it. March-in petitions can be filled by anybody, your brother-in-law who hates you, other companies, or representatives of foreign governments."

Joe Allen (00:40:29):

"If this became how our system worked, what impact would it have on small companies? Would VCs still back startup companies developing high risk inventions? Would entrepreneurs see starting companies based on academic inventions as a good use of their time? And how would it impact academic patent licensing, which largely goes to small companies willing to take big risks?" So let me just throw that one out there and anybody on the panel that wants to weigh in, please do, but we want to get back into specific issues facing Bayh-Dole. And I think we can all say that's probably the most significant thing facing this right now. So somebody wants to kick it off?

John Stanford (00:41:09):

You or me, Karen? I'm happy to jump in.

Karen Kerrigan (00:41:12):

Go ahead, John.

John Stanford (00:41:15):

So I think it's a great question and that's actually one of the successes we kind of point to and this will be a little roundabout, but I promise I'll get there. A few years back, we had legislation that outwardly was antagonistic to our IP system calling for compulsory licensing over pricing. And that was largely beaten back on a bipartisan basis. And so you don't typically see... I think a lot of folks on both sides of the aisle respect IP. They respect what Bayh-Dole accomplished. They respect that IP is integral. It was in the Constitution. It is fundamentally an American take on entrepreneurship. So to the question of what specifically concerns us, you don't see too many more outward, direct attacks at our IP system out of Congress, or at least they tend to be fairly fringe legislation when they're introduced. A couple years ago that wasn't the case and a compulsory licensing bill had a lot of support and we had to really do a lot of education around that.

John Stanford (00:42:23):

What concerns us more, I would say, is executive action. I'm sure we'll talk more about the march-in rights proposal. We leaned in heavily and opposed the march-in based on price. It's not what the law said. It's not... And Joe knows this more than anyone. It's not what was meant at the time. And it causes a grave concern to the investment community. That just because we don't like the price of something, the government could step in and take it away. That would put a big question mark on our investment and ultimately either dry up the capital or drive up the cost of capital, neither of which work to the benefit of entrepreneurs.

John Stanford (00:43:07):

We are concerned too, in our global trading position, anywhere where we're seeing this administration or past administrations walk backwards away from IP commitments. We were concerned by the TRIPS waiver conversation that happened this year. But I think the question from the audience is: is there legislation that concerns us. Not on IP, specifically, because we haven't seen... Many of the legislation that concerns us purposely leaves IP out because they know that most Americans strongly, strongly support a strong IP system, but Karen I'll kick it over to you.

Karen Kerrigan (00:43:50):

Yeah. I'll only add, and I agreed basically, what John is saying. Only that some members of Congress are encouraging sort of the unraveling of Bayh-Dole using, I think, their bully pulpits to support the administration on march-in rights and sending letters and just being very strong in their advocacy, urging that. Look, the concern from a small business and from a startup perspective about the unraveling of Bayh-Dole and just the uncertainty that this would cause. And I remember a long time ago, I think it was Commerce Secretary, Don Evans. I was sitting with him talking about startups and capital and he's a former energy industry guy, but he said, "Capital is a coward." Which it is. And so, this just would create enormous uncertainty and for many entrepreneurs and startups, who have a difficult time as it is finding capital and streams of capital from VCs or other ways to fund their businesses.

Karen Kerrigan (00:45:18):

The unraveling of Bayh-Dole, and what that would do from an IP perspective would just be devastating. I think, for many of these startups in small businesses, the money would definitely go elsewhere. As Peter said, he's in competition with other sectors and other entrepreneurs. And so capital is mobile. It's cowardly and it's mobile. Will go to its best use. And for the future of U.S. innovation, particularly, where we have a density of brain power and great ideas and great collaboration at the university level, I just think about all the innovations that just would not come to be. And obviously that would just impact the U.S. economy, our innovative capacity, our competitiveness. And again, the Congress and the administration is very focused on competition policy, very focused on standing up against international competitors like China.

Karen Kerrigan (00:46:30):

And right now we have the big bill, right, where they're going to the House and Senate are going to come together and try to advance... What is the name of it now? It's the COMPETES and the... I'll just say the COMPETES Act, okay. That is, why, at the same time, are we doing something that undermines all of that? And we do have a successful framework for innovation. So, yes. So the uncertainty would, I think, cause massive capital flight away from where we're getting all these great, innovative ideas that in the end benefit workers, consumers, our economy, productivity, et cetera.

Joe Allen (00:47:17):

Okay. Joy or Peter? So Peter, you started a number of companies and the way march-in rights work right now, which is what we had in mind. The reason why they've never [crosstalk 00:47:30] been misused is that march-in rights are to make sure that you're making a diligent effort to bring the product to market. That's their purpose. And remember also, this alternative is being pushed by people that don't like Bayh-Dole and don't like patents, which should tell you something. Under their

construction, if you have commercialized a product you've taken all the risk, you've got the venture capital, you've beaten your opponents, you're actually out there selling something successfully. What they would like to do is say, "Anybody can file a petition..." After you've, all the way through the system and say, "We don't think your price is reasonable."

Joe Allen (00:48:14):

Now that term is not defined. So it would be defined by the bureaucracy on a case by case basis. If the bureaucracy said, "Hey, Peter, we don't think your price is reasonable either." They could force a University of Michigan or any other university to license your competitors so they could copy your product. So what would that do to these seven companies that are out there? What would that do to your interest in spending the rest of your life as an entrepreneur, if in fact, once you succeeded, anybody could say, "We don't like your price." That would be determined by the bureaucracy on an ad hoc basis. There's no formula for it. And that's how our system works. So, how would you function under a system like that?

Peter Falzon (00:48:51):

It's just such a very easy answer, as I wouldn't be able to raise capital, because I wouldn't be competitive. If I'm encumbered in a way that none of the other companies that are out there buying for the same funding dollars that I'm buying for are, then it's not a level playing field. So as an entrepreneur, fine, I can continue to be an entrepreneur. I would just choose assets that don't involve university licenses because they'd be toxic. And there's a direct impact on what gets funded, but there's just this snowball effect of... And one of the reasons I'm back here at the University of Michigan is because there is such a vibrant startup ecosystem because there are such great assets available in coming out of these universities.

Peter Falzon (00:49:45):

And there's actually a process to license them and commercialize them and hire people and create jobs and raise capital. My eight million dollars of capital, six million of it came from outside Michigan. So I'm also bringing capital into my state, right? So there's an economic development component of this. So there are just so many layers of benefits that stem from this legislation, which has been in place for 40 years, that if you just start taking it apart, the system falls apart at its core.

Joe Allen (00:50:24):

Joy, a lot of people imagine that universities have people just lined up down the street to license your technologies, that basically, you get to pick and choose. And you give them terms and they basically accept them and say, "Thank you, sir." And go out there and do what they need to do. So if in fact, the opponents succeed, that we turn Bayh-Dole on its head. And in fact, after you have commercialized something, after you've taken all the risk and all the expense, so if I can come in and say, "Hey, we don't like the price of this." And they could take it away. Joy. What would that do to your ability to license technologies, particularly, to small companies or even big companies? What would that do? Would that make the line outside your door bigger? Would it make it smaller? Would it have no impact? What would that do on your ability to license the technology for the University of Delaware?

Joy Goswami (00:51:10):

Well, the long and short of it is it's a simple answer. It'll be detrimental, period. And the reason why I say that is because when I heard Peter talk, I really wish we had lots of Peters knocking at the door of Tech Transfer Offices in Delaware. Who's already started six companies and... Sorry. Successfully made six companies and looking for the seventh and eighth and going forward. But the reality to the matter is that it isn't. And having said that when you look at the national statistics that most university Tech Transfer Offices throw their technologies for commercialization through the startup vehicle, which is 70% of what it is. The remaining 30, of course, being the established pre-existing companies that have already done it in the past. It only goes to show how much effort that university Tech Transfer Offices are putting into making sure that these startups are the best vehicle for this technology to eventually commercialize.

Joy Goswami (00:52:11):

So it's a very hard situation for us. And you have to realize that these technologies, and if you're talking about drugs, they really are what we call NCEs, Novel Chemical Entities that are at a really early stage, a patent has been filed in and around the family. We don't know which molecule is going to end up working. And it's very, very, very... And I don't know, I got infinite on the word, very, early stage for the start to eventually pick it up and take it all the way across. To see that one molecule being patented from our end and eventually hitting the success milestone, right, is actually in the hands of consumers or actually is serving as a therapeutic drug is a long journey. And obviously along with the length of the journey comes a lot of de-risking, a lot of effort and a lot of resources that initially the startup and then the company that eventually buys up this startup will have to end up taking.

Joy Goswami (00:53:12):

So from our perspective, we look at all these early stage companies, startup companies, to be basically companies that are trying to build their business model. They don't have any real structure in place yet. They have a team together and they're really scratching their head after seeing a molecule in its early stage to see what its end product would be and how much they will eventually end up paying multiple times of what their efforts have been. And again, I compliment Peter for being successful in the number that he eventually ended up becoming, but that's really not the national average. Obviously, many of them go belly up and the technology never ends up reaching the end of the tunnel. So when these startups eventually establish, they're trying to figure out the intellectual property.

Joy Goswami (00:54:07):

They're trying to perfect the product itself. They're trying to stay focused on critical goals. They're trying to balance their jobs, university and venture. Find the right partners, looking for early stage venture capital. So they have a lot of moving parts. And if you then throw in the uncertainty of their prices being micromanaged by somebody like a federal entity, you are again, throwing in another big variable that only would be, in my opinion, of detrimental impact to the commercialization of the technology. So again, long and short of it is, it will be detrimental in my personal opinion. And I think the way we are doing it only goes to show that we have been doing it successfully. And needless to say, other countries are also picking it up and then trying to simulate the activities and the way we are doing it. And for us to eventually continue to be a superpower in the innovative sector, I think we have to continue to do what we are doing rather than rock the boat and do something differently.

Joe Allen (00:55:11):

Thanks. John, before we leave march-in rights, a number of early stage investors joined you in sending a really powerful letter to Secretary Becerra, which HHS actually has a march-in petition pending right now. And you were urging him not to misuse march-in rights with price control. So why did you feel so strongly about writing that letter? And it was a very strong letter. Not much ambiguity left in that letter.

John Stanford (00:55:36):

Yeah. We wanted to send a really clear signal about what this does to the capital market. Karen put it eloquently, we are cowards and that's because we're stewards of other people's money. And we are prepared to shoulder great risk and great burden in terms of entrepreneurial training, but we can't shoulder price controls. And I think what most folks found so frustrating. So patient access, one of our leading prior, and we've offered a number of solutions to the Hill to address some patient access issues, because we feel very importantly that it is bench to bedside, and it can't get mucked up in between with middle men. But a lot of us asked ourselves, "What problem are we trying to solve here?" And it seems what march-in is being used now for today is an end run around another debate about our healthcare system and quite frankly, our broken health healthcare payer system. But because no one wants to tackle those critical issues, they're pushing the easy button and saying, "Well, what if we just march in and take the product?" Because where does it end?

John Stanford (00:56:56):

And eventually it means, and the reason we feel so strongly about this, is it means our return. That third leg that I described earlier, is no longer certain. If you add more risk, we brought seven leading VCs to Washington last September, and this is their phrasing that investment would fall off a cliff. And that is because we simply cannot stomach price controls in our system. And we feel like we've been really clear about that. And instead of having the debates in lights of day, what we hope the secretary would hear is these march-in petitions based on price have nothing to do with the Bayh-Dole Act, have nothing to do with the true authority for march-in provisions, as you laid out, but are an end run around a debate about a broken healthcare system and rising out of pocket costs. And so it was really frustrating to see this tool being used so inappropriately. And that's why our community felt very compelled to stand up.

Joe Allen (00:57:56):

Well, I think the other thing that people don't realize even in life sciences is, the U.S. life science system is driven by small companies. I mean, a lot of people don't think that, but 50% of our new drugs come from small companies, 70% of our biotech companies are either spin-outs or formed around an academic invention. So even life sciences, which people think is an outlier is driven by small companies. And that's why, again, if you misuse Bayh-Dole, trying to go after multinational corporations for whatever reason, you're not going to hit them as much as you're going to hit the people that are really driving our innovation. So let's move on from march-in rights, we have a couple other issues we want to talk about. And actually John alluded to this a little bit earlier in his opening statement. The Bayh-Dole system is based on having well established rules that have been maintained for more than 40 years. Creating confidence that universities and federal labs are reliable R&D partners.

Joe Allen (00:58:51):

It was that confidence which caused companies to rush into partnerships to fight COVID-19. And we developed the world's best vaccines in record time. Ironically, the administration, which came into office inheriting these vaccines moved almost immediately to side with other nations saying that they needed access to our patents and company know-how, even though that was not the reason more vaccines weren't being produced. If the government can change the rules after a company has done what was asked of it, to give away their technologies and their know-how, what impact, if any, does that have on our system? What does that do to the hard won trust that government funded organizations are reliable research partners? So I'll throw that out to anybody who cares to weigh in. And hopefully somebody does, so that would be good.

Karen Kerrigan (00:59:43):

Well, I guess, I'll just start on that one. Again, the problem... Well, you're talking about the TRIPS waiver, right? The TRIPS waiver, the WHO... The administration supported the petition before the WHO. And again, the issue was really... I mean, there are plenty of vaccines in the world. The problem is getting the vaccines, right. The distributional issues and then issues in certain countries where there is a lot of weariness about actually getting the vaccine just as there was in the US, a certain amount of weariness here among our population. So our concern is this, one, that the process itself was being really used by countries that really don't respect IP rights. And it was a way to get at our IP, again, for all the wrong reasons.

Karen Kerrigan (01:00:57):

And so where does that end just like march-in, right? Where does it end, where you have these petitions coming before the World Health Organization on a whole range of things, technologies, or what have you, products, services, et cetera. And then the uncertainty, again, in the US regarding intellectual property, and eating away at these IP rights and protections that have been foundational to innovation and to capital raising and all that, number one. And number two is the US really has been a leader in urging many, many other countries to protect private property rights, to protect IP rights. If you want investment to come into your country, if you want economic growth, if you want entrepreneurship, if you want innovation, there are certain things that you have to do in order to... A policy environment, that's going to encourage all that.

Karen Kerrigan (01:01:59):

And property rights and IP rights and protections are critical to that. And again, for many years our nation, our country through the State Department... I mean, I've been all over the world with the State Department, working with other countries on how to develop their economies and their innovative ecosystems. And IP rights and private property protections was one of those pieces along with other things. So now we're saying something different, right? And I think it harms our leadership... Well, definitely would harm economic leadership if something like that were to move forward. But also all the principles and what we've stood for, for many, many years in terms of helping to build economies based on... Market economies, based on certain principles and policies that are going to encourage those economies to develop, so. Anyway, I'm all over the place on that one, Joe, but that's sort of my very broad look at that issue.

Joe Allen (01:03:05):

John, I think you had some thoughts about that.

John Stanford (01:03:08):

Yeah, because this was another one that certainly the investment community jumped up on. And I think everything that Karen said is right, so I'll spare everyone repeating it. But it is a terrible sign to our trading partners that the US took this frankly, bizarre backward step on IP in the global sense. Designing policy in a crisis, especially, a healthcare crisis is not the time to design policy because it's almost impossible. I don't fault anyone for how do we get vaccines out to the world? What many of us said is, "IP isn't the barrier." And IP is a good boogeyman for some of the groups out there. But as we see now, we see India decreasing production of the vaccine. We see vaccines stockpiling. We see South Africa who drove the TRIPS waiver conversation, saying, "Stop sending us. We don't know what to do with this."

John Stanford (01:04:08):

And that's what many of us were saying a year, two years ago, "IP is not the barrier. Let's take the energy we're having in this debate and address the real barriers in the developing world and the developed world." That's for policymakers of the day. I live in a world where we're looking 10 years into the future and what incentives are we giving the Peters of the world? And what I found sort of so perverse about this, because COVID, it was juxtaposed against the developing world. Well, one of the exciting things about mRNA that was in the headlines right after the COVID vaccine came out, is a possible HIV vaccine, and they're working that through clinical trials. But what concerns me is what we said to the world is, "If you develop a product that's good for the developing world, that IP is up for debate. But if you develop an oncology product that is only going to be available in the very wealthy world because of how it's delivered to the patient, that IP is still sacred."

John Stanford (01:05:18):

And so in this twisted way, what we were saying is to investors, “Don’t invest in these things that the world really needs from the developing world population. If you develop a drug that is only available in America and Japan and the EU, we’re not going to come after the IP, but if you develop the HIV vaccine...” We know that folks will be lining up for the same, take the IP. And I worry about the dangerous, dangerous signal that sends to entrepreneurs, to investors and ultimately to those patient communities. And that’s why we were so concerned. And we were proud to see the European Union up and say that IP is unquestionable. We had a little bit of a role reversal there, and I give a lot of credit to the European Union for staying strong on that.

Joe Allen (01:06:06):

No, I think it’s like march-in rights. Again, they start with one premise, which is life sciences, but the same system would be applied to a breakthrough in clean technology or anything else. And the other thing people forget is mRNA, which is one of the basic drivers now is one of those overnight successes that took 30 years, including a professor at the University of Pennsylvania who was actually downgraded because she kept working on this when everybody else told her to give it up. And luckily she found another academic researcher who had found a way to make it applicable to humans. And even then it was two small companies that developed mRNA and Moderna made no income for a decade. So people forget that. They think it just sort of came out of Operation Warp Speed and it was easy to do. And there it is.

Joe Allen (01:06:53):

But when you give away a base technology like mRNA, you’re not just doing for COVID vaccines, you’re doing a platform for the whole life sciences, which is developed here under our Bayh-Dole system, through entrepreneurial academic researchers and small companies. So Joy or Peter, do you have anything you want to add to our discussion about the government giving away key technology? If you make something too important, the government may actually say, “Hey, you need to actually give that to everybody.”

Peter Falzon (01:07:21):

I think one thing to keep in mind is that when we’re running an early stage company, we’re licensing the technology globally and we’re building something that’s going to be marketed around the world. And so we see time and time again, challenges where we’re trying to adjust or balance public policy, health policy, global health policy with business policies. And it’s always a balancing act. And there are a lot of policy levers that governments and international agencies have to try and provide humanitarian access or get the job done. And time and time again... And we deal with different healthcare payer systems around the world, and sometimes the price of the products that we’re developing.

Peter Falzon (01:08:21):

If a device is regulated in Belgium and it’s not in France and it is in the Netherlands. And so it’s always complex, but there are certain things that are sacred and the ownership and the value of the IP is always one of those things that’s sacred. That, and the fact that we’re going to have to file financial statements and pay income taxes, wherever we’re operating. So I didn’t actually take it too seriously when I heard the threat, because I’ve heard it before. And I thought, “Well, it’s such an easy and catchy thing for someone in Congress to propose, but it won’t make it through the vetting process because we’ve been there before and we know that there are better ways to accomplish the policy aim at the end of the day.”

Joe Allen (01:09:21):

Well, let’s hope you’re right. Joy. Before we go on, do you want to add anything on this-

Joy Goswami (01:09:24):

Sure. And I think I echo all the speakers, everyone that eventually pitched on this aspect. I do want to generally mention the fact that what we are really trying to accomplish this year, again, I speak for academic tech transfer offices here is to eventually try and commercialize innovations based on the least amount of uncertainty. The more uncertainty you add into the pipeline, the more it is going to be detrimental to an innovator trying to innovate technologies, and then finally commercialize it. And throwing all these policies could have a big impact and what it, eventually, also kind of puts in play is the precedence that it sets. I totally agree with the fact that this was a waiver that was being proposed during a global pandemic. Maybe it would never happen in the next 100, 200 or maybe a 1000 years. I hope it doesn’t.

Joy Goswami (01:10:20):

But once it sets the precedent, there are other countries that are going to try to pull this string. And it’s only when that happens, it becomes an active debate. And you start questioning that if you’re done it one time, why don’t you do it again and

again and again? And so that's throwing in more uncertainty. So, my general belief was that I think what happened at the end of the day was good and hopefully we'll have the pandemic gone across the face of this earth very soon. And so everything should be level playing field again.

Joe Allen (01:10:49):

And I-

Karen Kerrigan (01:10:49):

Can I just say one quick thing, if you don't mind.

Joe Allen (01:10:55):

Sure.

Karen Kerrigan (01:10:57):

Just one other thing I'd like to add is, for years now, that we've been working on some of these trade agreements and trade accords with other countries is we've been very strong proponents... And as John has the intellectual property pieces and components in chapters of some of these newer agreements, this has been a big victory particularly for small innovative firms. Because if you are doing business globally and someone rips off your stuff overseas, obviously it's very costly, very complex. I mean, we won't go into that whole debate. But the bottom line is that, again, the U.S. is leading on some of these IP agreements and protections and trade agreements, but then supporting this petition is just... The mixed message that it was sending was just undercutting, I think, everything that we say we have believed in terms of intellectual property and what we're trying to get the rest of the world to also honor, and to value and to do something in those countries where there's a lot of problems.

Joe Allen (01:12:06):

Great. Let's go on to another issue because our first question was, what are the issues pending? I think we've hit two pretty big ones. "A foundation of Bayh-Dole is that the roles of the game are clearly established and then the government gets out of the way, so the innovation process can work. But some reimposed federal micromanagement, which strangled tech transfer for Bayh-Dole. If agencies can impose arbitrary requirements and licensing agreements not sanctioned under the law, what does that do to our system? And what does that do to predictability?" We won't mention any agencies, but just say some or at least one.

Karen Kerrigan (01:12:43):

Yeah. Maybe Joy can talk about having these people breathing down his back and the red tape and the regulations. I think he'd be the sort of the first line of attack there, so.

Joy Goswami (01:12:54):

That's good. So the mechanism that obviously all these innovations eventually get handed over to a potential startup or an existing company's licenses. And we have these licensed deals that are created between the academic institutions that have developed the technology and have filed patents. And of course got ownership based on Bayh-Dole. And these licenses are always the most tricky documents because there are... I don't know. You can just think of any number of ways you can construct a license and you can, so consummating these licenses is really tough. And when it gets to actually getting a sense of how best to pass this technology on from the university to the commercial entity, that's going to eventually put the technology in the pipeline, all kinds of acts come into play. And two major ones, of course, are the university policy itself.

Joy Goswami (01:13:52):

So every university is built differently. Stanford doesn't work the same as Ball State University, for instance. So, the policies of universities vary depending on what kind of university they are, private, land grant, public, so on and so forth. And then of course the financial terms that go in and the kind of model under which that the transfer offices are operating. And obviously, so there are a lot of moving parts, even instructing the license agreement. So that itself builds in a lot of uncertainty to a potential startup. So when we have companies come and ask for the technology, the thing that they're really leery of is who's going to negotiate the license agreement and what terms would the license agreement have? And at this point in time, of course, if you worked in a university system like myself, for a reasonable amount of time. You know the culture of the university, and you can try and get something that is going to be approved and applied, and hopefully in a congenial way, sort of passed on in a collaborative way between the university and the company, but that all doesn't always happen by the way.

Joy Goswami (01:15:04):

So it does happen where your university proposes a license to a startup, and the startup is just not capable of taking it because they don't have either the bandwidth to take it on, or there's certain clauses in the license that don't go very well. And so if that

happens, obviously, the technology is sitting back in the university and may as well die on the vine. We don't want to do that. So what we are trying to do, in due course, is try and attribute the license and then give it on to the company in the best format possible, where it's a win-win for both these entities. Which in and of itself is tough and now, again, throwing in yet another variable where the granting agency has imposed certain policies that need to be mandatory in the license agreement. Again, just through wasn't yet another caveat to this whole process. So I personally wouldn't be in support of this.

Joe Allen (01:16:01):

Well, yeah. Basically, the Bayh-Dole Act was a uniform patent policy across all federal agencies. Before Bayh-Dole, there were like 28 different policies, so we don't want to devolve back into that system. We don't need to beat this one over the head, but agencies don't have the power to make up their own policies and put them into their funding agreements and make the universities either take it or leave the funding. So we have one more question here, and then we'll close things out. And this is, I think, an appropriate one for World IP Day. Professor Jonathan Barnett shows in the big tech patents and innovation economy, the U.S. patenting rates were declining between 1950 and 1980, which is the Bayh-Dole past. However, after the passage of Bayh-Dole and the creation of the Court of Appeal for the Federal Circuit, which restored our faith in the patent system, the number of U.S. patents skyrocketed.

Joe Allen (01:16:55):

He also shows that since Bayh-Dole, the percentage of private sector R&D performed by small companies increased by 400%. It was 5% before Bayh-Dole, but done by small companies. We've talked about the importance of Bayh-Dole, but how important is it to small companies to have a reliable patent system? And how would you rate small business competence in the patent system today? So does anybody want to take a shot at that one?

John Stanford (01:17:21):

I think Karen will be, by far, the best... I'll take a brief... The statistic you laid out to go back to the previous question is the answer. We've seen how this works without this framework in place. It didn't work. We put this framework in place and we saw 400%. And so if this question is sort of, what would small business owners do, if patents weren't reliable? I think it's very clear, history repeats itself. So this is one of the ones that's always a head scratcher to me. We had a perfect experiment, the US coming out of World War II, terribly innovative, not terribly entrepreneurial. We see Bayh-Dole and we see this just as a drive for intellectual property based entrepreneurship. But Karen, maybe I can kick it over to you about how small businesses feel about the patent world today.

Karen Kerrigan (01:18:24):

Well, I think, generally, in terms of the first part of the question, Joe, it's all about economics 101 and it's just amazing... I mean, that percentage to me is just really off the charts and just demonstrating the amount of pent-up or latent innovation that exists in the country and particularly in the university system where you do have this density of ideas and brain power and people who are all there, working on... I mean, that have the potential to work on great innovations for our economy. So again, it just speaks to the power and the success of Bayh-Dole and you want more of that and we should be looking at ways to strengthen the system rather than undermining it.

Karen Kerrigan (01:19:27):

I would say now with the patent system, generally... I mean, we can get into the weeds on that. I don't think we want to, but generally in terms of the certainty and in terms of the system, I think that startups and entrepreneurs and small businesses will say, "It has gotten better. It has gotten less complex." I mean, there's been efforts over the years to make it less costly, which is all good. I mean, certainly there's always room for improvement, but certainly far, far better than what it used to be. And I think efforts over the years have only served to improve the experience and navigating through the system. And again, if you look at our economy and all the innovations and... I mean, it's working.

Karen Kerrigan (01:20:25):

And so again, we have to strengthen what's working and sort of get away from some of these ideas and proposals that will just undermine all the success that we have. Again, particularly, now in terms of where we are in the global economy, what we need to be doing as a country, how we need to recover from pandemic and just the great potential that lies ahead given this acceleration to the digital economy, telehealth... I mean, there's so many... The 5G. I mean, there's so many neat things that are coming online and America should be leading in all these innovative areas, so.

Joe Allen (01:21:09):

Peter, as our entrepreneur in residence today, do you have any thoughts about the patent system and how important it is-

Peter Falzon (01:21:17):

I do, but I've quite been working in the context of the current patent system for 25 years. And what I have seen are great steps forward in terms of harmonization of our patent system and rules and procedures with Japan and the European Union. So if you're running a global business, the number of years and the way that the patent protection system works is starting to make sense across the wider international market. And those improvements have helped business for the same reason everybody keeps repeating here, is that it simplifies things and it allows us to rely on a set of rules that we understand and not have to spend an inordinate amount of time navigating patent potholes, and instead focus on our competition and technology development.

Joe Allen (01:22:28):

You're very good. Listen, before we close this, anybody have any final comments they want to make about anything we've covered today or anything we might have missed? Well, I don't hear any. And I think this has been a great discussion, we actually covered all the points I wanted to get through and you hit it right on time, which is always a sign of a veteran panel. So before we close, I want to thank Max Bodach, who did great work in putting our logistics together, making us look good. Luckily having everything run like clockwork and also Emily Troisi and David White for their putting together and publicizing our program. And I want to thank you for joining us and hope you go out and celebrate World IP Day. So thanks again. We appreciate all of our panel. Thank you for your time, and we'll see you down the road. Okay. That's it.

Karen Kerrigan (01:23:17):

Thank you.

Joy Goswami (01:23:17):

Thank you.

Karen Kerrigan (01:23:19):

[crosstalk 01:23:19] Take care.

Joe Allen (01:23:19):

[crosstalk 01:23:19] Thank you.