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P R O C E E D I N G S

MS. BLUMENSTYK: Well, while everyone's getting seated, we'll get ready to begin here. Hello and welcome to this Brookings panel discussion which will look at issues that affect how academic technology transfer can best serve the public interests.

I'm Goldie Blumenstyk and I want to thank Walter Valdivia for inviting me to moderate this session. I've been following this issue for more than 20 years as a reporter for *The Chronicle of Higher Education* and that's been a great perch to see the many developments in the fields and also the evolution of a debate over Bayh-Dole and the Bayh-Dole Act, the law that was passed in 1980 that set most universities on this tech transfer path.

Many of you here in the audience know that's not a simple story to tell. Tech transfer groups like the Association of University Technology Managers have documented each year and that report that they put out called *"The Better World Project"* and in other publications, Bayh-Dole and the tech transfer system have helped to produce thousands of new innovations, great new drugs, and many energy-saving ideas that are now helping our economy. Universities and academic groups have also committed to a set of principles that are known as the Nine Points to Consider, which are meant to guide them in the licensing of their technologies so that they do actually license in the public interest.

But, as folks on this panel and many of you in the audience know, academics and academic institutions have also come under fire for some of their practices under the Bayh-Dole Act and in tech transfer. They've been criticized and sued by patients with Fabry Disease who are challenging an exclusive licensing deal that

Mount Sinai Medical School has that's now limiting their access to a drug to treat their disease. They've been challenged by public interest activists over the pricing of an anti-AIDS drug called ritonavir. It's an interesting case that we may get into a little bit here today on the panel.

Those of you who read not just *The Chronicle,* but read *Fortune* magazine may have seen a recent story a few weeks ago that questioned some of the patents and licensing arrangements that Wake Forest University has had for many years on a wound-healing system called the VAC. If you read the articles, it suggests that some of the patents and licensing arrangements that Wake Forest has for the VAC system is actually really driving up Medicare costs and basically suggesting that we are all paying for this patent and licensing arrangement that Wake Forest has.

And the decision by many major research universities to side with the biotech industry and the legal fight over gene patents, a case that the Supreme Court recently agreed to take on, the Myriad case, has also raised some eyebrows.

So, before we turn to our panelists, I just also wanted to summarize a little bit of data from the most recent report from the Association of University Technology Managers licensing revenues and patents. The top research universities in 2011 earned more than $1.8 billion in licensing revenues, but that sounds like a big number, but consider that the amount that North Western earned in that total, $191 million, accounted for more than 10 percent of that whole total. Add up 5 other universities that made $100 million or more and that's 40 percent of the total and of the 153 colleges and universities that responded to that survey, 23 reported licensing in $15 million or more. That doesn't take into account their costs. And for most of the rest, it was a lot less.

So, I think that sets a little bit of the stage here. Now, I'd like to introduce our panel.

I'd like to begin with Walter Valdivia of Brookings who has some ideas about where the policymakers should be placing their focus for improving tech transfer and Bayh-Dole.

Walter?

MR. VALDIVIA: Thank you. Thank you, Goldie.

Let me start for those who are not intimately familiar with Bayh-Dole to give a brief introduction of tech transfer conceptually, technology transfer. I was going to talk about technology transfer conceptually briefly because for many years the notion that innovation happens as a pipeline, as a conveyor belt from basic research to applied to development to commercialization stood out, but we think of technology transfer very differently now, not as one way to inception from research to firm organizations but as a much more complex exchange of technical information. Intellectual property is only one part of technology transfer.

Having said that, one of the areas in which my research has focused and one of the areas that we will develop in this conversation is the Bayh-Dole Act and whether the Bayh-Dole Act that is unified government policy in 1980 on the patents that the research contractors of government take after performing grants given by the government. Unified in favor of the research contractors. So, the Bayh-Dole Act allows any research contractor that wants to Title II patents produced with research coming from this federal grants and as this sole proprietor of the patent, then they can license it in the terms that they consider most convenient. It could be exclusive or nonexclusive licensing.

So, it brings this an important question which is: Whereas Bayh-Dole was intended to widen a bottleneck in the innovation system and allow for the research that the government was paying to be commercialized, to introduce the profit motive in

this process, it also begs the question as to whether what are the terms and most adequate conditions in which companies can commercialize in the best interest of the wider public, research that in the first place was funded with tax dollars? So, in the particular case of research funded by the federal government and despite the fact that the public was transformed into a private asset through Bayh-Dole, the question remains as to what are the best uses that will return the investment to tax dollars in research.

When we bring this question, then we start thinking about how well suited is the technology transfer system and particularly Bayh-Dole to promote the public interest. Just last year, Richard Levin was addressing the American Council of Allocation and he said, and I quote him literally, “Congress did not intend to give us the right to maximize profits.” He’s speaking to universities. “It gave us private property rights for a public purpose, to ensure that the benefits of research are widely shared.” He’s giving ostensibly recognition to this normative impetrative of universities to serve the public interest while at the same time they participate in the market forces that may accelerate innovation.

How do we start thinking of how the technology transfer system fits the larger question of whether the innovation system serves the public interest? Well, there are many angles to it. We could take the public health view that a lot of the new medical procedures and treatments that are developed at universities are actually reaching those in need, not only nationally but internationally. We could think of whether science and technology research is actually making and improving national security in its multiple aspects. We could take also one particular aspect and which I would like to drive some attention which is are the benefits of innovation being widely distributed and particularly those coming from public research? Is the distribution of the benefits of innovation resembling any notion of (inaudible)?

One of the tenants that receive wisdom of (inaudible) is the imperative of accelerating innovation and when innovation scholars think about how to reform and structure and configure the innovation system, the challenge needs to be how to increase and accelerate the pace of innovation. This because we know that innovation promotes productivity gains, economic growth, jobs. So, it seems to be an ambition in the public interest.

What we discuss much less is that the modes in which we choose to expand the economy are also specific modes of distributing that additional income and additional wealth. Every time we advocate for accelerating the pace of innovation, we are also implicitly advocating for a particular form of distribution. And if there is a clear proposition that I wanted to drive is that innovation doesn't take place in a single way or in an organic and natural way, it takes place under different modes of innovation and these different modes of innovation will have different distributional outcomes, different modes of distribution. And, so, when we think about technology transfer and the public interest across the dimension of the distribution of benefits of innovation, then we need to think what kind of reforms are we to introduce to the tech transfer policy that help configuring a mode of innovation that best promotes those ambitions that in the first place were placed on publicly-funded research, that is to expand the public interest, to reach out with the benefits of innovation to as many in the population of taxpayers as we can. So, that is a big challenge that we are trying to consider.

And specifically now talking about university knowledge transfer, as Goldie pointed out, university technology transfer is about business for universities. On my own research and doing some very conservative calculations on the cost of universities, I found that out of those 153 universities, 91 operated at a loss. So, a big and important question also to think about is: What are the new modes of technology

transfer that universities are doing precisely to advance or restrict their public interests?

Across the dimension of inequality, if the key question is how to configure the industrial organization of emerging markets, are universities and the modes of technology transfer that are emerging favoring structures that are monopolistic or are favoring the emergence of new industries along lines of competitive markets? Those are the big questions which I'd like to frame this dialogue and I'll go back to Goldie --

MS. BLUMENSTYK: We'll come back and probe this a little bit. That's great. I'm tempted to think about that old joke, but yes, they make it up in volume. (Laughter)

Bhaven Sampat, you've been studying this system for your entire academic career as far as I remember, knowing you as a young graduate student at the time, also, and you've been looking at both the U.S. practices and practices overseas.

What do we think we know about tech transfer and what should we really know?

MR. SAMPAT: Okay, so, it's a good question. I have been studying this for a long time and actually my own views on this have evolved a little bit. So, let me sort of take you through this or take you through my thinking on this.

So, Bayh-Dole, as Walter pointed out, had several goals. One was to create some uniformity across patent policy. Before Bayh-Dole, you had a range of government agencies, each of which have their own policies with respect to patenting of research that emanated from them.

I think the number I remember is there was 26 different patent policies or something like that across government agencies and it just became confusing to contractors, to researchers, to institutions, and others. So, I think the one thing that Bayh-Dole did that I think is probably unambiguously good, though maybe some people

would push back on that, is create some kind of clarity and uniformity. I think the clarity is more important than the uniformity, by the way, in government patent policy.

The other was that I'm an empirical economist by training. I should note that one of the classic papers on the economics of the patent system, on empirical work, on patents was published 25 years ago in the Brookings paper of economic activity and the author was Richard Nelson before he was president of Yale and involved in all these big debates. He is also a pretty good economist and one of the things that Levin, et al. point out in the 1987 piece is that patents work very differently in different industries. Pharmaceuticals and chemical-based industry patents are really quite important and others, they're not as important as other mechanisms for appropriating returns to R and D and that has implications for thinking about Bayh-Dole and university technology transfer.

So, to your question, Goldie, I mean, we can think about the intended effect of the Bayh-Dole Act and then we can think of unintended effects, and there's been research on each of those two fronts.

The intended effect was to promote commercialization of academic research and the concern during the 1970s amidst the competiveness crisis and fears of Japan Inc. and things like that was that the U.S. is spending a lot of money on academic research in general but we're not actually seeing returns. People were trying to figure out oh, what's going on there and then some individuals pointed to problems with government patent policy which respect to federally-funded research as being part of the problem and the idea that was advanced. And this is actually part of a broader debate that goes back to World War II, but it kind of came up again in the 1970s was that the reason we're not seeing commercialization, we're not seeing returns to federally-funded R and D is that academic institutions or contractors in general when they come up with stuff, they put in the public domain, but that research often requires much more research

before its actually commercializable and if it's just in the public domain, no individual actor has seen incentives to sort of take the ball and run with it or take it to the next stage. So, that was the argument for Bayh-Dole.

It's different from the classic argument for patent protection, which is patents are needed to create incentives for R and D. It's rather than patents are needed in order to create a mechanism to commercialize embryonic research is a little bit different and there's been work that's been done on that on the intended effect. I mean, one set of studies just looks at trends and patenting and licensing and license income since 1980 and basically everything's going up and says see, Bayh-Dole worked and that really wasn't the trends that other countries that are thinking about emulating Bayh-Dole-type policies are looking at.

And, so, I think this is a hard question, by the way. But in some of the work that I've done just sort of case study research, it looks like universities are, in fact, patenting stuff that needed to be patented to be commercialized. That's some of what lies beneath the aggregate trends.

So, 70 or so drugs have come out of academic research. Since the Bayh-Dole, it's hard to imagine that without sort of exclusivity, pharmaceutical firms would have actually commercialized those things. But on the other hand, there's a lot of stuff that universities are patenting that would have effectively diffused or been transferred depending on which construction you prefer, even absent the patents or licenses.

So, Google, Stanford had a patent on the Google algorithm. It's really hard to imagine. I mean, that allowed Stanford to earn some money, but it's really hard to think that without that patent; we'd still be using Lycos or Alta Vista or something like that. I mean, if you kind of look in the details of it, it was a way for Stanford to extract rents, but not really about technology transfer. The same is true for a number of

prominent biotech research tools.

So, I think to me, the question is still open on the effects of technology transfer. I don't want a filibuster here, so, let me just list the other questions. That way we can come back to them later on.

I think less is known about unintended effects including whether Bayh-Dole has distorted research agendas away from “basic research towards applied research.”

A second question people are concerned about, were concerned at least 10 years ago is that increasingly, academic institutions are patenting science in a world where as Isaac Newton noted, we are “standing on the shoulders of giants.” There is concern that too much patenting of upstream research discoveries could in fact increase the transaction costs of science and kill the goose that’s laying the golden egg.

And then there are also concerns about conflicts of interest, another unintended consequence of Bayh-Dole that clinical researchers in particular own patents on discovery on drugs and devices that they're testing and that could create biases.

And there's some research on each of these, but I think we should hear from the rest of the panel. We can come back to those questions.

MS. BLUMENSTYK: Right, those are all very important questions. I was also struck by some of the writings that I’ve seen from you and others that talk about the arising commercialization coming out of universities also corresponds with a giant rise in federal increases in federal research funding and the rise of the VC industry, and, so, to identify everything and attribute it back to Bayh-Dole, as you point out, might not be necessarily accurate.

Sam Howerton from the State Department, where does tech transfer fit into the overall United States foreign policy in three minutes?

MR. HOWERTON: In three minutes. (Laughter) That's not hard at all.

MS. BLUMENSTYK: You can have five.

MR. HOWERTON: Okay. So, I'll first agree with Walter that I think that tech transfer has to be seen as kind of a fluid process up and down. So, when we look at it from a foreign policy perspective, we don't look at it solely as the remit of transfer from university to industry, but a much more fluid process that involves what we call the innovation ecosystem, which is language that I think that you would hear if you went to talk to people from commerce or trade or some of the other aspects.

So, tech transfer as part of this larger innovation kind of ecosystem is also part of our economic state craft and what we're really after when we talk about tech transfer is promoting regional economic stability from the individual to the institutional level. This has a couple of benefits.

So, from a very introspective way, it's promote opening markets for the United States, which is something that the Department of Commerce is interested in, but it's also promoting kind of a national security agenda which the Department of Defense is also interested in because as economies become more stable and people have jobs that are productive over a long period of time, people are less susceptible to outside influences that may be deleterious to their personal or their national health.

And, so, from that perspective, I mean, I'll take less than three minutes, I'll answer it very simply, that it really is an economic driver by and large for the Department of State right now. It does touch on things like university industry partnerships and we can certainly get into those with the Q and A portion because I would say, too, that the way that we approach tech transfer as a department differs with each country that we interact with with each multilateral organization, and, so, there is a lot of nuance which I am certainly not an expert in all the countries that we engage in, but

I can certainly talk to it from the science and technology perspective because that's certainly where the office that I represent looks at it primarily from.

MS. BLUMENSTYK: So, Sam, I'll start with you. I've done a little bit of international reporting on tech transfer and gotten a little bit of a sense that there might be a different eco in some parts of the world about tech transfer than we have in the United States, at least in some European countries. I don't know if it's more of an explicit commitment to the idea of a public mission or some VCs who get frustrated with it might call it ambivalent to a commercialization, but do you see this different sense of a public mission in dealing with countries overseas?

MR. HOWERTON: So, the short answer --

MS. BLUMENSTYK: And, obviously, it's a big world out there.

MR. HOWERTON: It is a big world and the answer is succinctly put yes, and not only from the perspective of those who are in the universities or in the private sector whether they be multinationals or regional, but I would say that where in my personal experience now you see it the most is in the very cultures of the countries that we're talking about because all of these issues that you've described are actually national outgrowths of the culture that you have. Tech transfer innovation here in the United States is a reflection on us as a nation the same way that it is in other countries.

And, so, when we look across the globe at large, we seem some areas of the world that are very risk-tolerant where innovation and tech transfer kind of hand in hand become the norm and you see this partnership and in others we see where there's a great risk intolerance where people who may be interested in innovation and taking their idea, transferring it to the private sector, developing it themselves. It's kind of a one-shot deal that if they're successful, that's great, and if they're not, they're effectively ostracized from their cultural norm.

And, so, it's a very abstract answer to your very specific question, but the answer really is that we do see a lot of difference, and, so, that's a challenge for us as a department is to recognize and learn about the very cultures that underpin these topics that we're discussing today.

MS. BLUMENSTYK: And I think as Bhaven mentioned, Bayh-Dole in the United States was created a lot from some of the pressures that the United States was feeling from Japan Inc. and it was an economic threat. From what you see, what imperatives are driving this in other countries?

MR. HOWERTON: I would say right now --

MS. BLUMENSTYK: Again, how many countries are there in the world? There are a lot of countries out there.

MR. HOWERTON: Those that are focused on this issues, and, so, not all countries are focused on this issue, right? So, let's be honest, that in order to be focused on tech transfer, you have to have some sort of science and technology base from which you can build off of and not all countries are at that level. So, for those that are, let's say then the developing world or the industrialized world, it is almost right now a focus on economic development, that the great recession has hit everyone.

Independent of the processes that individual countries are using to identify tech transfer processes, when we talked to other governments, when they look at the strategic landscape, they all want to build their economies to employ people to increase their GDP.

MS. BLUMENSTYK: So, it's not the public mission that's driving it in other countries?

MR. HOWERTON: I think that there are countries where that is important where the social good is a factor, but I would say that in the countries that we

get asked the questions most about, the Bayh-Dole Act, which are typically developing countries; it is seen as an economic agenda, which has social positives. So, the --

MS. BLUMENSTYK: That's a lot, regional stability, economic stability.

MR. HOWERTON: It is and it's ensuring that as these governments begin to look forward in time, especially governments that have a population inversion that's different from those of the industrialized world; that's where there's a larger number of youth versus mature adults, that that's the lens that we typically see them looking from. We see highly-educated individuals from universities throughout the world who are unemployed or underemployed who have a lot of good ideas. And, so, the governments when we talk with them are curious to know how can we harness the intellectual power of these young people for the collective good?

So, I don't want to give the impression that it's pure capitalism and at the end of the day that the GDP increase is the only thing that these countries are interested in, but I think that you start at a very singular idea and then you begin to work down from it.

MS. BLUMENSTYK: Did you have a question that you want --

MR. SAMPAT: Well, yes, just on that, I mean, I've only looked at a handful of countries. I'm most familiar with India, but also sort of followed the debates in the Philippines and Brazil, and way back when also in Italy, and one of the motivations I think in addition to all that Sam pointed out, which I agree with, one of the other motivations is actually we need a way to fund science and funding science is expensive, especially in developing countries. It's hard to find resources out of scarce budgets to fund science and I think there is some view -- and I think this represents a misreading of the U.S. evidence -- that in fact if we allow universities to patent, they'll license their stuff out, they'll make a lot of money, we can invest this back into research and it's kind of

viewed as being this free lunch way to fund science. And, anyhow, there's no such thing as a free lunch.

MS. BLUMENSTYK: Yes. (Laughter) So, it's an idea, but it's not necessarily --

MR. SAMPAT: Well, I think it misreads exactly the evidence that you pointed out, which is that it's a handful of universities and a handful of inventions and it's not a sustainable model, especially if you don't already have a science base.

MS. BLUMENSTYK: Go ahead.

MR. VALDIVIA: I was going to chime in and precisely following on the notes that Sam said, in the case of India, there was a proposal for a Bayh-Dole bill that was introduced and you can confirm, it didn't get anywhere.

MR. SAMPAT: It's being rewritten right now, but yes.

MR. VALDIVIA: And it has to do with precisely there's different cultural business and different innovation culture and a country may require a strong revision of the principles that are in this kind of policy and India is a solid democracy and the internal debate will probably pitch people with different views of how important it is to import this policy innovation itself, Bayh-Dole, into India. And as you'll see, it already has pushed the bill into further debate and revisions and it hasn't passed yet.

MS. BLUMENSTYK: Bhaven, I want to make sure we get onto this distorted research priority issue that you raised because it's a critically important one.

I first just wanted to ask you: In the paper you wrote a couple of years ago, you talked about some of the safeguards that other countries should make sure they include in whatever version of a Bayh-Dole Act that might want to introduce. I was struck by some of the provisions about transparency, that the system ought to have this great deal of transparency. Mostly struck because I don't even know that we have that level of

transparency here. So, I guess I'm wondering do we have that kind of transparency here, and if we did, how would it help?

MR. SAMPAT: It's a good question. I think it would help people like me. So, by transparency, I think what Goldie means is information on what kind of licenses are being signed, with whom, what's happening at the end of the road? That would certainly help people like me in just trying to assess whether this thing worked or not, whether exclusive licenses are more likely to result in commercialization and other kinds and things like that. But it's not just for me that it's useful.

MR. VALDIVIA: Or me.

MR. SAMPAT: Right. Beyond the people on the stage, I mean, this is taxpayer-funded research and the taxpayer has a right to know what's going on with this research. There is some discussion, hasn't gotten very far, about things like march-in rights and using academic control of important technologies, primarily by medical sector, to try to do things like influence prices and things like that. That really hasn't gotten off the ground for a range of reasons, including some debates about whether that was actually something that people were thinking about during the Bayh-Dole hearings, but also because it's just really hard to know exactly where the government has a stake.

I have a paper with Arti Rai in *Nature Biotech* a few weeks ago that looks at the extent to which universities have been complying with their Bayh-Dole requirements to just report to the government whether there was government funding for a patent and it's getting better, but there's a fairly massive under compliance there.

So, I think transparency on that front, especially if you want it to harness university ownership to try to do some public interest oriented stuff, including prices or whatever, that's one reason that it would be an important thing.

And just one other safeguard since you opened that door, the main

safeguard, it's not even really a safeguard that I would want to build in, it's some sort of guidance on exactly what the kind of stuff is that we want to have patented and exclusively licensed, what kind of stuff that we just want to put out in the public domain. There is a belief out there in India and other places that the only way to disseminate research outputs is through patents. I mean, in fact, they came close in their first bill to mandating patents by academic researchers. I think one needs stronger guidance in other countries, Bayh-Dole-type legislation on exactly the type of stuff where patents and licenses are important for technology transfer and the types of stuff where other modes of dissemination would work just as well.

MS. BLUMENSTYK: Bhaven, do you think of this as something by fields or by scientific areas or --

MR. SAMPAT: Yes, so, there's a question of whether you can draw bright lines. I tend to think that pharmaceuticals are one area where the patent license regime is more important than in others, but even in the biomedical arena, the NIH put out guidance about research tools and things like that. So, I think it would be a set of principles rather than necessarily rules, but I think that would just be important and orient the technology transfer office to --

MS. BLUMENSTYK: To kind of set some norms out there.

MR. SAMPAT: Just set some norms, yes.

MS. BLUMENSTYK: This is in this kind of a field, licenses. Patents are less likely to be useful. This is in this kind of a field.

MR. SAMPAT: I think that's right. I think that's right.

MS. BLUMENSTYK: Could we talk for a minute about pricing standards? It's a very big issue in the petition about the ritonavir AIDS drug. There's a group of people who are trying to challenge that whole patent right now and ask the NIH

to march in and take over the license, saying that reasonable prices are not being charged on that drug.

MR. VALDIVIA: Yes.

MS. BLUMENSTYK: Does anybody have some thoughts about whether that makes sense as grounds for march-in? By the way, I think the number I last heard was there had been 31 petitions for march-in rights and zero granted. So, the government is apparently very reluctant to use this power in the Bayh-Dole Act for march-in and do we think it ever has a place to go in prices?

MR. VALDIVIA: We were just talking about safeguards and the march-in right provision is one of those safeguards introduced in the original bill of Bayh-Dole and what it does is first any contractor that takes a title in a patent emerging from research funded by the government needs to assign a paid-up license to government. Government then has the authority under this provision to use that license in a particular and a very narrow set of circumstances to protect a -- I believe the text, of access, a public health need. Perhaps, you remember the specific text. And if there is no evidence that the holder of the patent or their licensees are not practicing the patent, that is developing a product with it, the NIH under previous five march-in provision petitions that it received found it to be specific for the practicing of the patent and not broad enough to cover the control of prices or the regulation of prices, even if there is evidence of excessive pricing practices and some other forms of abuse. So, the legal department of NIH has interpreted the act in this way and it's, of course, a literal interpretation of the act, but it may be warranted given that the act was explicit in not introducing price controls.

The question remains whether there should be some form of amend or if further agencies should take a different approach to regulate abusive practices, anti-

competitive practices, or excessive pricing when this happens and when there is evidence that it's happening, particularly with products that emerge from publicly-funded research.

So, in other words, perhaps there should be a review of the march-in rights provision that will allow (inaudible) allotted to agencies to advocate and on behalf of the taxpayers that funded the research. Also, certain practices that would allow the firms to keep a profit margin, but at the same time not to pursue monopolistic pricing strategies.

If such a modification to march-in rights could be achieved, then perhaps it would be a mechanism to --

MS. BLUMENSTYK: Does it need to be modification or is there authority in the law right now that would allow -- if they deemed it, they could agree at the margin based on reasonable pricing?

MR. VALDIVIA: That's a tough question because agencies are bound to interpret the law to the best of their ability within the bounds of what has been the previous experience and what is the law saying or intended to say? However, when there is an obvious and there's strong evidence that there's this anti-competitive practices, there could be other statutes that could come into play and that could be tagged on march-in rights without having to modify the text of march-in rights. Perhaps what it needs to be is an explicit government policy that ties existence statute on anti-trust law with the march-in rights provision such that agencies would have seen their executive power increased and be able to curb some of the behaviors that are perhaps more egregious.

MS. BLUMENSTYK: So, for those of you who haven't yet read this march-in petition, it raises some very interesting issues about pricing, U.S. pricing versus

pricing overseas for this drug and I don't know that it's actually be the thing that tips the balance, but it certainly might be something that influences the debate going forward.

Walter, you've also talked about Bayh-Dole actually contributing very explicitly to the rising health care costs. It's a very big issue in the Wake Forest case. It's called the WAC System, by the way.

MR. VALDIVIA: Yes.

MS. BLUMENSTYK: It's an argument that its competitors to the company that makes the WAC are certainly making that Wake Forest patent should have never been granted in the first place and that its exclusive license is basically costing the rest of the country a lot of money.

Do you think this is a place to really use the lever of Bayh-Dole to --

MR. VALDIVIA: I like the question, but let me modify it because I believe that Bayh-Dole -- I'll modify this because I don't think Bayh-Dole is a direct contribution to increasing costs, but I would see more as Bayh-Dole could have been an important message to stop fast growing of health care costs and whether it could play that role, this is still an open question and it's a question that will have to be addressed the moment further reforms by law are considered.

Let me tell you why I see this as a possibly for Bayh-Dole to have a larger role than simply promoting patenting, but it could contribute to curbing some of the inflation in the health care sector and that is let me draw the specific example of the biomedical industry and specifically of genetic medicine.

At the beginning of the '90s, there was about 100 promising biotech startup firms. Almost all of them by now have been absorbed by one of the major pharmaceutical companies. What seemed to be an emerging new industry, ostensibly the result of publicly-funded research, has in time become completely absorbed by an

existing cartel of pharmaceutical companies. I say “cartel” because the small number of large pharmaceutical companies would satisfy that definition sometimes.

MS. BLUMENSTYK: Perhaps.

MR. VALDIVIA: One would think. The point is we haven't seen the “creative destruction” that Schumpeter would presume is the role of innovation, that a new cohort of firms come to replace an old cohort and that creates a thriving economy, that creates competition, and innovation comes with higher quality, lower prices, and a new generation of products. Could Bayh-Dole had the role to allow for these startups from the biotech sector to emerge on their own, that is an open question. Maybe it could have had a role, but as we confirmed --

MS. BLUMENSTYK: How would that work?

MR. VALDIVIA: Well, if we are saying that the biotech emerged largely from university laboratories, largely from federally-funded research, then the university managed a portfolio of patents that eventually became the portfolio of these startups, eventually became a portfolio of biotech companies. If the universities would have followed policies that facilitate and help these firms to emerge on their own, to stand on their own on the kind and became a competition, then they may not have been absorbed.

Now, there's the development of medical treatments has very high costs, particularly through the clinical trials for FDA approval. Very, very significant costs. So, any new startup confronts significant cash challenges as they walk into standing and become a company that could be a competition. It is these cash needs and particularly as they walk this period of low equity called (inaudible) when these startups are more vulnerable to be absorbed by incumbents of the industry.

So, one on the side of managing the portfolio and how exclusive license versus nonexclusive license could have been managed by the university system is the

role of Bayh-Dole, but again, I'm saying it would only have contributed to a larger effort to create a new industry that it stands on its own instead of being absorbed completely by the existing pharmaceutical industry. That's what I see not as Bayh-Dole as the principal instrument, but one instrument that could help promote competition.

MS. BLUMENSTYK: One of the things I guess I've always wondered about also is even if those big forces were coming through and it couldn't stand in the way of that, if there had been some cultural norm or something along the way that would have sort of included some kind of -- I'll say the word -- price controllers, something like that, something in the licensing of the patent that would have given the public a little bit more protection in the patenting system along the way. I always wondered why that couldn't have worked, but --

MR. SAMPAT: I believe that in original drafts of Bayh-Dole, there were -- perhaps people in the audience know better than I, there were some limits on profits that could be earned by licensees. There are some windfall profits provisions, but I think it was killed in conference. I'm not sure.

MS. BLUMENSTYK: We'll ask people about that.

Walter, you've also talked about if Bayh-Dole were to come up again today, some tweaks you'd like to see in either in Bayh-Dole or perhaps in other NIH or agency funding bills to kind of reward great proposals that have a different patenting regime thought behind them.

How would that work?

MR. VALDIVIA: Yes.

MS. BLUMENSTYK: Different point system, I guess.

MR. VALDIVIA: This was part of policy recommendations that were introduced at a previous Brookings paper. Now I'm self-promoting.

MS. BLUMENSTYK: Yes, you're laughing.

MR. VALDIVIA: A previous paper, but the policy recommendation, this specific issue is that federal agencies could shift without waiting for a modification by law, could shift to favor non-exclusive licensees when these licenses go to large companies. Perhaps, exclusive licenses are better suited for startups, emerging companies, they have very little assets. So, most of their ask portfolio is based on intellectual property, but already existing incumbent large companies. Well, agencies could help curb the behavior of how licenses are structured and whether periods for exclusive licenses could be shortened and nonexclusive licenses kicking in before the 20 years of protection of a patent --

MS. BLUMENSTYK: I can already hear the objections to that, the licensing path is so far away from -- the research occurred here, licensing could be 20 years down the line. Is this kind of idea really enforceable or feasible?

MR. VALDIVIA: Well, special care will have to be made to see how much further of exclusivity a patent enjoys. Again, Bhaven was earlier speaking on how a lot of the patents coming out of universities are prototypes, that they take a while to be developed and placed in the market. So, the patent protection starts way before the product goes into the market. That means that product receives patent protection in the marketplace on a much lesser period of time. However, and I'm going to defer to Bhaven because I understand that there is some evidence that compares the market life of patents and the marketplace. (Laughter)

MR. SAMPAT: This is an analysis I promised Walter I'd do over some drinks yesterday, but I didn't get to it, I guess. (Laughter) There could be, yes.

MR. VALDIVIA: There is some research to be done that compares the market life of a patent coming out of the university versus the market life of a patent not

coming out of a university, and by “market life,” we would mean the time during which a given product receives the protection of the patent and if the university patents are shortened, then it effectively is coming as a form of regulating the length of a patent protection. Bayh-Dole, that is.

However, if that evidence is not found and you have equal market life because products are built from a number of patents, and, so, the patents can be staggered --

MS. BLUMENSTYK: Right.

MR. VALDIVIA: To extend the protection given to a particular product, this is the case by the way, of antiviral cocktails that do not have a single --

MS. BLUMENSTYK: Right, 1,000 --

MR. VALDIVIA: Yes. So, if we were to see that the protection given during the market life of a product is not different for university patents than other patents, then Bayh-Dole could be used, again, to more strategically manage the tenure of patent protection and allow for an earlier introduction of competition and generics and --

MS. BLUMENSTYK: Yes, I’ve always heard that university patents are early stage developments, and, so, ultimately, the market life of a university patent is relatively short because if the patent starts way back here, it takes such a long time to develop it as a product that it only has a few years left on the market by the time that patent runs out.

I guess I wonder if that’s an argument for more exclusivity or less because at the end of the day, if it’s not going to make that much -- the patent isn't going to matter that much more. Maybe there's just been a lot of work and effort and expense to keep a patent that isn't going to produce that much in the end. And you're only getting five years of commercial activity out of it anyway, perhaps. Maybe it’s not worth all the

effort.

MR. VALDIVIA: In certain blockbuster patents coming out of the university that have been licensed on an exclusive basis, we have seen significant profits.

MS. BLUMENSTYK: So, it is worth the effort.

MR. VALDIVIA: So, at least there is -- until Bhaven gives us that imperialistic, the system might be --

MR. SAMPAT: Yes, I think it's an empirical question and really, we have to be careful because, as Walter pointed out, I mean, generally, but not always, the universities on a drug, if we're talking about drugs now, are going to have the compound or active ingredient patent which is the strongest patent and but then people stack on different patents on top of that and some of those hold up in court and others don't. So, I think it's actually quite complicated and an empirical question --

MS. BLUMENSTYK: I want to go to the audience for questions in a minute, but before we do, I just want to get back to your point about the way Bayh-Dole and tech grants in general may be sort of distorting research priorities.

Can you help us understand a little bit about what that means?

MR. SAMPAT: So, I was just laying that out as a concern. So, the idea is the concern that people raised is that if you start introducing profit incentives into academe then all of a sudden researchers would stop doing blue sky research, but instead would shift their attention to research that would be more likely to generate patents and money and there was talk in the early '80s about people being jealous of their colleagues driving in with Porsches and this and that and academics suffer from tremendous status anxiety, it turns out.

I got to say I was one of the people, not that long ago, but when I think we first met, I was one of the people who was concerned about this distortion of research

agendas. I read the evidence as suggesting it actually hasn't really happened. It turns out that increasingly now people who do a lot of publishing now also just take out patents on what they were publishing. So, I haven't seen much evidence of a strong distortion of research at least in the large sample data. Yes.

MS. BLUMENSTYK: Yes, maybe in the smaller. I mean, that's the thing I've always wondered about. Within smaller fields, does it sort of shift to one place or the other? Everyone's still going where the money is, so --

MR. SAMPAT: Right, that's what makes it hard.

MS. BLUMENSTYK: Right.

MR. SAMPAT: Because, ultimately, academics aren't calling the shots, it's the NIH and the NSF that are kind of calling the shots in some ways. So, you can't just decide you're going to do this if there's no money for it.

MS. BLUMENSTYK: All right, so, we have Mitch. Mitch, in his last week at Brookings, is going to help us.

If there are people who have questions here, I'm going to ask you all to identify yourself, please, and if you have a question, we'd love to hear it. If you have a treatise to deliver, maybe do that at another time. But if there's anyone here with some questions.

We have some in the back. The gentleman with the green tie there. Let's start there. If you could say your name --

MR. SANG: Jim Sang. In Professor Sampat's description of unintended consequences, he mentioned patenting science. I was wondering whether you'd have any comments about questions about how well the patent system is working in general, whether that in fact is a problem was how Bayh-Dole is working, that patent or PTO and the courts are allowing patents that should not or probably not conceived at the time of

Bayh-Dole.

MR. SAMPAT: Yes, that's a great point. Consistent with what I alluded to earlier, Bayh-Dole is part of a bigger package of reforms that are going on or changes that are going on around the same time which is why I think it's difficult to attribute anything to Bayh-Dole per se. One of those changes was changes in patentable subject matter in bio and in software in particular in the early 1980s and also there's been various things that have happened, including the creation of a court of appeals for the Federal Circuit in the 1980s that have led to kind of an explosion of patenting in this country and I think the question -- you said Jim? Was that the name?

MR. SANG: Yes, Jim.

MR. SAMPAT: Points out, there's a lot of concern about a patent quality crisis or at least there are concerns about patent quality that led Congress to pass the biggest patent reform in 50 years I think a year or 2 ago. We'll see how that does, but part of the problem surely is that a lot of stuff now is patentable now that wasn't previously, including a lot of sort of basic science that in a previous era if we can kind of be anachronistic and put some of the DNA stuff into the 1960s or 1970s, given the patent standards of that era, it probably wouldn't have met the utility or obviousness test.

MS. BLUMENSTYK: Yes, you're not a patent lawyer, I guess, but do you have a sense that with the court taking the Myriad case and looking at the gene patents that we're about to see something very big on what's patentable among genes?

MR. SAMPAT: I'm neither a patent lawyer nor a prognosticator, so, I don't know what's going to happen in this case. Yes, I don't know. But, yes, the issues are out there. I mean, the Supreme Court took this case I guess last week --

MS. BLUMENSTYK: Last week, yes.

MR. SAMPAT: And it's about patenting isolated genes and it's going to

be interesting, yes.

MS. BLUMENSTYK: Another question back there.

Sir?

MR. GUPTA: Robbie Gupta from the World Bank.

The Bayh-Dole Act obviously operates within a given intellectual property regime and there is increased concern about so-called Non-Practicing Entities or NPEs and universities are licensing out their patents and technologies to companies such as Intellectual Ventures, which some allege (inaudible) controls. This is a fairly recent phenomenon. I do not know if this is a trend and maybe you can comment on that. And, also, if it is a trend, then does it rise to a certain level of concern that either the Bayh-Dole Act or the intellectual property regime needs to be changed to prevent non-practicing entities amassing such patents which arose out of tax-funded dollars?

MS. BLUMENSTYK: So, “non-practicing entities” for those of you who read the popular press, there's a word out there that they call that patent trolls. That’s the other word for it. The gentleman from the World Bank is obviously too polite to use. (Laughter)

MR. VALDIVIA: Well, responding directly as to whether this has been a significant concern to draw attention for universities, yes, indeed, and about three years ago led by the dean at Stanford, university’s issue, the Nine Points to Consider in university licensing, and then there's association of university managers, technology managers often jump onboard of this statement of best practices. One of these nine points calls on the care that should be taken not to license to patent trolls, so-called patent trolls. So, that responded directly to your question.

And in addition, we were just talking about march-in rights under which the government does have such authority to enter and intervene in a particular

circumstance is if the patent is not being practiced. And, of course, non-practicing entities by definition fulfilled by this requisite.

So, the act already has a safeguard against this type of practice, plus now ostensible university alertness should prevent this kind of use. We would hope to see this kind of activity at least with university's patent going in decline, but that would be an interesting and critical question to see if it all those measures do act as detrimental forces for patent trolls to try to build portfolios of patents with university patents.

MS. BLUMENSTYK: One thing I've noticed from going to auto means and it's not driven so much I think by the concern about the patent trolls, but just about the money in general, more and more universities are hiring auditing firms to kind of go back to their patent portfolios and I think in some cases, that might be turning up instances where patents have been licensed to non-practicing entities because they're saying well, we licensed this four years ago, where's the product?

MR. VALDIVIA: Right.

MS. BLUMENSTYK: But it's more driven, I think, by the economics of the tech transfer office.

MR. SAMPAT: I will say transparency will help with that, right?

MS. BLUMENSTYK: Oh, there's a question up here. Bring it, Mitch. (Laughter)

MR. POOL: Sean Pool with Science Progress, the Center for American Progress.

One issue that I think is interesting that we haven't talked about on this panel yet is the free agency discussion, and, so, in a certain sense, and feel free to correct me if this is not the right understanding, but the way I understand it, the Bayh-Dole Act kind of devolves IP management from the government down to the university

level. There's a proposal that's been put on the table by the Kauffman Foundation and others to then devolve another level from the university to the individual inventor. I understand that there are a number of issues with this proposal. It's an active debate.

So, I'm wondering what the folks on the panel think about a free agency in the context of if Bayh-Dole is ever going to be amended or tweaked in any way, do you see that as being part of the conversation or not?

MS. BLUMENSTYK: So, free agency would mean that rather than have the control of the patent be sort of managed by the tech transfer office or some other office at the university, the inventor his or herself could sort of manage the commercialization of the patent?

MR. VALDIVIA: Right. Well, it's important to understand the motivation behind this proposal and the motivation is that they have seen -- well, I was reporting, as I was speaking, how many offices of technology transfer operate at a loss. So, not only is about business, but many universities do not have a tradition of having the organizational capacity fully deployed to make technology transfer efficient.

So, part of the concern and motivation of this proposal is to introduce efficiencies in the system that those who advocate for this view see it as very inefficient and very slow and actually discouraging, all the rigmarole of having to go through the office of technology transfer, discouraging patenting from faculty. So, they say well, if we allow and the government now creates a Bayh-Dole for inventors, for faculty who invent and the title is given directly to them, then they will have to go to some office of technology transfer, some expert, and that creates a market of experts and a market of experts will create more efficient office of technology transfer perhaps in the nation to which the inventors can go and shop for that who provides the best quality service.

So, there's a clear motivation for efficiency and introducing efficiency in

the system. What I'm afraid this proposal doesn't fully take into consideration is that efficiency is not the only value that Bayh-Dole advances. Bayh-Dole has the safeguards of the public interest, fully aware of some of the risks that we have been discussing here on this panel.

So, would transfer title of patents directly to the inventor and creating this more efficient market of office of technology transfer also allow for the safeguards of the public interest to exist if we have seeing some inadequacies in the system already when universities are the stewards of those patent portfolios not being able to fully protect the new products from entering monopolistic markets, from having excessive prices in policies, would inventors be able to do this? That remains an open question and I think the proposal could be reconsidered to balance both things, the concerns for efficiency and the concern for --

MS. BLUMENSTYK: Given all the concerns we have out there with conflicts of interest right now, too, involving research grants, difficulties of journals to find uninvolved reviewers to even look at articles because everyone's getting paid by somebody, I guess I wonder whether free agency would have additional conflict of interest issues.

MR. HOWERTON: I guess I would address it from a more individual motivation of the two, right? So, if I take a step back to a previous life when I was a scientist, I think of what was the motivation that brought me into that field to begin with and what was that of the colleagues I was with and was it a profit-driven motive or was it intellectual curiosity? So, I think when you ask questions about free agency, there is an abstract value to asking those from a policy perspective, but when you look at the individuals that will be affected by it, you have to ask will they even utilize that capability at all?

There are certainly professors that I know that it worked with who were very competent and very interested in developing products, but I would say that the vast majority of them were much more interested just in figuring out how the world and the universe worked and whether or not they made millions of dollars doing that or they made just a small -- seemed to be just okay for them.

MS. BLUMENSTYK: I also think that the recent case, the *Stanford v. Roche* case, has sort of made it more important. Universities have responded to that by making it very clear that they own intellectual property rights and that's probably having a somewhat of an effect on kind of putting more of the control of the commercialization back into the university.

There's a question back there from the gentleman in the red tie. If you could, again, identify.

MR. WEARING: Thank you, Mike Wearing, University of Michigan. And I just want to say that that's correct, that I think free agency has lots of problems and that's a whole separate discussion we could have on another occasion here.

I've been listening with interest to the panel today talk about some concerns about the way the process works. It's not a perfect process. Are there specific reforms that you think should be changed either legislatively or through regulation? Are there specific things that you think need to be done to fix these problems that you perceive or are you just expressing some concerns about the way it's working and trying to put a public light onto some of this so that we can think about it, whether there are things we can do internally or externally about that because I was trying to hear if there was any specific like a legislative agenda or a regulatory agenda that you want to put on the table that is the solution to this problem?

MS. BLUMENSTYK: Well, Bhaven and Walter, you both talked about

the value of putting patents into research patent-to-patent pools and how that might affect things a little bit. I know that's one of the items on your agenda for legislative reform or regulatory reform.

Can you talk a little bit about how that would work? MR. VALDIVIA: I'll start very briefly and let the panelists also propose or discuss their own policy proposals, but I see both proposals are placed along a spectrum from easy to difficult or easier to difficult or more feasible to more difficult. Of course, suggesting reforms that Congress needs to introduce is a long shot because not only Congress will have to decide on many other issues in the near future, but that will take priority on technology transfer policy. But there's, of course, a long debate to be had there.

So, thinking about reforming Bayh-Dole, the most important reforms that I would advocate are increasing the effectiveness of the safeguards of the public interest already in the act. As we said, the act has already a few safeguards, one of these being march-in rights, and, nevertheless, we see that the experience, the historical records shows that it has never been used. So, introducing a language modifying amending the march-in rights provisions such that agencies have an increased power to intervene particularly when there is evidence of excessive pricing practices. Then that would be a good and important reform.

But then moving down the spectrum of what is feasible in policy down to the executive level, agencies could create a set of new incentives that do not contradict any of the parts of Bayh-Dole or the current regime that can nevertheless incentivize researchers and universities to structure their licensing contracts with an eye on the public interest.

And one example of this was, well, Goldie just mentioned patent pools, encouraging patent pools, encouraging across university collaborations, even universities

of different regions would be giving grants then the patents that emerge from this university consortiums are shared patents and the different regions in which these consortiums operate could benefit from different lines of development without neither being exclusive at the national level, but perhaps exclusive at a regional level.

Additionally, agencies could be somewhat stronger on encouraging or discouraging these excessive monopolistic practices when the patents emerge from further research and how to do so is create clauses in the licensing contracts that would shift a patent from an exclusivity to a nonexclusive license should certain conditions are met or not met. So, we would go from Congress to executive agencies to what universities could do and I believe that in a moment of states cutting funding on universities, universities do need alternative sources of income. They may be looking into technology transfer to be one of those. And, so, part of introducing the protections necessary for licensing at universities is to have an eye on the public interest, should also include a discussion of how to more adequately fund the research activities of state universities.

MR. SAMPAT: Yes, just very quickly, I think that's a great question. I think four things that I would propose, and policy doesn't always have to come from Congress.

One is, as I suggested earlier, I think the funding agencies should provide more guidance on what kinds of things should be patented, what sort of things should be patented, exclusively licensed, what kind of things should best be put in the public domain or disseminated by other modes of dissemination. That's one.

Two is whatever we decide on march-in, and I think price controls and all that, that gets into pretty complicated territory, but I think there just needs to be more clarity about march-in. We've been arguing for years and years about whether it's

actually in there or not. I think there just needs to be more clarity on what the government can do.

Three, more transparency and accountability and I think there's ways to anonymize the Edison data, which is where a lot of the licensing data are kept, in a way that it can made available to congressman, academics, and taxpayers so we can figure out if we're licensing to trolls and we can figure out what works.

And then, finally, if I were to push Congress to do anything, and I'm not pushing Congress to do anything, but it would be a statutory research exemption such that academics can't be sued for infringing on other academics patents.

MS. BLUMENSTYK: You mean sort of expanding what's called the Explorer's Experimental Exception?

MR. SAMPAT: Yes, so, there's a Bolar, but that's for regulatory purposes. The U.S. does not have a research exemption on the law that prevents people from doing pure academic research if there's any of those left, though it sounds like some of your colleagues are, from being sued for patent infringement.

MS. BLUMENSTYK: Yes, I guess a court decision 10 years ago basically kind of put the decision the other way. They said universities are basically in the business of research and as businesses, they don't have the experimental exception anymore.

MR. SAMPAT: Yes, I think all that is unfortunate. I mean, and I agreed with the (inaudible) made a decision, but anyhow, it's a longer discussion.

MS. BLUMENSTYK: One last thing. Walter and I have been talking a little bit about metrics. What would you measure to help reflect this, too, because, obviously, what you measure sort of drives policy quite a bit. I'm wondering if people in the audience or others even have some thoughts about what one might count to help

bring this debate over to a public interest mission a little bit more closely.

There's a question in the back, as well, but let's go here and then to the back.

MR. SMITH: I'm Toby Smith with the Association of American Universities.

I guess on that one, one thing that I get a little bit troubled by and even as reflected, although some of the things in the back of the Brookings report here, but I just read the second paragraph in this paper and it says "The government invests $147 billion in U.S. research and development with $90 billion going to institutions of higher learning to underwrite faculty research projects and the training of graduate students and postdoctoral fellows. However, based on licensing fees, federal dollars generate a very small return on investment. Given the billions of dollars in government, money invested in higher education research, there should be a higher yield in the net for universities."

And my point is that's all about licensing fees. If you talk about public mission, the public mission of research universities is to do research, get it published in open literature, and educate students.

And I worked at MIT for a number of years and Chuck Vest always said our number one means of tech transfer is the students that go out and generate, and I guess lost in the public mission and when we talk about tech transfer, it all comes down to getting things on the marketplace and that's all good, but I think we forget the many other ways that information from publicly-funded research gets out there. A lot of it is openly published in literature. You can point to whole new sectors of industry that came because not because anybody made a profit, because academics published it. I can point towards Dow, a whole line of plastics; the academics behind the people who published the papers that were funded by the DoE in that instance didn't get a dime.

So, sometimes, I think we need to put it in a broader perspective, I get worried. And particularly for metrics, it's hard to do that when we start talking about trying to -- so, I'd like your comments on that because it gets to the public mission of research universities, it gets to trying to ensure that things don't get distorted because there is all this talk and we see NIH moving towards we need to do more translational research.

I worry sometimes that translational research itself is distorted because policymakers think you can start with an idea and just know what you're going to commercialize at the beginning. We've even seen that in policies and that's not the way it works. It's about translating good ideas from universities. It's not translational research per se.

So, I'd just like your comments in general as it relates to metric --

MS. BLUMENSTYK: Toby, you've been looking at this issue for a long time already.

Are there some things that you've sort of come up with already that you think makes some sense to count?

MR. SMITH: Well, I think those non-quantifiable things, the things that we do that are the hardest to count are probably the most important. Educating students and the problem is in metrics, is once you have to force it down into things that we can quantify, we will lose sight of the things that are absolutely there's no way to ever quantify the qualitative things. So, I just remind people about those qualitative things, the fact that a lot of the value of having research universities, having a lot of smart people together, getting those people to talk together. That generates a lot of positive outcomes, but they're not always easy to measure.

And I get worried when particularly from policymakers the measure becomes how many jobs did you produce? Because I can tell you we're not at

universities into creating jobs directly. Indirectly, absolutely, but how you trace the productivity of an investment in a federal research grant to the jobs it produces, it gets really hard and that's why I worry a little bit about if we try to quantify too much, we're going to lose sight of the great value of the American research university which at the heart of what other countries do emulate, we can talk about what they do emulate and want to do is produce that research base that we have that they don't have and that has really led to we can be critical and say more things should get out, but look at what we've done here in this country. It's quite amazing in terms of the things that have been generated by research universities.

So, that would be my point is we got to look at those and also tell those stories better because the other thing is we're horrible at telling the stories of how things actually did get out of universities.

MS. BLUMENSTYK: Sam, do you see anything overseas that sort of would be a lesson here?

MR. HOWERTON: Yes. So, let me try to organize my thoughts because you said a lot of things that resonate with us, those who report to Congress and these sorts of things.

So, output metrics we're always going to have and I do agree that you have to be careful on where you bend them. But we are focused on the outcomes, right? And you're right that when we engage with our partners overseas, they look to our university system as really one of the gold standards in the world. The Europeans, as well, but the way that educate and then work with our private sector is important.

But the outcomes that we're measuring, so, I'll take a step back because working in the State Department, I can say that we look over the horizon for the sorts of changes that we're interested in and those are the things that you're talking about, right?

It's jobs created, business created, we track those things, but what are we actually looking for? We're looking to change a cultural norm, right? To create, to help create the systems that they want that lead to these, whether it be economic development activities.

But on an even more abstract level, where we see value, especially those few scientists who work in the State Department as myself, engaging the U.S. university systems is you export the very ideas of science that underpin the way that the democracy here works, open and transparent governments, meritocratic systems, right? Scientific decision-making, right, the idea that it's based not on what you know, not necessarily who you know.

So, all these sorts of things -- I'm being very discombobulated because you get me excited because now we start talking about the stuff that we really care about here over in the State Department, and we do see these things over there, that as I kind of alluded to at the very beginning, there are people that are interested in the economic output, but they're also looking to change things at a very fundamental level and that the university system is the heart of that because that is where people get to not only be exposed to new ideas, but experiment with them and then go out into their life and into the wider world to see how does that work for you, so to speak?

MS. BLUMENSTYK: Well, so, you started this discussion by talking about one of the goals of the U.S. foreign policy would economic stability and social stability and I'll add food security in there and some other things. Those are hard to count, but they're sort of you know them when you see them overseas?

MR. HOWERTON: Absolutely.

MS. BLUMENSTYK: I'm wondering if there are comparable kinds of you know it when you see it kinds of norms or values that we want to have coming out of our tech transfer system here in the states that would sort of comparable.

I'll let you guys ponder that for a second. I want to go to the gentleman --

MR. SMITH: I just had one other comment because I think it's relevant to when we talk about tech transfer offices. I think the metrics for what their success should be really need to change, but I think they are changing and they're moving towards more of a model of faculty service and those are very hard to measure, too.

I talked to one tech transfer officer who said that part of his job these days is spousal placement because when they are getting faculty, recruiting faculty, the number one issue is okay, where's my spouse going to work? Guess who knows the places in the companies past the university? You can't measure that, but it gets to something that I think is happening --

MS. BLUMENSTYK: You say that, but I can't imagine that a tech transfer director getting hired because they're really good at faculty service.

MR. SMITH: I agree. What I'm saying though is the mission of what these offices are seeing, in part because they're starting to realize themselves there's not money to be made, and that's a change because I think there was some blockbuster things that came out right after Bayh-Dole, there were a lot of pent up things. It drilled a behavior that probably wasn't all that positive at tech transfer offices. I think the tech transfer community as a whole though is starting to realize that they have to change what they do and it has to be more about doing deals, not necessarily making money.

Now, having said that, do I believe that at all levels of the university that there's that view? Absolutely not. Some universities get it. Rick Levin, for instance, gets it, that it's not about money. Other universities don't, and there's huge pressure from the external communities, the republics, the state governments, the board of regions who think that this is a magic bullet to raise the funds that they can't provide anymore and I think we all have to tell the message, even if you do this well, you're not going to make up

those loss revenues to a successful tech transfer office and that shouldn't be what their mission is.

So, I just say the measures. I use that one kind of flippantly, but that I think in terms of how we evaluate at our own universities, the effectiveness of tech transfer, we need to broaden that and that needs to come and I think the academy did a great job in their report of saying we need -- starting point is universities need to have a policy of what they're trying to achieve in this area and they need to do a better job in terms of defining that.

MS. BLUMENSTYK: The gentleman in the back. I really bad we haven't gotten to him yet.

MR. GUPTA: Robbie Gupta from the World Bank.

My question is perhaps less related to the (inaudible) but more related to the intellectual property regime and that has to do with anti-commons, the concept of probably mostly articulated by Professor Michael Heller, and my question is: Does Bayh-Dole Act have any role to play on this problem of anti-commons or does it stem primarily from the intellectual property regime that we have? And in either case, what are the possible modifications either to IPR or to the (inaudible) that can (inaudible) this problem?

And most significantly especially for the World Bank for developing countries, when they try to enact their own version of Bayh-Dole Act, what kind of provisions can they put in place to sort of preempt this kind of situation of anti-commons?

MS. BLUMENSTYK: I think this is Bhaven's.

MR. SAMPAT: So, anti-commons, the tragedy of the anti-commons as articulated by Heller and Eisenberg in *Science* in 1998 which draws on Heller's earlier work, just in case everybody here doesn't know, is the concern that if you have too many owners of intellectual property rights and this fragmentation of ownership of intellectual

property rights that are needed for a chip or a gene or something like that, then bargaining can break down and you won't see a development happen at all. It's sometimes also used loosely, though I think incorrectly, to refer to patenting of science in the first place. But that's maybe just a technical distinction.

So, does Bayh-Dole have anything to do with it? Yes and no. And my answer to the other question, I mean, I think changes in the strength of patents in general has been probably the more important source of these problems.

By the way, there's some debate about whether this is a real problem or whether there's bargaining around it that's affected.

But, second, why it interacts with Bayh-Dole is because with Bayh-Dole, we have a range of new owners of upstream technologies which contribute to the fragmentation. So, what could be done to solve this problem if we stipulate it exists? I think, again, a research exemption would help. There would be panacea and I certainly that any other country's Bayh-Dole-type laws or implementation of TRIPS' compliant patent law should think seriously about research exemptions. But I don't know that'd be a panacea, but moving in the right direction.

MR. VALDIVIA: Let me chime in there to respond to your question and at a less specific, more abstract level, also responding to Toby's observation on the American University System and thinking of what other countries could look into to emulate the American University System.

The historians of the university system in the U.S. found a particularly trajectory that is different than those models in which at any given point in history American universities look up to the German model or the British model. It was configuring a particular way such that the American university was more attune to the needs of the specific localities and the states in which they emerged. That, I think, has

been the greatest virtue that has created a system as solid as the American University System.

The question, therefore, and I'm going between both comments, is Toby said what kinds of measures, how can we monitor or advance, how we go forward in a structure in the technology transfer system and structure in the university? And I think the measures will have to go in the direction of how well the university has its fingers on the pulse of the needs of the nation, of the needs of the region, of the needs of the state. And, therefore, the counterpart for developing countries, how will they structure the university system to be attuned to the needs of the specific needs of their own countries, of their own societies, of their own cultures and stabilities?

And technology transfers should be imagined in a way that plays a role in this and I don't think Bayh-Dole should be completely considered counter to this effort, but also we should think of Bayh-Dole and how the reforms of Bayh-Dole should be calibrated, fine-tuned to make the university and to make it one of the resources the university uses to have a sense of what are the economic demands and economic needs and economic trends of the region and the state and nation that they serve. Imagine the technology transfer as part of this larger system of metrics of where to go forward. I think it's a very important challenge, but I think this would be a very productive way to think of it.

MS. BLUMENSTYK: And I think that's probably a great way to conclude our session today. I want to thank our panel and thank all of you for coming and I suspect they'll be more discussions on this in months to come. (Applause)

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