President Biden’s March-in Framework: A Conversation with Joe Allen, Kate Hudson (AAU), and Dave Kappos (C4IP)

December 14, 2023
Joseph P. Allen (00:00:01):
Let’s start. Again, my name is Joe Allen. I’m the Executive Director of the Bayh-Dole Coalition, and we welcome you for our fireside chat to discuss the recently announced march-in guidelines. The guidelines just came out actually a couple of days ago, actually just a few days before the 43rd anniversary of the Bayh-Dole Act, and the administration is endorsing a long-rejected theory that the government has the right to second guess how a product is made on a federally funded invention is priced in the marketplace. We have two distinguished panelists joining us as we consider what does this mean and what are its implications for American innovation, wellbeing, and economic development. Kate Hudson is an Associate Vice President and Counsel for Government Relations and Public Policy at the Association of American Universities. Before joining AAU, Kate was an attorney advisor with the U.S. Government Accountability Office, the GAO, and also with the Office of Personnel Management, and was a key member of the Office of Government-wide Policy at OMB in the White House.

(00:01:04):
David Kappos is the Co-chair for the Council for Innovation Promotion, a bipartisan coalition dedicated to improving our intellectual property rights system. He’s a partner at Cravath, Swaine & Moore and is recognized as a world expert in the field. He also served as the Under Secretary of Commerce and Director of the U.S. Patent & Trademark Office in the Obama administration. We welcome your questions, which you can submit on the Q&A button at the bottom of the screen.

(00:01:31):
Because many joining us today may be new to the issue, let’s just take a minute to review what is the Bayh-Dole Act and what are march-in rights? I was privileged to have been Senator Birch Bayh’s staffer on the law. I was in the room when we first learned about the problem within existing government patent policies, which doomed federally-funded inventions to waste away on the shelves, benefiting no one. Although they didn’t agree on much, Senator Bayh and his Republican colleague, Senator Robert Dole, decided this policy simply couldn’t continue, and even in the midst of a contentious election year, introduced bipartisan legislation to address the problem. I put together the hearings of the Senate Judiciary Committee, wrote the report on the bill as it was sent to the Senate floor, staffed its passage through Congress, and later oversaw its implementation at the Department of Commerce. Before Bayh-Dole, if the government funded any research lending to an invention, it took the patent rights away from the inventing organization and made them freely available to anyone who wanted a license.

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While nobly intended, this doomed these discoveries to waste away, because there were no incentives for any company to spend their resources and time necessary to turn these inventions into useful products. Bayh-Dole changed that. It decentralized technology management from the Washington bureaucracy, allowing academic institutions and small companies to own inventions they make under grants and contracts. The law allows the government to use these discoveries for its own purposes, requires universities to give preferences and licensing to small companies, and those who will make the product in the U.S. to use any royalties they receive to fund more research, pay patent-related costs, and to reward their inventors. The government was then to get out of the way, but a fail-safe mechanism put in place to be used in emergencies. Before Bayh-Dole, if the government funded any research lending to an invention, it took the patent rights away from the inventing organization and made them freely available to anyone who wanted a license.

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Bayh-Dole built on this model, establishing four triggers for the rare cases when they could be needed, but like airbags in your car, these are for use only in case of emergency. Because universities were new at patent management, the first trigger applies only to the patent owner, which is normally a university under the law, not the licensee developing the product. It says that good faith efforts must be made to bring the invention “to practical application.” That term, as partly defined in the law, is making sure the invention is “available to the public on reasonable terms,” because Congress wanted to ensure licensing terms encourage commercialization,
and the university was monitoring it so they could rescind the license if key milestones were not being met and the developer was really not trying to commercialize the technology.

**00:04:24:**
The three other triggers applied to both the patent owner and the licensee. They stipulate that the product can be made in sufficient quantities to meet national emergencies, like health and safety needs, or to meet the requirements of federal regulations, and the licensee is meeting their commitment to make the product in the United States if they agreed to do so. If these situations occur, the government can march in and foresee diversity to license others “upon terms that are reasonable under the circumstances,” mirroring the same language about licensing terms as was used in the first march-in trigger.

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For this first 20 years, no one questioned how the law worked. Then two enterprising law professors claimed they’d found a secret meaning in the decades-old statute. They claim that “available on reasonable terms” meant the government could march in if someone thinks a successfully commercialized product is too expensive. I remember laughing when I first read the paper. The theory is based on quoting non-Bayh-Dole hearings or critics of our law, but I wasn’t laughing when The Washington Post ran the professor’s op-ed, titled, “Paying Twice for the Same Drugs.” That introduced another canard, that the government’s funding not only early-stage research, but also product development. I contacted my old boss, Senator Bayh, and he got in touch with former Senator Dole, but The Post would not give them space for an op-ed, so they had to squeeze their arguments into a letter to the editor, but they clearly said their law did not allow the government to second guess pricing, only to make sure the product was being successfully developed whenever possible.

**00:05:55:**
Nevertheless, a series of petitions were filed asking the government to march in against successfully developed products because of their price. At its only public hearing on the issue, Senator Bayh appeared. He showed the petition deliberately misinterpreted the Senate Judiciary Committee report that I had written and added that if we had intended for the government to set prices, we would’ve defined what is meant by a reasonable price in the law and included licensees in the first march-in trigger. That petition was denied, as well as all subsequent ones found over the last 20 years seeking price control. The most were denied in the Obama-Biden administration. Ironically, nine months before issuing its guidelines, which endorsed the reasonable pricing theory, the Biden administration itself rejected that very concept in March of this year in the most recent decision.

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Underscoring Senator Bayh’s argument, here’s what NIH said in its denial. “Therefore, the patent owner, the University of California, does not fail the requirement for bringing Xtandi to practical application, as the drug is manufactured and on the market in the manner of other prescription drugs.” Note that NIH said the patent owner, the University of California, not Astellas, the developer, which sets the price, had met the requirement of bringing the invention to practical application. That’s a key point in the law. By the way, I don’t ask anyone to take my word on any of this. The Bayh-Dole Coalition has painstakingly created a digital library on our website, which has every foundational document related to the evolution of government patent policy going back to 1945. It also contains every march-in petition denial, so I encourage you to read them for yourselves. So, enough background. I want to bring our distinguished panelists into the program to share their thoughts about what happened last week and what it means. So Kate and David, what do you think about the proposed draft guidelines, and if they’re implemented as written, what’s your impact? Well, you have to talk.

**Kate Hudson (00:07:57):**
Well, I’m happy to go first. Obviously, the university perspective is really vital in this, given that university research advancements and the developments that are discovered on both our campus labs and in national labs with university research faculty really are the drivers of part of this innovation ecosystem. And so you have the research conducted on universities, you have private industry, and you have the federal funding, and that is one of the most unsung, I feel like we can never talk about it too much, one of the major drivers of the economy is this three-part
stool that works together. But that technology transfer, that process from the university through commercialization, is really where that economic powerhouse is in the United States, and a lot of people don’t realize that. A lot of people do not realize that so many of the products in intellectual property that we interact with on a daily basis began, long ago, probably, began as an idea or a research advancement on a university campus.

(00:09:07):
And so, this type of research that is conducted at universities is absolutely vital and it is what makes the United States just the absolute leader in the academic research enterprise overall. For me, reading this framework, it really appears to afford the executive branch such broad latitude to interpret its rights under Bayh-Dole using really highly subjective criteria and considerations. That’s really what struck me about reading it the first time, now that I’ve read it for three or four times since it came out last week. Among other things, it does not clearly state which prices should be considered or whether a price is reasonable, who gets to make those kinds of rules. And that’s just one of those gray area concerns that I really have with this draft framework if it is to be adopted. It is not an overstatement to say that if adopted, the draft framework’s approach to march-in rights could significantly impact licensing and collaboration arrangements between universities, biotech companies, and other parties.

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University research advancements are, by and large, at very embryonic early stages of development, which is very high-risk. And the greater the chance that the federal government marches in, that adds such another layer of uncertainty and risk, that overall, small and medium-sized firms and startups will just not be able to license that technology at all. They will just make other choices with how they spend their venture capital and how they develop their business models. And so it’s so important to not forget that this framework is not merely confined to pharmaceuticals. This touches every single sector of university research across the board. So everything from agriculture, green technologies, infrastructure, semiconductors, defense sector research that all universities perform. That this is much wider than just this ongoing public discourse on the cost of drug prices. And so this framework impacts all of that and it could be extremely, extremely detrimental to that entire innovation ecosystem if it is adopted. And with that, I will jump to Dave.

David Kappos (00:11:46):
Thanks, Kate. Great to be with you, Joe, and thanks everyone for tuning into this. So look, I’ll put a very fine point on several of these initial threshold items. Number one, will this proposal do net good or net harm to the U.S. economy writ large and the U.S. innovation economy? This will be a very damaging move if made by the administration. It will do tremendous net harm to our innovation economy. That’s point number one. Point number two, is this really about drug prices? Answer, absolutely not. As Kate said, and I’ll just be very clear about this, on its face, this proposal is technology-agnostic. It applies to artificial intelligence, it applies to our national defense infrastructure. It applies to quantum computing. It applies to areas like Kate mentioned, materials, agriculture, computer science, you name it. It applies across the board. It is not just a pharma-related provision.

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Third point, will it actually do anything to help control pharma prices? Now, on that, I would start by saying we’re all concerned about affordability of healthcare to our families and our fellow Americans. We all care about that. We all want drug prices to be reasonable, but this provision will have absolutely nothing to do with making drug prices more reasonable. The data shows, and the Bayh-Dole Coalition has collected a lot of this, that the vast, vast majority, I mean in the high 90 percentage, of drugs on the market are not the product of government funding. And so you could turn that around and say, “Well then, why is anybody worried about this?” Because of the dramatic impact it’ll have outside of the pharma industry, as both Kate and I have already said. So the intended effect, minimal or non-existent. The collateral damage, enormous.

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A couple of other points and then I’ll stop. We can have more of a discussion. So why will this provision do so much damage? Well, we recognized during the Obama administration when I was running the USPTO, because there was
a flood of these kinds of petitions coming in. We realized then, like every administration, Republican and Democrat has for 43 years since the Bayh-Dole Act was passed, that it is a tremendous folly to go down the road of equipping the government and arming the government to march in. Why? Because you freeze investment incentives across the board. My day job is doing deals, mostly doing very big deals. They involve boards of directors, company CEOs, senior management teams that I advise on whether to make investment decisions.

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And the advice that people like me are going to have to give after this proposal goes into effect, and I would expect every intellectual property lawyer in the country’s going to be mandated to give essentially the same advice, is to say, “Look, if you are going to invest as a company in a technology that is based on federally-funded R&D, that’s resulted in a patent position, you should plan on that patent position being worth nothing. In fact, you should plan on that patent position being a detriment, an inhibitor, rather than a benefit to your ability to commercialize the product or service that you’re in the end trying to put in the marketplace.” So why should you take that position? Because, of course, if you are unsuccessful in making a marketplace entry or having a product that consumers want to buy, it’ll be no problem.

David Kappos (00:16:03):
Nobody will care. Nobody will want to march in. And that’s fine. However, heaven forbid that you should be successful because if you are, you can be guaranteed that there will be some company somewhere, and it’ll probably be a very large company, which after all will have a great narrative, more resources, access to capital, tremendous development capabilities, tremendous marketing and sales capabilities and after product support services and all of that, that company’s going to have a great narrative. And you know what? It’s going to be so fact-bound that you’re going to be up at the Court of Federal Claims three, four years later before anyone can figure out whether that petition made sense or not. So what I’m going to be telling companies that I advise, and I expect every other lawyer in the nation is, stay away from federally-funded R&D. It’s now toxic. It’s contaminated. Don’t touch it.

Joseph P. Allen (00:17:04):
I think these are great points. Again, the more we look at this, the more ramifications are on. The other thing we should mention is this doesn’t just affect university research. Small businesses that make inventions on the federal funding, like if you’re in the SBIR program, you now have a target on your back. And to me, the shame of this is until last Thursday, I could have told you how Bayh-Dole works. And before Bayh-Dole, companies didn’t want to work with universities, companies didn’t want to work with federal laboratories because if you did, there was a chance the government could take your invention away. So we segregated our best and brightest minds in the public and private sector. Even after we passed Bayh-Dole, it took years to have companies have confidence that government could be a reliable partner.

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Now in less than a week, that’s been blown up. And the other thing that we should mention is anyone can file a march-in petition. It could be somebody who doesn’t... It could be a rival company. It could be somebody who doesn’t like you, could be a gadfly who calls you up and says, “Hey, Kate. Really would be a shame if somebody filed a march-in petition while you’re trying to get venture funding. Maybe you should make it worth my while not to do that.” Because even if it’s not successful, the announcement that you have a march-in petition filed against you, what venture capitalist is going to fund a startup company with this hanging over your head? And the other thing we should mention is what about the people that have already commercialized a Bayh-Dole invention, assuming they knew what the rules are? Now suddenly, no one can tell you what a reasonable price is. There is no statutory definition of a reasonable price. And as Senator Bayh said if we’d intended that, we would’ve defined it. It’s completely capricious.

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So now, as opposed to Bayh-Dole being decentralized and universities actually managing their portfolios, federal laboratories, you’re going to make a petition, it’s going to go to Washington, and either some bureaucrat or some
political appointee is going to decide whether your price is reasonable or not. And again, you can go to court and petition it, but how long is it going to take you to get that done? So this opens up a whole can of worms.

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And the final thing is, having looked at this for a little bit, the places it’s least likely to make an impact is on drugs, because as David and Kate said, drugs have multiple patents around them. There may be a federally-funded invention part of it, but you can’t practice the drug. You have to have the whole portfolio. A march-in right only gives you the right to that federally-funded invention. So there was a study that came out between I think 2007 and 2019. 99% of the drugs, march-in rights would have no impact on them. If they were commercialized in that time period, no impact, because you couldn’t get all the patents you need.

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However, if you’re starting an environmental, company spinning off of a university technology, an energy company, an agriculture company, it’s very likely that your key patents are in fact covered by Bayh-Dole. And that’s where this is really now you have a red letter attached to your back or target attached to your back, and so somebody can go to the Department of Agriculture and say, “Hey. I think these apples are more expensive than other apples in this grocery store. It’s unreasonable. You should license a competitor.”

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The other thing is foreign competitors can file a march-in petition. So I think we’ve now started a new cottage industry of people who are going to make a living harassing our companies and just again, even if they’re not successful, “I’ve undercut you when you really need to get funding.” And what venture capitalists is going to invest in startup companies now, which is one of the drivers of our economy, with this hanging over their heads?

David Kappos (00:20:32):
Yeah. And-

Kate Hudson (00:20:32):
Yeah. Go ahead.

David Kappos (00:20:35):
Oh. Sorry. Go ahead, Kate. Sorry.

Kate Hudson (00:20:37):
I mean, those are definitely top-of-mind points for me, especially here in the university sector, not the least of which that while we license our technologies 70% of the time to small businesses, we continue to be the holders of the intellectual property. And so those small businesses aren’t the only parties involved if there is going to be some kind of march-in inquiry. So it would drag my universities, all universities, sorry, any university that is holding that IP into these kinds of inquiries, which is a huge drain of time, of talent, and resources that obviously could be used in much more beneficial ways in higher education. And so I do worry that not only are all of the holdings right now, everything that universities have participated in that would be subject to Bayh-Dole, it would be subject to this draft framework in its current form, but into the future.

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So right now, it already feels like we are on shaky ground, and if this draft framework is to be adopted, it would just jeopardize not only all of our current licensing agreements but everything into the future. And universities are just staring down the barrel of this type of an inquiry coming down from any federal agency that they receive federal funding from. There’s an enormous host of federal agencies that fund federal research. And so this isn’t just NIH or HHS or others. This is everything. The lack of that delineation, we’re all in this together. All sectors are into this together because there is no delineation, but it means that it is going to affect the academic research enterprise writ large.

David Kappos (00:22:25):
Yeah. Kate, just I’d like to go a little further into this point about the factual nature and burden on universities and
the burden on small companies, which after all are going to be predominantly the ones that are getting attacked with march-in petitions. Think about an issue like pricing. It’s among the most fact-driven decisions and the most sensitive decisions and the most thoughtful decisions that any company has to make. Think about issues like ability to manufacture, ability to service, ability to scale up, time to market. All of those are extremely fact-bound decisions that are subject to many, many, many factors. And I mean, the kind of factors that we know how these things work when we have disputes in our country that get subjected to formal dispute resolution processes, that being the court system. This is where we see literally millions of documents produced that are bringing forward the facts that are involved, and now suddenly, we’re going to have our country’s universities right in the middle of that. It’s absolutely crazy to think about how this is going to work.

So there’s some... I don’t know. Is it like a GS9 person in the Department of Commerce who’s going to then receive a pallet load of documents? It’ll be probably electronic now. So it’ll be in a data room, and it’ll be like 15 million pages. And I’m not kidding with a number like that. And this GS9 person then is going to be in charge of deciding whether this big company that says it can bring the product to market faster, cheaper, with better servicing or whatever, whether they’re right. And then what about when the startup entrant says, “Well, their data’s all slanted. They didn’t tell you the whole story, Ms. Or Mr. GS9 in Department of Commerce.”? And I’m not picking on government employees. I think they’re great. This isn’t about the government not being able to do its job at all by the way. I’m just trying to get everyone’s heads in the game here, how this is going to work.

So then the small company’s going to respond by saying, “Well, this is crazy. Their data’s all wrong. This is not how the product works. Nobody can manufacture it for that amount of money, blah, blah, blah.” And now you’re going to have a back-and-forth. So now you need an adjudicatory process. You’re going to need discovery. You’re going to need depositions. You’re going to need expert witnesses. This is an absolute mess. And all those points are exactly why no previous administration went down this road knowing this road leads to disaster.

Joseph P. Allen (00:25:23):
It’s actually worse than that because what people don’t understand is there is a process in Bayh-Dole that has to be followed for march-in petitions. First of all, the agency has to say, “Okay. Did you meet the criteria?” And that’s where all these have been dismissed so far. There’s not gone further than that under any administration. Even the Biden administration in March said, “You didn’t meet the criteria. Price is not an issue if it’s been commercialized. So that’s why we stopped there.” But suppose they say, “Yeah, you have.”? Then you start an administrative hearing. The patent owner, the university, and the licensee can petition a finding if they disagree with it. That goes up to the secretary. If the secretary says, “Okay. We’re still going to march-in,” that’s not the end of it. Now you can go to the Court of Claims.

So anybody who thinks that march-in rights is a shortcut to get things out there, it’s anything but that. Now you’re into a mess. And here’s the other thing, just like people are misusing the patent system now, that costs money. And so the people most likely to suffer are the small entrepreneurs. People may not know this, but 70% of patent licenses in universities go to small companies. We’re the only country in the world where 50% of our new drugs come from small companies. Now, they don’t necessarily commercialize them, but they start the research. If you look at immunotherapy, which won a Nobel Prize, if you look at the AIDS cocktail, a lot of those came out of university research where they couldn’t find any licensees. University of California couldn’t license immunotherapy for 10 years until they finally found a small company. Same thing happened with mRNA. Now those companies now may spend a decade of their own time and expense trying to make this into something useful, and they can only do that if they can get venture funding.
somebody filed a march-in petition. Can you afford to spend three years on fact-finding and litigation? Maybe you should make it worth my while to go away.” So this is not a shortcut to having somebody say, “Hey. I don’t like Kate’s price. I’m going to march-in, and a couple months later, this will be out there for other people to use.” Hey. We do have one question here. Dave, this is for you. I don’t necessarily understand it, but I’m just going to read it as it came to me. “Follow-up question for David Kappos. How will large company interests tie up patents that come out of government-funded research?”

David Kappos (00:27:53):
Yeah. So it’s a great question actually. So the scenario will be as follows. I’m a big Co. and a successful innovation has come out, let’s say, in the material science area, and it came out of government initial upstream funding at some great university that Kate represents that made a breakthrough in material science, and this breakthrough enables much lower cost air conditioning, as an example, just making things up here, and the patents that resulted have been exclusively licensed by Kate’s university to a small company that’s now industriously, seeking access to capital, trying to raise funding, building prototypes, getting in the marketplace, working with joint venture partners and development partners, all the things that companies do, very hard work, that by the way is a long, probably like a five to 10-year timeframe, even longer in the biopharma area, but plenty long enough in an area, let’s say, like material science.

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And so I’m big Co. that comes along and I’ve got a market cap of a half a trillion dollars and I’ve got 250,000 employees, let’s say, and I’ve got factories all over the U.S. and all over the world, and I’ve got lots and lots, tens of thousands, of engineers. I’m going to be extremely motivated as soon as I learn that that breakthrough exclusively licensed patent really works. When little Co. publishes their data that shows that material breakthrough really works, I am immediately... In fact, it would be a breach of my fiduciary duties to my board of directors of my public company, big co, if I didn’t march in, go into the Department of Commerce, if it’s administering this, and file a petition that says, “I’ve got tremendous market reach. I can bring this product to market quicker at scale, less expensively because of my ability to buy raw materials less expensively than this little company, my ability to put engineering talent on this breakthrough. I’ll bring the product to market quicker and less expensively than this little company.”

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That’s going to be a very attractive petition 100% of the time. I mean, this isn’t a close call, you guys. This is every time the big company is going to have a huge structural advantage on every axis of the decision-making process over the small company. So get ready for this being a, “Let’s help the biggest companies have an easy time to get access to intellectual property after it’s been de-risked by the little companies.” And you know what that means? The little companies aren’t going to get capital in the first place because the people around me in the big tall buildings here in New York City who fund those inventions, they’re not dumb, and they’re not going to fund them if there’s no guarantee of an exclusive position. And what this march-in proposal says is there won’t be a guarantee of an exclusive position anymore. It’s as simple as that.

Joseph P. Allen (00:31:18):
This turns our whole system on its head. It’s been driven by small companies, and now you’ve got a target on your back if you either license or make an invention with government funding. Hey. We have another question here, which is... Actually, we’re getting some great questions. “We just came through a global pandemic where life-saving technologies and therapies could not come fast enough to prevent patients from being turned away from medical facilities and lives being lost. What creative approaches/channels can we use to explain to naysayers naturally concerned about pricing that putting a black mark on federally-funded inventions will not help fill the goal of making sure that research benefits people?”

Kate Hudson (00:31:57):
I mean, for me, the creative approach is to not adopt this draft framework, is not to put this into practice, and to
share that undercurrent of American innovation and entrepreneurship. That is what drives our economy. I think talking about that and socializing that is one of the best ways to do it.

(00:32:20): And I think there was another question about at this point, they're not asking for questions about the pricing clause in the NIST framework. So does that mean that that is already a foregone conclusion? I think that's a very good question, especially for our policymakers all over Washington is be visible, be vocal. This is a draft framework. There's still time to pump the brakes on this. And getting in there and being active advocates and very visible and loud in this space is probably one of the best things that you can do to talk about the specific ways that this will inhibit innovation coming out of university campuses and national labs. They are one of our greatest assets in the United States, and this is literally shooting ourselves in the foot and then having to run a marathon, against every other country by the way.

(00:33:12): This is not great in when we talk about the overall competitiveness challenges with China and other countries, this is absolutely an unforced error. There's no reason to do this to ourselves. And so telling your policymakers that is probably the most effective thing you can do at this point.

Joseph P. Allen (00:33:31): Yeah. I'm sorry. We should have added that people have until February the 6th to make comment on this. So it's not a done deal, but I think most of us were shocked to see that the Biden administration, which just ruled against this in March nine months ago, has now suddenly... And the law wasn't changed in the last nine months as far as I know, and I do know it wasn't changed in the last nine months. But suddenly we've turned around and for some untold reason, adopted something that's been rejected for 43 years. David, I'm sorry. You were going to say something.

David Kappos (00:34:02): Yeah, well, I was first going to just add to Kate's point that look now's the time to make calls, to send letters, to get to your elected officials in addition to the administration, I mean like your members of Congress and members of the Senate as well as the administration to tell them what you think of this.

(00:34:24): Coming back to the question for just a minute. First of all, I want to say that's a great question. I want to give a big hug to whoever submitted that question because it really does get to the point of why this is so important. So if you step back, of course, Covid was a terrible global scourge and a disaster of unprecedented proportions, and so many of us suffered through it. And again, I think we can all be united in saying that we want everyone who needs to get treated for Covid or any other disease to have access to that treatment at a price that's affordable and in a timely and effective basis.

(00:35:03): Now, we actually owe the fact that the U.S. was able to lead the world in addressing Covid, along with some partners in cases in Europe, and that the technology existed, and importantly was able to be taken from the nascent stage to the deployed stage in a shockingly short period of time. We owe all of that to the Bayh-Dole Act and federally funded research because it's the precursors, the upstream research that was done that benefited from the Bayh-Dole Act that enabled the applicable companies to get in position so that when Covid became what it became, they were able to pivot, deploy resources, and address it as quickly as they could. So we have the Bayh-Dole Act to thank 100% for our ability to respond to the pandemic as quickly as we could.

(00:36:07): The one other thing that needs to be mentioned is yes, there were a lot of problems with deploying treatments of all kinds and diagnostics relative to Covid, especially in the early days. There were problems, particularly in lesser developed countries, and we all feel terribly about that. There were problems with refrigeration because these drugs need to be in temperature controlled environments. There were problems with last-mile delivery logistics. There were problems with travel and transport, moving things around in these countries. There were problems with
just trust in the government, with people who have so little faith in their government that they didn't believe that these treatments were going to be effective. There were problems with corruption in cases where treatments were taken and moved to other places for profit. All terrible problems that needed to, and hopefully in most cases were addressed. Notice none of those problems had anything to do with intellectual property. The patent system -- not part of the problem. It was part of the solution.

And to the great credit of the many companies in the supply chains that needed to work together, they did. And they quickly inked literally hundreds of agreements to get product manufactured and to move it as quickly as possible toward patients. So yes, we could have done a lot better. Yes, we need to do better next time. But the way we do better is, number one, we keep and promote a very strong intellectual property system so that the incentives are in place to develop the infrastructure ahead of time, the intellectual property, and the substantive vaccine infrastructure ahead of time. And number two, we make sure that we’re helping countries in other parts of the world that don’t benefit from the kinds of advantages that we have to put the physical infrastructure in place so that when the next pandemic comes, we can help them and they can help themselves to cure their people.

So IP, again, is absolutely critical to the solution and in no way connected with the problem.

And just to build on what you just said, which is excellent, you have to wonder now again, that happened because people had confidence in the rules of the game. And despite what the critics say, companies brought billions of dollars of resources to the table overnight on Covid when everybody else was locked down. University researchers and federal lab researchers and company researchers working around the clock together because they trusted each other. You have to wonder if we had another pandemic, God forbid, would that happen again? Because now is government still a reliable partner? What are the rules? I can't tell anybody right now, and I’ve been working on this for a long time until last Thursday I could tell you what the rules are, now I can’t.

Well, Joe, it’s interesting because we are definitely concerned with the outcomes, and Dave is giving us a great landscape of what this will look like if a march-in inquiry happens. But the larger, more existential question is that if this framework is adopted and those risk calculations are too high, and the technologies and the research advancements are not licensed at all, we will not have a drug to distribute. We will no longer have them. And that’s not just drugs. We will not have what we are trying to research now in drought-resistant crops. We will not have those additional semiconductor processes and those advancements in quantum that are being made on almost a weekly basis we read about. So much is happening in the development of so many critical technologies right now that those things will not happen. It will never leave the shelf. It will do what just happened before 1980.

I think your figure is 33,000 patents were just sitting on a shelf before 1980 and not being developed. And that is what we will revert to because the risk calculation and the lack of predictable defendable IP rights will just make that calculation too high for anyone who is looking to invest in emerging technologies of any kind across sectors. Including biopharmaceuticals, including the things that we want to be able to prolong our lives to cure diseases and help the next generation of our children live longer and to not struggle with many of the diseases that we take for granted now that other generations took for granted in the past. Those things just will not happen. It will just disappear. You won’t have a market to fight about because it will not be there.

And also, we’re talking about green technologies, environmental technologies, all the things government’s spending billions of dollars on now, you’re going to have research papers and not products if this happens the way I’m afraid it’s going to.
But we have one question here I’m going to take real quickly. Can you share any information about why this change in Bayh-Dole won’t affect drug prices? Is there a report that can be shared here? Yes, there is. Vital Transformations just put a report out just a couple of weeks ago. If you go on the Bayh-Dole Coalition website, I actually wrote about this earlier this week. And so my article is linked there, and I have a direct link to the Vital Transformations study, which shows that 99% of the drugs developed, I think, I believe the years are like 2007 to 2019, but I may be a little bit off on that. But 99% of them would not be affected by march-in rights because most of the patents involved in that drug are not federally funded.

And there’s a reason why the critics of Bayh-Dole Keep going after Xtandi. They filed maybe six petitions on Xtandi, all of which has been dismissed back to the Obama administration. Obama, Xtandi is an outlier. Xtanid’s core patents were federally funded, which is why the critics keep going back to Xtandi. But other than the Xtandis of the world, which are again outliers, 99% of the drugs developed in that time period would not be affected by march-in rights. So that’s why to claim this is a huge cudgel now that’s going to beat down drug prices, it’s not. It may beat down alliances between life science companies and federal laboratories and universities, but it’s not going to have any impact on drug prices.

Kate Hudson (00:42:43):
Yeah, Joe, I think, if I remember the report coming out, out of 361 subject inventions, right, only 5 could be traced, fully traced back such that they would be subject inventions under Bayh-Dole. And two of those were radioactive isotopes, and one was Xtandi, and two others. So out of 361, that’s how little it is.

I mean, I see that there are some questions about drug prices overall, and there are avenues for that, but that’s not what the focus is here. We want to prevent the adoption of this draft framework. There’s a lot of work to be done on drug prices, as Dave said, we want those prices to be reasonable, but this is not the way to do it.

Joseph P. Allen (00:43:31):
And in fact, if you look at the guidelines, the scenarios they have about pricing are not related to drugs. Their scenarios are related to highway signs and all kinds of things. So even the guidelines are making clear the White House, the political operatives are making this big thing about, oh, we just unleashed this fury that’s going to lower drug prices. Read the guidelines for yourself. Look at the scenarios. They’re not drug price scenarios, they’re scenarios on other technologies. So we’ve now unleashed a hornet’s nest on our own innovators. And again, the people that are going to get stung aren’t going to be the drug companies. They’re going to be the small startup entrepreneurs that drive American innovation. This is going back to the pre-Bayh-Dole era, where government funding was radioactive and you took it at your own peril, and that’s a real shame.

David Kappos (00:44:22):
I wonder if we go back for a moment, Kate was making an important point before about the effects of, we’ll be going back essentially to the pre-Bayh-Dole days. We should be clear-eyed about this proposal, it kind of kills the Bayh-Dole Act. So think about the result as going back 43 or more years into the past, and I think it is a foregone conclusion that there’ll be far less uptake of university head-end research, basic research by companies in the US.

But I’ll tell you what, I’ll take that a little further. If I were advising Chinese companies... And by the way, I have nothing against China and some of the things they’ve achieved, but it’s well known that of course China watches us technology and does its best to take it, copy it, and benefit from it. As long as they’re not stealing it, it’s their right to do. Unfortunately, they do steal a fair bit of it too. But now they’re not going to have to steal anything, right? If I were advising a Chinese company or the Chinese government, I’d be saying, this is actually great, because now American companies that used to pick this IP up aren’t going to be picking it up. It’s going to sit there. We can pick it up in China. We can gestate the technology, and of course, it’s easy because we can just read the patents in the patent applications. It’s all published.
(00:45:43):
So we can pick it up in China, we gestate it with our giant bolus of government funding that's available from the top down management of the economy there. And then, like a U.S. company in stealth mode. We keep it in stealth mode until we're ready to come out with a new product or service. And then we've got the time to market advantage. We've got the surrounding intellectual property that we develop in addition to the basic intellectual property. So we've got a strong intellectual property position, and we get to be the first into the market. So the new markets of the future are going to get built in China, not in the U.S., based on the free copying of U.S.-based technology funded by American taxpayers and abandoned due to this presidential decree. So it's shockingly against our country's best interest.

Kate Hudson (00:46:37):
Isn't that just a cosmic irony that the openness of our patent system would be bludgeoned against us using march-in?

Joseph P. Allen (00:46:45):
Well, making it even more ironic, the Chinese have copied Bayh-Dole. But you can be sure they're not going to copy this.

Kate Hudson (00:46:52):
Right. That's a good point, Joe. I mean, Bayh-Dole has been such a successful public policy. It's been adopted in 16 countries, including countries in Europe who we talk about the differences between their patent system and ours. But we have a very good public policy on our hands already, and several of those countries have adopted their own version of Bayh-Dole that works in their own government frameworks. That's how good of a public policy this is and has been for 43 years. Why would we mess with this?

(00:47:22):
I mean, sure, we can talk about ways to better bring developments over the valley of death towards commercialization. Yes, absolutely. Those are things that we can work on in the processes and ways for the government to assist in that. SBIR and STTR are incredibly successful government programs to help this nascent technology grow. But doing this and adopting this framework is the antithesis of that.

Joseph P. Allen (00:47:53):
Another irony is that Senator Joe Biden was on the judiciary committee and voted for Bayh-Dole, and then later in his career he voted against an amendment by then-Congressman Bernie Sanders to-

Joseph P. Allen (00:48:03):
So up until last week, I really wonder if President Biden understands what his political operatives have done. This whole thing strikes me as a campaign document as opposed to a serious policy document. The other thing is, and again this is just speculation, if you read it carefully, it looks to me like a lot of the career people on the Interagency Committee knew this is a stinker and actually put things out there, considerations about this, which actually undermined what this is doing. My feeling is political operatives instructed them to put this in the interagency work as opposed to they came up with it themselves.

(00:48:46):
Now we don't know that, but one thing we do know for sure is Chairman Sanders, now with the Senate HELP Committee, actually held up the NIH directors' nomination and said, “I'm not going to consider this nomination until the Biden Administration bows to my demands to endorse reasonable pricing.” A month ago, that hold was lifted and the nomination was approved, and now we have this document coming out. So I'm not alleging that something behind the scenes happened. Lord knows that never happens in Washington, but it is curious that in March, the Biden Administration says, “This is not how it works.” In December, they said, “Yes, it is.” So you can come to your own conclusions there, but this gets more perplexing the more you look at it.

David Kappos (00:49:32):
Hey, Joe, and Kate, I wonder if we can go while we have just a few minutes left here-
Joseph P. Allen (00:49:36):
Sure.

David Kappos (00:49:36):
... if we can go deep one other place. Kate mentioned another thing that was important, which is the agreements that universities have in place already as the creators of this basic technology. So people may be asking the question, “Well, maybe there’s some goodness in this because it’ll cause companies that have licenses from universities to really get their act together and bring things into the marketplace quickly.” Well, okay, the problem with that is that universities already have every incentive to do that. In fact, they already do it, right? I spent a lot of time dealing with university agreements that license their head-end patents down to implementers, usually exclusive licenses. Again, this is across the board. It’s information technology, it’s artificial intelligence, it’s quantum, it’s materials, it’s biopharma, it’s everything.

(00:50:28):
It’s totally standard for universities to grant those licenses, and these are big documents. We’re not talking about like a three-page document. We’re talking about like 160-page document. It’s got committees that are formed. It’s got many milestones that are required. It’s got timelines. It’s got policing. It’s got reporting. It’s got reports. It’s got audits. These agreements are built for scale and they’re built with 43 years of experience in universities developing practices to ensure that their licensees actually do act with haste to put products in the marketplace. By the way, the universities reserve the right to take the licenses back if the licensees aren’t able to, or for whatever reason don’t perform. Again, they’re not dumb.

(00:51:16):
They’ve had a lot of experience and they put very bulletproof agreements in place. So what that leads me to is look, if your concern is that companies move as fast as they can, that’s a good concern. We all have that concern. The universities definitely have that concern. They’re the ones that are at the so-called coalface in this regard. They’re living with these issues. They know how to deal with them, and they absolutely do deal with them. So this is a perfect example in my mind of where the private sector works so incredibly well. It has worked incredibly well for 43 years. It makes absolutely no sense in my mind to substitute a government bureaucracy for the giant amount of infrastructure that the universities and the collaboration partners already have in place and work extremely effectively.

Kate Hudson (00:52:06):
Maybe Dave, if you could also build on the point that patents don’t last forever. They don’t last forever. So if you are sidetracked by a march-in inquiry, what kind of impact would that have on just the lifecycle of your patent protection at all?

David Kappos (00:52:24):
Well, right. It’s another factor that will devalue all government-funded research ‘cause the clock’s ticking, right? Patents last 20 years from their filing date, and that 20 years turns out to be very short. In the case of biopharma, by the time the first product goes on the market, it’s on average, going on 14 years. So you are already down to maybe six years of exclusivity left by the time the product goes in the marketplace. As you were saying, Kate, the whole dynamic of the patent being a time-limited asset lights a fire under the universities to get the licenses in place under the collaboration partners to go out into the marketplace, do the clinical studies, or whatever else they’re doing and get products there, the system works extremely well. It actually works quite well.

Joseph P. Allen (00:53:16):
I think that’s an excellent point because as I mentioned in the beginning, the reason we have the first march-in trigger was in 1980, universities were new at technology management, and Congress wanted to make sure they, in fact, were enforcing their licenses and not allowing people to license something for the purpose of suppressing it. That’s never happened. The reason we haven’t had any march-in cases is because universities are, in fact, enforcing the licensing agreements, and if somebody misses milestones, they terminate it and license somebody else. The other point is Bayh-Dole decentralized management out of the Washington bureaucracy and let universities
manage their portfolios, this now centralizes everything to Washington. Now Washington is micromanaging the process, and it’s all arbitrary, so this turns Bayh-Dole on its head. Now Bayh-Dole is uncertain. It’s centralized and it destroyed all the incentives that Congress put in place 43 years ago, which The Economist Technology Quarterly said Bayh-Dole is the most important policy change in the last 50 years.

(00:54:16):
More than anything, it helped reverse America’s precipitous slide into industrial irrelevance. That’s what we’re playing with. If you look at what the upside is of this, I frankly can’t see one. But the downside is ominous, and this is not a small thing. So I appreciate everyone’s time here, and I think this has been a great discussion. We have have some closing remarks here, but if we can get one thing across to the audience, this is a big deal. This is not some small obscure patent thing. This is fundamental to American innovation and it’s fundamental to the American economy. When we pull apart our public and private sectors, as we did before in 1980, it’s really dangerous, and this is a dangerous world. There are hard-nosed people who are happy to take advantage of any blunders, and we’ve just made a serious blunder. So Kate and David, do you have any final thoughts you want to share?

Kate Hudson (00:55:17):
Since this was so recently released, a lot of us are still processing, getting our arms around this, and figuring out what’s the best way to answer this and to talk about this both now and into the future. The comment period obviously ends in February, but that’s not the end, right? We can continue to advocate, to tell the stories of amazing innovations that have benefited global society. We can continue to talk about these things and continue to speak to policymakers on the Hill. Their voices carry a lot of weight even though they’re in the legislative branch, and this is an executive branch framework, there’s a lot of leverage to be utilized here. So this is an opening conversation, and I know that if we pay attention to this space and advocate visibly with policymakers and with the public at large, perhaps through polling survey research, get in touch with your congressional delegation and just talk to them about this issue and bring it to their radar, those are the steps right now in the short term that would be most effective.

(00:56:28):
Then moving forward, hopefully we can make some inroads there, but continue to advocate. The fight is not over. But we do have some short-term things to get through, so submit comments, avalanches of good, thoughtful comments. If you are at a university or you are at a company or another entity that will be affected by this, tell NIST, share it in comments. We need an absolute avalanche, tsunami of comments, and that is the short-term goal right now. We also need you to reach out to your members of Congress. Those are the two things that I would close with. If you are on a university campus or you’re affiliated with the university, hey, maybe you’re just an alumni that likes the football team, reach out and see what you can do for the alumni association. Get in contact with your university leadership and ask how you can support their efforts.

Joseph P. Allen (00:57:20):
David?

David Kappos (00:57:21):
Yeah, great comments. Thanks, Kate. Yeah, so I would just come back to make sure everyone is really clear on the basics here. Number one, this is not primarily about biopharma. It affects all areas of investment in technology in the U.S. across the board. That’s point number one. Point number two, while this has been captioned and pitched to us as lowering drug prices, it’s going to have next to no effect or perhaps absolutely zero effect on drug prices, as has been explained during the past hour here. So you were hoping that this would somehow moderate drug prices, forget about it. Not going to happen, right? That’s point number two.

(00:58:05):
Point number three, this is absolutely 100% sure to chill investment in great ideas coming out of our universities to in effect, it’s a repeal of the Bayh-Dole Act. We ought to be honest about how we assess the situation. It’s just that important to know the effect of the change that’s being sought after here. Then lastly, this change works at 180 degrees opposite to other investments that the U.S. has been making through its federally-funded research, through
legislation like the CHIPS Act that’s hugely dependent on government research funding and can be expected now to cause companies to run headlong in the opposite direction. So it’s a policy choice that is impossible to reconcile with the other policy choices that this administration has been making.

**Joseph P. Allen (00:59:16):**
Well, listen, we really appreciate it. David and Kate have been very generous with their time. These are very busy people, and we put this thing together very quickly because we thought this is an issue that really needs to be vetted. But we deeply appreciate the time that you both have given us. We really appreciate the time of all the folks that have joined us. The Bayh-Dole coalition is certainly going to stand up about this. I was hoping this day would never come, but the wolf is at the door, and I think we have to deal with it. So anyway, we look forward to working with you down the road. Thank you again for joining us, and don’t give up hope. We’ve been through battles before. We’ll get through this one, but this is a fight that’s really worth having. So thank you. Have a good day, and thanks again for joining our fireside chat today. Again, thank you for Kate Hudson. Thank you for David Kappos, and I-

**Kate Hudson (01:00:04):**
Thanks, Joe.

**Joseph P. Allen (01:00:05):**
... hope everybody has a great day. Thank you.

**Kate Hudson (01:00:07):**
Great. Thank you.