Unleashing America's Entrepreneurs: The Bayh-Dole Formula for Economic Prosperity



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

Hi, I'm Joe Allen, the Executive Director of the Bayh-Dole Coalition, and we thank you very much for joining us today in our webinar called "Unleashing America's Entrepreneurs: The Bayh-Dole Formula for Economic Prosperity." I don't think it'll be any surprise to anybody on this webinar, and we actually have some folks internationally, but the United States has just come through a pretty contentious election and there was a lot of things that the parties disagreed about. But one thing that everyone agrees on is we need to grow our economy, we need to broaden our domestic manufacturing base, and we need to confront a very serious threat posed by China to the world order. So luckily, we have a secret weapon to meet all three of those challenges: The Bayh-Dole Act brings together the best and brightest minds in our public and private sectors to transform federally funded research into useful products that improve lives both here and abroad.

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And unlike other policies being floated about, Bayh-Dole doesn't cost anything additionally and doesn't create any new bureaucracy. All it needs is to be appreciated and protected. So we have four really distinguished experts to talk about these issues. What I'll do is I'll introduce them, then I'll ask them to make a brief statement, and then we're going to go into questions and answers. Also, we're going to take questions from the audience, so you have a Q&A button at the bottom of the screen. Just fill a question out, send it in, and we'll get to as many of those as we possibly can. So we want to make this interactive, and again, we really appreciate everyone giving us some time this afternoon. Our first panelist is Almesha Campbell. Almesha is Assistant Vice President for Research and Economic Development at Jackson State University. Previously, Almesha served as a director of technology and commercialization and continues to manage intellectual property there. She was also the chair of the AUTM Board of Directors.

(00:01:50):

Walter Copan is the Vice President for Research and Technology Transfer at the Colorado School of Mines. He also served in the first Trump administration as the undersecretary of Commerce and Director of the National Institute of Standards and Technology, where he actually oversaw the implementation of the Bayh-Dole Act. Walt also received the highly prestigious 2022 Baldridge Foundation Award for Leadership Excellence in government. Brian Darmody is the CEO of the Association of University Research Parks. Previously Brian served as the University of Maryland's Assistant Vice Chancellor for Research and Development and also was the director of State and Federal Relations. He's on the board of the Maryland Technology Corporation Venture Board. And Franck Journoud is the Senior Director of Technology Policy at the National Association of Manufacturers, where he leads its policy development and advocacy on all issues related to technology, including immigration and intellectual property. Before joining NAM, Franck was the Vice President for Federal Relations and Technology Policy at the Motion Picture Association. So we really have a great panel, and what we want to do is I'll ask Almesha to kick things off. So Almesha, if you don't mind, it's all yours.

Almesha Campbell (00:03:04):

Thank you, Joe, and thank you so much for having me on this panel and with my great colleagues here, of course. Thank you for all the work that you're doing with the Bayh-Dole Coalition. Such a very important initiative. So as you know, the Bayh-Dole Act of 1980 has transformed the innovation landscape by allowing universities, including Historically Black College and Universities such as Jackson State University, to attain ownership of inventions developed with federal funding. This pivotal legislation has catalyzed economic growth, empowered entrepreneurship, and bolstered the commercialization of groundbreaking research. By bridging academia and industry, the Bayh-Dole Act has positioned higher education institutions as engines of innovation and economic vitality. My perspective as an HBCU administrator is that the Bayh-Dole framework represents a unique opportunity to elevate the role of HBCUs in the national innovation ecosystem. These institutions often underrepresented in research funding and tech transfer, can leverage the Act to amplify their contributions to entrepreneurship, diversify the innovation pipeline, and promote economic development in historically marginalized communities. Our role, an HBCU leader might say, is not only to create knowledge, but to ensure that this knowledge transforms lives and economics, particularly in underserved regions. As we explore the intersection of entrepreneurship, public policy and economic prosperity, the Bayh-Dole Act exemplifies the power of equitable innovation. It calls for collective commitment to fostering an inclusive ecosystem where institutions like HBCUs, minority-serving institutions and tribal colleges have the tools and resources to thrive in the nation's entrepreneurial future. This is why this Act is so important to me and to others. Thank you, Joe.

Joseph P. Allen (00:05:02):

That was great. Thank you very much. Walt, can I ask you to go next?

Walter Copan (00:05:07):

Thank you so much and greetings everyone. It's a real pleasure to be with you. And also as the former director of the National Institute of Standards and Technology that has regulatory oversight for the Bayh-Dole Act, it's a real privilege to be thinking about where next for U.S. innovation. While I was NIST director, one of the initiatives that I had the privilege to lead is one that we called Renewing American Innovation and "Unleashing American Innovation," indeed. And that resulted in a broader nationwide conversation about the innovation ecosystem of our country, what's working and what can be enhanced. One of the bedrocks that was identified for U.S. innovation, and whose core needs to be protected and preserved and built upon, is the Bayh-Dole Act of 1980. It was transformational for the United States at that time when the United States was facing unprecedented competition internationally and especially from Japan.

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And it was a recognition, also, that the public and private sectors need to work together to leverage discoveries that ultimately could have economic impact for the nation, enhancing job creation, enhancing manufacturing, deployment onshore, and also enhancing national security in its linkage with economic security for the United States. Since 1980, a lot of things have changed. We have certainly seen a tremendous positive benefit from the Bayh-Dole Act that's applied not only by the nation's universities but also our research institutes that have some degree of public funding. It also applies to small companies that may be eligible for utilization of public funds to leverage their discoveries and to take them from the laboratory into the commercial marketplace. The other things that have changed in addition to the major impacts on the economy has been the ascendance of China. And the role of the United States is certainly being challenged within this revised world order with China ascendant, with China, building a much stronger research and educational enterprise and, of course, having both learned from as well as having stolen from the United States and from other nations.

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So the importance of intellectual property protections that are enshrined in the Bayh-Dole Act — and also going back to the foundation of the United States, enshrined in the U.S. Constitution, are absolutely part of the bedrock that the Bayh-Dole Act represents for the nation: the security of intellectual property rights that enable investors to go forward and to understand clearly the business, the technology, the regulatory risks of a new enterprise. But the last thing that we should see is that these companies so often are founded principally on the value of the invention. And so relying upon a system of law that protects that invention without ambiguity is absolutely core to any innovation economy and is certainly core to the U.S. Bayh-Dole Act. The United States government has a critical role to play with respect to basic research, discovery research that is long-term that corporations really cannot see a return on their investment in pursuing. Because these are discoveries that, in many cases, take decades to advance into something that even has a remote commercial opportunity behind it.

(00:09:26):

During the Covid era, we certainly saw the leverage of government-funded research with the discovery, but ultimately the practical deployment of Messenger RNA-based vaccine strategies. While I was serving as NIST director, I was privileged to be a co-leader of the National Quantum Initiative, and Quantum Science and technology also. Many, many decades of investment in the United States and abroad, but is now leading to an important engine of economic development that brings basic discovery research in a way that's really intertwined with economic opportunity, but also with national security implications. We also are in a time in our current administration and also within the United States where there has been concern about the cost of goods and services. And there have been proposals made, including one that came from my former agency, a framework for interpretation of what's called march-in rights — so the government being able to step in to a commercial license for a technology that arose from federal funding and then to change those terms and conditions with a licensee.

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The original goal of Birch Bayh and Bob Dole, the really bipartisan leaders of the Bayh-Dole Act, was to provide great clarity around intellectual property rights and when march in could be utilized. And their goal was certainly to ensure that pricing was not a consideration of when the march-in right would be exercised. And we've had, unfortunately, over the past years, several misguided attempts to utilize march-in rights and to advocate for march-in rights on the basis of the price of products like drugs. The Senators made it very clear that was not the intent of the Bayh-Dole Act. The government should not be in the business of price control by controlling intellectual property, but we are in a free market economy. And enabling, then, other regulatory tools to deal with the pricing matters was absolutely core to our democracy and the way in which our economic system works.

(00:12:10):

So I'm sure we'll be discussing further in this webinar the implications of the misuse of march-in rights. But let me just wrap up my comments by saying that Bayh-Dole is proven as a brilliant legislative stroke for the United States to advance our economic competitiveness, our national security, and to enable public-private partnerships and bringing private sector investment to take the fruits of the inventive spirit of the United States, our research base, and ultimately to convert that into new enterprises worthy of downstream investment to create jobs and to contribute to the vibrancy of our U.S. economy with job creation, with advanced manufacturing deployment opportunities, and ultimately to reduce regulatory burdens so that we can achieve innovation at speed and scale. And I'm excited about the opportunities within also our incoming administration to look at how the United States continues to lead the world in our innovation ecosystem strength. Thanks.

Joseph P. Allen (00:13:24):

Well, thank you very much. Brian, could I ask you to go next?

Brian Darmody (00:13:26):

Yes, thanks Joe. Brian Darmody. I'm just to correct the record, I'm Chief Strategy Officer for AURP. We are the Association of University Research Parks. We are a nonprofit membership organization of research parks and innovation districts across 46 states. Our headquarters, it happens to be at the University of Arizona Research Park, but I operate out of our DC region headquarters at the University of Maryland Discovery District in College Park, Maryland. So you're probably familiar with many of our famous members like Stanford Research Park, the world's first research park, Research Triangle Park in North Carolina, University City Science Center in Philadelphia. But as mentioned, we have members across the country, places like Madison, Wisconsin, Lincoln, Nebraska, Baton Rouge, Brookings, South Dakota, Fargo, North Dakota, and other places in urban, suburban and rural areas. And these all are areas of innovation and entrepreneurship. And university tech transfer offices and incubator facilities are often part of these research parks, because this is where the companies can grow using the kind of resources that both the university and the innovation district provide.

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That's why preserving Bayh-Dole is important to our members. I want to give you two examples because I worked at the University of Maryland for over 30 years, and I launched our tech transfer commercialization office. So I know the opportunities and challenges of taking IP from federal research to create companies. So one example, and I'm glad Walt just spoke, is IonQ. It's a quantum computing publicly traded spin-out based on IP that currently, I just looked this up, has a market cap of nearly \$8 billion. So it's the first publicly traded quantum computing company, and it was based on IP started a long time, actually jointly with NIST and the University of Maryland. So these things are not flash in the pan. This takes a lot of time and effort, 20 years of fundamental research. But thanks to some investors who saw this, IonQ is now this publicly traded company, but at one point it was just interesting research.

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So the private sector invested in it. And by the way, IonQ needs to protect itself and it now has over, or nearly

600 patents. So you can understand the importance of patents in protecting other countries from encroaching on things like quantum computing — because I can tell you, Walt knows this, around the world countries are spending billions and billions of dollars on quantum computing because it's both an opportunity and a threat to decrypt a lot of technology. So it's housed in a former surplus warehouse. It's not impressive, but what's going on inside? And again, to show you the power of being in an innovation district next to it, the university's building a 750 person graduate housing complex. And next to that is the University of Maryland's computer science program, which by the way is the country's largest computer science program. So you can see if you're a company, where would you rather be than next to graduate students in a large computer science department?

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And that story could be replicated across the country at our research parks. So I want to give one other story. It's another Ion, it's called Ion Storage. In this case they are manufacturing solid-state batteries, batteries that can't catch fire. And they also were based on IP. This was funded by the Department of Energy, and they are now manufacturing solid-state batteries in a place called Beltsville north of the University of Maryland, just a couple, mile or two up the road. And they're in a 20,000 square foot building that is not just doing research but actually manufacturing these solid-state batteries, which are world-class and customers like NASA, the Department of Defense, automotive companies, are buying them. So, because we are within the University of Maryland, literally within the beltway, but you can see examples of what's happening with Bayh-Dole. I invite anybody who wants to come out from the hill or whatever to see a research park in action. And it's these kinds of things that are happening across the country among our 46 members across the U.S. And if we had march-in rights, that would definitely mess up this system — that takes a lot of certainty — and I would say that the march-in rights would create a lot of uncertainty. And you wouldn't have an \$8 billion quantum computing company or you wouldn't have a manufacture of solid-state batteries, safe solid-state batteries taking place in the state of Maryland if we had march-in rights.

Joseph P. Allen (00:18:34):

Well, Brian, thank you very much. Franck, If we can get your perspective, we'd appreciate it.

Franck Journoud (00:18:38):

Sure, happy to. Thanks, Joe, for having me on this panel. So let me for context before I go into R&D and specifically the Bayh-Dole Act to give you an idea of what the manufacturing industry looks like and why R&D is so important to us. So manufacturing in the U.S. is 13 million men and women who, as we like to say, "make things in America." You find them in small, medium and very large global giant companies. Manufacturing — it's autos, pharma, high-tech construction materials and sort of everything in between — it's basically, when you look around you, if it's not a cloud, if it's not a tree, it was made by a manufacturer. And one thing that I often point out when I go to the Hill is that you find manufacturing in every single congressional district in the U.S. and I say that, to say, as a way of communicating that manufacturing is really integral to the fabric of the economy and of communities throughout the nation.

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So that's manufacturing for you. The importance of R&D and innovation to manufacturing: it's really essential. So one thing that people rarely know that I didn't know before I came to the NAM is manufacturing in the U.S. performs almost 53% of all private sector R&D. So to give you an idea, we're about 10% of GDP, but we do more than 50% of the R&D, so it means we're significantly more R&D and innovation-dependent than the rest of the economy. And so that's why we care. That's why I'm here today on this webinar. To give you an idea in absolute numbers, in 2000, manufacturing R&D was just over \$130 billion. That's in 2000. Last year we had reached a record of more than \$400, almost \$405 billion. So those are not trivial numbers. The reason why the Bayh-Dole Act and, generally, public-private R&D partnerships are important, essential, to the manufacturing industry is, [it's] important for all manufacturers, small, medium or large, and across all sort of manufacturing sectors.

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But I want, in particular, to emphasize smaller and medium-sized manufacturers. So for context, 93% of

manufacturers have fewer than a hundred employees. And when you're a small or medium-sized company — not that R&D investment is a trivial proposition for any company because it's particularly speculative, it's potentially a very costly investment — but so those speculative and costly and yet essential investments, they're even harder to justify to shoulder for small and medium-sized companies. And so being able to turn to partners in particular government-funded partners, universities, to be able to leverage, to partner with them to leverage and commercialize their innovation is really, really important for manufacturers, in particular smaller and medium-sized manufacturers.

(00:22:10):

So that's why, just as our members partner with particular local universities and local educational institutions on developing their workforce and training their workforce, they also partner with them for innovation and to commercialize those innovations. And so that's really why we are here today. I'll say a couple of things to build on what others said about what was proposed as guidance by NIST on march in, in particular, on how to account for pricing in the decision by an agency to march in. So as you may be able to hear in my voice, I have a slight accent because — well, I like to think my accent is slight, but it might be bigger than I thought — because I'm originally not from the U.S. I'm originally from France, and before I came to the U.S., I already knew about the Bayh-Dole Act, not just because I'm a policy geek, but because it is known throughout the world as not just brilliant piece of legislation, but one that is really one of the central and most unique to United States, or was unique to United States, policy mechanisms that supports and fuels America's innovation economy.

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I knew about it because the groups that I was working for would come to the U.S. and say, well, how do you have such a brilliant innovation economy? And one of the couple of reasons that we always heard of was Bayh-Dole, the partnerships bring academia closer to the world of business so that the latter leverages the innovations of the former, commercializes them, et cetera. And so that's why it was so almost bizarre to me to hear that four years later, we're thinking, oh, actually maybe we should go back on that sort of brilliant piece of legislation and strike at the heart of its logic. And let me say why I think it would really have struck at the heart of the logic of Bayh-Dole is, Before Bayh-Dole, we don't have to speculate about what a world without Bayh-Dole looks like. We know what it was like before 1980.

(00:24:37):

You had all of this investment, federal investment in R&D, that was basically just collecting dust on shelves. We had these fancy-looking patents that would be hung on walls, but that would never make into products. The reason why is there was this terrible expression that was used: "Those funds are contaminated," "That R&D is contaminated by federal funding." And so you don't know you can get a license, but you don't know that that license is not going to be exclusive. And so you kick the tires into how to turn that innovation into a natural product, how to do more innovation to complement it, and how to then figure out how to produce, how to distribute, how to market, and how to price that innovation into a product. And then a competitor's going to swoop in and say, oh, thanks for figuring it all out, and I'll get a license too and then I'll replicate your success.

(00:25:34):

That is just, it's a non-starter for an entrepreneur. So that's really one thing and that's why it bears repeating that price was not one of the criteria, explicitly rejected as a criteria, that would've been included in the original Bayh-Dole Act. And so that's why we thought that it wasn't just a bad policy idea, but one that was a departure from the clear letter of the Bayh-Dole Act And last thing, pricing is very complex. Figuring out how to price a product, it's not just of the original R&D, but all of the money that you've invested in further developing the product, in setting up your production, what are your distribution and marketing costs, et cetera, et cetera. That's why recently the Centers for Medicare & Medicaid Services had to hire dozens and dozens of economists to figure out how to, it's been described as negotiation on drug prices, but in fact those weren't negotiations.

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It was more of a unilateral decision by CMS on that they would require that certain drugs be sold at certain prices,

at least to federal agencies, and they had to hire dozens of economists. And I don't see any government agency if this NIST guidance had been finalized, adopted, no government agency would've hired dozens and dozens of economists. So how would've they gone about double, second-guessing the pricing decisions made by this or that company, whether manufacturer or not, in pricing a product that incorporates a federally-funded innovation. And so that also was kind of disturbing. But anyway, I'll stop here Joe, and I'm happy to go further in the Q&A.

Joseph P. Allen (00:27:28):

Well, we couldn't have had a better kickoff. I think you guys have raised some — and "guys" meaning also Almesha — you all have raised some great points. And let's just have, I want to follow up on those. Also, again, if you have questions from our attendees, just type them in the Q&A box and we'll be happy to get to those. Just building on a couple of points you made, I think one thing we should point out is: Bayh-Dole is one of the first statutes that emphasized domestic manufacturing. So that was a, I remember, and I was on Birch Bayh's staff, we put that in there. People were like, why do you care about that? That was one of the first there. And the other thing is our system is, I think probably the only system in the world, that's driven by small companies, particularly startup companies.

(00:28:09):

So lemme just ask a general question for you all to comment on. And again, the premise of Bayh-Dole, and this is again different than the approach of other countries, is decentralizing technology management out of Washington and giving it into the hands of those actually making federally-funded inventions either at universities, federal laboratories or companies, particularly small companies, and providing them the authorities and the incentives and getting the bureaucracy out of the way. So how important is that basic concept as far as why the United States is by far the most innovative country in the world? Or is it important? Could you do the same thing if you had top-down management as we had before 1980?

Walter Copan (00:28:50):

Let me jump in on that and it's a wonderful question, Joe. Going back to the founding of the nation, our intellectual property system first and foremost was one that supported the small guy, the small entrepreneur. The founders of this nation realized that the process that was in place by the crown of Great Britain favored the large established players to be able to demonstrate certain types of technology and to be in a favored position to do so, to be granted letters patent. In the United States, it was all about how do we, in the American frontier, "how do we actually create inventions and leverage them from home and abroad?" as the language of George Washington's first State of the Union address reads. It's absolutely intended to support the small guy and the entrepreneurial startup. And ultimately, the genius of the Bayh-Dole Act was to recognize that it's the local connectivity, it's the institutions and their local innovation ecosystems that really matter.

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These are the ones who understand the invention. In many cases, we consider the faculty, the students, the postdocs working on a technology as vectors to take the idea into the commercial marketplace and to be part of a new startup. Washington can't do that. And as we look at companies — and I really appreciate Brian's example of Ion Q, so that's a company that I engaged with while I was still NISTdirector — and it's a great example of a regional ecosystem, federal laboratory, university startup company working together, finding partnerships, but also building this on intellectual property. So these people who are passionate about the idea can actually, with reliability, move forward with an investment scheme. And as Franck was saying, without that reliability, the market valuation of these companies would never be achieved because it's all about the power of the idea — in addition to the protections that are afforded and all the other criteria that are important to investing in an early-stage company that may grow to scale, may wind up becoming an acquisition target, may become the seed corn of many new opportunities through a platform technology to benefit many organizations, many people and many corporations across the United States and also abroad.

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A key element here also is the strength of the U.S. intellectual property system and its reliability with our international partners and competitors. And so as we look at the ability to protect our intellectual property here in

the U.S. and also abroad, these rights enable then the small company to do business with the giants of industry and with global multinationals. And to take that seed corn that may have been a professor's idea and catapult it into a world scale operation.

Brian Darmody (00:32:27):

And to follow up with what Walt said — Brian Darmody here — yeah, both Ion Q that we talked about and Ion Storage, they both qualify for small SBIR grants. So this \$8 billion market cap — it started as a small business. Every business starts small. And then they can grow if they're lucky and they have the right market acceptance. So making sure we continue to have the kind of support for small businesses like the SBIR program, which I think is a fantastic program that's supported on both sides of the aisle, is one of the things that we should be focusing on, and frankly not march-in rights.

Joseph P. Allen (00:33:09):

Almesha, how important is it for you as you're managing technologies in Jackson, Mississippi? Do you know more about your inventions or could somebody from the federal government in Washington manage those just as well as you're doing?

Almesha Campbell (00:33:22):

That's a good question. No, of course I would understand it more. I'm here on the ground. But one of the things I want to add is that this Act incentivizes our faculty to continue doing research to translate the research into the market. It really gives you that edge where you can see the competitiveness in America based on this research and based on the inventions coming out of those research. But not only that, it has helped bolster the industry-university partnerships that work together to increase American competitiveness. So that's why it's so important for us to engage in this space. That's why decentralization is so important as well, because more players — smaller players, large players — can engage in the system and can move it faster than the government can.

Joseph P. Allen (00:34:08):

And one thing we saw with Washington management is when we have industrial policy, no one's looking at Jackson State, no one's looking at South Dakota. They're looking at the coast, they're looking at where they went to school, the people they know. No one would ever, no one imagined when we passed Bayh-Dole that Salt Lake City, Utah would become a center of the life sciences. And that only happened because somebody there, just like Almesha and Brian and Walt and Franck, understood the technology and had to do the hard work of finding a commercial partner. So this is not the flyover states now, as Brian said, are very, very much involved in our competitiveness, which they were not really before Bayh-Dole. Franck, did you want to add anything to that before we go onto the next question?

Franck Journoud (00:34:53):

No, I think it's right. I just want to reiterate that is, when this or that governor or economic development office in this or that state thinks, oh yeah, we should support the development of this lab at whatever university we have — It isn't just because it's great and it's prestigious to have this lab, and the researchers may be well compensated, so we want to have that in our state, is they always thinking about "how do I build an ecosystem around that?" So let's give incentives for companies to set themselves up in this kind of research and industry park around it, and how do we create, what does it look like relative to the economic activity that we already have? And how can we leverage that and build upon that? So, this is all very local, extremely localized decisions that have to be made about how to develop a region, a county, a city economically.

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And it's all extremely sort of speculative. I mean it's pretty famous in the world of biopharmaceutical research, but it's true in actually all of the areas of research that most of the money ends up being a waste. You spend millions, billions of dollars, years, decades sometimes, and it's a lot of dead ends. And you never quite know which of these avenues is, in fact, not going to be a dead end and is going to lead to a product, and a product maybe changes the world. And so that is why it's important to be extremely flexible and have those decisions made as close as possible to the action rather than that far away.

Joseph P. Allen (00:36:45):

Well listen, building on that, and also one thing that Brian said in his opening statement, you're talking about the importance of patents and private sector investment. A lot of critics have Bayh-Dole claim that these partnerships are just a giveaway of taxpayer-funded research to private companies who then just come in, bubble wrap them and make enormous profits and charge whatever they want to at public expense. So are companies' licensing of federally-funded invention — are they taking much of a risk in doing that? And if the project dies in the development pipeline, does the company take the hit or the government?

Franck Journoud (00:37:19):

Let me jump in here and I'm going to try not to sound too angry, but...

Joseph P. Allen (00:37:25):

You can sound angry if you want. This is all friends. You can sound angry if you want to.

Franck Journoud (00:37:27):

I think there's a couple of things that just do not make sense that are worth pointing out here. First, even if you accept the premise that, oh, the company's just going to rake in the big bucks — let's set that aside, that sort of ideological logic for a second — is go back to before Bayh-Dole. Well, I guess no one was raking any sort of benefits, was profiting from anything. It was just as I said, fancy-looking patent certificates that were hanging on walls, but it didn't lead to any products, whether there were pharmaceutical products or IT or whatever it is. So at least right now we have innovation that is great for the pursuit of knowledge being also translated into actual products that create economic activity, jobs potentially change the way we live, et cetera. So that's one thing. But the second thing is I wish it were that simple that like, oh look, there's this patent.

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They came up with this new molecule, this new material, whatever it is, I'm just going to turn that and I'm going to put it in my factory and by Monday we'll have a product on the shelves here and I'll rake in the billions. It actually is vastly more complicated, vastly more expensive and vastly more risky commercially. Because generally you take that one invention, you have to supplement it with a bunch of other R&D developing other molecules or whatever it is. So generally it's not just one patent, you're going to have to develop a bunch of other patents. Then one thing that people often forget is product and production are in fact not two separate things in the process of R&D and commercialization of inventions and technology. You can't just sort of develop, as I said, the molecule, the material, and then how to make it into a product will take care of itself.

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You have to figure out the production process and how you turn the product, sorry, the invention into a product. It requires a lot of production and process engineering. All of that is expensive. All of that is risky, speculative, and often, as I said — the wow, this molecule sounded brilliant, we thought we could and in fact, no, it turned out to be nothing because we, and maybe no one could figure out how to turn that into an actual product and something that would be useful to consumers and customers. So that sort of knock on Bayh-Dole, it just doesn't withstand the test of reality.

Walter Copan (00:40:22):

Let me jump in on that too, Franck and a great, great question, Joe. Because this has often been used in the argument that this is nothing but corporate welfare or that this is a system of giveaways. No, when we look at how the research enterprise in the United States and the other civilized nations of the world work, research-based investment from federal governments results not only in the seed corn of new ideas, but foundational discoveries and basic physics, the materials that help us to understand our planet and life. Research investments help to educate our students and also provide the opportunity for our teachers, our faculty to be both excellent educators but also excellent researchers. And that research, that discovery, both positive and the failures along the way are part of that entire ecosystem of building a powerful research enterprise and preparing the next generation of leaders.

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We need to remember that industry invests dramatically more in research and development than does the federal government. This goes to Franck's point that the initial discovery is often very low cost and productizing that, de-risking it, including regulatory risks and market risks. And there are plenty of examples of product failures, promising new drug therapies or medical devices, that then wound up having a safety issue and other challenges. And they may die at the very end of the investment of sometimes billions of dollars by the private sector in taking that great concept and seeing where it will go. I think the other dimension too is that, in addition to federal funding now to create the seed corn science, science philanthropy has become a very important engine of innovation. And so philanthropic foundations, institutions that invest back in the things that the federal government wouldn't invest in, because they may be too high risk, they may not have survived the peer review process by knowledgeable faculty, because they would've said the risk was too high, the government shouldn't invest in this. But yet philanthropy will step in.

(00:43:05):

And so that's another avenue for concept development into the commercial marketplace. I think it's also absolutely essential to realize that other nations have similar systems of basic research at its academic institutions and national research institutes that are also creating the seed corn of new opportunities. Sometimes they're international collaborations that are incredibly important. And without the Bayh-Dole Act supported by clear intellectual property rights that are enforceable internationally, that seed corn of U.S. innovation coming from the public funding sector would dwindle away because the risks of private sector investment would go away. And so we see to the point that's been raised earlier on, other countries have copied the United States. They've copied our Bayh-Dole system; they are trying to replicate in many ways if they can, our innovation ecosystems, and looking and benchmarking the various parts of the United States that deliver great companies, great technology-based enterprises.

(00:44:34):

And our current competition with China indicates that the United States needs to continue to invest by the public sector to ensure that the United States can maintain momentum for our national security and our economic security needs. And so these arguments that this is a giveaway does not look at the reality of where investment actually goes. And we also recognize that at this time, other countries are not only copying our processes and building their own analogs of our educational and innovation systems, including their types of Bayh-Dole, but they're also really looking at how they may be able to take strategic advantage at this time. And that competition between the United States and China is a perfect case in point.

Joseph P. Allen (00:45:33):

Almesha and Brian, you are at ground zero. I mean you're there when these inventions come in, you decide the only thing we should add is: under Bayh-Dole, universities pay the patent costs and you pay your tech transfer costs, the government does not pay that. If you decide to file a patent and you're trying to license it, are people lined up outside your door going 'they're going to make a billion dollars,' or are you trying to find a licensee who's willing to risk a billion dollars and knowing full well they may lose it?

Almesha Campbell (00:46:00):

I wish they were lining up outside the door. I would, that would even make my job harder, right? Because I have to figure out who are the really good players that are coming at the door. But no, definitely this is the universities taking on the burden of the patent costs and of course, keeping the patent protected over the lifetime of that patent. Of course, this is an investment. One of the reasons why universities like mine is engaging in this process as well is because we understand what it means and the communities in which we serve, right? If we are able to create the technologies that can support our communities. Plus, when you're looking at our faculty researchers who are doing all this hard work, one of the best ways to incentivize them is the protection of the intellectual property, and then begin that negotiation process of how do we commercialize these technologies and what's the return on investment?

(00:46:53):

Oftentimes, and not a lot of us are going to make a lot of money from it. Oftentimes we are spending more money patenting than we are receiving. But the public good of this entire process is what drives us to do technology transfer and commercialization, right? The majority of us will tell you it's all about societal impact. Of course, it impacts the economy that allows us to have more innovation. Look, most of the people that are doing work in this space are small startups. They're small researchers doing great things, and then we have some big universities who do some wonderful thing as well. But without these innovations taking place at our level of the ecosystem, we won't have American innovation and competitiveness the way we have it today. True, a lot of people are trying to copy our system. I've been to a few countries in my term as chief of AUTM, and they've asked us, what the thing that works for you for Bayh-Dole and what doesn't work? Because they're trying to see how to strengthen their own system.

(00:47:55):

All of that is about competing against the United States of America. So why should we weaken our system while others are trying to strengthen it? If we want to stay ahead of the game, we've got to continue strengthening this system. We've got to continue protecting it. Which is why the work of the Bayh-Dole coalition is so important. And I think having a call such as this to engage our community, and to spread this word out farther than our community, is so important. It is one that I believe is one of the strongest pieces of legislation, bipartisan legislation, we've had. And look how long it's been, it's been since 1980 and still going strong. We've got to protect it at all costs.

Joseph P. Allen (00:48:37):

Thank you. Brian, do you want to add?

Brian Darmody (00:48:39):

Yeah, yeah. So we have a saying in the tech transfer: failure is an option. A lot of our startups fail. I mean the CEO for the Iron Storage company. I mean he's a prolific researcher, prolific patent holder, but he had several failed companies, right? But he didn't give up. And so by the way, people don't realize a lot of these companies in our research parks, they're not hiring PhDs, they're hiring people from local — so technicians, other kinds of folks that are growing the local ecosystem are employed. But I do want to go back to the overall question. So if you think about it, we kind of just accept that we have a huge biotech industry here. Prior to 1980, it was Europe that had, and if you think about a lot of pharmaceuticals, they still had their headquarters but not their research in the EU.

(00:49:33):

So 1980, the Cohen Boyer patent was issued, Genentech went public, and the Bayh-Dole Act passed. So that was a really fundamental year. And the biotech industry — I was just at a Council of State BIO Associations meeting in Phoenix earlier this week — we just accept that. But that was not a given that that industry that employees has, I think over a trillion dollars, they just came out with an economic impact statement. We kind of just assumed that's true and there was no certainty that would ever have happened. So I think that's a tribute to the Bayh-Dole Act and others who built that industry.

Joseph P. Allen (00:50:17):

That is a great point. And the other thing is actually I had brown hair when we passed Bayh-Dole. When biotech came out, Washington wasn't sure if they wanted biotech or not. A lot of people thought this is a really dangerous technology. And the other thing that we didn't envision when I worked with Birch Bayh's staff is, that shows the genius to me of decentralized technology management is, a lot of times universities can't find a licensee, which is very often, they spin out a company. Now that is one of the things that's driving U.S. innovation. And so again, to me, that's one of the things that makes us different than China and other places is, most of those companies are going to fail. When they fail, they take a hit. Washington doesn't pay them back. But I think you deserve a lot of kudos here because the technology managers decide, rather than just leave it on the shelf, maybe the inventor wants to start a company, maybe we can put a company together.

(00:51:09):

And those are not done at Washington's expense. They're done at private sector expense with a lot of people realizing they may put 10 years into this before they even see a payoff. And maybe not even then. This has been a

great discussion. So let me ask another question here before we run out of time. Just again on the general premise about how we're doing internationally. We have the best research, public research institutions in the world and they're driving the boundaries of science and technology. But as many of you have said, China and other people, particularly China, is trying to adopt our Bayh-Dole system. So their universities can eclipse us in both basic research and manufacturing. So how serious is that threat? And what would happen if the critics of Bayh-Dole are successful while we're facing this, if we consider this a threat, if the critics are successful reintroducing Washington micromanagement so they can second guess your deals, take your technologies away if they don't like your price. So what are the consequences on the table now if we get this wrong? And again, apparently the Chinese think Bayh-Dole works because they're putting a lot of money into their research universities trying to actually eclipse our lead. Is this something we should take seriously or not? Or should we just sit here and just assume that everything's going to be great because nobody's going to beat us and maybe we can mess around with our system, it'll continue to work?

Walter Copan (00:52:35):

Joe, I think there have been several comments made here already about the significant threat that China poses. And a substantial part of that is the research enterprise and the educational enterprise that has genuinely been a focus of the Chinese Communist Party over the past decades. And we can look 20 years ago and see the amount of research, the amount of publications that were highly cited in the top journals globally. And China was hardly a factor. And we look today, some of the world's top universities in every field are based in China. The quality of the publications, the rate of intellectual property protection and the degree of intellectual property protection that's being provided in China is world-class. And it's a threat to be taken seriously technologically because, unlike the Cold War era with the Soviet Union, the United States is intertwined economically, our supply chains are closely tied with Chinese manufacturing and delivery.

(00:53:58):

And we also see that China has had access to the inside of global organizations, including attempts to infiltrate U.S. institutions to try to get access to the best ideas and the best innovations coming out of this nation. The U.S. had contracted with an independent Australian think tank to do an analysis of the innovation strengths of China, rather vis-a-vis the United States and with other players. And they came out with a very interesting study a few years ago called "Picking Flowers, Making Honey." And it was a study that identified the Chinese strategy to tap the leading edge research coming from around the world that could be then productized in China. It was the point that Franck made earlier on that a lot of research leads to failure. Well, if you're only going to be picking up the successes and then leveraging those to benefit your own economy, you avoid a lot of the upfront R&D investment and discovery.

(00:55:22):

And so we have a formidable competitor who is also an economic and manufacturing powerhouse, which is why the principles of Bayh-Dole Act for sound intellectual property protections, a focus on U.S. manufacturing and rebuilding the base with American technologies. And also the recognition that in the United States, we not only have the importance of the Bayh-Dole Act to be maintained as an integral part of our innovation system, and with a few regulatory improvements that were initiated while I was NIST Director, one of those recommendations on pricing related to march-in rights was not moved forward into regulation and adopted. And that's the one on pricing, this whole issue of uncertainty in intellectual property rights that we're just discussing now. We have also a companion legislation called the Stevenson-Wydler Act that has many similar provisions to the Bayh-Dole Act but focuses on federal institutions. And there is a legislative proposal to modernize the Stevenson-Wydler Act as well, which is an important part of the U.S. innovation system side by side with Bayh-Dole as we look to the future.

Joseph P. Allen (00:56:50):

Okay, we're almost out of time, so I want to give everybody else, the other panelists, a chance to make some closing statements. And this has been a great discussion. I've really enjoyed it.

Brian Darmody (00:56:58):

The one thing...

Franck Journoud (00:56:59):

Go ahead. Go ahead.

Brian Darmody (00:57:00):

Okay. One thing I would say, instead of focus on what the federal government could do, they passed the Chips Plus Science Act, right? They authorized, but they haven't funded the NSF engines and the tech hubs. Three percent of the NSF engines has been funded, 3%. EDA tech hubs, 5%. So the authorization's already there. Congress just needs to fund it. So that would be my pitch. And a lot of our members across the country are eager to get new NSF engines and EDA tech hubs.

Franck Journoud (00:57:36):

Just real quick, what I'd add to what Brian and [Walt] just said, is a couple of things. First, you're never going to make R&D cheap and you're never going to make it uncertain. It is defined by the fact that it is a costly and extremely uncertain — you fail way more often than you succeed — type of endeavor. So what the Bayh-Dole Act does is actually really, again, a fairly brilliant bit of policymaking, is reduce the cost and reduce the uncertainty. Because for a company, you come in and there was an R&D investment that has produced a patent. Now there's still a lot of uncertainty about whether you can actually eventually turn that patent into a product that's successful in the marketplace. And so that also is going to require a lot of additional costs, but at least some of the costs and some of the uncertainty has already been taken care of.

(00:58:39):

And so that's really fantastic. And so that's why we remain strong defenders of the Bayh-Dole Act and we're concerned about the draft guidance on march in. I would be remiss in sort of not mentioning that another, a really important way to reduce the cost around R&D is to allow companies to immediately expense their R&D costs. So until 2022, and it had been the case for 70 years, the U.S. tax system allowed a company to immediately expense for tax purposes the year that it incurred R&D costs to immediately expense those costs. That expired in 2022. And that is a major priority, not the only priority, but a major priority of tax reform for the NAM as Congress looks to a tax reform next year.

Joseph P. Allen (00:59:42):

Almesha, you started things off, so we're going to ask you to close things out.

Almesha Campbell (00:59:45):

Thank you so much. This has truly been a great session and very informative. Like all my colleagues said, this is a very important Act. I think instead of trying to weaken it, we should focus on strengthening it. We should focus on ensuring that America stays competitive through all this stuff. But more so I want to echo what Brian says, fund this Act, fund the Chips and Science Act so that these provisions can help not only early-stage technologies, but it can help with the engines, the tech hubs, and all of the other programs that we need in our innovation ecosystem so that we could continue growing, we can continue translating the technologies, and we can also continue helping with economic development in our communities. But thank you so much for this opportunity.

Joseph P. Allen (01:00:31):

Well listen, on behalf of the Bayh-Dole Coalition, I really appreciate all of your time. This has been a great discussion and we'll look forward to having another webinar on similar topics down the road. So again, I hope everyone has a great day. Thank you for joining us. And we'll also have this video posted on our website fairly soon. So thanks again and we'll see you down the road.

Franck Journoud (01:00:51):

Thanks, Joe.