The Three-Pronged Attack on U.S. Innovation and Intellectual Property

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Bayh-Dole
COALITION

Joseph P. Allen (00:00:00):
Hi, good afternoon. I'm Joe Allen, I'm the executive director of the Bayh-Dole Coalition, and we welcome you to our program on the three-pronged attacks looming over the American innovation system, just as our economy teeters on the brink of recession and as China moves to pass us by as the world leader in technology.

(00:00:18):
Each of these threats is serious on its own, but combined, they pose a self-inflicted body blow to our innovation system, which leads the world in developing breakthrough products through partnerships between our public and private sectors just as we need them the most.

(00:00:36):
We have four distinguished panelists who will discuss what Section 1498, the TRIPS Agreement, and Bayh-Dole's march-in rights were intended to do and what the consequences are if they're misused as being proposed. We welcome your questions, so pass them along to the Q&A feature on the top of the screen and we'll get to as many of them as we can. So, let's get right to our program.

(00:00:58):
Our first speaker is the Honorable Susan G. Braden. Judge Braden served as the chief judge of the US Court of Federal Claims. Since leaving that position in 2019, she served as a public member of the administrative conference of the United States and on the Patent Offices Private Patent Advisory Council, in addition to being an arbiter to resolve disputes under the U.S.-Mexico-Canada Trade Agreement. Judge Braden, please kick things off.

Judge Susan Braden (Ret.) (00:01:26):
Thank you very much, Joe. I assume my sound is on, I'm just double-checking again. I want to thank also the Antonin Scalia School of Law, where I am also the jurist in residence. I've worked on a paper which is being provided to the participants through the Center for Intellectual Property Protection. It will be published by the Food and Drug Law Institute Journal, probably within this next month. I hope you all have a chance to take a look at it.

(00:01:59):
The topic of the paper and my brief remarks today are that use of Section 1498(a) is not a prescription for lowering drug prices. As Oliver Wendell Holmes said, "We begin our analysis with the statute." You'll have to forgive me, having been a judge, but bear with me.

(00:02:20):
Section 1498(a) states, "Whenever an invention described and covered in a patent of the United States is used or manufactured by or for the government without license of the owner, or unlawful right to use and manufacture the same, the patent owner's remedy shall be by an action in the United States Court of Federal Claims, for the recovery of reasonable and entire compensation for use in manufacture."

(00:02:54):
Most people don't know what the United States Court of Federal Claims is and what it does, but we're across the street from the White House. We're the only federal court that does not have criminal jurisdiction and we adjudicate all money claims against the federal government. Including government contracts, large tax refund cases, patent, intellectual property cases of all sorts involving the government, primarily in the military and other contexts. It's very interesting and it has a long history in our jurisprudence.

(00:03:27):
The origins of the statute which we adjudicate, according to the Supreme Court, came about after World War II. The purpose of it was to stimulate contractors to furnish what was needed for the war effort, without fear of being liable themselves for patent infringement. That makes perfect sense. Congress amended the statute and later, after World War II, essentially to immunize contractors who had worked on the war effort. Again, and this time in World War II, in the event that they happened to have infringed someone else's patent. That's the purpose of this statute.

(00:04:13):
Fast-forward to 2018. I was in my living room, reading the New York Times in an editorial which said how the government can lower drug prices. Announcing that a possible solution involves an obscure part of the federal law known as 1498. According to the New York Times, this provision is sort of an eminent domain for patented inventions. There's a law in the government to circumvent the patent invention, patent owner's rights and allow the patent owner, if the patent owner is compensated.

(00:04:51):
The author of this editorial cites one source of authority, a law review article that was written in the Yale Journal of Technology. Authored by a professor who we'll talk about later on, who appears frequently in these discussions and a handful of her favorite students. Three years later, we find that the Senator Bernie Sanders introduced S.909, a Prescription Relief Act of 2001.

(00:05:31):
There are different variations of this bill that have been introduced and supported by other members of the senate. This bill basically would authorize the Secretary of HHS to infringe a pharmaceutical patent or require the owners to enter into compulsory licenses at a royalty rate established by HHS, where they decide that the prices were deemed to be excessive.

(00:06:01):
Aside from the threshold question of who determines what the metrics are for whether a patent drug's prices are excessive, the Yale article nor the legislative history to date offers no empirical evidence the government-sanctioned infringe would even lower drug prices. Instead, what we're told by the Yale authors that it would provide us with significant social gains that would bring prices into a risk-adjusted rate. Hard to imagine how one would define what that would include.

(00:06:39):
A copycat article popped up a couple months later by a group of Pennsylvania law students, who went further, arguing that if the infringer is sued by a patent owner in district court, HHS should intervene in the private lawsuit. Move to transfer that case and move it to my old court, under 28 USC § 1498(a). The article also posits that HHS should coordinate with infringers to implement this massive infringement scheme. If that doesn't shock you, I don't know what would.

(00:07:18):
We have historical understanding of the importance of private property rights in our country that are enshrined in the Constitution. Most notably, the right to own a patent, which essentially is a right to exclude for a limited time period. Most people don't understand what a patent is, they think it's a grant in perpetuity. Far from it, but that's a different lecture.

(00:07:48):
I have just located or identified at least three or four major ways that this law, if it's ever enacted, can be challenged. Let me go over them and I'll do it very, very quickly. The first one is under the Administrative Procedures Act, which essentially says that the act of the agency would be reviewed under arbitrary and capricious standard. Certainly, deciding who decides what's an excessive rate and what goes in there is ripe for review under that statute.

(00:08:17):
The second is under the statutes itself. There are two prongs under what's considered to be used for the government. A predecessor to the Federal Circuit issued a binding presidential decision, which is still in the books, that says the fact that the government has an interest in a program like Medicaid and Medicare, or generally funds or reimburses all or part of its costs is too remote. Too remote to make the government the program beneficiary for purposes of 1498.

(00:08:48):
The court properly reasoned that if every program could be viewed as for the government, there will be no end to

cases asserting Section 1498(a) and for compensation. Another case in the Federal Circuit that's still precedent, one in 1980, basically described another case where there was attempted misuse of the statute. Saying this is not the type of activity that Congress intended by enacting 1498 to cloak with immunity an infringer from injunction.

(00:09:22):
This last term, the Supreme Court issued a decision in the environmental law context, but I think has a lot of bearing on it. It's the West Virginia Case and, basically, the court has resurrected what's known as the "major question" doctrine. The issue there really is, did Congress really consider when they enacted a statute such as 1948, the significant political end consequences for which the act is being used by an administration?

(00:09:55):
Certainly, there's no evidence in the statute, in the strict construction of the statute by courts to date, nor in any of the history of the statute that Congress intended to have this statute used and misused in this manner. For those of you that think this is an academic matter, it's not. This last summer, a letter was sent to the HHS Secretary, imploring him to use his powers under 1498(a) to do just what I have described. This is not an academic issue and it's important and deserves your attention. Thank you. Joe?

Joseph P. Allen (00:10:42):
Thank you very much. That was a great opening statement and we really appreciate it. Our next speaker is Patrick Kilbride. Patrick is the Vice President for the Global Innovation Policy Center at the U.S. Chamber of Commerce. Before that, he led the Chamber's policy team for the Americas and was the deputy assistant secretary for the U.S. Trade Representative. Patrick is also a member of the Bayh-Dole's Advisory Council. Patrick, please talk to us about the TRIPS Agreement.

Patrick Kilbride (00:11:09):
Thanks very much, Joe. Great to be here with you and Judge Braden and everyone on the call. I've been asked to talk about the waiver of the WTO TRIPS Agreement related to Covid-19. So, I'm going to try to do three things. For those who are not as familiar, I'll spend just a brief moment describing the WTO TRIPS Agreement.

(00:11:35):
Second, talk about why it matters. And third, really spend the bulk of my time with you describing the implications of the waiver that has already been applied to vaccines, Covid-19 vaccines as of this past June, that has been proposed to be expanded to cover a much broader range of Covid-19-related therapeutics and diagnostics. That is currently being debated in Geneva.

(00:12:05):
First of all, if you haven't spent time with the WTO TRIPS Agreement before, this is the agreement on trade-related aspects of intellectual property rights that, together with agreements on goods and an agreement on services, form the three-legged stool of the original WTO Uruguay Round Agreements. You may remember that in 1995, countries came together to form the WTO through the Uruguay Round Agreements as a successor to the General Agreement on Tariffs and Trade.

(00:12:43):
This was effectively the initiation, the start of the rules-based multilateral trading system. We went from a system that was mostly aimed at opening markets through tariff reductions to one where there were specific disciplines in different areas. Related to services, related to intellectual property, related to subsidies among other mechanisms. Those rules were binding and enforceable through the World Trade Organization's Dispute Settlement Unit.

(00:13:17):
Now, the important thing about TRIPS is that it's intended to be a set of minimum standards for the protection of intellectual property rights. That's actually written into the agreement that this is a floor, not a ceiling. That countries can, and I will argue should actually be, much more ambitious in how they protect and promote the ability to access and protect intellectual property rights within their own markets and as they do trade around the world.

(00:13:49):
It's also important to recognize a few other things about TRIPS. Most importantly, that for Least-Developed Countries, they have never, in all of the 26, 27 years now that this agreement has been enforced, Least-Developed Countries have never been required to actually implement the agreement. Countries like the United States, Europe, Middle-Income Countries have, but the Least-Developed Countries have not.

(00:14:17):
Even more so, there have been specific exemptions from the rules of the TRIPS Agreement for pharmaceuticals, believe it or not. So, many countries have never yet been required to implement the TRIPS, even though we're talking about a waiver of those commitments in the pandemic.

(00:14:41):
Why does the TRIPS Agreement matter? Well, our economy today, as I think is probably apparent to everyone, is driven by knowledge-related assets. The kind of assets that are protected by intellectual property rights. When you think about where growth is coming from in the future, where technological leadership, where productivity comes from, it's increasingly from knowledge-related assets.

(00:15:09):
To give you a sense of it, 40 years ago, the vast majority of corporate market value, looking at the S&P 500 as a measure, was in physical, tangible assets, plant and equipment. About 15% of that value was in what are called the tangible assets, including but not limited to registered intellectual property rights. Like patents, like copyrights, like trademarks, which protect invention and creative works. Brand names and corporate reputations, among other things.

(00:15:53):
Today, 40-45 years later, the situation is exactly reversed and about 90% of corporate value is found to be in intangible assets, including intellectual property rights. Only about 10% is in the physical goods that these companies own. This makes sense if you think about it, because take a company like UPS for example. Not to pick on anybody, but just as a hypothetical.

(00:16:25):
UPS owns tens of thousands of trucks and airplanes, they own distribution facilities all over the world. But, where does the value of a UPS really reside? Is it in those trucks and planes? No. It's much more in the know-how that connects those trucks and planes and facilities, makes them all work together to get a package from point A to B, C, D and finally E, at your door. It's that know-how that drives the effectiveness of a UPS. That's true across our economy.

(00:16:59):
You see that increasingly, we rely on knowledge-related assets to drive the productivity and productivity growth of our physical assets. In the WTO TRIPS waiver debate, and in the pandemic, this matters because countries that have not implemented the TRIPS agreement or implemented intellectual property protections to a proper level find themselves at a horrible disadvantage.

(00:17:27):
They've not been able to participate effectively in the ecosystem for innovation that delivers, is continuing to deliver, these Covid-19 solutions whether it's in the life sciences space, vaccines and therapeutics and diagnostics or other tools like the telecommunications tools we're using to communicate with each other today and many, many more.

(00:17:52):
All of the tools of technology that have kept us safe and sane and productive, to an almost unimaginable degree during the pandemic, were based in intellectual property rights. The reason that intellectual property rights are so important to this is because they connect an ecosystem. When you think about where a vaccine comes from, it's never just one stakeholder.

(00:18:16):
You think about the schools that train our scientists, you think about the government funding for basic scientific research. Government laboratories, universities that work on grants and do groundbreaking research that then license the discoveries they make, oftentimes to small startups in the biotech space. Think about a Moderna for instance, which just two years ago, right before the pandemic, barely had enough money to stay in business. They were having to access private equity, they were having to look for venture capital support.

(00:18:56):
All of these stakeholders are connected in a network through their collaborations, but importantly, those collaborations are made possible by intellectual property rules and contractual arrangements based on an acknowledgement of who owns what. It's this network of collaborations that allowed the development and scale-up delivery of Covid-19 solutions in record time during the pandemic.

(00:19:27):
That's why TRIPS Agreement is so important when countries want to see more local production of these Covid-19 solutions in their own markets. There's a way to do that, and it's by becoming part of the network, by respecting the rules at a high level. By creating that predictability and reliability and transparency around the contractual arrangements between stakeholders, so that more stakeholders in the developing world can be plugged into this ecosystem for innovation. They can be part of the solution, instead of waiting on the sidelines for solutions to be delivered to them.

(00:20:06):
When we hear talk of a waiver, whether it's the waiver that's already been applied to the vaccines or the waiver that's being proposed for therapeutics and diagnostics, you should know that it is not only not helpful, it's actually actively counterproductive to the goal of getting more technology transfer, getting more countries involved in delivering solutions. The way to do that is through a better application of the WTO TRIPS Agreement.

(00:20:35):
That's why we've been so active. I've been into Geneva five times in the last year meeting with leaders of the WTO and the World Intellectual Property Organization, meeting with country missions. Likewise, many folks on the Hill have seen us talking about this, it continues to be very important for U.S. technological leadership in the world, but also for the rest of the world in the future, in future crises.

(00:21:01):
This is not the last pandemic. There's going to be climate-related challenges, there's going to be food security, energy challenges that we all have to face. The way that we do it successfully together is to sustain that ecosystem for innovation that's connected by intellectual property rights. Joe, I'll stop there and look forward to the discussion. Thank you very much.

Joseph P. Allen (00:21:24):
That was a great remark and we very much appreciate it. Our next speaker is Brian O'Shaughnessy. Brian chairs the IP Transactions and Licensing Group of Dinsmore, one of the nation's largest law firms. He's the past president of the Licensing Executive Society of the U.S. and Canada and he still serves there as the Senior Vice President for Public Policy. Brian is also the chairman of the board for the Bayh-Dole Coalition. We'd like to have Brian talk a little bit about the Bayh-Dole Act and also what march-in rights are. Brian, it's all yours.

Brian O'Shaughnessy (00:21:57):
Thanks a lot, Joe. Well, first I'd like to say it's really an honor and a pleasure to be a part of this very distinguished panel. The-

Brian O'Shaughnessy (00:22:05):
To be a part of this very distinguished panel, really an incredible collection of knowledge and wisdom here, so I'm honored to be part of this group. I guess we have a very distinguished audience today, a very sophisticated audience. Many of you deal with issues involving the innovation ecosystem on a regular basis. But for the benefit of those who

don't weed into these woods on a regular basis, I'd like to start with first principles. As Judge Braden mentioned, the basis for our patent system is found in the Constitution, where the founders and the American people adopted the notion that we would be able to encourage and promote the progress of the useful arts by granting to individual inventors, the exclusive right to their discoveries, the right to exclude others from profiting from their discoveries.

(00:23:05):
Now, fast forward to World War II, also referenced by Judge Braden, when there was a phenomenal amount of research and development, both in military applications but also healthcare applications, and FDR charges the director of the National Office of Scientific Research and Development, Vannevar Bush, with compiling a report in response to four questions, which basically asked, what can we do to make sure that we convert all of the military knowledge from research that we have developed through the course of the war, as well as the healthcare knowledge that we've gained as a result of the war and turn those into useful peacetime purposes for the American public? In addition, another question was, how do we develop programs to ensure that we identify and cultivate the youth of America to advance and continue those scientific endeavors? In other words, how do we contribute to our intellectual capital and make sure that we sustain that pace of technological development?

(00:24:19):
Well, among other things, Dr. Bush compiled a very lengthy report called Science: The Endless Frontier, ultimately delivered to then President Harry Truman in 1945. Among other things, Dr. Bush suggested that the federal government should take an active role in funding basic research at America's universities and among smaller enterprises. This ultimately gave rise to the National Science Foundation and it gave rise to a very robust role for our federal government in funding research and development. Now, that was an incredibly inspired report, and I encourage anybody who's interested in learning more about the American government's role in scientific research to review the report. Then, we fast forward to about 1980, 1980 when Senator Birch Bayh produced a bill, which ultimately became the Bayh-Dole Act. It was co-sponsored by Senator Bob Dole, making it a bipartisan bill. Among other things, Senators Bayh and Dole recognized that although the federal government was abiding by the recommendations of Dr. Bush, a great deal of the scientific research that was being produced by federal funding was not finding its way into the marketplace.

(00:25:59):
The Bayh-Dole Act said we need to have a mechanism for encouraging people to take that basic research, invest the time, talent, and treasure necessary to develop those basic inventions, those basic discoveries into useful inventions that can then be put onto market shelves for the benefit of the American people. What the Bayh-Dole Act did was it allowed universities and small enterprises to take title to the intellectual property that's produced as a result of some amount of federal funding of the basic research that takes place at universities and smaller enterprises. Now, universities have the ability to take title to patents that were acquired as a result of research. Even if that research only had a modicum of federal funding, they could now take title to it, and this then allowed universities to create tech transfer offices, which then were in the business of finding private entities and sponsors who would license that technology, further develop it, and turn it into useful products.

(00:27:21):
Now, it's worth mentioning that prior to Bayh-Dole, there was not a single drug that had been discovered with the aid of federal funding that had been developed and put through clinical testing and put onto the market. Since Bayh-Dole, there have been over 300 drugs that have been subsequently developed at great expense and great amount of time and investment, and have now been turned into FDA-approved drugs that are on the market improving the lives of people around the world. Those drugs would not have been possible but for the existence of the Bayh- Dole Act. The Bayh-Dole Act has been an enormously powerful economic engine that has allowed this partnering to take place between private enterprise and universities to develop that basic research into useful products.

(00:28:20):
I think that one of the things that we really need to focus on with Bayh-Dole is that it has created a virtuous cycle.

The federal funding comes in, it funds basic research, the basic research then is protected by virtue of a patent, the patent then gives private enterprise the comfort of knowing that if they take a license under that patent and they invest the time, talent, and treasure to turn that into a useful product, that they will have a protectable asset at the end of the day and they will be able to recoup that investment. Without the insurance that those patent rights will remain in place and remain viable, no self-respecting private enterprise could ever make the investment that's necessary, for example, to turn a basic investment into a useful drug on the market. It would literally be, arguably, a violation of their fiduciary duty. They would be frittering away assets or putting them unnecessarily at risk. One of the things that the Bayh-Dole did is it also created a hedge, if you will, a protection for the federal government, that if certain patents that are the result of some amount of federal funding are licensed to a private enterprise and that private enterprise does not make a good faith effort to develop that product into a product and put it on the market for the benefit of the taxpayer, then the government could engage in what is called march-in and they could march-in on that license and they could either demand that the university license to another or the federal government could effectively take control of those patent rights and it could license the patent rights to another.

(00:30:26):
But bear in mind that the march-in rights are only to remedy that specific situation, the situation where the results of federal research are not being developed in good faith toward a marketable product. This was confirmed in an op-ed that Senators Bayh and Dole co-wrote in the Washington Post in, I think it was 2003. They specifically said that march-in was put into the bill for this very, very specific and limited purpose. Now, fast forward to the present. Unfortunately, we have a number of people who have, I think through perhaps naivete, but also through just a willingness and a desire to try to alleviate the high cost of drugs, they have stepped in and said, "Well, this march-in provision gives the government the opportunity to march in on any license agreement, and if they don't like the prices that are being charged, they can license it to another for a better price." Well, that is clearly not what march-in was intended to do. March-in was intended to only remedy the situation where the product was not available. It was not intended to be a price control mechanism, and this was expressly reiterated by Senators Bayh and Dole in their op-ed. Nonetheless, people continued to advance that argument. The danger of that argument is that if potential licensees, the private sector, were to understand the march-in right was going to be used arbitrarily by the government, any time a resulting product was being produced according to or made available at prices that the government didn't like at that given time, no self-respecting entity, no responsible and prudent entity would take that license because they know that if they were to invest what it's an average of 10 years and $3 billion in investment for a drug to turn that drug into a useful product, only to then find that the license was going to be marched in upon by the federal government, they would have no way of recouping that enormous investment, and so therefore people would no longer be taking licenses to university research and we'd find ourselves back in the same situation as existed prior to Bayh-Dole.

(00:33:16):
There's another thing about the virtuous cycle of Bayh-Dole. Because Bayh-Dole has made these patent rights available to the private sector, again, for subsequent development, investment and turning those products or those discoveries into a useful product, the private enterprise has stepped into partnering with many of our universities on a regular basis and is funding a great amount of follow-on research and development research at America's universities. Private enterprise is now stepping in as a supplement to the federal funding that many universities are getting, and through sponsored research, they are developing a great amount of additional research. That sponsored research funds the laboratories, the facilities, the fixtures, and perhaps most importantly, the salaries that pay the principal investigators, the faculty members, and it makes it possible for millions upon millions of graduate students to get graduate degrees in science, technology, engineering, and mathematics, because that sponsored research is making it possible for them to go to graduate school while at the same time performing research that pays for their education.

(00:34:49):
As I say, Bayh-Dole has created what is truly a virtuous cycle that has produced innumerable new inventions. They produce thousands and thousands of jobs every year. They produce effectively the development and the

start of three startups on average a day in America, and this is all made possible by the ability of universities to license that technology out. It should also be mentioned that licensing out to private enterprises produces a great deal of revenue back to the universities. Aside from the sponsored research, the revenue that companies pay back to the university likewise has made it possible for faculty members to remain as faculty members and oftentimes to be well-compensated competitively with the private sector. It allows our universities to retain the best and the brightest as their faculty members without having to necessarily be compensated as a faculty member might otherwise be compensated.

(00:36:05):
I think all of these contribute to a great amount of development, a great advance of the innovation ecosystem for the American people. If we were to invoke march-in rights as has been proposed in the same letter that Judge Braden referenced to our Secretary of HHS, if we were to use march-in rights for those purposes, that whole innovation ecosystem and the virtuous cycle would collapse. I think, as Judge Braden says, these things are not academic exercises. They are pivotal and incredibly important to America's preservation as its role as a leader in the innovation ecosystem globally. Joe, I'll stop there and thank you once again.

Joseph P. Allen (00:37:04):
Well, thank you. That was an excellent summary of, actually a very complex topic. Last, but certainly not least, we have Jon Soderstrom. Jon recently retired as a managing director of Yale University's Office of Cooperative Research. Under Jon's direction, they launched 75 startups with over $42 billion in venture funding and another $7 billion in private equity financing since 2000. Jon also served as a Director of Program Development for the Oak Ridge National Laboratory and was past president of Autumn. Jon is also a member of the Coalition's Board of Directors, so we'd like to have Jon react to the presentations we just had and help set the stage now for the panel subsequent discussion. Jon, it's all yours.

Jon Soderstrom (00:37:48):
Thanks Joe. I, like everybody else, am very honored to be part of this distinguished panel. I want to build on a couple of things that Brian and others have spoken about, and I'm going to sum it up with what is this all about? The answer is providing incentives to invest in innovation. The problem that we are facing right now with these various challenges is that they are removing incentives for investors to invest in very high-risk, long-term R&D that has the ability to predict success is limited. We talk about things, the way we reference things, they're drugs. The universities that these drugs that are on the market were discovered at universities. That's not true. In fact, it is extraordinarily rare that a drug would be discovered at a university. University research is basic science. What we are doing is discovering tools that can be used by others in an applied setting in industry to actually discover a drug.

(00:39:08):
The interesting dynamic here is that, yes, we do have patents. We do have ideas about how these patents could be used and developed into profitable products downstream. However, they're nascent, they are embryonic, they are going to require significant investment. Brian referenced that it takes up to 10 years to develop a drug. Well, that 10 years is after the drug has been discovered. There's a whole timeframe before that, before we even have a candidate that is a drug that takes time, energy, and is high-risk. When I talk about high-risk, a drug that ... a discovery made at a university being translated into a drug that is approved by the FDA has to go through an extensive regulatory review. The probability of success is about 1 in 10,000. I want to repeat that, 1 in 10,000. That's the probability of success.

(00:40:19):
Now, the second misconception is that these inventions are being licensed to deep-pocketed pharmaceutical companies with an army of scientists and technicians who are going to muster their resources to drive this thing forward as quickly as possible. That also is not true. Most of the technologies that we have are actually being licensed to startup ventures that are backed by venture capital. Venture capital for those who aren't in the know is basically investors who have given our individuals, who have given investors, venture capitalists, money that they

believe that the venture capitalists can profitably put into a new venture and get a rate of return that exceeds what they would get from just buying stock in the public markets.

(00:41:18):
While that is true, the success rate is not 100%. It's actually quite low. Most portfolios in venture capital are, if they get 10% are winners, they're happy, because that 10% pays for all their failures. There is somebody who has been doing this with venture capitalists for many, many years, there are many hurdles to overcome in convincing venture capitalists to actually write a check for these embryonic, new venture technologies. The amount of money that a university is actually, or the federal government is investing in a university to develop these technologies is in the hundreds of thousands of dollars.

(00:42:06):
The amount of money that a venture capitalist is putting into the new venture to start the process of developing what will ultimately become a potential drug is in the tens of millions, and the amount that a deep-pocketed pharma that's going to actually ultimately take this through clinical trials is in the hundreds of millions, so that when you combine it all, the number that Brian quoted, we can argue about whether it's $3 billion. I can tell you it's at least a billion that it's going to take to get from when it was licensed from an academic medical center to a new startup, to partner with a big pharma, to actually become a drug that is reviewed by the FDA for approval is at least a minimum of a billion dollars. There's ample evidence, either anecdotally or subsequently in the scientific literature behind that.

(00:43:05):
What drives people to actually make these investments? They believe that they're going to get an unfair rate of return for making this high-risk investment. They could have invested their money anywhere. Think about yourself. As an individual, would you be willing to write a check to a company whose potential success is in the 1-in-10,000 range? That's a big risk for any of us, and I would hazard to say that most of us would say, "No, I'm happy with what's going on in my stock portfolio, in my 401k." That's not what venture capitalists do. They make big bets, long-term, high-risk with the hope that they'll be successful in driving those things through.

(00:43:55):
Joe mentioned that I've been involved in probably 50, 60, 70 startups over the course of my career. The number that actually succeeded was actually probably in the 10 to 15 range. By succeeded, I mean they actually were able to generate a product that made it through the FDA, had an initial public offering, there are certain still a number that were in play, but it's still a high-risk game that we're playing. But without it, none of these technologies, none of these technologies move forward. When we sit as we do today and look back at, as Patrick so correctly pointed out, we just faced one of the biggest health crises the world has seen in a hundred years, and we were able to combat it based on technologies that have been developed over the last 40 years, and we were able to do it in record-breaking time. We should be celebrating that fact, not trying to figure out how to undo the rules and the regulations that underlie.

Jon Soderstrom (00:45:05):
To undo the rules and the regulations that underlie the reason why this whole process was successful in the first place. The technologies that drove the vaccines were all developed under the Bayh-Dole Act and licensed to various enterprises. And as Patrick pointed out, Moderna tried the technology on multiple cancers and was failing. And in fact, the person who actually was appointed to run Project Warp Speed, who happens to be a friend of mine, Moncef Slaoui, did not believe that mRNA vaccines would work. And this is a man who has probably been responsible for 30 vaccines being approved over the course of his career. He absolutely did not believe it, he thought it was a very high risk. And for us to sit back after the fact and say, "Oh, we all knew that that's what was going to happen," is self-delusional. And for us to now say, " Well, let's just give that technology away." Friends, if we do that, the incentive to invest in the next innovation that will be mandatory to solve the next health crisis that we have will not be there.

(00:46:17):
We will not have the safety net of being able to reach into our trove of treasures that have been developed over the last 40 years and say, "let's use this." And so folks, I really want you to think about this. We are removing incentives to invest in very high-risk, long-term innovation enterprises. And it takes a certain amount of certainty that you have the potential to get a return on your investment to write that check. And if you don't think it's true for yourself, think about the venture capitalists. They're doing the same thing, they're doing it with other people's money, but they have a fiduciary responsibility to make investments in the interest, and they are inundated with possibilities. We want them to pick these because these are the ones that are going to change the world and the way we live. Thank you Joe.

Joseph P. Allen (00:47:19):
Thank you Jon. That was excellent. We're going to bring every one of the speakers back on now and we're going to spend the rest of our time in a panel discussion. Again, if you have any questions for any of our panelists or something that you'd like to ask about any of the issues we've covered, just put that in our Q&A. And also I got one logistical thing, which I should have mentioned earlier, is that we are recording this and this will be on the Bayh-Dole Coalition website early next week. So if you have a colleague that missed it or if you couldn't watch the whole thing, we'll have it then. I think everyone did an excellent job, but particularly in Jon's closing remarks, these are not theoretical issues, these are real issues.

(00:47:57):
So since people addressed different aspects of it, let me just open up to the whole panel now and see if there's anything you want to say about the other issues discussed or if you want to expand on some of the comments you made. So just general comments you want to make right now, and then we'll get in some specific questions. Anybody want to?

Patrick Kilbride (00:48:16):
Joe, I'll offer a quick comment just picking up on the very last point that Jon made, which I thought was so important about the allocation of resources to innovation. Arguably what the United States has done better than any country in the world is to take otherwise dormant resources and put them to work in the economy. And even more importantly, because of our rule of law-based system to enable their allocation to high-risk investments in innovation that are anything but guaranteed of success. And you pointed out yesterday, Joe, in our private conversation, that when the government is a reliable partner, then you can have that rules-based interaction. And when the government's not, when rules change retrospectively or arbitrarily as with an IP waiver or misuse of provisions of law like 1498 or march-in, then the government is not a reliable partner and the whole system starts to break down, becomes much more difficult for private investors to exercise their fiduciary responsibility to allocate resources to innovation.

Jon Soderstrom (00:49:29):
To that point Joe, what Patrick is pointing out is that one of the things that a university has to do when they're licensing their patents to a startup is we have to represent and warrant that we actually have the right to actually provide these rights to the company and that we'll protect them. And what we're hearing in terms of the judge's comments and what Brian and Patrick are saying is that our ability to do that is going to be significantly eroded. And if we can't do that, then the venture capitalist in their fiduciary role is going to say, "Ugh, I can't guarantee to my partners that we actually are going to have the rights to practice that we thought we were going to have." And that is at the heart of this, is that we are going to remove their ability to actually support this innovative investment.

Joseph P. Allen (00:50:28):
Judge Braden or Brian, anything else you want to add?

Judge Susan Braden (Ret.) (00:50:31):
Yeah, I'd like to come back to something we talked about yesterday, or at least I talked about, and it's a larger point than what Jon has mentioned, that the whole point of all of this is we want to have a democracy in this country. It's not a Republican or a Democratic issue, we want a society. In order to have that, what do we need? We need to

have a populace that is fed, that is not rioting on the streets because they don't have enough to eat. We need people to have a stake in the system that they want to really protect what we have. We want people to get up every single morning and want to be Bill Gates or somebody, or Jonas Salk or whoever it is. I mean, we want them basically to have that ambition and have the opportunity to be able to bring their talents and their ideas to the commercial market. And if the law does not do that, then it serves no purpose in our democracy. That's a much bigger point, but it's important for us to realize because all of these little things around the margin may seem like well, it won't make any difference. It is going to make a heck of a lot of difference about whether we continue to have the economic base to sustain a democracy in this country, whether it is run by one party or the other. It's that serious. And it's one of the reasons that I felt so strongly about not only the particular issue I wrote the article about, but just spending the time that I have left so long as my gray matter holds together here, wanting to try to work in this area. I have two grandsons. I want them to be part of what I enjoyed growing up in America, and I'm worried about whether that's going to happen or not. Again, it's not a political statement, it's a statement about what do we need to sustain our economy And this is a huge, huge part of it.

Joseph P. Allen (00:52:55):
Brian, anything you want-

Brian O'Shaughnessy (00:52:56):
Yeah, thanks Joe. I have just a couple of quick observations. One is I always get the feeling that we're looking at the wrong end of the pipeline here. We're talking about making drugs for example, more cheap, more cost-effective, if you will, by taking away the property rights of the people who made the drugs possible. Nobody has really shown that the price of drugs is in any way an outlier relative to the risk, the investment, the development, the time that's needed to turn it into a drug. As Jon very eloquently stated, it is a high-risk enterprise, takes a lot of time, takes an incredible amount of brain power, ingenuity and genius to turn these things into products, and you don't know whether that's going to happen or not. And relative to any other industry, we can look at what the cost is, what the risk is, and the market will always make an assessment of what that value is and that value ultimately comes out in the price of the product.

(00:54:05):
Well, there's no showing anywhere that the pharmaceutical industry is in any way different. Yes, drugs are expensive. Drugs are expensive because they're inordinately expensive to discover and create, but there's been no evidence to show that in somehow the patent system is being abused to make that possible. It's really all attributable to the cost of development. And I think Judge Braden is absolutely right, the founders created the provision in the constitution that empowered Congress to grant for limited times the exclusive rights to individual inventors. There was a recognition at the time that if we as a fledgling country were going to move from being an agrarian-based economy to what was at the time the developing industrial economy, we needed to incentivize people to develop those inventions that would make Americans competitive on the global marketplace.

(00:55:14):
And the founders very explicitly recognized that by putting in Article I Section 8 Clause 8 of the Constitution, and that's what is the basis for our patent system. It was unique for its time. No other patent system provided for rights to individual inventors and no other patent system in the world created the protections of having to have disclosure, et cetera, et cetera, in exchange for that exclusive right. As a result of that patent system and the foresight of our founders, we have become perhaps the most innovative culture in the history of mankind. And that is largely because of the incentives of our patent system. Were not for our patent system, one might argue that we wouldn't have been as successful or as innovative as we have become. Now the challenge is how do we preserve that system and protect it against what I would call inland-formed attacks? So that's what I think the mission is and that's the ambition of this presentation.

Jon Soderstrom (00:56:25):
Joe, can I just add a couple of things to what Brian has said?

Joseph P. Allen (00:56:27):
Sure.

Jon Soderstrom (00:56:27):
First of all, the Constitution establishment of the patents, there's a quid pro quo. Yes, you get exclusivity, but you have to give up something. You have to fully disclose everything about the invention to the public. It has to be on the public record so that anybody else who's skilled in the arts could copy what you just did. That's the quid pro quo for a patent. The second part of that is, and this gets back to something I neglected to study in terms of academic, the work that the federal government is supporting with respect to inventions that we ultimately license to biotech companies that are going to pursue this. The clock starts ticking when the invention is made. When we file a patent application, the clock starts ticking and there's a 20 year timeframe for that. Would that we could, we don't license things right away, it takes a while. And so by the time a product is actually approved by the FDA, the average patent life on the work that was invented at the university is usually about six years and that's it.

(00:57:45):
That's not a long time to recoup your investment, but it also speaks to the fact that there's a lot of other things that have to be done in that intervening timeframe. Those 14 years between the time it was invented and the time that a drug is actually approved, there's a lot of investment that's going on and it's not being funded by the federal government. The federal government did not fund Covid vaccines, it assured a market for the vaccines, but it did not fund the vaccines. Those were all developed in the private sector based on science and discoveries that were made in academia.

Patrick Kilbride (00:58:21):
Just very quickly to Jon's point, I think the most important thing the government did through Operation Warp Speed was make those advanced purchase orders that de-risks the scale-up of manufacturing so quickly, but it really wasn't about funding the R&D. That happened over many decades, and it just goes to show that it really is an ecosystem and it's a lot of partners, it's the IP that connects them.

Joseph P. Allen (00:58:52):
Let me just start this off with one question that actually occurred to me while you were making your excellent presentations. It's really ironic that if you look at the purpose of 1498, the TRIPS Agreement and Bayh-Dole is to promote patent-driven innovation. That's why we did them. Now they're attempted to be misused and what we're hearing is this needs to be done because of drug prices, but the irony is if you start these precedents in any of those three it's inevitable they're going to expand to other technologies. In fact the UN Secretary General has already said after we said we would give away our Covid vaccines and now maybe our therapies, that breakthrough energy technologies should be the common property of everyone and then patents should not stand in their way.

(00:59:41):
So we may talk about the impact on the drug industry which is certainly significant, but I think the thing we shouldn't lose track of is once you let the genie out of the bottle, any technology that somebody wants to copy or micromanage falls under the same regime. So what does all this do if in fact... And the other point I'll make real quickly is these are self-inflicted wounds, these are not things that the Russians or Chinese or Iranians are forcing us to do, these are things that some of our political leaders are voluntarily saying that we should do. So what's the impact on American innovation if in fact we go down this path? And once you start down this path, how easy is it going to be to make a course correction to actually get back to where we are right now where we're leading the world in innovation?

Brian O'Shaughnessy (01:00:34):
Thanks Joe. I'd like to expand on a couple of things that Jon said. One is again, going back to first principles I often like to cite to the fact that the very first patent system was created in the Venetian duchy of the 16th century. The purpose of the patent system was to promote disclosure and in fact to weaken the guild system, the guild system of course which mandated that you maintain all of your technological savvy in trade secrets. And so the Duke of Venice at the time said, "Well, this is really hindering our development and we are a mercantile-based economy so

what we really want is we want people to disclose all of their technology so that other people can build upon it and so that we won't be victims of the guild system." So it is very much the very purpose of a patent system is to promote the disclosure of information, and to wean us away from a system based upon trade secrets where all of the most valuable technology is clouded in secrecy.

(01:01:45):
We don't want that. We want information to get out, we want it to be free. And in exchange for the disclosure, we allow people a very limited exclusive right to the meets and bounds of their invention. So the notion that somehow the patent system fuels monopolies and helps big companies couldn't be further from the truth. In fact it makes it possible for the little guy to elbow their way onto the market because without a patent how are you going to compete with the well-funded major corporations that oftentimes dominate an industry? Well, you do that when you have a legally enforceable property right in your innovation so that the big companies either have to license it or they have to design around it, but without that property right the little guy, the startup hasn't got a prayer. So we need a patent system, we need a patent system to fuel innovation, we need a patent system to protect the little guy and to make more invention possible for the betterment of all.

Joseph P. Allen (01:02:56):
We just actually got a question from the audience which I'd like to throw which I think is really something that's part of the debate, and I'd like to get your thoughts about it. This person said, "Can you talk about alternative approaches that will be much more effective in addressing the problems of high drug prices, windfall profits, et cetera?" So we've talked about what the problems could be in some of these approaches, so what are ways of actually making sure that people can get accessible healthcare and also to make sure that our innovation system is actually functioning the way that it was intended to do? So anybody that wants to address that, please go ahead.

Jon Soderstrom (01:03:32):
Actually the judge actually can speak to this probably better than I because she cites the Hatch-Waxman Act in her paper, and I think that's a classic example of what we have done to try to create opportunities for generic versions of these proprietary drugs to come onto the market faster. And it works astoundingly well in terms of controlling prices, and what's very interesting is that you look at most of our top prescribed drugs almost all of them have a generic version at this time. Now, that was really done in a time when most of these things were small molecules, but the biologics are slightly different, but it created a fast track for getting an alternative version onto the market to create competition. There it is, competition.

Brian O'Shaughnessy (01:04:31):
I guess I'd like to... Oh sorry, Judge has her hand raised-

Joseph P. Allen (01:04:33):
No, please go ahead.

Judge Susan Braden (Ret.) (01:04:37):
90% is the number. 90% of the prescriptions that people buy are generic. No one talks about that. The 10% is a very small amount, many of those drugs are targeted for very specific I don't want to say obscure, but drug diseases that not the general population has and there are not a lot of people to buy that particular drug. But if you happen to have that problem, you are really happy to know that that drug is available for you. And the issue of the price is the initial prices on many of these drugs are hot where there's a limited market. But the statistics show that it drops considerably in a very short period of time and the companies as you know, continue to try to reach out to people who have limited means that need these specific drugs to see if they can help provide that. That's not discussed in TV shows that I know of. I was listening in the car yesterday on public radio, a woman who claims she is a doctor with... I'm trying to think of the name of the big company, but anyway she's a doctor, she's a regular contributor and she was talking about stuff that was totally wrong including the fact that FDA gives out patents. How in the world can they have someone on public radio who doesn't know where patents even come from and is criticizing the system? We're living in an echo chamber and they're a group of people and they're well meaning, they're smart people that maybe they have too much time on their hands I'm thinking, but they're academically in a little

hothouse world writing and talking to each other and it takes on a life of its own. This... the law review article I talked about comes to the New York Times and then all of a sudden there's senators writing bills based upon this stuff and no one looks at what's being said.

(01:06:56):
Is there any basis for what's being said in these articles? It's dangerous, and I don't mean to say that they're ill... They're smart people, they're well meaning people, et cetera, but they really have not thought through the consequences in a bigger picture of what they're suggesting.

Brian O'Shaughnessy (01:07:19):
Joe, if I can offer a further observation and to build upon-

Judge Susan Braden (Ret.) (01:07:22):
Kaiser. She's a doctor with Kaiser and she's had some type of newsletter they put out in blog and whatever. It's just unbelievable. Sorry.

Joseph P. Allen (01:07:34):
Brian?

Brian O'Shaughnessy (01:07:36):
Just again, building on something that Jon said. At the end of the day when you finally get a drug you might only have six years left on a university patent that really was the foundation. If we were engaging in a pure point-counterpoint type argument and if I was permitted the opportunity to be the devil's advocate here, the logical extension of that argument is if you want cheaper drugs, let's extend the term of the patent. Let's make it 30 years instead of 20.

Brian O'Shaughnessy (01:08:05):
... the term of a patent, let's make it 30 years instead of 20. And that gives the pharmaceutical company an added amount of time to amortize its investment. If it has an added amount of time to amortize its investment, it can charge a lot less for its drugs. But if you know you've only got maybe, oh, before it's eligible for Hatch-Waxman challenge, you've only got either three or five years of exclusivity, and then it's eligible for an attack under the Hatch-Waxman Act. That means, I've got to make back my billions of dollars in five years. If I knew I had 10 years, well, I could charge half as much. But nobody's really looking at it from the standpoint of an economic argument. They're just looking at it as, well, these are really expensive and they shouldn't be that expensive because it seems really expensive.

Jon Soderstrom (01:08:53):
Yeah. Remember, you're also amortizing all your failures across that profit as well.

Brian O'Shaughnessy (01:08:56):
Right.

Jon Soderstrom (01:08:57):
I mean, they have to make a profit, because the amounts in money they have to invest are so large and the risks are so unquantifiable that they have to be able to make these untoward. And that's why when people say windfall profits, windfall profits suggest that you're doing something in a commodity way and suddenly you're charging much. That's not what this is. This is not windfall profits, the way we used to talk about oil and gas.

Brian O'Shaughnessy (01:09:24):
Right. Yeah, and I would like to add to that too. The premise of the question is that somehow our innovation ecosystem is not working. Well, explain to me then why prior to Bayh-Dole, for example, the US was responsible for less than one-third of all new drug discovery. More recently, the US is responsible for roughly 80% of all drug discovery. One would look at that data and say, "Well, our innovation system is working remarkably well. We are the most innovative economy the world has ever known." And it is undoubtedly attributable in large part to the functioning of our patent system, which has incentivized investment in very risky technologies, as John has said. So

in my view, there is no foundation for the notion that we need to fix this system. What we need to do is support this system and breathe life into it just as the founders had contemplated.

Joseph P. Allen (01:10:29):
Let's get a couple more questions here, because we're going to run out of time here before too long. Actually, we're getting some excellent questions. Another person had just written, "Judge Braden discussed the law related to Section 1498, what case law exists directly or indirectly on the question of whether Bayh-Dole's margin or the Bayh-Dole Act allows margin based on lowering prescription drug costs? How difficult will it be to prove litigation that Bayh-Dole does not allow that use of margin rights?" Actually, I'll take a crack at this. In full disclosure, I was on Birch by staff before I did this, and the answer is that's never been litigated. And one of the reasons is because the government has never marched in.

(01:11:10):
This is another theory that came up out of theoreticians. Actually, people that opposed Bayh-Doyle, 20 years after it was passed, said they found a secret meaning in the law that turned the whole thing on its head and allow the government to set prices, not just for drugs but for anything. That interpretation has been rejected by every administrations looked at it over the past 20 years, and the most were rejected under the Obama, Biden administration. So what happens is, the people on the other side just keep filing the same petitions over and over again. But the fact is, there has been no litigation about this because in fact, the government has never marched in, because Republican and Democratic administrations all agreed that's not how the law works.

(01:11:49):
So again, if the law is misused, you will have some litigation. And I think then you could have things quoted like Brian said, by Senator of Bayh-Doyle, "If you look at the statute, it's clear that's not what it means. But a lot of this is done for political purposes, not just for the law." And that leads me into another question I just want to pose real quickly. Either words in the laws mean things or they don't. And I think we're getting to an era where apparently people say, like the Red Queen and Alice in Wonderland, "Words mean exactly what I want them to do, no more and no less." If in fact, laws and policies can be just turned upside down according to political whims if we represent power, do we even have a system? Anybody?

Patrick Kilbride (01:12:36):
That's a great point, Joe. When there's a rule of law environment where contracts are respected, everybody can do business together, and only the government can provide that rule of law environment. And when they take actions that call into question, everything else underneath it falls apart. So really the government is the guarantor of the rules-based system of the ability to take risks, to invest in long-term time horizons, to be able to look ahead and say, "I could fail nine times out of 10, but if I succeed once I can get a return on investment, so I'm able to make this investment." And I'll just say, small digression but, when we talk about intellectual property, I hate to hear the words incentive and reward use, because I think it creates a misperception.

(01:13:35):
When you invest in a car or a house, your title is not an incentive, right? The incentive is your utilization of a car or a house. By the same token, your exclusive right to your car is not a reward. It's simply the rules that make it possible to do business in an economy. And think about how much would you be willing to invest in a car if you had to leave it on the curb with the keys in it every night, probably not a whole lot, then nobody's going to be able to invest, able, not incentivized, but they won't be able to invest in things like drug discovery and other technological solutions unless we have these rights guaranteed by government that enables their investment.

Brian O'Shaughnessy (01:14:27):
The NIH already ran this experiment, right? Didn't the NIH for a little while, they put a term, a clause into their contracts, when a technology was being licensed out of NIH, it said that the licensor or licensee would commit to selling the resulting product at a reasonable price. And what happened is nobody took those licenses. So-

Jon Soderstrom (01:14:50):
It was for cooperative research and development agreements and nobody signed up to it.

Brian O'Shaughnessy (01:14:54):
Right. Okay, thanks. So yeah, nobody signed up to it. We've run the experiment, we've seen what happens, people run away. We don't want that to happen again.

Joseph P. Allen (01:15:07):
You're exactly right that we have done these experiments numerous times, but unfortunately a lot of people don't know that. And so, we have to go back to the same basis. It's a very expensive experiment. We have another question here based on, I think, what John was talking about earlier, "Can you discuss something about the role of risk in calculating a return on investment by early-stage investors?" And let me just add to that something we mentioned which needs to be brought out. Our system is driven by small companies, even in drug development, 50% of our new drugs come from small companies.

Jon Soderstrom (01:15:40):
It's higher than that, Joe.

Joseph P. Allen (01:15:42):
Okay. But across the board, if you look at what we're talking about, we're talking about small companies who have to get funding to take that risk. So can you talk about it a little bit more about, what it's like... We actually had a program just a couple months ago from four really impressive energy technology startups. And one of them talked about what it's like to not take a salary for three years, or to almost have to lay your staff off the week before Christmas because you can't get the new round of funding. No one ever talks about that. So in addition to windfall profits, you're more likely to lose your house at this business than you are to suddenly hit the jackpot.

(01:16:20):
But again, let's go back to some of the basic things again. What's it like as an investor? If somebody comes to you with a Bayh-Dole invention or early stage invention, has a gleam in their eye, as the former president of BIO said, most biotech startups have two assets, they have a smile and a patent. So what's it like when someone walks in your office like that and says, "Hey, are you going to invest in my company?"

Jon Soderstrom (01:16:46):
Well, I'm going to turn it around. I'm the one who's out there with the smile and the patent. I've been doing this for a long time. As Joel attested, before I started doing this, I actually had hair. I mean, this is an interesting world to be in, but the point of fact is, is that if we go back to risk adjusted premiums, I mean, there's a time everybody who deals in finance realizes there's a time value to money. And you try to achieve a certain rate of return based on how you allocate your resources between various opportunities with different levels of risk that you think have different payoff, time payoffs. That's why everybody, in your 401(k), you're urged to diversify. Well, what are you diversifying against? Well, things that have a higher risk versus a lower risk rate of return for your portfolio. So that in good times you can exceed the rate of return that you get and in bad times you've got to hedge against the downside.

(01:17:53):
It's just that when you're dealing with VCs and with corporate investors and the pharmaceutical, they're looking at it across all the different opportunities that they have to invest. Recognizing that, in the case of venture capitalists, here's a little alone thing, they're raising money about every two years. They're raising a new fund about every 24 months, they're out trying to go back to people asking. And the only thing that they can do is point to their past track record of success. So they have to have a rate of return that justifies the risk they're taking so that the next time they ask for money, people are saying, "Okay, you did well, I'll give you more." It's not like it's a one and done.

(01:18:43):
They're constantly looking at this. And so, when you're presenting to them, they're always saying, "This is great, John, but I think you're too early." I can tell you, 90% of the presentations I've made in front of VCs, that's the

response I got. Really interesting technology, but way too early, need to have more demonstrable proof that it actually works.

Judge Susan Braden (Ret.) (01:19:06):
They are.

Jon Soderstrom (01:19:07):
And the question that my faculty inventors look at me and go, "But where are we going to get that money? Where is that money going to come from?"

(01:19:25):
And by the way, Joe, when I said it's higher than that, for first in class drugs the rate of development in terms of small biotechs versus big pharma, I think it's like 65 or 70%, for first in class.

Joseph P. Allen (01:19:42):
Yeah. One of the things that seems to be driving the other side of this argument is the belief that the way to solve these problems of not having enough is to take somebody's property away and give it to other people or to have the government set prices. Are any of our competitors giving their technologies away? Again, are the Chinese or anybody else following our model, or what do you think they think of us as they're trying to overtake our lead and actually copy our system, and then to sit down at the table, like in Geneva and to find the US government is actually in favor of giving away our Covid technologies that were just driven by the private sector, or now you're expanding that to any Covid related therapy which nobody even knows what that means? What do you think people make of that?

Jon Soderstrom (01:20:27):
With respect to the Chinese, they actually demand that if you are going to be in partnership with... In order to do business in China, you oftentimes have to have a Chinese presence.

Joseph P. Allen (01:20:38):
Right.

Jon Soderstrom (01:20:39):
And in order to have a Chinese presence, they demand that you actually transfer the technology to the company, so it can practice that technology.

Joseph P. Allen (01:20:48):
Right.

Jon Soderstrom (01:20:49):
And you can only imagine, what happens is the technology gets transferred, people move, suddenly it shows up somewhere else. And all, I was going to say, all hell breaks loose. But all hell breaks loose. Because you no longer have control of the technology or the market opportunity, your rate of return just drops. And by the way, it then shows back up in the United States as a repackaged version of your own technology. I mean, we're sitting there trying to be super fair when the Chinese are doing exactly the opposite.

(01:21:28):
When a company establishes its presence in United States, we don't require them to have a US based partner. We don't require them to disclose their technology. We don't require them to share their technology openly with everybody. Quite the contrary, the reason they come here is because they know that they can make a rate of return that justifies the risk that they're going to invest. And by the way-

Joseph P. Allen (01:21:535):
What about price controls, Joe?

Jon Soderstrom (01:21:57):
The Europeans are doing that. I mean, that's part of the explanation for Brian's comment about why the innovation

has flipped. It used to be two thirds of research in pharmaceuticals were done in Europe, now it's one third. And part of that is just driven by the fact that they have price controls.

Judge Susan Braden (Ret.) (01:22:16):
Right.

Jon Soderstrom (01:22:16):
And they're rigorously enforced.

Joseph P. Allen (01:22:179):
Well, we brought you all together because we wanted to have a plain English discussion. And I think this is certainly been that. And also, I think we, hopefully, we've got through to the audience, this is not just a theoretical exercise. We just have a couple minutes left, does anybody want to make any closing observations about anything we've covered or any new points?

Judge Susan Braden (Ret.) (01:22:39):
I do.

Patrick Kilbride (01:22:39):
No, just specific to the trips waiver, one element that's often left out of this debate is the importance of intellectual property to patient safety. And what we've seen through the course of the pandemic is that as the innovators have licensed out technology to licensees around the world, we've often seen unauthorized versions of those products start to proliferate. Some cases it's diversion of legitimate product, but many others, it's just the market being flooded with counterfeits. They might be missing the active pharmaceutical ingredient that makes the drug work or they might actually contain harmful toxic ingredients that actually make people sicker. But this is a huge problem and one of the things that intellectual property does is give some discipline to both the innovator, the regulator, and the downstream purchasers and distributors. It creates that rule of law connection. It's almost like a legal blockchain in effect.

(01:23:49):
And that's really why the system works. It's the disciplines that IP brings to the ecosystem that allow partners to come together and to have accountability. None of this should be lost in the debate.

Joseph P. Allen (01:24:06):
Judge Braden?

Judge Susan Braden (Ret.) (01:24:09):
Yes. I've asked recently, why don't I hear anything on radio, TV or anything, that really pushes back on this. And I have an ad, here's my ad, everybody in this audience knows someone that has dementia or Alzheimer, or know someone in their family, in their neighborhood, where they work, former colleague, put those faces on a screen with the people that have put millions of dollars at stake trying to find a remedy, a relief for those. As I said it, they've spent millions of dollars essentially, which have gone down a rat hole. Nothing has been produced that has been successful. Does the viewer of the American Public want pharmaceutical companies and investors to continue to try or not? That's the question. It seems to me an ad like that would get people's attention, which is, there is a need but it has a cost and it has a benefit. And it's not a short term always solution. It may be one for the long term, but it's well worth the effort. Thank you.

Joseph P. Allen (01:25:48):
Well, listen, that's an excellent point and we actually had another question here, actually was a question's a comment, which I really liked. It says, "This has been a great discussion. How do we convey this to the public?" That's what we're trying to do. That's the reason the Bayh-Dole Coalition was set up. We spend too much time talking to ourselves and we need to get this message out because these are critical issues. This really is serious business and the consequences are enormous. It's like turning a giant ship. Once you change direction, it's not easy to get back again. And the other thing is, it took us a long time after Bayh-Dole passed and we strengthened

the patent system to have companies believe that the government could be a reliable research partner through our Federal laboratories and universities. And we're really in danger of losing that.

(01:26:38):
And unfortunately, once you lose that, it's going to be even more difficult to come back again because it's like Charlie Brown with the football. After you've done it a couple times, people are not going to trust you. So we really hope that you'll help share this program. Like I said, it'll be on our website early next week, we'll have a transcript available. But we need to really convey to the American Public and policy makers that this is really serious business. We've been down this road before, we've run these experiments before, we've tried this whole thing about making everything freely available, destroying patent systems, and we have patent driven system. And the record is clear, if you choose to look at the record, the record is clear.

(01:27:17):
And the other thing I'll say is, the Bayh-Dole Coalition doesn't have theorists on. We have people like the folks you see today, they actually have done this in real life. These are not people who just made up a theory in the ivory tower. And we really want to help get that message out. So again, please look at our website, help circulate the thing about the program. I hope everyone has enjoyed this as much as I have. The panel's been fantastic. This is really what we like to do and we hope you'll join us in a future program.

(01:27:46):
And before we close, I want to really thank Emily Troisi and Jack Dunn, who've just done a fantastic job pulling this whole thing together behind the scenes. We have a tremendous staff and I really do appreciate it. So again, we hope to see you in the future. Thank you for joining us today. Please share the program and we hope you'll turn in again when we have a next one on another topic that really bears scrutiny. So thank you very much and have a great rest of your day.

Judge Susan Braden (Ret.) (01:28:12):
Thank you.

Brian O'Shaughnessy (01:28:14):
Thanks Joe.

Patrick Kilbride (01:28:15):
Thanks Joe.

Jon Soderstrom (01:28:15):
Thanks Joe.