UNITED STATES PATENT AND TRADEMARK OFFICE

PROMOTING INNOVATION IN THE LIFE SCIENCE SECTOR AND SUPPORTING PRO-COMPETITIVE COLLABORATION: THE ROLE OF INTELLICTURAL PROPERTY

Webinar

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P R O C E E D I N G S

MS. DIXTON: Good afternoon everyone. Thank you for joining us for day 2 of the joint workshop hosted by the Department of Justice and the U.S. Patens and Trademark Office on Promoting Innovation in the Life Science Sector and Promoting Pro-Competitive Collaboration. Yesterday, the PTL hosted an excellent program on how patents and copyrights can facilitate procompetitive collaboration. And today we focus on competition and the antitrust aspects of collaboration and this important sector of our economy including collaboration and COVID-19 therapeutics and vaccine. We will hear from governments, industry, and academics on this critical topic, and we encourage our audience to send questions to our panelists or to our mailbox at ATR.lifescienceworkshop@useoj.gov throughout the program.

My name is Jennifer Dixton and I'm Special Counsel for Policy & Intellectual Property at the Antitrust Division and I will be the Master

of Ceremony for the program today. It is my great pleasure to introduce Assistant Attorney General for the Antitrust Division, Makan Delrahim, who has been in that leadership role since September of 2017. And among AAG Delrahim's many credentials and vast experience in both intellectual property and antitrust law, he holds a master's degree in Biotechnology from the graduate school of Johns Hopkins University and is very familiar with all the issues that we'll be talking about today. So without further delay, I will turn the podium over to AAG Delrahim for some opening remarks. Thank you.

MR. DELRAHIM: Well, I will repeat all the nice things I've said about you Jennifer. I wanted to thank you for covering this today and for all the work that you have done along with our friends at the Patent and Trademark Office to make these two days possible and go as smoothly as possible given the pandemic. Good afternoon to all of our colleagues who are tuned in. On behalf of the Department of Justice along with our

partners at the U.S. Patent and Trademark Office, I want to welcome you to the second day of the workshop on Promoting Innovation Through Life Sciences. I'm looking forward to today's excellent time lineup, which follows on a fantastic set of presentations and panelists yesterday.

I want to start by thanking Dr. Elias Zerhouni for agreeing to deliver our keynote speech this afternoon. As the 15th director of the National Institutes of Health, Dr. Zerhouni established a bold strategic roadmap for medical research that insured the NIH, and thus the United States remained an international leader in researching and developing lifesaving medicines. As an inventor himself, an academic at the forefront of research, and a business leader, I could not think of a better speaker to participate on these important issues today. We're lucky to have him here to discuss these topics and we'll look forward to listening to him later this afternoon.

Now is a fitting time to discuss innovation, collaboration, and competition in the life sciences sector. As we speak, people around the world are undertaking an incredible effort at historic speed to develop safe and effective treatments and vaccines for COVID-19. Their work is a reminder that innovation in the life science sector is not just important in theory. It is important in practice. It shapes how we can respond to and recover from crisis. Today, about half of the world's research and development for new drugs is funded by U.S. firms. For many, these drugs are an essential part of their everyday life. For many more, the research and development pipeline offers hope for the future, hope to live to see that grandchild, of hope to see the daughter's wedding, or hope to see the next graduation.

Count me among those with hope and optimism. I believe breakthroughs in genetic and gene therapies will pave the way for drugs that treat or cure diseases like cystic fibrosis,

diabetes, or perhaps even cancer. Artificial intelligence and machine learning as well as advances in molecular biology will help to accelerate these breakthroughs. Breakthroughs in computing technologies are opening up new frontiers in the life sciences as well as they have in some many other fields. These breakthroughs are not inevitable, as this audience knows full well. They depend critically on innovators' incentives to take risks, to invest valuable time and resources in uncertain endeavors. Every good researcher is a risk taker. They have to be. They embark without knowing where their work will take them. As Albert Einstein put it, "If they knew what it was, they were doing, it would not be called research, would it?"

As so many of the presenters and panelists noted yesterday and Director Yeh who articulated well. Intellectual property rights are a critical tool for encouraging this type of risk taking. Their remarks echo what our

country's founders also understood that strong intellectual property rights are critical to an innovative developing society. That is why patents and copyrights are mentioned explicitly in the U.S. Constitution under an amendment in the Constitution itself. Abraham Lincoln, the only President with a patent to his name so far, understood this as well. He explained in 1858 that patents, "Add the fuel of interest to the fire of genius". Intellectual property rights indeed add fuel to the innovative creative fire. In doing so, they also encourage critical competition. As Justice Scalia explained, the promise of a limited monopoly, "is an important element of the free market system" that antitrust law protects because it, "induces risk taking that produces innovation and economic growth". Thus, as I've said many times before, intellectual property law and antitrust law work in tandem to encourage innovation and dynamic competition.

Collaboration can also encourage innovation and competition. For example, this

antitrust division recently issued a business review letter analyzing the collaboration between companies who wanted to share information about their ability to manufacture monoclonal antibody treatment for treating COVID. Working together, these companies will be able to scale up manufacturing more rapidly. That means lifesaving medicine making it into the hands of American consumers sooner.

Because these companies committed important safeguards like not exchanging information about price of the treatments or the input that they use, American consumers get these benefits faster without sacrificing competition. To be sure, some collaborations can harm consumers by suppressing competition or impeding innovation. For example, some firms use joint ventures or collaborations to conceal efforts to actually fix prices or allocate markets or avoid having a merger subjected to antitrust scrutiny. In these cases, we will not hesitate to enforce the antitrust laws. Collaboration should provide a

benefit to consumers including safeguards as appropriate and have a co-competitive objection.

Distinguishing between collaborations that benefit consumers and those that nearly mask anticompetitive conduct is and will be a difficult task. It is also a familiar one for the division. Workshops like this help us find the right balance in our enforcement activities to ensure maximum incentives for innovation. They also provide transparency for the public for the researchers and the investors so that they could properly engage in the activities that benefit consumers. I look forward to our discussion today and to hearing more about how enforcers, life science companies, and other stakeholders can work together to get it right. Co-competitive collaborations like balanced intellectual property rights play a vital role in fueling innovation in life science sector. That innovation is as important now as ever. And the U.S. competitiveness relies on strong intellectual property rights. We must ensure that we provide

the maximum incentives for innovation including in the life sciences.

Now, it is my privilege to invite Director Iancu and Judge O'Malley of the U.S. Court of Appeals for the Federal Circuit to join me in our virtual "fireside chat". Judge O'Malley has contributed greatly to the development of patent law during her years on the bench, a period marked by significant innovation and technological development in which our IP law system play a critical role. She has tremendous experience relating to the issues we are here to discuss today, and I'm honored that she is -- she was able to join us. Thank you. I'll turn it over to you, Jennifer, to make the appropriate introduction.

MS. DIXTON: Thank you, Makan. We're very excited to have Judge O'Malley here as Makan said to help moderate this fireside chat this afternoon and we're very pleased that Director Iancu and both AG Delrahim can be here to talk about some of the issues that we'll address today and just begin our day -- start the day off right.

So thank you very much, Judge O'Malley for being here and I will turn the podium over to you to start the first question and I look forward to hearing. Thank you.

MS. O'MALLEY: Thank you. I want to let everybody know that I have been invited by Assistant Attorney General Delrahim and Director Iancu to use their first name, so I do so based on that invitation and -- but with all due respect for their positions and the important roles that they play. So let me -- let me start with you, Andrei, and I'm going to pick up on the risk taking component that -- that Makan referenced in his opening remarks.

I know that the U.S. PTO has taken steps to help small companies across all industries to be more comfortable with the patent system and to be willing to take the risk with respect to innovation knowing that they can turn to the patent system. Can you talk about some of what those steps have been?

MR. IANCU: Sure. Thank you, thank you

very much and really an honor to be here with you, Your Honor, and with Makan, always great to -- to collaborate on events like these and so many policy issues surrounding the interception of IP and antitrust. Yes, look, patents are so important obviously as being the head of the patent and trademark office, so you'd expect me to say that. But I happen to believe it to be the case as Makan mentioned in his opening remarks, patents really play a pro-competitive role. They obviously incentivize innovation. They invite the disclosure of innovation, and they create financial instruments that allow a transfer of technology from lab to market and so many other avenues. But before we get into all of that, you know, the specific question you asked, Judge, was with respect to small companies.

Patents are especially important for small companies. Obviously, they don't often have the market power, the clout, and you know, many times a patent is the only tool they have to be able to protect their technology and penetrate a

particular market. We have studies that show that for a startup, obtaining its first patent increases its employment growth over the next 5 years by a remarkable 36 percentage points. And the growth in sales actually is even larger than that. So that just tells you. So, at the PTO, we -- we're very much focused on that and making sure that we make this available and assessible to all, I think particular to small companies. U.S., for a long time, is one of the very few countries that provides the significant discount for small entity applicants, for example.

But right now we need to focus on this pandemic. We have done a whole number of -- we've provided a whole number of initiatives to help small businesses in particular, although some of them are applicable to others, but for small businesses in particular, for example, for them alone we have provided an expedited examination process, both on the patent and the trademark side for applications relating to COVID-19. On the patent side, we promise to get the patent out

within six months or get the resolution out in six months if the applicants themselves cooperate. We have created a licensing platform. We call it Patents for Partnerships and you can see it on our website where folks with patents or published patent applications can list those assets voluntarily on our website and indicate their availability for licensing, and those who want to manufacture or are looking for new technologies relating to COVID-19 can search and identify -- identify those things as well.

You know, we've extended deadlines and pushed the payments of fees for many, especially small business and individual inventors under the CARES Act from earlier this year. And let me stop there, but we have a whole host of initiatives relating to COVID-19 to enable the acceleration of innovation in this area and you can see it's all at USPPP.gov at one of our dedicated websites.

MS. DIXTON: Thank you. All right, Makan, you, in your talk, represent the founders and the founders' vision. I have heard you on

many occasions refer to Madison's vision. His vision was a democratic vision of IP rights because he believed it was the small innovators that were going to be the future of our country. So how I should stick with the theme here about small businesses, what resources do you have at the Justice Department to help small businesses navigate, you know, not just the patent system, but navigate the -- the complication of the antitrust system as well?

MR. DELRAHIM: Thank you, Judge, for the question, and I often refer to two of my heroes, both James Madison and Robert Jackson often in talking about antitrust and also the proper role of antitrust where its limits are. At the Division, we at the Antitrust Division and our friends at the Federal Trade Commission, we try to explain how we approach enforcing the antitrust laws in this area. We have the joint guidelines that we have issued on intellectual property that have been updated over the years and is available on our website. A lot of times we also provide

guidance to provide as much transparency into our enforcement priorities and approach through some speeches and more recently through a program where we file amicus briefs into the proper interpretation of the law. In various private cases we have -- I think filed maybe 26 or 27 or so statements of interest and amicus briefs around the country on various issues including on intellectual property and the proper role of antitrust.

For a lot of the small businesses and other, even large businesses, we also have another tool that has become a little bit more prominent and utilized since the COVID is the business review letter process. That is when businesses want to engage in certain types of activity, whether it's a joint venture or a new marketing campaign or a new business model. They can apply, write to us a letter and ask what our enforcement objectives are. We will evaluate that. And the Life Sciences area, at beginning of the COVID pandemic, I announced expedited process, typically

these take about 9 months or so to evaluate and issue a letter either positive or -- or otherwise about our enforcement objectives. And what we did was commit to 7 days and we have, I think, issued three or four now including one on the therapeutic, the monoclonal antibody, by a number of companies to engage in collaborative -- in a collaborative effort. And we might suggest certain safeguards and often those might have some value in future litigation and private cases because we provide an analysis of how that -- that type of proposed activity should be interpreted within the antitrust laws. So, the most important goal for us is to be as transparent as possible for the innovators out there, and in addition to that, advance the proper role of antitrust law, where we can do that within the various cases. So, we have you know, the guidelines, the collaboration guidelines, the business review letters, and then some of our speeches in public violence that provide some tools, provide transparency.

MS. DIXTON: Makan, as a follow up, I -- you know, you realize of course that -- that some of your amicus filings and -- and statements of interest have been getting a lot of attention lately. Is that practice either new under your leadership or has it expanded, or is your use of it in IP different than what occurred in the past?

MR. DELRAHIM: So it's not new. It is -- it's certainly expanded. So Congress, you know, has given the Justice Department and the Attorney General to see that the laws, where we have an interest, are enforced properly in the courts and interpreted. And so we have the right to enter into various private cases. To do so, in the past we have been invited on tough issues, often at the Supreme Court, but I remember when I was a deputy 15-16 years ago, the Second Circuit had asked of the views of the government to enter in. What I thought was useful given the fact that there wasn't as much government litigation; however, unlike other areas of the law, what we enforced as antitrust enforcers is the same exact

law that the private sector litigates and a misinterpretation or you know, an improper interpretation of that law has a direct impact in our enforcement capabilities. You know, outside of our criminal enforcement capabilities, but the civil, the same exact law and we're bound by those precedents. I thought it was important for us to weigh in earlier than just at the Supreme Court. And so when I first joined in '17, I remember in October there was 27 or so judges at University of Chicago at a conference, and I suggested that I believe we are going to be more active in ensuring that the prop -- the antitrust laws are property interpreted earlier. And I say, 8 or 9 different judges, Court of Appeals and District Court came to me and said, "This is a God send", you know. We very much appreciate it when the Justice Department you know, comments on these because you know, the number of resources we have are limited and sometimes these are very complex issues and you have two diametrically opposed parties saying two different things. And I said, you know, we

hope to be helpful, to always promise to be objective, and what we think it is. So we have, I think dramatically expanded the number of filings we have done. And it's not just been on intellectual property. It's been on various areas of immunities from the antitrust laws, whether statutory or implied immunity that often defendants would advance. And I'd say, you know, half of our filings have been in the proper interpretation of an immunity. So it's not overly broad that affects us. So that is -- it has been -- it's had -- the other effect has been, it has provided for a largamente of opportunities for the Division's antitrust appellate section lawyers so that they have been able to not only hone their skills, but we've been able to recruit more and better attorneys that in the past because we did not have as many arguments, we would not attract. So it's -- it's had an institutional positive effect, and then I think in the court system, and I -- I forget we -- we -- we do have internally, we keep a score of how well we have done in the

various filings, but I think those that have reached final judgement, we might be I think, 18, 1 and 1 as far as our record, as far as the you know, the analysis. We never file on either side of either party. It's always in support of neither party, but here's the proper analysis.

MS. DIXTON: Andrei --

MS. O'MALLEY: In addition to -- to engaging in intervening in cases and filing amicus briefs at the PTO, one of the things I've been most impressed with is your tireless willingness to speak to many organizations and to spread important messages about the importance of IP, to not just life sciences, but to all innovation. With respect to programs like this and other talk, what's the primary message that you want to get across?

MR. IANCU: Well, number one, that innovation is critically important to the United States, to the U.S. Economy, and to the well being of humanity in general. Innovation has been the driving engine of -- of economic growth and

human development especially since the founding of this country and the inclusion of IP rights in the constitution itself. I think everybody generally agrees with that, but I think in today's world it's especially important to highlight the awareness of the importance of innovation because especially nowadays, we have competition on this front from everywhere in the world, from the smallest countries to the largest and everyone in between. And some of that competition, by the way, is not all that (inaudible). So refocusing and rededicating this nation to innovation, to me is one of the most important things.

As I said, most people agree. But the second point that I think is equally important and an area where perhaps not everyone agrees is the importance of intellectual property as the backbone of that innovation ecosystem. So to me, this was one of the most important areas to focus on since I got here, and I know Makan's doing the same from the Antitrust Division, and there are others in the administration as well emphasizing

that IP rights, a strong reliable IP system is the critical engine to create that innovation that we absolutely need, especially at this time given international competition and especially as we look forward to the technologies of the future.

So, those are some of the main reasons I -- I try to speak a lot, one of the main messages I try to communicate. And then finally, to find a way to reach more people, to excite more folk across the demographics and across the geography of the United States, to get into this fantastic system, to become inventors, become entrepreneurs, and get involved in the IP ecosystem. So we want to broaden the IP ecosphere. We want more women to participate, more minority folks to participate, folks from communities located far away from the current tech centers. And to me, people need to hear about the benefits of the system to themselves personally, to their companies, to their communities, and to the country. And they need to find role models and mentors. So the more we speak about these things,

about the excitement of innovation, about the great Americans who have come before them, that they can look up to them and see themselves in them. The more we make folks aware of this amazing sphere of innovation in this country, I think the higher the chance we have as a nation to be more inclusive in this -- in this spectrum.

MS. O'MALLEY: As a follow up to that, Andrei, there's a lot of talk right now that IP rights should just be thrown to the side during the whole fight, the COVID fight. So why is it important that we protect or respect IP rights even during a pandemic?

MR. IANCU: Well, it's always important to respect IP rights and I would say actually that it's perhaps even more important to do it during a time of crisis. You know, here's why. There are many reasons, but here is the -- the -- in my mind, the main reason. The reason we are able to talk even about a vaccine in a matter of months and the reason that we can talk about treatments and cures and whatnot in a matter of months is

because of all the incredible innovation that has taken place to date, especially in the life sciences area. That innovation is very risky, very costly, and very time consuming. Without IP rights, it is very difficult in the long-run for folks to invest the necessary time and resources in order to have a robust life sciences, biotech, and so on, system, and to lead the world as we do as a nation in this area of technology.

But, if those IP rights on which all that innovation was built are not respected, precisely at the time when they are needed, what will incentivize the inventors of the treatments and the inventors of the cures for the next pandemic and the next crisis down the line? We have to have a very firm eye on making sure right now in the middle of this pandemic that we balance of course the protection of the property rights of the innovators and the access of the public to the various cures and treatments. At the same time, we must have our eyes firmly on the crisis of the future to make sure that we don't desensitize the

future inventors that we'll absolutely need because I am certain as certain can be that there will come a crisis at some point after the crisis is solved.

Let me leave you with this. Some people do talk about let's put IP rights to the side because we need to focus on access and IP is acting as a -- as an inhibitor or as a block to access and to the distribution of -- of -- of medicines and cures and whatnot. Whenever somebody says that, I would ask where's the evidence? Before you make these claims, show us the evidence that in fact, IP rights are blocking access right now to -- to COVID-related technologies. Show us the evidence that somebody -- somebody wanted to make a new vaccine and is ready to make a new vaccine, but they just can't because somebody else is asserting the patent rights against them and they are refusing to give a license. To the contrary, the evidence to date shows that the collaboration with respect to this pandemic is unprecedented and the collaboration

between the various (inaudible) and the public, both domestic but also internationally is -- is remarkable and folks are acting voluntarily in a variety of ways from various creative licensing deals, and other collaborative tools to make sure that we get the cures and treatments and vaccines in record time. We have to make sure that there is a balance, but any such discussion must be evidence-based.

MS. DIXTON: All right, Makan, I know you've already talked about efforts that you've made to endorse collaboration and I'll let you get back to that if you'd like, but I wanted to turn to one thing about your background. I know you probably realize that many in the IP arena were very happy with your appointment because -- because of your background. So can you tell us how your background in life sciences and IP has helped color your vision or impact your vision for the job that you're doing now?

MR. DELRAHIM: Yes. Well, thank you. I -- I'm proud to in addition to being an antitrust

lawyer, I actually started out as a patent lawyer. I came out to the East Coast having studied physiology in undergrad. You know, a little confused, not knowing what I wanted to go to the medical school route or -- or -- I really didn't have any plans to be a lawyer. But as I studied, what fascinated me in undergrad was this big fight, two big patent fights that went all the way to I think one of them to the Supreme Court. One was Amgen versus Chugai (phonetic) Pharmaceutical, and it dealt with you know, an infringement over a certain cell lines, which I think became their blockbuster drug, Epogen, at the time. Now, Amgen was founded by some UCLA grads where I was and the headquarter was just down the street from where I grew up, so I was naturally glued to it and I in fact began following those headlines. I was really fascinated by the intellectual property laws. So I came out to become a patent lawyer and started working at the NIH's Office of Technology Transfer doing licensing of the government funded patents when I went to law school at night. So

I've had this fascination with intellectual property, but particularly in the life sciences since the beginning. Through some work I began to fall in love with antitrust and switched out. My friend, Professor Mark Lindley at Stanford did the exact opposite thing, which just shows his level of intelligence, is that he started out as an antitrust lawyer and became a patent lawyer and probably did a heck of a lot better financially than I did during a time when patents became a good area to practice. But I've had this love of both and where folks say they're in conflict, I've always seen the fact that the two are such great compliments of each other. And I loved, and there's no place, I think no institution of medical research that is more important than the NIH and the work that the scientists at the NIH do, I mean obviously Dr. Fauci has become a cold figure these days unfortunately, but I remember during the AIDS crisis he was also a Rockstar then. And of course, Dr. Zarhouni, who was one of the inventors of the way we do biopsies today

and these are folks who sometimes may not be as popular as you know, Jay-Z and LeBronn James and Kim Kardashian, but my goodness, the effect that they have on all of our lives and the work that goes on at the NIH and the intellectual property law that allowed for the actual development of the basic research that goes on, are fascinating. And I saw firsthand the value of it, so I've had this -- just a nerdy fascination with both sides and I'm proud to actually be a registered patent lawyer until Andrei takes that away from me for being unqualified to do so. (Laughter) So it's been a -- it's been an honor to do what I've done.

MR. IANCU: I have great plans for you, Makan. You know, Thomas Jefferson when he was Secretary of State, was also the first Examiner of Patents for the United States? And now learning that you actually have a PTO registration, we're going to start sending you some files for you to examine in your spare time over there at the DOJ.

MR. DELRAHIM: Thanks so much, we're happy to help.

MS. O'MALLEY: Sadly, we only have a few minutes left. I could have -- I could go on with this for quite a while, but -- but let me just finish up with this question you make. And you mentioned technology transfer. What's the Antitrust Division's view of pooling and technology transfers and licensing?

MR. DELRAHIM: The -- the transfer of those who aren't (inaudible), there was a period of time where antitrust law and enforcement looked -- frowned upon the type of activity such as field abuse restrictions and the licensing or pooling of patents and we learned, you know, that actually those were very pro-competitive and consumer enhancing limitations. So we have, you know, with now experience and also empirical evidence through decades, we view those as collaborative efforts that actually benefit consumers. It removes a lot of the friction for transaction and exercising patent rights and so there's a -- there's a -- I think those go hand in hand as a part of the way to actually effectuate the fruits of the

innovation that the patent laws incentivize. And antitrust laws ensure that there's competition, so we certainly do not want to take, you know -- the antitrust laws still frown on certain licensing practices that for example disincentivize new research like exclusive grant backs and things like that. And also licensing where it limits you know, price competition or quality or innovation competition. However, when there is a pooling of patents for complimentary technologies, we very much now look favorably upon those. We have issued guidelines specifically you know, in this area, for both collaborations and poolings, and also issued a number of business review letters in this area on standard setting and pooling that shows the analysis that we go through to determine the legality of it. But as a general matter, we very much view those as the types of collaborations that have a pro-incentive effect and you know, not as limited as used to be in the 60s and the 70s.

MS. O'MALLEY: Okay, Andrei, I'm going

to give you the final minute if there's a final word that you would like to share with all of us in terms of where we go from here with the rest of this program?

MR. ILANCU: Well, with respect to this program in particular, today is DOJ's day to run and focus on with respect to the cross section of antitrust and IP. I am very grateful for Makan's leadership and his team at the Antitrust Division for working with us on a program like this. The bottom line is that IP and innovation are critically important, and we want these two days to focus on the importance of that as we all work as a nation and frankly as an entire planet to solve this pandemic. And I agree with Makan's opening statement that I am very optimistic, as he is, that given the ingenuity of our people and the incredibly hard work that everyone is putting into this, we will get to -- to a solution soon and we will soon be able to have meetings like this once again in person and who knows, maybe even (inaudible) maybe even shake hands once again. So

thank you, Your Honor, for moderating us and for agreeing to be with us and I think you, Makan, and your whole team.

MS. O'MALLEY: Well, thank you folks. I know that you're going to -- you can just imagine the silent applause that you're getting but thank you all. It's been a pleasure.

MR. DELRAHIM: Thank you, Your Honor.

MS. DIXTON: Thank you, Judge O'Malley for moderating this great discussion. Thank you, Director Iancu. Thank you, Assistant Attorney General Delrahim for the discussion today and we look forward to a wonderful program going forward. I really appreciate the terrific start to our day and the insightful exchange. So thank you for all being with us today. I'd now like to introduce David Lawrence, the Chief of our Competition Policy and Advocacy Section who is planning to give us a short overview of our program today, what to expect, and he's going to go ahead and introduce our first program, our first panel. Thank you.

MR. LAWRENCE: Great. Thank you, Jennifer, and can you hear me?

MR. DELRAHIM: Yes.

MR. LAWRENCE: Okay, great. So it is -- thank you so much, Jennifer, and as she mentioned, I've been asked to sort of set the table here today. I think I know why Jennifer asked me to do that because as the Chief of the Policy Section, we've now done five of these workshops this year and I can say credibly in that role that this afternoon's program is as interesting and brings in as many expert people in as timely a situation as any that we've held, and we've had some terrific panels, but you know, for those of you who found the remarks we just heard incredibly interesting, I know I did, there's much more to come this afternoon, so I encourage you to stick around.

I also -- I saw it important -- you know we talk about innovation and intellectual property and these are big concepts, but just to ground the conversation, you know, I always think about my --

my childhood. I was the son of an inventor and a patent holder in the biotech space. My mother is a researcher, so I was toddling around under that bench on which all the equipment was arrayed while she was busy inventing. And something I didn't think about then was how did that equipment get there? Microscopes, cameras, lenses, all of the tools of innovation, these are hard for inventors to get ahold of, and the -- to make the time to make an invention is difficult to take, and what we talk about I think when we talk about the patent system and the antitrust system, is innovation. How do we support the innovators? How do we keep them there? And I think there are two answers to that question that are going to be very important this afternoon.

One of them is the free market. We don't take a natural planning approach to this. We rely on the free market to drive those resources to where they need to go. The other of course is the patent system allowing the researchers and innovators to get the rewards for

the work they do. And those two concepts drive at what we're going to talk about this afternoon, which is the collaboration and competition among researchers, which I think, as you'll see laid out in the panel, is among the most fascinating and challenging concepts in the antitrust law.

So one of our goals in the antitrust law is of course competition. Competition is the nature of science. You're looking to find that next invention first. You -- you're in a -- you're in a basic competition with the other innovators. On the other hand, it's a fundamentally collaborative enterprise. You don't have peer review without peers. You don't bring a complicated product to market without sometimes generations of scientists building on each other's work. That's the nature of the enterprise. And so when we think about that out there in the market, we want our innovators working together. We want innovative firms working together. But on the other hand, we don't want their conduct to cross over into the kind of anticompetitive

collusion that causes the free market to break down. And that intersection, I think it's fair to say, is one of the most fascinating and important areas in the antitrust laws. So that's what we're going to work through today.

The first panel is really all about collaboration. We have Deputy Associate Attorney General, Brian Pandya, as the moderator. I'll allow him to introduce some of the esteemed folks we have on his panel, but we'll have representatives from the private sector, the public sector, the nonprofit sector, and the education sector to talk about collaboration in this space. Then in our, the next panel, which is the sixth of the overall series, we'll talk about the government's role in all of this. How can government, whether the Patent Office's role or the Department of Justice, or Federal Trade Commission, how do our efforts lend the most support to what -- to the competition and collaboration we expect to see out there in the market? And we'll have another terrific

moderator, Deputy Assistant Attorney General, Alex Okuliar, to help us walk through that with a great panel that includes one of our colleagues from the Federal Trade Commission, Alden Abbott.

For panel 7, the third panel today, Jennifer, we'll turn back to you and walk through examining anticompetitive effects, you know -- I did a quick hand gesture to say, well we don't want the collaboration to turn into anticompetitive collusion. There's an awful lot that goes into figuring out whether that had happened and where those lines are, and Jennifer is going to help with a terrific panel to walk through some of those issues.

And then before our last panel, and I want to put a marker down for those of you who watch some and tune in and out today, at 4 o'clock, we have a keynote speech from Dr. Elias Zerhouni. Of course, he needs no introduction as a former Director of the Nation Institutes of Health, and you heard from AAG Delrahim what an esteemed voice he is in this space. And so I'm

personally, particularly looking forward to his 4 o'clock remarks. And finally, we'll end the day with an economic and academic view of collaboration and competition, these contexts, moderated by one of the Department's own PHD Economist, Patrick Greenlee. So, as I said, it's just a terrific program we have today. I'm very excited to have a wonderful lineup of panelists and panels, and I hope you all enjoy. Thank you, Jennifer, back to you.

MS. DIXTON: Thank you. Thank you, David. We're going to turn the podium over to Brian Pandya, who is the Deputy Associate Attorney General for the Department, and he is going to introduce our first panel and moderate that panel. So thank you, Brian.

MR. PANDYA: Great, thank you and good afternoon. David, thank you for that kind introduction and Jennifer, thank you for all your hard work putting together today's program. I also want to thank one of Judge O'Malley's former law clerks who is now a star antitrust attorney at

DOJ, Eric Dunn, for all his help with this panel. And I'm Brian Pandya. I have the honor of serving as Deputy Associate Attorney General.

As one of two registered patent attorneys in DOJ leadership, Makan, of course being the other as we heard a few minutes ago, it's exciting that we're here today to talk about patent rights and precompetitive partnership. The title of our panel is Collaboration and Licensing Strategy, and we're joined by six individuals who have seen all sides of product research and development and can share their experience on those strategies from a university professor taking from lab to marketplace, jointly sponsored research, to representatives from leading pharmaceutical companies, to university, nonprofit, and government licensing officers.

In the hour we have together this afternoon, we're going to talk about some of the different ways innovators collaborate. What works and what can work better, from public private partnership to private joint ventures, exclusive

and nonexclusive licenses. We're going to talk about issues that arise when you have data rights involved and emerging technology like artificial intelligence and drug development. We may even talk about how licensing and collaboration impact equitable access to medicine. First again by asking our panelists to introduce themselves and tell us where they fit into the licensing and collaboration world. Since we're on Webex, we'll do this in alphabetical order. So, Laura Coruzzi, you're up first. Laura, are you here?

MS. CORUZZI: I am. I'm trying to start my video, but it doesn't seem to want to do it.

MR. PANDYA: Well, we can -- we can hear you fine. Hopefully the video gets working soon.

MS. CORUZZI: Okay, don't know what's going on. Anyway, glad that you can hear me. Thank you so much for that introduction, Brian. I'm a Patent Attorney with a PhD in Biology and over 30 years of experience in the biotech sector. I was a partner of Penny and Edmonds in and Jones Day before joining RegenXBio. My experience

includes patent prosecution, litigation, and licensing. One of my cases as a member of the team that handled the Myriad case that went up to the Supreme Court.

I handled patents in the early days of gene therapy before it crashed, and I never thought the industry would come back until years later I took on RegenXBio as a client and this was founded by a group of smart people who understood the technology and its potential. I was really impressed by the work done at RegenX. I remember getting a chill when I learned about the first incident with the genetic disease that was treated using their technology. That inspired me to leave life at the law firm and to join the company in-house. So RegenX is a clinical stage biotech company. We use components of a harmless virus called AEB, not known to cause disease, and we call this our NAV technology, N-A-V. And we use that to package and deliver genes to cells in the body as a one-time treatment for various disorders. The patient cells that acquire the

gene become bioreactors that supply the corrective gene product or therapeutic product like an antibody to provide long-lasting effects.

We're currently developing gene therapy product candidates in ocular, metabolic, and degenerative diseases, and we've in addition to our internal programs, we've selectively licensed the technology to a number of companies. We've got over 30 licensees and partnerships and our technology is involved in at least 15 clinical trials currently underway. So that -- that's who I am and where I am and thank you for inviting me to be part of the pane.

MR. PANDYA: Great, well thank you. We're glad you're here. Up next is Lauren Foster from MIT. Lauren?

MS. FOSTER: Yes, good afternoon and thanks so much for inviting me to participate. So, Lauren Foster, I am the Associate Director of the Technology Licensing Office at MIT. I am also like Laura, a bit of a reformed scientist as I like to say (laughter). I do have a doctorate in

cell and molecular biology and chose to pursue my career first in patent law. So I'm a registered Patent Agent, but then became intrigued by the business side of things, so after spending about 7 years in private biotech doing technology acquisition and business development, I came to MIT to lead up the Life Sciences Team. So, at MIT, our main goal like many university and tech transfer offices, is to promote the transfer of the outcomes of MIT research for (inaudible) benefit. But really in doing that, we really seek to cultivating an inclusive environment of the scientific and entrepreneurial excellence and try to bridge connections between our research community and industry, and startup and venture capitalists, and in furtherance of that we strategically evaluate the outcomes of MIT research and protect and license intellectual property that we decide to protect.

MR. PANDYA: Great. I think up next, we have someone who unlike myself and Laura and Lauren who is an actual scientist, not a reformed

scientist. Sheridan Miyamoto from Penn State University.

MS. MIYAMOTO: Hi, good afternoon. And to the speaker, thank you for having me. I'm an Assistant Professor in the College of Nursing at Penn State and the Director of the Sexual Assault Forensic Examination Telehealth Center that was launched with funding from Department of Justice. And as part of that service, our goal is really to provide forensic nursing expertise to rural and underserved communities by partnering with local nurses to deliver care via telehealth. And as part of that goal and as we evaluate a technology that existed in thinking that this is really truly a growing area across multiple states, that we found that technology was actually lacking. And so we -- we started to build new systems in our lab and -- and some of that was funded by the Department of Justice as well to kind of kick that off. So I am at the stage of working with OTM and helping to share of the things that have been helping to me as an academic and also being able

to get my career into innovation entrepreneurship.

MR. PANDYA: Well, we're looking forward to hearing your perspective. Now up next is Mita Mukherjee from Emergent BioSolutions. Mita?

MS. MUKHERJEE: Yes, thank you, and thank you. It's an honor to participate in this panel. I've also started as a Basic Researcher with boots on the bench. I did graduate work in biochemistry and then became interested in patent law and switched over to patent law and started work in the space in Washington, D.C. in a law firm and (inaudible). After that I came into industry and then came into (inaudible) and then AstraZeneca. And currently, I am a -- I'm the VP of IP Emergent BioSolutions, having come from AstraZeneca recently. So I -- I -- you know, I -- I really love the intersection of law and science and I really look forward to this discussion given the background and having come from different types of pharma. So I'm really looking forward to this and thanks again for letting me in.

MR. PANDYA: Thank you. Next, we have a

government colleague, Mark Rorhbaugh from NIH. Mark?

MR. ROHRBAUGH: Lost audio, it's disconnected right now.

MR. PANDYA: Okay, so we'll skip over Mark for a second and we'll -- we'll go to Dick Wilder and then Mark, when you're -- when you're online we'll -- you can unmute yourself. But in the meantime, Dick Wilder from CEPI. Go ahead, Dick.

MR. WILDER: Yes, thanks a lot, Brian. This is Dick Wilder, calling you from the Adirondack Mountains in Upstate New York. I'm on holiday this week, but I'm calling in for this event, which I consider to be very important and appreciate the opportunity to participate. A couple of things I'd say about my background is that I -- I am a registered Patent Attorney before the U.S. Patent and Trademark Office. I have worked at the Patent and Trademark Office for some time in what was then the Office of Legislative and International Affairs. And I've practiced law

in private practice at the Sidley Firm for a number of years and then I joined Microsoft where I was the head of Intellectual Property Policy Group. And after that I in essence went back to the Gates Foundation, because I had been there before, have done work for them before when I was in the Sidley Firm. I went to the Gates Foundation in Global Health Program and provided legal support you know, for the work that they do there including helping to establish the -- the program on global access, sort of the open access licensing mechanisms that they have in place. And then went there, did an organization on that now was founded, CEPI, the Coalition for Epidemic Preparedness Innovations, which is where I am now. I am General Counsel and Head of Business Development. We run an organization that is funded by a number of sovereign states as well as by foundations including the Gates Foundation and Welcome Trust in the UK. And our mission is twofold. One is to establish research projects and to fund them for the development of vaccines

against new and emerging infectious diseases, and second is to fund and establish new platforms that can more rapidly bring into existence vaccines.

In the case of COVID-19, we have 9 projects that are now underway for the development of vaccines against -- against SARS, COV-2, the virus that causes COVID-19. We have quite recently been engaged with other organizations to establish an entity called COVAX or the COVAX Facility and we're going that with GOBY, which is the international organization that funds procurement of vaccines for poor countries as well as the World Health Organization. And we just this last week completed a cycle of work there whereby we have now 156 countries that are participants in the COVAX mechanism that will fund and manage the allocation and distribution of COVID-19 vaccines in those countries. And the countries include not only low and middle income countries, but high income countries as well.

And in connection with the work we're doing on funding and ultimately manufacture and

distribution of vaccines, all of our programs are built on collaboration. And the collaborations that we have include those that have universities involved as well companies and government labs including NIAID. I work very closely with -- with the NIH. And as part of that collaboration, intellectual property plays an important role in intellectual property licensing. And you know, I'll be talking a bit more, I think I have at least one or two questions that address the question or go to the question of how is it that one can manage an intellectual property in connection with global programs like I've described, and where a significant piece of what we're doing is to address the needs of low income populations around the world. And I'm here to say that there's no inconsistency between intellectual property managing and intellectual property for that purpose that can both serve the needs that I've described, but then also you know ensure that the -- the commercial requirements of the companies involved are preserved and protected as

well. Thank you.

MR. PANDYA: Great, well that's some exciting and important work that CEPI is doing, Dick, and we look forward to hearing about that and I agree, there's no tensions between those two things, but it will be great to explore the topic. Mark, were you able to get connected now or are you --

MR. ROHRBAUGH: Yes, sorry for the delay. Thank you very much for the opportunity to speak today. My background is that I received a PhD in Biochemistry and Molecular and Cell Biology. After a post doc, I worked for two startup biotech companies and then moved to the NIH, received a law degree at night while I was working and then moved my way up to be the Director of the Office of Technology Transfer. At NIH, it was the central office that managed patenting and licensing from interareal scientists at NIH, CDC, and FDA where about 6000 doctoral level scientists who work at NIH, the largest of the three programs. After that, I moved -- about

5 years ago I moved over to the Office of the Director to be a Special Advisor for Technology Transfer. I advise on transfer matters in that office.

I wanted to mention just the broad expansive new efforts at NIH to address the COVID-19 challenge. There's -- we've used practically every single mechanism available, all business grants, research grants, procurement mechanisms, other transaction authority, numerous consortia including one that's coordinated by the foundation for the NIH, the accelerated COVID-19 therapeutics and interventions active. So all hands are on deck in addressing this challenge with every mechanism you can imagine.

I wanted to speak briefly about the licensing experience at NIH and how NIH manages those issues especially with respect to balancing public health needs with incentives needed by industry to move technologies to the marketplace especially those that require the approval. It's a long -- as you all know, it's a long difficult

process, high risk, high cost. And so often an exclusive license is needed or as an incentive for a company to invest in that way. But let's not think of exclusive, nonexclusive as being in and of itself nonexclusive or explosive for all rights in a patent. So often we reserve rights for -- we always reserve rights for research, but for example, on a monoclonal antibody, you might have an exclusive license for commercial development of a therapeutic and a nonexclusive license for using it as a reagent in a laboratory. Likewise, many therapeutics could be divided between multiple different development efforts at the same time with multiple exclusive licenses. So it's not necessarily an exclusive license for all fields of use of a particular technology. Thank you.

MR. PANDYA: Thank you and thank you again NIH for all the important work you're doing in the COVID crisis and the public health space more broadly. We're definitely going to get into some of the exclusive and nonexclusive licensing issues as the panel goes on. So let's -- let's

get started. So we'll set the table and explore the role of licensing and collaboration plays in the development, manufacture, and distribution of therapeutics and vaccines. So Laura Coruzzi, I'm going to call on you first and, well, let's break drug development into four stages: Basic research, product development, clinical trials, and scaling up to manufacturing. I know that's -- that's oversimplification and it's a lot more that happens there, but just to get things started, can you rank the importance of licensing and collaboration team stage and which stage has the most room for improvement and innovation within licensing and collaboration?

MS. CORUZZI: So, can you -- can you hear me this time and see me?

MR. PANDYA: Can hear you and we can see you.

MS. CORUZZI: (laughter) Wow, technology. So really collaboration I think is important at each and every stage and we've been experiencing that at RegenXBio, from -- and -- and

David Korn of PhRMA and Hance Sauer (phonetic) did a really good job explaining that yesterday in session 2. Just the skillset that's needed for the basic discovery and then the skill sets that are needed for the clinical trials differ and so partnering with different skillsets is important for the whole process.

What I'd like to focus on today is the initial process, the basic research and how that gets translated to companies. And RegenXBio can be a case in point on this. When our company was founded in 2009, gene therapy was considered to be very risky to pursue. Many investors were not at all in. Groundbreaking research had been done at UPenn that led to the discovery of hundreds of AAVs, the AAV vectors that we now call NAV, that have the potential to be useful for gene therapy applications. The diversity of this NAV portfolio is important for scientific reasons. You want to make sure the vector's going to get to the organ you're trying to target, and you want to make sure that patient antibodies don't neutralize the drug

and then you have no effect. So Penn has licensed these rights to a big pharma who kind of sat on them for a few years and really did nothing with it. RegenX was founded by this small group of smart people that I mentioned before and they rescued the technology by licensing it from big pharma and residual rights from Penn and then began developing our own internal programs and licensed out what we couldn't do as a small company to worthy partners who have been continuing to develop the technologies and there are -- our list of partnerships and licensees are on our website. We're, as I said before, we're in 5 clinical programs of our own and at least 15 carried on by our partners licensees, and one of those NAV products, Zulchinzma (phonetic) has been proved by the U.S. FDA and EU to treat a devastating disease called spinal muscular atrophy. And that was the first patient that I got the chill about (laughter) who was treated with the vector to begin with. These early risks wouldn't have been taken if the patent estate

wasn't in place.

MR. PANDYA: So I want to pick up on some more about you mentioned earlier that some of the earlier research was not taken by a -- by a big pharma company, but luckily the patent rights were still in place. Now Mita, you've been with a giant like Astra Zeneca. You're now with specialty company Emergent. Do you agree with Laura's answer on which stage of (inaudible) is most important and a two part question, would you have given the same answer at Astra Zeneca that you're giving today at Emergent?

MS. MUKHERJEE: (Laughter) Yes. Thanks for the question. I think generally, I mean, I agree with Laura in that ever stage is important and what I would say is that regardless of size of the company, that innovation and collaboration are absolutely vital and I think that IP plays a very important role in balancing the of course large investment and resources that it takes to develop a product and then get a return on that investment. So I think that IP then also is a

mechanism by which to help structure collaboration relationships in a competitive fashion. And so I think regardless of the size, those are both -- that they're both critical. I think at every stage along the way, I know regardless of what company I've been at, innovation is extremely important and there is a very strong recognition that a lot of the cutting edge basic research science has done in academics. And some of these companies have set up collaborative sites and centers near academia so that they can collaborate with them. I think there are very, very good reasons to do that.

You know, the big pharma expertise is of course in translating the basic research into a product for patients and that is the area of expertise. So you know, I would say maybe one of the differences is that how would you determine the right fit when you enter a collaboration? And that's where perhaps there's a little bit of difference in the sense that you know maybe big pharma had a broader set of therapeutic areas, a

broader set of modalities they can work with. Perhaps more resources to sort of connect disparate sets of the expertise. And you know with this, this focus on how can we translate this product into a medicine to deliver to patients who need this? Whereas smaller companies like Emergent look more at what specific niche or skills are expertise do we have, do our researchers have? We are experts at scaling up manufacturing in the back team stage. We work with the government and we work in the public health thread space. So for us, where do we partner with those different organizations that really make sense.

So I think that's where I see the difference and so what players and at what stage to do it? I think it may be different because of these situations, but at every step along the way I think it's absolutely essential and absolutely vital.

MR. PANDYA: Yes, well I -- I -- I like your -- your characterization. IP is the

mechanism to structure relationships and collaborations, and a lot of it is about determining the right fit. So Lauren Foster, let's look at this from a university perspective. Tell us about some of the mechanisms that MIT uses to structure its relationship in collaboration. Can you use -- use exclusive licensing? Do you use certain nonexplicit licensing? Lauren?

MS. FOSTER: Absolutely. Thanks, Brian. So I -- I would echo a little bit what we -- we heard before in that we certainly find in the therapeutic space that as a sort of general (inaudible), exclusivity is required, but there is an enormous amount of nuance on what exclusivity really means. (laughter) So, speaking from the nonprofit sector, like -- like the NIH, we feel very strongly committed in even all of our exclusive commercial licenses, and I use that term deliberately. It is a commercial license, so we reserve broad rights for research in the academic and nonprofit sector to continue to move the technology forward. The exclusivity typically

only pertains to product development and commercialization. And then we use the same tools that many of us are familiar with, whether it be field abuse, which allows for especially in the context of enabling technologies that may not be the actual let's call it, drug product itself, but has sort of an underlying role for example, drug delivery. We use field abuse to try to certainly balance the competitive advantage that our licensees need. It is our primary goal and sort of our mission, which is to make technology broadly available and sort of living true to -- to that as well.

You know, some of the other things that are interesting and actually pertains to work that we've done in the public health sector as well as we think about even if we do for example give strategic control over an asset to a partner, there are certainly diligence terms and expectations that you can create contractually that your partner will develop technology in a certain way, and if they don't to really encourage

an incentivize them to partner with other organizations where it makes sense, meaning organizations that are noncompetitive with them, but that would meet the goal again of having the technology have broad access. And we -- we like to say fine, if you partner, you get the economic benefit of that. (laughter) You know, rather than us having you know five different partners, sometimes we do choose to put all of our rights with a single partner with a sort of a partnering mindset and a, we call it, mandator sublicensing (laughter) or -- All that to say is that partnering is built into the expectation knowing that it, in some instances, again, more an enabling technology that is unlikely that a single entity will exploit the technology to its full potential.

MR. PANDYA: I want to hold your thought there on enabling technology through our partnerships and explore that with Dick in a second. Before we get there, Mark, can you chime in and tell us if NIH's approach different from

MIT? I mean, your report being there are universities and government largely on the same page. Is there -- are there any other key differences you want to highlight about how NIH's approach to licensing compared to MIT? Mark, you're on mute again.

MR. ROHRBAUGH: Sorry. It's very similar with respect to how we approach licensing. I think the field has evolved so much in the last 30 years that applying diligence and carefulness and defining the scope is much more on our minds and access than it was many years ago for the better of everyone. The differences lie more in the statutes and regulations that apply particularly to government labs. So for example, you cannot grant an exclusive license without advertising it in the federal register for comment and possible objection. So, when there's concern about the potential process in the collaboration, we might use a mechanism called a Cooperative Research and Development Agreement, which of note does not require the advertisement and gives the

collaborator an option to elect an exclusive license.

The other differences are more in how we partner with industry. We don't have the same freedom of and mechanisms to collaborate with industry and startups in holding equity, in managing the startup and collaboration outside of the day to day work, that is say on scientists' personal time collaboration. Those don't exist in that way in the NIH, so the approach -- the overall approach is very similar. Details of the mechanisms do different.

MR. PANDYA: How often when you publish an exclusive license in the federal register, how often did you receive comments or objections from the public?

MR. ROHRBAUGH: Well, it's common for us to receive comments. In terms of an objection from a potential licensee, it's not common and often when there is an objection from another company that desires an exclusive license, we can find different fields of use. Maybe one company

wants to apply it to its own particular proprietary platform, which can be separated from another company, or one who wants to use it, a drug, or biologic for a particular disease and the other wants different. So it can be carved out and sometimes it can't, and then we must choose -- we must favor small businesses, but otherwise let's make the decision of which is most capable.

MR. PANDYA: Dick, can you -- can you chime in here? I want to -- I mean you're I think in a really unique role. Your work is funded by nonprofit, the Gates Foundation, by the government. Tell us how you -- tell us more about your platform and talk about -- I would -- I mean, I would like to hear more about enabling technologies, but tell us -- explain how the platform works and what -- what role licensing and collaboration play.

MR. WILDER: Yes, I can talk about platforms in a couple of senses. You know, one is with respect to CEPI as such, and we are a platform in a sense that you know we are an entity

that provides funding for the development of vaccines or as I indicated before, for the development of platform technologies that can be used to rapidly develop and deploy vaccines. With respect to you know, CEPI as such, we engage with universities that are working on early stage technologies as well as companies large and small, you know, that are developing either the technology itself or undertaking to do a manufacturing and ultimately, you know, sales and distribution.

Our interest is insuring a couple of things. You know, one is that, that work is successful. That is that the research and development activity that's undertaken is successfully done, so we have very carefully negotiated agreements with our partners as to how the work is done, the timeframe, and who -- who's all going to be involved including you know, the primary grantee as well as the collaborators. We also you know, have specific requirements around what the end result is intended to be. I mean,

not just the fact that a vaccine comes into existence, but also what's going to happen with respect to that vaccine and regulatory approvals and the countries of the world to which it's going to be circulated. And with respect to COVID-19 vaccines, you know, it's intended that they have a global distribution of both high income countries as well as low and middle income countries. And price is important, you know, with respect to the low and middle income countries, and so we have some specific requirements around that.

We manage connection with how we you know, establish the projects and manage them going forward. I would say one last thing on that is that you know, with respect to the intellectual property that arises from our funding, we don't take an ownership interest in it. We don't necessarily take license rights with respect to the technology. We have particular contractual obligations that the awardees are expected to follow and you know, we -- we manage them by contract to say, you know again, you will do

certain things and you have agreed that you know, the ultimate product will be distributed on certain terms and conditions, all of which we monitor very closely as the project unfolds.

We may obtain certain intellectual property rights more as a remedy in the event that they don't follow through on those obligations, much like you know, the NIH has the possibility of so-called step-in rights. You know, we have something similar that will allow us to then you know, step in and take a project and move forward with someone else, but you know, by far the -- the key to success in this space is to you know basically work with the partners that you've selected from the beginning, manage the projects well on a collective basis, and -- and ensure them the intellectual property is (inaudible) to achieve the result or the outcome or distribution that we have agreed to with our partners. Thank you.

MR. PANDYA: Great. Well, I think your comment, the reason I think I'd like to hear from

Sheridan about when hearing the perspective of lawyers and licensing officers opine on more licensing increasing sufficiency, but you're an innovator, particularly in telehealth, so can you tell us about safety system. I want to ask us what our colleagues are saying -- what they're saying today is consistent with your experiences and collaboratively developing a product and trying to license that product, and tell us anything else about you know -- I think you're working on platforms similar to what some of the companies in Dick's portfolio work with. But walk us through your experiences. You're the -- you know, you're the -- you're the patentee here while we're the -- we're the -- the talkers.

MS. SHERIDAN: Sure, so you know the first thing I think is that it can be really challenging for an academic to balance both research and teaching and to think about stepping into an area that requires a lot of work with your action to develop technology. So I think there were a couple of things that were really key to me

and being able to make some of that transition. And the first was really to have some flexibility in the initial grant from DOJ or a program officer that was willing to set -- to invest some in prototyping, and that I didn't have to completely shift away from my research and my program to find funding for this idea, but I could step into it somewhat with the recognition from the funder that this might be an important technology for the field. So I think had I had to go search for funding completely separate and outside, that would have potentially been a barrier. So that was really helpful.

The second, and I -- I -- I don't think the things I'm hearing are things that I've heard at Penn State, so I feel that relatively quickly I was able to be connected to our Office of Technology Management and they were incredibly supportive coming over and talking to me about what this process might look like and answering my questions, really being available as a resource to help me think about how we would take steps to

move some of these things forward.

Some of that was also investment from Penn State and Invent Penn State, which is a -- a -- one of the President's initiatives to really try and provide some aid funding for investigators to explore their ideas and to be really well connected to OTM to -- to advance this initiative. So those were -- were kind of the early things. The place where I felt like I started to get some of the education that I'm hearing about from the panelists today was that there's a Penn State venture and IP conference, and that was just a whole different way of thinking for me, to be able to hear from licensing agents and people who can talk about how someone like me might find different sorts of funding, angel funding or investors, as well as some of the legal considerations being able to talk to patent lawyers and -- and people who can talk about copyrights. So -- so that was a whole new place for me to get a different type of education and that was really helpful.

The other piece of those sorts of conversations, being invited to be part of tech tournaments. And I think that was really key because it encouraged me to talk differently about my work than I needed to and to kind of put it out there, which is a little bit scary; however, academics would like everything to be done before we share our work, with business people that could ultimately give me feedback and gave me some sense that wow, maybe this is something that's viable. Maybe it is something that I should be spending some time on. So -- so that kind of infusion of a little bit of confidence that this was a worthwhile endeavor and you know, worth adding more to my plate was also really important.

And then the final thing that I think has been absolutely essential is they started a startup leadership network that really aims to pair researchers and Penn State tech startups with executive leadership matches. So recognizing that they don't necessarily want their researchers to leave their academic position, how do we find the

right business partners that can help bring that along. And that -- that has been absolutely key, is to have time to get to know some of those people and determine if they're the right fit and you know, provide some of those people that can actually move the work forward more expeditiously than I could by myself. One of the new things that they're piloting is actually bringing together, and a lot of these are either Penn State alums that have been successful in business startup, is to bring them along with a couple of companies and act as an advisory board and really give a researcher like me the opportunity to understand what it might be like to have an advisory board that can give you feedback on your business ideas. So that's a year long process and has -- has greatly moved my work forward.

MR. PANDYA: Have you entered into any licensing agreements yet?

MS. SHERIDAN: No, so we're still in the context of finishing our initial prototype, but I've been keeping the OPM apprised of our

developments as we go so that -- and they're checking some of the agreements that we have with different partners that are building out aspects of that for us. So just making sure that we kind of have everything in a row and then doing things along the way that -- that's to come.

MR. PANDYA: Great. That's such exciting work now. I know we're unfortunately, we have only about 15 minutes left so I want to shift gears a little bit and we're talking -- when we talk about licensing, I think one of the challenges is legal uncertainty over the enforceability of the rights that you're licensing. Now, I submit, there's always been some uncertain key patent to be invalid for being anticipated or for being obvious, for not being in able black and written description. But in the past decade we've even increased an invalidation for patent, even in the pharmaceutical space, for failing to claim patent of full subject matter. Laura Coruzzi, how is that in your opinion changed licensing that leaves things more uncertain, but

how has it changed things and I think you have some strong views on that topic and have gotten things for the better. But what can -- what -- how is the change, what can we do, what can you tell I need to start making things better?

MS. CORUZZI: Well, Judge Michelle pretty much summed it up yesterday. The major challenge that we all face, and I think this affects universities and that stage that I was talking about of getting university discoveries translated to real products for patients. It's the 101 eligibility standard. I mean, I'm going to give you a thumbnail historical view of what this should have been. So in 1980, was the year that was. That's when the Supreme Court ruled in Shakra Bardi (phonetic) that genetically engineered micros could be patented. And that gave birth to biotech industry. That same year the Bayh-Dole Act was passed and that was to encourage licensing government funded inventions made at universities with the private sector to collaborate to make sure that these basic

discoveries translated to medicines for people to help patients. And that led to all of the game changing biologics that we have, the antibody drugs that didn't exist before. Thirty years of court precedence supported these inventions and these products. Basically, the courts held that isolated and purified forms of natural products could be patented and that supported patents on antibiotics, cancer chemotherapeutics, antibodies, DNA primers and probes.

Flying in the face of this 30 years of precedence, the Supreme Court in the Mayo and Myriad decision stripped away patent ability from diagnostics calling them diagnostic laws of nature, which I think is an oxymoron, but the Supreme Court doesn't, and genes on the grounds that they're natural products. And these holdings aren't based on any statute. They're based on the original exceptions created by the Supreme Court that were then expanded by Mayo and Myriad. At the oral argument, Justice Ruth Bader Ginsburg asked, "What's going to happen to the patent

ability of vaccines if we follow this line of thinking that a natural product could not be eligible?"

So these decisions, Mayo and Myriad, stifled investment in diagnostics and expensive proposition with a low profit margin as it is and universities today where breakthroughs are made in genetics, many universities are no longer filing on diagnostics, on genes, primers, and probes. And startups that want to license this technology are not able to raise the funding that's needed to support commercialization. So we really are, contrary to the purpose of Bidol, we are in my opinion squandering taxpayer investment dollars in government funded university research and patients are being harmed because these basic discoveries are not being translated to diagnostics and medicines so sorely needed today. I mean, if all of us think, how better prepared we could have been to test for COVID-19 had the -- a more robust infrastructure existed within our diagnostic industry. And finally, it's put the U.S. at a

competitive disadvantage because we're the only country in the world that you can't patent a purified natural product or an engineered natural product, or the genes that make the primers and probes for diagnostics.

China and other countries are moving into the area that the U.S. unilaterally surrendered by the Supreme Court decisions. And you know, I ask, my bottom line is does anybody doubt that had Mayo and Myriad come out differently we would be in a much better place today. I don't think so and I think we need legislative change and I'm hoping that David Kappos in the next panel will address some of the ideas that are percolating about how to fix this.

MR. PANDYA: Oh yes, there's a couple things to unpack there. First of all, does anyone or can -- can I get anyone either if you believe it or have a fond (inaudible), maybe Dick, I'll call on you because you -- you agree with Dr. Coruzzi and those narratives and facts that certain things are not patentable or more

difficult to patent. Does that have some vital benefits, or do you agree with Laura?

MR. WILDER: No, no, I think you know I generally agree with the notion that you know, the Supreme Court decisions obviously have made you know, patent ability and certain subject matter more difficult. You know, from -- from the perspective of the work that -- that we do at CEPI or in the nonprofit sector let's say generally, you know, we -- we don't take a position that patents or patentability -- let's just say patents are a bad thing and therefore, you know, the scope of what's patentable is -- is a bad thing or a good thing for that matter. But rather, again, going back to what I was saying earlier is that -- and maybe the -- from our perspective, you know, what we draw distinction between is what's often said in Europe, between the extents and the exercise of intellectual property rights. So as you know, intellectual property rights are brought into existence, what we're more interested in is how one actually exercises those rights to achieve

a public health outcome, whether that has to do with you know, supplies for certain jurisdictions, pricing, or -- or -- or anything along those lines, and do that you know, in cooperation with the agreement of our partners who are the -- the intellectual property owners.

You know, I would also say that in a lot of areas that we work in, the vaccines being one, is that patents are important and you know, again, we can take a great (inaudible), you know we respect the intellectual property rights of our partners, but there's other forms of exclusivity, you know, beyond patents that are important as well, you know, that -- that companies are using. I -- I think that there are certain areas where the -- the -- the additional exclusions that were mentioned for biological subject matter for gene sequences and -- and extraction rights in terms of (inaudible) that have had an effect, you know, have gone into that much detail as was just discussed, but I think it does have an effect. What I would say, like I say, it's in our

perspective, we're focused more on the result in terms of what comes from the -- the work that we're doing collaboratively and all of the intellectual property rights and licenses are arranged. Thanks.

MR. PANDYA: Mark or Lauren, can you respond to what Laura said about the Bayh-Dole Act? And then we'll go back to Laura.

MS. CORUZZI: May I?

MR. PANDYA: You still have -- yes. Go ahead, yes.

MS. CORUZZI: So just two points. I -- I completely agree that how you manage the patent right is important, but these decisions knock the legs out of the patent rights to begin with. So if we don't have a patent then how you use a patent becomes immaterial. That's number one. So -- and -- and it is putting us behind other countries, so I really think we need a 101 fix.

MR. PANDYA: Great. Lauren or Mark, can you respond on -- on the Bayh-Dole Act or talk about university licensing?

MR. ROHRBAUGH: I would say under -- under Bayh- Dole, Bayh-Dole gives the freedom to universities to manage and exploit intellectual property as (inaudible) with their responsibility primarily to make sure that it's developed for the benefit of the economy and the public who might purchase or consume those products. So universities have done an excellent job with that. The restrictions are that they cover every state's license for government use purposes for or on behalf of the government and there are -- there's a march-in statute. But things -- the progress has been fantastic in the last 30 years with respect to 40 years with respect to Bayh- Dole and how universities and recipients of funding have used their -- their authority to advance commercialization.

MS. FOSTER: Sorry, I was on mute. I -- I could not echo Mark's comments better. And just to pick on where Laura left off, I -- I think any uncertain about the ability to obtain IP puts the real burden on specifically innovation coming out

of nonprofit organizations where if I talk wearing my MIT hat, we are a true blue academic institution. We are a training institution. We are often forced to file quite early because our whole mission of our trainees and faculty is to publish and disseminate, so we are -- we do our best to evaluate, and any uncertainty about our ability to get intellectual property in already a compressed timeframe (laughter) when we're operating on -- on forces, we don't hold the outcomes of our research for years and years and years until we perfect a product. I do think it -- it can be extremely challenging. I mean, some of us are lucky enough to be able to roll the dice a little bit, but is certainly -- it is certainly an issue that comes up in our licensing practices and we have really -- we always have, but it is even more under the microscope to make sure that the benefit that we receive under our licenses is very closely tied to successful IP, and there's a lot of uncertainties the longer it takes to get IP for the system or have the subject to challenged

in the like. That -- that really takes a hit on -- on the licensor because we will not share in value until it's sort of rock solid.

MR. PANDYA: Okay, we have one minute left, unfortunately. So I want to talk briefly about COVID and talk about collaboration and partnership in the time of COVID. So Mita, this question's for you and I think from the private sector one of the hardest things about bringing (inaudible) specialty companies, but as we're trying to bring COVID back in to market other treatment, we have to find a way to scale things up to get to hundreds of millions of doses in an incredibly amount of time. So how is the emerging tackled scale of problems and if you have any anecdotes you could share about how licensing and collaboration could play a role in that to -- and help companies scale up at a -- at a -- at a rapid pace.

MS. MUKHERJEE: Yes. Well, as you all know, we are manufacturing COVID vaccines already for several companies and I think -- I think a

very holistic and creative and adaptable approach given the time constraints, I guess that's what I included, is the way to do it. And I think just allowing the mechan -- you know, allowing companies to the resources and the ability to collaborate freely and to basically help big pharma utilize small companies, resources, and expertise such as ours where we know how to scale a vaccine. We know how to do it rapidly. We know how to do it quickly in areas where they may not. So it -- I do think that having very creative solutions, adaptable solutions, in which partners such as the government or other external forces can also help provide incentive is really, really a vital point, and also ways that we can have mechanisms to really protect tech transfer and do it quickly and you know, protect you know, provide insurances that people, products, and their intellectual innovations will be protected. And again, that goes back to patent, which provide again that mechanism I think, to be able to allow that to happen. So --

MR. PANDYA: What are some of the creative ways that you're into? Can you share anything?

MS. MUKHERJEE: You know, I think a lot of it in terms of tech transfer and space is sort of allowing you know, structuring agreements such that you allow different parties to utilize information, materials, knowhow from other parties all at the same time. So a lot of these processes involve multiparty agreements and so I -- I think those are kind of some of the things we'd have to work through. How do you get two or three different parties to allow this? How do you allow you know, us to have access to your IP and your technology and your knowhow and still allow us to use other parties where we may need to so that this can go as quickly as possible. So, truly being able to get everyone at the table together and work through all of the issues and understand the underlying incentives and motivations. I think that's the key thing.

MR. PANDYA: Well I wish we had more

time to explore that point but we are out of time, but before we to, there's one question from the audience, and the question is how is access for global public health provided in your license agreement? Does anyone want to answer that question or just -- Anyone want to take a stab at that?

MS. FOSTER: I can say from the MIT side, we try to be as deliberate as possible with technologies that are in the biomedical stage to put in terms that put at the forefront that should the technology, and it's not always the case, but should the technology have applicability for we call it you know, at-cost markets or potentially even under resourced markets that can exist anywhere in the world, that we look to our licensees to address those markets and we also on many occasion if products are being sold at cost, we will do things as simple as waiving a royalty obligation through MIT so that sort of because we owe MIT money, but for that (laughter) we would be developing these products but your royalties very

well prevent us from being able to you know, make this economically viable. We -- we have a large number of tools available to us, so sometimes contractual like Dick and others have mentioned, we use intellectual property patenting strategies, you know, no IP is not the same as access, so we use very nuance territory and country patenting decisions to -- to facilitate. But it -- I think the key that I'd like to say here is that it has to be deliberate. It cannot be an afterthought. And -- and we've learned a lot through working with folks like the Gates Foundation and others to make sure that when biomedical technologies are developed and licensed, if they are licensed exclusively, it's a big if (laughter), that we -- we put it on the forefront of what the expectations are.

MR. PANDYA: Great, well let's thank all of our panelists. It's a great -- great discussion. I wish we had a lot more time, but we scratched the surface on a few of these topics, but thanks again everyone for joining us. Thanks

to the audience, and with that I will turn the floor back over to Jennifer, Dave, or to our next panel.

MS. DIXTON: Thank you. Thanks, Brian. Thank you to all of our panelists for sharing all your experiences and perspectives and collaboration in licensing in this area. Was a great panel. We're going to take a few minutes right now to go on a break, about a five minute break. We'll be back at 2:35 Eastern time. We're running a little bit behind, but we have a lot to cover today and we'll try to take up some time as we go through, but we'll be back in about five minutes. Thank you to everyone who (inaudible).

(Recess)

MS. DIXTON: Welcome back everyone. We're now going to move on to our next panel on how regulation and antitrust enforcement impacts competition and incentives for innovation. And this panel will be moderated by Deputy Assistant Attorney General Alex Okuliar, who is in charge of our civil antitrust enforcement and he will be

introducing our distinguished panelists. Thank you, Alex.

MR. OKULIAR: Well, thanks so much, Jennifer, and welcome everyone. So our panelists today will discuss the extent to which regulation and antitrust enforcement are needed to maintain competition among safe and effective products, which can impact the incentives for innovation. They'll also address the tradeoffs of antitrust enforcement and regulation, particularly in terms of the incentives for innovation during a pandemic. Our esteemed presenters today include Alden Abbott, the General Counsel of Federal Trade Commission. Welcome, Alden. Ernst Berndt, who the Professor Emeritus Economics at the Sloan School of Management at MIT. Welcome, Professor. Dave Kappos, Partner at Carvath, Swaine & Moore. Welcome, Dave. Bill Kovacic, the Global Competition Professor of Law and Policy, George Washington University Law School. Welcome, Bill. And Dick Wilder, General Counsel, Coalition for Epidemic Preparedness Innovations. Welcome, Dick.

So we're going to spend -- we're going to start with a discussion about incentives to innovate and then we're going to pan out a little bit and talk more broadly about regulation and enforcement and the tradeoffs between antitrust and intellectual property policies. We'll leave a few minutes at the end for questions, so please keep your questions in mind as the -- as they come up during the discussion.

So, Professor Berndt, I'd like to start with you. In terms of incentives to innovate, what factors govern an individual firm's incentive to innovate in the life sciences market?

MR. BERNDT: Thank you. Can you hear me?

MR. OKULIAR: Yes.

MR. BERNDT: So, I'm Earnie Berndt. I'm a Professor Emeritus at the MIT Sloan School and our national view of economic research, most of my research and testifying have been in life science industries and in particular, I spent a lot of time worrying about what happens to brand and

prices for branded products as a face loss of exclusivity. In that stream, we are very familiar with that. For small molecules it's felt, also beginning to occur for biosimilars and biologics, and I think what I'd like to sort of basically point out is that there are important incentives for follow on innovation that are very important in the life science industry. This creates issues and conflicts with other goals which include access to low cost medicine, and so very briefly what my research and testifying has been involved with is I think originally when Pat Swaxmon was passed most academics and certainly the Federal Trade Commission predicted that in response to generic entry brand and products would compete on price and lower prices. We haven't observed that. In fact, very seldom we do brand and products lower price in response to competition from generics. What usually happens, is a brand increases prices. The conventional reason that's given for that is that there are brand loyal customers and you can take advantage of brand

loyal customers by giving them the privilege to pay higher prices.

The other reason, which has not really been explored much but is important for discussion today, is that a lot of branded products pursue follow on development of products, and in some cases launch those products prior to the loss of exclusivity. And this raises the issue for the pioneer product manufacturer, what do I do with the pioneer product, as I now have a follow on as well? How do I manage this joint product? Do I invite cannibalization, or do I try and quietly retire my pioneer product? What we've observed quite frequently is that the branded product will raise its price, will lower its micro marketing efforts, and try and switch products to the next generation follow on. In more extreme cases, and this is where their conflicts really emerge, is that in some cases a branded product will remove its pioneer product from the market prior to the loss of exclusivity in which case consumers and payers are forced if you want to stay with the

same molecule, to switch to the new product. And this basically eviscerates the market for extensive and active generic market. And so we have our conflict here incentives, you want to increase the incentives for follow on products, but we also want to make sure that there's a -- that as they lose exclusivity, there's a very active and extensive generic market that provides access at low cost to consumers and payers.

MR. OKULIAR: Thanks, Professor. Any thoughts on -- on ways in which we could accomplish that objective? How does market based pricing sort of effect innovation incentives, for example?

MR. BERNDT: Well, if there's no market for the generic product because it -- there's no reference product on the market to which you can be ruled as being interchangeable by the FDA, that means that basically you have a policy that prevents a market from emerging where we would like to have a generic competition come in at low cost. But if -- if that market is precluded

because there's no reference product on the market to which the generic can claim AV rating, that sort of removes the possibility of there being competition.

MR. OKULIAR: The case you're suggesting is a form of product hopping?

MR. BRENDT: Yes.

MR. OKULIAR: So, can I turn to Dave Kappos or others, do you have a reaction to this and ways in which we might be able to address the issue that the Professor is raising?

MR. KAPPOS: Yes, Alex, thanks for giving me an opportunity to comment on that. And thanks to the DOJ and the U.S. PTO for convening this important conference. I think this is a great opportunity. You know, I think the answer to the issue of product hopping, as least so far, our deepest concern is a strong (inaudible) requirement to ensure that patent protection is only provided for new drugs that really are new and really are unobvious.

MR. OKULIAR: Thanks, Dave. Let me take

a step back a little bit. I mean, do you think that there are enough incentives for innovation currently in the life sciences market and specifically, what is the U.S. patent system's role in incentivizing innovation including the role attached to our subject matter?

MR. KAPPOS: Yes, well thanks Alex. So I would tell you, and I'll -- I'll show evidence of this in a moment if it's okay. I've got a short slide that you can queue up that unfortunately, while the U.S. patent system should play a central role, it unfortunately has been disabled and is playing less and less of a role and in fact is becoming quite marginalized in terms of its role in incenting investment in innovation and especially incenting the work that's required to bring basic innovations out of great universities like MIT and Penn State and some of the others that we've heard from here in the last two days into the marketplace. So I don't know Alex, if you're able to turn over to the slide deck and I could just very briefly show

what I would say is the effects of lack of incentivization through the patent system. In other words, what happens when the patent system leaves the playing field?

And so you can -- you can skip forward to the first substantive slide, and what you see here is just a quick snapshot of just a few of the many companies from many different industries that are stepping forward and saying that the patent system is broken and particularly the ability to apply what we call section 101 or a broad view of statutory subject matter, the kind of inventions that are included in the scope of the patent system has been unduly constricted. Broad range of companies, broad range of industries.

If you go to the next slide, now let's take a look at the data. This to me is all very important because the subject of this conference is you know, life sciences and innovation, and this panel is about the role of incentives and the role of government and I will show you the role of incentives and what happens when your incentives

go away. So you see here, quite frankly that investment is fleeing technology that's impacted by our constricted state of statutory subject matter of patentable innovation in the U.S. Decreases of over 80 percent of investments moving out of technologies that are no longer protected by patents. We'll have lots of new skin creams, but we will have not very many new diagnostics as a result of what's going on right now. And while I love skin creams and I'm sure many others do, I'd also like to see diagnostics. And then I'll also mention at the bottom of this slide, unfortunately, and this should be of interest to the DOJ, Alex, it's small companies that are hurt the most.

They now cannot get patents as a result they cannot IPO, as a result they cannot get access to the capital markets, and as a result they cannot grow. So if you go forward, so here's another look at the data. Venture capital funding has dropped dramatically in key technology areas, the areas that you see at the top of the slide

here, drug discovery, surgical devices, pharmaceutical, etc. So you know, it's a great time if you look at the bottom of this slice, to have a dating app company, and while I'm sure it's just great to have more dating apps out there, I'd also like to see more investments in cures for cancer and diagnostics, important pharmaceuticals, vaccines, we could use some of those right now for obvious reasons. And unfortunately, as you can see, the data shows that, that investment is just drying up.

So if we go to the next slide very briefly, and how is that investment drying up? Well, the venture capital industry is voting with its feet. It is moving decidedly out of technology that are patent-reliant as you can see from the data here with a drop in investment that leads to a drop in competitiveness that leads to damage to consumer welfare, again should be of great interest to the government and a great area for policymaking and a great area for the Department of Justice to get involved in, in its

role of promoting competition, competitiveness, and consumer welfare. And this isn't just a patent problem, right, just because the national competitiveness issue. And I'll talk more about that if you look to the next slide.

So, individual inventors, as I mentioned before, disproportionately hurt. Individual inventors are the disruptors. They're the creators of new paradigm, dynamic competition now being destroyed, being driven out of the marketplace in disproportionate numbers. As you could see from the data here, I'm sure that runs to the benefit of entrenched players. I do not think it runs to the benefit of the competitive process or to our nation overall.

If you flip to the next slide, so this comes back to the role of government and what happens to government. And I'll build on something that Laura mentioned on the previous panel here. When you see the U.S. Department of Health and Human Services running headlong away from the patent system, which is what the data

here shows, and therefore, decidedly less patenting in areas like mitral valves, cardiac valves, aerosol delivery of medicine, you could use some of that right now, and these are areas that we truly care about. We truly care about improved cardiac outcomes, cures for COVID-19, and of course, guess what it means when there are no patents in these areas because the Department of Health and Human Services is electing not to see patent protection where it knows it can get patent protection, of course it means there's no interest in taking the innovation, the basic innovation created by (inaudible) and moving it into the market place, and of course, that means there's no commercialization and that means there's no competition to be had at all because there are no products or services.

And so billions of dollars of NIH spend, which is all great, goes to naught now because there's no incentive for anyone to pick it up and take it to the marketplace. If you flip over, I'll conclude here very briefly. So what's

happening upstream in the patent system, again, the data. A patent filer are voting with their feet. They're leaving (inaudible)

MR. OKULIAR: Mr. Kappos, we are just losing your audio. Dave -- Dave we're losing your audio. I don't know if you can hear me, but I don't know if it would be possible for you to dial in, but I think your -- your bandwidth, your internet connection is -- is insufficient bandwidth.

SPEAKER: Yes, I just muted him.

MR. OKULIAR: Okay. Well, let me get Professor Berndt, let me ask you. Falling onto what Dave was talking about with respect to China and the diminution in innovative activity in the United States and patent filings I think in particular in the United States, should we be thinking beyond intellectual property rights to create incentives for innovation? And if so, do you have some suggestions for what some of those might be?

MR. BERNDT: I think obviously patents

plays an extremely important role here and there are different ways of granting exclusivity. The FDA has obtained tools to be able to extend exclusivity based on criteria other than patents, for example, pediatric studies, studies in rare diseases. It's presumedly possible that certain exclusivities could be awarded for the COVID treatments, or for that matter, for the vaccine without it being patented. So I think -- I think there are other possibilities. Yes.

MR. OKULIAR: Well, thank you. Thanks Professor. Dick Wilder, in -- in -- turn to you in the context of the pandemic, what sort of incentives have there been and what more, if any are required just for rapid innovation, where there may be more failures than successes in development of drugs?

MR. WILDER: Yes, thank you. Thank you very much for the -- the question, Alex. And thanks for the opportunity to participate in this panel discussion. Just to say a couple of words about my organization. I talked about in the last

panel, but CEPI, the Coalition for Epidemic Preparedness Innovations, among other things, is focused now on developing vaccines against SARS COV-2, which is the virus that causes COVID-19, and we have 9 vaccine development projects that are up and running. We're working as well in cooperation with the World Health Organization and with GAVI to set up a mechanism called COVAX, which is now up and running. We have now over 150 countries that are participating in that, a mechanism through which they would secure access to vaccines once developed and to do so in a way that meets price requirements, especially in low/middle-income countries, but high income countries would access vaccines through that mechanism on a global basis.

And a couple of things specifically to your question about innovation in this context is that you know, we -- we recognize the role that the patent system plays domestically in the U.S. and globally, and as we work with our partners, which include universities, government labs,

companies large and small, you know, intellectual property is one of the threads that runs through our funding for research and development and collaborations that we put up. You know, there's other forms of exclusivity as have been mentioned including other forms of intellectual property, and you know, those play a role as well and we manage those in our funded projects and manage them in the collaboration, and they are managed when it comes to this global mechanism for manufacture and distribution.

What's really unique and what presents some challenges when it comes to innovation, and I would say presents some challenges as well for antitrust enforcement, is -- is the, if nothing else really the speed with which we're acting in -- in the face of this pandemic. And I think you know, we all recognize the urgency to develop vaccines and get them through regulatory approvals and into the market as soon as possible, you know ensuring that the vaccines are good, they're safe and effective and so on. And consequently, we are

doing a lot now in parallel that in -- in times before these one would have done in sequence. You know, for example, we're standing up manufacturing for these vaccines even before they go through the development process. So you know, after you have phase one data, you then begin funding you know, setting up the manufacturing capacity for -- for the vaccine. And this means that the Department of Justice and the FTC have responded well to this challenge, and I'll just mention that there's probably a couple of things that could be done further, but to say that you know, as -- as all of these entities on the global basis are setting manufacturing capacity, you have some that's being done by the companies themselves, you know, especially the larger vaccine companies. But also a number of contract manufacturers, contract research organizations, and what's needed is a pretty significant, pretty rapid sharing of information about how it is that, you know, that capacity -- what -- what capacity is available and how that capacity can be managed. And you know,

there with the joint antitrust statement between the DOJ and the FTC, on COVID-19, you know a really positive statement around I would say a more purpose of application of antitrust enforcement to enable you know that kind of activity to take place. And then the business review letters, there was one mentioned in the last -- or in the discussions earlier today with respect to the development of medical interventions such as VNAB. And you know, in that sense, it enables the companies to -- to share information that you would view as precompetitive.

You know, there's -- there's instances where as we're dealing with companies that are you know working upstream to develop vaccines and then the companies downstream where there has to be you know, some bringing together of different arrangements around things like indemnification where it would be good to -- to be able to have more collective discussions on that, which you know, really have nothing to do with you know, setting or regulating or bringing on prices or --

or market, you know, market allocation, you know nothing along those lines, but facilitate, you know, this process of being able to move forward -- to move forward rapidly and to move forward rapidly, you know, in cooperation and collaboration with you know, all the entities that have to be brought together.

So you know, in summary I would say that you know, we are -- you know, this -- this is a collective and a global project endeavor, you know, that requires significant collaboration that you know, existing intellectual property system can you know, manage in a way through licensing and so forth in order to ensure that you know, these collaborations can be -- can be built and you know, can achieve what needs to be done in terms of developing vaccines and providing them on a global basis. You know, including ensuring that you know, certain markets, especially in the developing world can be served at lower prices, perhaps than other markets. And you know, again, you know there is a fair amount of work that's

been done in order to ensure that the antitrust trust system of antitrust trust enforcement in particular is -- is aligned you know, toward that results. And you know, I think some more thinking can be done and I'm sure after this pandemic is over and we look back at -- at what has been done, there will be some additional steps that can be taken in order to facilitate this kind of just massive work and massive amount of collaboration on a global basis to address this global pandemic. Thank you.

MR. OKULIAR: Thanks so much, Dick. You mentioned that information exchange and collective discussion of course, prompts the question in my mind about potentially antitrust issues and -- and how we balance those issues against innovation and patentability and the like. So I think -- why don't I turn to Bill Kovacic. You know, what ways does antitrust enforcement promote or hamper innovation in circumstances like what Dick Wilder's talking about? Bill on? Bill are you there?

MR. KOVACIC: Thank you, just thanking you and your colleagues at the Antitrust Division and at the PTO for the wonderful opportunity to participate in the program. I think as our -- our colleagues have already suggested, one of the -- one of the premises to the competition law system, and I think a lot of literature on innovation is that rivalry can be a powerful force in inducing firms to come up with the better product, the better core of business organization, the better process to the trilogy that Schumpeter mentioned in his famous work in the 1940s.

Competition law can provide a mechanism to ensure that new ideas do enter the marketplace and are successful. Just to mention three contributions that I think have been positive. One has involved in a sense, policing the integrity of the rights granting process itself through lawsuits from time to time that challenge efforts by incumbents to mislead the regulators. Fraud on the patent office is the traditional concern of competition law. I look at the

experience in the 1960s with the Federal Trade Commission's case involving tetracycline where the FDC successfully challenged an effort by pharmaceutical producers to mislead the Patent Office about the state of the art and thus to distort the rights granting process.

A second is to attack cartels. One method that firms have used over time is to use the guides of cross licensing of other licensing arrangements basically to facilitate cartelization. And especially a series of cases brought by the Department of Justice in the 1930s and 40s, attacking efforts by firms globally to establish an allocation of production areas, an allocation of customers, so much so that during the wartime mobilization effort it became apparent to the Division that these cartelization agreements had severely impeded the capacity of U.S. industry to mobilize and support the war effort after the U.S. becomes a participant in World War II. These highlighted by Thurman Arnold in his case for the expansion of antitrust

enforcement.

A third area deals with standard setting, and I'll pick one category of standard setting cases where U.S. Agencies have been alert to instances in which incumbent providers of a product or service have basically captured a standard setting organization and have used that position to boycott or to disadvantage a firm trying to enter the market with a new idea and to use standard setting as a way to exclude them by defining specifications in a way that made it impossible for the -- the entrant to get a foothold.

These are three areas in which antitrust policy I think has played a very constructive role in seeking to preserve the innovation process and it's to fulfill a number of the expectations that guide the development of the IP system itself.

MR. OKULIAR: So -- so how do these -- so there is some antagonism between competition law and intellectual property, at least depending upon who you ask. So -- so how does the root to

that modern antagonism play a role in antitrust enforcement today?

MR. KOVACIC: I think -- I think the example that I mentioned, is where much of it comes from. The Antitrust Division mounts a very powerful enforcement program in the late 30s into the 40s. The FTC does a number of studies and their focus is on a series of agreements, I guess the most important in the chemical sector where U.S. and foreign enterprises in disturbing instances, U.S. and German enterprises during a period of national socialism, join arms to basically carve up the globe, and in many instances to retard innovation in specific sectors. And this repeated exposure to how patent licensing served as the device to cement cartelization, I think was a scarring experience for the antitrust enforcement officials and they came to -- basically to equate licensing arrangements in many instances with sinister motives. So that when antitrust officials saw a cluster of licenses or a cluster of relationships

among competitors in the IP space, the immediate suspicion was this was up to no good. So I trace a lot of the antagonism on the part of antitrust people to this formative period in the 30s and 40s when the repeated exposure to international cartels and the use of cartels basically to orchestrate global production sales and innovation became the frame through which many competition officials regarded the IP system and in particular, regarded the rights granting process as deficient in its failure to properly police the application of standards for patentability.

In the 1940s when the temporary National Economic Commission issued its report on competition law, one of their main themes is we need a dramatic upgrade in the resources and capacity of the patent rights granting officials to do their job in a way to ensure that standards of patentability are followed and maintained, and in fact, a distrust of the right granting process and a distrust of industry in the way in which they use licensing. That attitude carries forward

a long ways.

MR. WILDER: But Alex, this Dave. If I can reenter the discussion now. I think if you -- that's all very interesting history going back to World War II, but if you fast forward about you know, 80 or so years, the current times, look at the current administration. You guys have done a great job of seeking harmony between intellectual property and antitrust, and look at the standard setting industry as a -- as a prime example where the DOJ has been leaders in explaining that a strong patent protection is an enabler for setting good standards and ensuring that innovations make their way standard. So while there may have been some historical issues, I would tell you I don't see any tension in the current administration between strong intellectual property rights and antitrust enforcement. But one other thing I would mention is that you know, if there's any recognition, and this is also positive, it's that the patent system has become unduly weakened by constituents who seek to weaken it in order to

support other kinds of business models, and I think great support by the DOJ, working with the U.S. PTO to sure up the need for an important and a strong patent system.

MR. OKULIAR: Thanks, Dave. Let me -- that's a -- that's a good perspective and let me ask Alden as well. Alden, you know, do you -- do you -- how do you see the -- the sort of interplay between competition law and intellectual property today? Do you agree with you know, Bill's insights that there was this early antagonism that was caused by these events back in the 30s, 40s, and 50s that carry forward for particular decades? And what do you think the situation is like now? Do you agree with Dave that the situation these days is one of -- of greater harmony across the -- across the two spheres?

MR. ABBOTT: There is greater harmony and I agree with Bill that historically his concern about licensing arrangements, particularly as including restrictions. That lasted through the 1970s, the Justice Department in fact

propounded the lid of so-called nine no-no's of licensing agreements like exclusive licensing and various sorts, grant backs, and so on, that is -- will likely live to antitrust prosecution. Now, that changed dramatically under -- under the Regan administration, which propounds sort of economic efficiency justifications or patent licensing and leads really to the adoption of guidelines in 1995, which were reiterated, slightly tweaked in 2017, which basically have three major principles and the antitrust agencies agree. The three principles in looking at IP licensing arrangement is one, to apply the same analysis to conduct involving IP as to other forms of property taking into account the specific characteristics of a particular property right. So just as you have generally favorable treatment of vertical restraints, licensing with all vertical restraint. Two, not to presume that IP and in particular, patents, create market power in the antitrust context. Often you have competing patented goods or processes for example. Three, recognizing that

IP licensing allows firms to combine complimentary factors of production and (inaudible) is generally procompetitive. I think that's certainly a state of the art when it comes to the general licensing issues. Now that doesn't mean as was pointed out, it might not be situations and it's making (inaudible) where licensing might be used to facilitate a -- a cartel. You always have to look at the hard facts of a particular case, but -- but in general, basically vertical licensing is not a cover for collusion, explicit or tacit generally will be looked at fairly favorably. So I -- I certainly agree also with Dave that we have to be very concerned about innovation and certainly no argument from me that strong patent system supports innovation and supports that by promoting dynamic competition by strengthening property rights and often incentivizing new products and processes from entering the market.

MR. OKULIAR: Thanks, Alden. So taking and offering a -- I'm sorry, go ahead, is that Bill?

MR. KOVACIC: Yes, I was just saying that in -- I don't disagree with Dave's description of the modern -- modern path. Basically, I -- I finished my own review of Casablanca that left out the last 10 minutes, but the -- the -- the -- another thing I'd add from I think the experience of the U.S. Antitrust agencies is that they've seen ways, to go back on the previous panel, how a variety of other government policies deeply influence the innovation process. The use of public procurement resources as a direct source of R&D funding is a stimulus for new entry and competition. The entry space act says a very successful participant in the launch service vehicle sector is a testament to how choices made by public purchasing officials can provide a path for new firms to come in. And there are a host of exciting experiments taking place at the Department of Defense, which in many ways use prizes for innovation as a way to elicit new ideas and in some ways an expansion of product development efforts by firms. I think we're

seeing in a couple of areas how the government it realizing in a more direct way, by the way in which it structures its purchase of goods and services, can have a major impact on innovation as well. That's certainly something that's come into the Field Division of the FTC.

MR. OKULIAR: Let me get thoughts on -- thanks, Bill, and thanks for -- for completing us Casablanca for us. (laughter) So -- so, let me ask, how is the -- the role of an enforcer? Or how is the antitrust enforcement fundamentally different from regulation. And Alden, maybe you want to comment on this first, but you know, how much regulation as compared to competition enforcement is needed? Where do we find that balance to keep in particular life sciences market markets competitive?

MR. ABBOTT: Can you hear me?

MR. OKULIAR: Yes.

MR. ABBOTT: That's good. Clearly safety and efficacy regulation are important in life sciences area, FDA tech regulation. However,

that's very different than economic regulation, which tends to set up ex ante command and control rules often restricting entry or affecting pricing, basically affecting a way a firm can distribute its products in the marketplace, historically associated with so-called natural monopolies like electricity transmission, generation, telecommunications, transportation. Often, however, those supposedly natural monopoly industries turn out with because of new technologies, no longer to be natural monopolies but regulation lingered. And some of it is a problem with political capture. Economic regulation in my view was not a good model unlike other forms of health and safety regulation, for life sciences. They tend not to be natural monopolies and indeed, attempting to have economic regulation in this space, through rigid rules, is an antithetical point I cross. So it's an exposed analysis of particular circumstances, whether particular licensing arrangements or a payment between a patent holder and a potential generic

inference. There -- you need to be able to look at the hard facts of the specific case in order to determine whether competition is likely to be lessened. Ex ante regulation doesn't take that into account as well, so again, while the right kinds of regulation are -- are fine and compliment antitrust, indeed safety and efficacy increase competence in the marketplace and they're very important, that it's not at all the case of economic regulations. So my -- my instinct would be this is around the world in the area of platforms and other areas that seem to have an increased interest in ex ante regulation. That is -- promotes stagnation and -- and lack of innovation and is inconsistent with the idea of -- of competition being promoted.

MR. KAPPOS: If I could comment just to -- to add on to what Alden said, I couldn't agree more with all of what Alden said. I would also mentioned you know on the international point that Alden articulated at the end, we've seen so many instances of U.S. regulatory statements ex ante

statements being misinterpreted or misapplied or extended overseas in other countries to make the antitrust law then a tool of you know government manipulation in order to champion the interest of local entrance to the disadvantage of consumers and the competitive process that it -- it just -- it's turned out to be very dangerous to go out with broad ex ante regulation.

MR. OKULIAR: Thanks, Dave. Bill, let me just ask you very quickly, where do you find the balance here in terms of regulation and enforcement to incentivize innovation?

MR. KOVACIC: I just, first I -- I -- it will be nice to have some time to debate specific example of what Dave has in mind. That would be an interesting discussion to have, that I don't think we're going to have here. But I -- I think a crucial foundation for making all of these judgements is a deeper awareness of what has taken place in the marketplace, especially as a consequence of previous public policymaking. And this is an area where the FTC in particular has a

distinctive capacity to study the effect of policy choices made before. A lot of effort has been made in the last 20 years to adjust the rights granting process. It would be interesting to know what the specific effects of that have been. It would be interesting to know more in more detail what the effects of interventions designed to deal with the specific patent licensing or patenting activities have been. And in effect to develop more of a competition law biography in specific sectors, to get a better idea of what's helped or what's hurt. So I see a -- I see a crucial input into making these judgments and I agree with Alden's framework, is a better idea of what's taking place in the marketplace, and that's where I would say if we're demanding something in public policymakers, whatever policy tool they want to use, this investment in knowledge is a crucial foundation for making those judgments and I would just exhort especially the FTC to use this distinctive capability that it has to inform the policy debate.

MR. OKULIAR: Bill, thank you so much. I'm sorry, Dick? Yes, Dick.

MR. WILDER: Yes, just -- just one point to make and just to you know, it would be to shift the conversation a little bit and talk about you know, something that's quite similar to what was talked about in terms of economic regulation, contract regulation, and so on, and that is to say that in the space that I work in, which is global public health, there has been a lot of efforts over the years to impost certain standards or norms in terms of how intellectual property should be licensed, not necessarily because of concerns about competition law or antitrust law, but rather out of concern that certain markets need to be served in a certain way. So low income markets for example need to have access to pharmaceuticals and vaccines at low price because they have less of an ability of purchase. What -- what's happened, the sort of evolution of that thinking over time has been shifting away from having you know real, specific imposed ex ante notions about

how intellectual property should be licensed, but rather focusing on the result achieved. And you know, the work that I'm doing now at -- at CEPI, looking at global development of vaccines, global procurement distribution and utilization of vaccines, the focus is on assuring that all markets will be served and served at the same time at least initially so that there isn't any time lag between vaccines that are available in high income countries to those in low income countries. And for the pricing discussions, you know, ensuring that price is not an obstacle, you know for those that need COVID-19 vaccines to be able to get them to address this global pandemic.

And so rather than starting you know at the outset with some specific notion about whether patent should be licensed exclusively, nonexclusively, whether you know each agreement that you enter into should have certain terms of conditions that are like boiler plate included. The focus is on the result, you know, what is it that is agreed as the right result in terms of

time of availability, scope of availability, market server prices and so on, and them come up with an arrangement, you know, in the individual cases both with the countries that are receiving the vaccine as well as the companies that are producing and making them available. And so just to say that, like I say, in a different context some of this, the concept that have been talked about here, I think they're coming to the same conclusion you know, that there is more of a disoriented focus you know, rather than a -- have a fixed notion at the beginning as to how things should be managed from an intellectual property and intellectual property licensing perspective. Thank you.

MR. OKULIAR: Thanks, Dick, and thanks to all our panelists. Really appreciate it. We've reached the end of our time. Thank you to the audience and take care everyone. We're adjourned.

MS. DIXTON: Thank you everyone. I think we had a break scheduled right now but I

think we're going to go directly into our next panel since we're running a few minutes behind. And I think it's a nice segue into our next session, given that we've been talking about how competition, enforcement, and regulation can impact innovation. We're going to transfer now to talk about how antitrust risks come into play in collaborations and how collaborations can -- can be both successful and procompetitive. And we have some very distinguished panelists with us that have a lot of extensive experience in counseling clients about antitrust risk and collaboration and I'm very pleased that they were all able to join us here today. And I'm going to go ahead and introduce them and then start off the panel with some questions.

So I would like to first introduce William Diaz, who recently joined Amgen as Senior Counsel. Will, are you -- are you with us here?

MR. DIAZ: Yes.

MS. DIXTON: Great, yes. So Will recently joined Amgen as Senior Counsel, but

before that he litigated and counseled clients on numerous antitrust issues including mergers and defending clients against government investigations and he has extensive experience at the (inaudible) in both antitrust and intellectual property including with respect to standard setting and licensing issues and in the biotech and pharmaceutical space. So I welcome Will here today, so thank you for joining us.

We also have Andrew Finch, who is the Co-Chair of the antitrust practice group at his law firm, Paul Weiss, and he recently rejoined his firm after working with us here at the Antitrust Division. It was wonderful to work with Andrew for quite a few years. He was the Principal Deputy Assistant Attorney General and also the Acting Assistant Attorney General, and in those roles he really was involved in all aspects of The Division's work in both the criminal and civil role that we play in antitrust enforcement, and he was also involved in much of our litigation and appeal. So we're very pleased that Andrew could

come back to The Division and participate in this panel. Thank you, Andrew.

Next, we have Luba Greenwood. Luba are you also able to -- can you just say hello to everyone, so we know that you're here.

MS. GREENWOOD: Hi, hello, you can hear me, great.

MS. DIXTON: Thank you, Luba. Thank you for joining us today. Luba Greenwood, she has very -- a -- like many -- has many hats and has vast experience in the biotech industry. She is a veteran biotech and tech investor. She's built companies from the ground up. She's served in many roles including an executive at Google Life Sciences. She also has served as the Vice President of Global Business Development and MNA at Roche. She currently lectures at Harvard University in the field of Engineering and Applied Sciences, and she's a Senior Advisor to the CEO at the Harvard campus, so we're very pleased that she could take this time today.

And last but certainly not least, we

have Charles "Chuck" Loughlin, who is a partner in the Antitrust Competition and Economic Regulation Group at Hogan Lovells, and he's had more than 25 years of experience in antitrust work in both the public and private sector. He was at the FTC for quite some time as FTC (inaudible) counsel, and in that time, he was awarded the FTC Award for (inaudible) Service while at that agency.

So I thank you to everyone for being here today and taking the time to (inaudible), and I'm just going to start off the panel with a question to Andrew, and I wanted to ask what really makes a collaboration or joint venture in the life sciences sector both successful and procompetitive. This is the section we're looking at today. And can you just stress some of the hallmarks of procompetitive collaboration?

MR. FINCH: Sure. Thank you, Jennifer and the Antitrust Division and the PTO for the invitation to participate today. It's great to be back at the Antitrust Division virtually, at least. I'll start with the hallmarks of a

successful joint venture because I think it really boils down to three things. One of them is an efficiency enhancing integration, the bringing together of complimentary assets that can have the prospect of enabling the participants in the joint venture to increase output and reduce prices, innovate faster, improve quality, bring products to market more quickly.

The second key element is clear boundaries, an understanding of what's in the joint venture, what's outside the joint venture, and boundaries in other regards too, like the temporal dimension, when its duration is, how long it's going to last, what the partners are going to do, where they're going to do it. The geographic dimensions, that's crucial. And then I think the third element for an effective joint venture collaboration are safeguards or mechanisms to police those boundaries, how you make sure that the joint venture stays on its rails and doesn't go off the rails, as people are fond of saying, and how the questions about the operation of the

joint venture can be answered, how they can be policed, how their risks of collusion are minimized, and the joint venture is enabled to fulfill its promise without -- without having anticompetitive effects. Those are really the three I think, key elements of a successful joint venture. And in the life science sector, the promise of joint ventures is particularly great, I think because you have the opportunity to bring together people who have technology, who have ideas, but don't have the ability to monetize it or commercialize it, manufacture a product or get regulatory approval. You can bring those people together with people who have those abilities. So maybe a small firm that has technology but can't manufacture is brought together with a firm that can manufacture and has experience bringing things to market and distributing.

And so the -- the potential in life sciences in particular is extraordinary and it's brought to fruition through joint ventures often. Obviously, the key thing we're all talking about

and have been talking about all day is sort of what does the pipeline look like? What is the R&D pipeline and how do we best set up our regulatory system to enable the pipeline to be productive and new products keep coming out of it year after year? And you do that by reducing the risk for investment, and joint ventures can do that. They can reduce the risk and make it less risky than say, an all out acquisition and they can enable firms to come together and achieve efficiencies without having to be acquired and everything that comes with that. And the agencies have done a terrific job, I think, in two ways in resulting that over the years. One of them is the Competitor Collaboration Guidelines in 2000, and the other is the business review process, which I applaud the Justice Department for what it's done especially during COVID with the -- the business review letters that have come out very quickly to enable collaborations in order to -- to facilitate products being manufactured more quickly or equipment being distributed more effectively.

MR. DIXTON: Thank you, Andrew. Would any of our other panelists like to add a few thoughts to what Andrew told us about procompetitive collaboration and the elements that go into making sure collaboration stays procompetitive?

MR. DIAZ: Sure, can you hear me okay?

MS. DIXTON: Yes.

MR. DIAZ: Okay. Yes, just to echo some of the comments Andrew made about you know, life sciences industry being a particularly good one for procompetitive effects of collaboration, I think you have a variety of things that work well in this industry. One is, and I think Andrew touch on, the complimentary capabilities that the companies have. You can have one that has a particular experience in a certain space, maybe with respect to regulatory approvals or manufacturing, and another may have you know, experience in commercialization or -- or other aspects. You also have the benefits of risk and cost sharing. This is an industry where there's

high failure rates for these products, especially in the biologic space, so they're very difficult to make and so to be able to share my thoughts and really can help companies continue to develop products.

I think you also find that this helps companies fill portfolio gaps, which are sometimes essential to have a full portfolio when you're negotiating with payers and other players in the -- in the industry. And -- and there's things such as combination therapy where you have independent products that each work that can work better together. And so collaborations in that area are -- are very important.

MS. DIXTON: Thank you, Will. I want to address a question to you now just building on that. So if you're collaborating and you're a larger biotechnology company or pharmaceutical company, how do you -- what are the most significant antitrust risks that you might save and how to you navigate those from the company's perspective?

MR. DIAZ: So, I like to take a step by step approach on these collaborations. The first thing you start with is can this collaboration happen. You know, because you've looked at it from you know, a sort of merger guidelines approach. You know, are the products that are going to be part of the collaboration competitive, and, you know, if so, are they early in the development pipeline or are they actually commercial products. You know that, that's the key question because the earlier they are, the less -- the less concern there would be from a -- you know, from an antitrust perspective.

You also have to look at the market share of the parties, how concentrated the market is, and -- and if you get comfortable with all that, then you can you know, move forward with some of the, you know, the other issues that I'll talk about in a second. But even if the products aren't competitive, you also have to look at whether the parties themselves are competitors in other states, because that can create some issues

in terms of the information flow that can be difficult to manage and -- and in some cases, you can address them and in some cases it may not be worth the effort because of the significant issues that can arise.

You also have to look at the function of the collaboration, if it's going to be an R&D collaboration for instance, those are highly procompetitive and usually don't raise the types of antitrust issues that other commercial types of collaboration can raise. You really have to understand what -- what the collaboration is going to be doing. If it's going to involve sales, marketing, manufacturing, those are areas that can get into sensitive antitrust issues and so you've got to be aware of those.

If you are going to have a collaboration that involves those types of issues, then you really have to ensure that it's an efficiency enhancing and procompetitive venture. You -- you have to make sure that there's something new that's going to be developed and something that's

going to require meaningful integration among the parties because you don't want something that looks like it's just covering up what would otherwise be a naked, you know, a price fixing arrangement or market allocation scheme or anything like that. So you really want meaningful collaboration between the parties and the guidelines. The competitive collaborations guidelines talk about that.

The next step I would say is then you've got to understand what are the collateral restraints that are going to be imposed by the collaboration. And these are often necessary. If you could (inaudible) there are going to be some types of restraints that they have to agree to, to the make collaboration work. And you have to ensure that those restraints are reasonable and narrowly tailored and -- and -- and aid in achieving the procompetitive aspects of the collaboration. A very common one is that the parties agree not to compete with the collaboration itself. If it's developing a new

product, that their efforts are focused on that and not on developing something else outside of it. And those are often upheld, but you can have situations where the parties already have some products and that can -- that could raise some -- some concerns. You know, you don't want somebody shelving a product because of the collaboration especially if it's in a concentrated space. So you've got to watch out for whether those restraints go too far, especially the ones that are mentioned in 310-ers where the parties for that venture agree to not compete with each other on standalone products, not even on the venture itself.

So you have -- you have to be careful about those collateral restraints. And then finally, I think you have to have some information flow guidelines or restrictions in place. You may need firewalls depending on the relationship of the parties in the marketplace if they're competitive today so that the key people that need to understand the information to make the

collaboration run effectively have access to that, but that, that information does not flow to other areas that could involve you know, parties that are otherwise competing on a day to day basis.

MS. DIXTON: Thank you, Will, and I wanted to ask Chuck or Andrew who counsel clients in this area, if they have anything to add to some of the safeguards and ways to navigate risks that Will shared with us.

MR. LOUGHLIN: Jennifer, I just have one thought, and I like everything Will said, but I would just add one point which is that it's very important that you make sure that your documents are really clear about what it is you're doing and what you're not doing, how that information is going to be shared, what will be shared, what won't be shared, so that there's no ambiguity between the parties and that there's no ambiguity later on when someone's looking at your document.

MR. FINCH: To build on that for a moment, it's also important that the documents, not just the joint venture agreement, lay all

these things out with clarity, but can also be very important that the business people who are involved day to day once the joint venture is up and running, have clear plain language explanations of what they can and can't do. And sometimes those documents can be as basic as saying, look, red light, don't do these things, green light, you can do this, yellow light, if you have any questions, call counsel. Right? So that they're clear guidelines that acknowledge that sometimes there are hard questions where you need to pick up the phone and call counsel to seek additional guidance about the operation of joint venture, and that's the best way you can get people to pick up the phone and call and get some additional guidance. And this can happen years after a venture has been put in place. A new question will come up about a new product or a new geographic area, and that can be very helpful.

MS. DIXTON: Thank you, Andrew. I wanted to turn to Luba, because Luba's worked with you know, some smaller biotech companies and

wanted to get her perspective on what's an efficient collaboration for a smaller company, and then what kind of antitrust concerns would that company have in maybe partnering with a larger company, larger pharmaceutical company to bring it up to market and engaging in research? So can you share your perspective with us?

MS. GREENWOOD: Sure, happy to. I do want to say, Andrew, I love the -- the light idea with the red, yellow, and green. I can attest that business people do want them. They get a little confused with the yellow, but they would like to be green most of the time and say, oh yellow kind of means green and you say -- and it depends. Those that drive through the yellow light usually that means it's green to them and those that stop, it's a red to them. (laughter) So it's an interesting one to navigate, so thank you for that perspective. I think that really for business people that are starting, even just starting from the term sheet when you have to be aware and cognizant of antitrust issues as you're

putting things in paper and start sharing information, having that yellow, green, red right up in front is extraordinarily important. So I absolutely agree with that.

From the small biotech perspective, I do want to say that the world has changed actually quite a bit, even in the last 5 years for collaborations between biotech and pharma companies. Whereas we used to do quite a bit of joint ventures and mostly between large pharma companies, quite a bit of acquisitions in stage 3 and commercial assets, today, the world is very different even than 5 years ago. So we -- one of the reasons for that is if you look over the last 10 years, returns on R&D for pharma companies have dropped significantly. Their internal development, also as Andrew was mentioning, you have to look at the pipeline, internal pipeline of pharma companies, has become quite inefficient and it's producing a lot less innovation and at the same time at a higher cost. So as a result of that, pharma has started looking externally to

biotech companies for innovation and also partnering earlier and earlier in the R&D process. So from the biotech perspective, it's you know, the best type of collaboration with the pharma companies today, it's actually an acquisition of an early asset, so an early clinical development asset, so way before phase 3, or you can say clinical or collaboration with -- with terms for -- for acquisition, stage acquisition later on.

You know, MNA who are predominantly as I mentioned with assets in phase 3 before, but as we're moving now and biotechs are being acquired at an earlier stage, again, it doesn't mean that they are being acquired at a cheaper rate. They're actually, the valuations are increasing higher and higher, so it's actually becoming very expensive to acquire biotech companies that are clinically -- that are commercially, already have commercial assets. So that actually decreases many of the antitrust concerns that you had before, previously before this shift had happened. And foreign biotech companies really have, and the

other panelists were just talking about the complimentary capabilities, that is absolutely critical. However, that -- the complimentary capabilities have changed as well. Basically, the biotech main strength is in early regurg in finding novel targets and (inaudible). It's really not in the regulatory commercial or even manufacturing space, and whereas previously biotech companies would turn to pharma for their commercial strengths and their commercial capabilities and knowledge to distribution and sales power, or even for funding, today they receive a lot of lifeline funding from big pharma companies. Again, there is so much money that's been raised both in venture and public funding, and that's available even today during COVID times to biotech, but what they really look at and rely on pharma for is regulatory expertise throughout the entire clinical stage, and now more importantly in manufacturing expertise. And the reason for that is because biotech companies are now focused on discovery mostly of large molecules

and also new modalities such as for example, gene therapy, antibody therapy, and they require very difficult and actually highly IP protective proprietary manufacturing processes. This is where pharma companies offer really their true value to biotech, so there is a lot of complimentary activity.

And then also, MNA is now less about sort of commercial for pharma companies. It's all about kind of locking up those key modalities and platforms. I know there's been some discussion on other panels previously before this one throughout the day about platform strategies. And this is again, very complimentary because that is where biotech companies have been built very comprehensive technology platforms internally and what's good now is that they can utilize those to discover compounds not just in a particular indication where they did that before, but ideally in multiple indications. So the kind of collaborations that they're doing now is partnering up different assets meeting different

indications in that platform on an exclusive basis with different pharma companies. Again, on an exclusive basis you have to be -- you have to be careful there and ensure you're thinking about some of the antitrust concerns even if it's just a collaboration. For this reason, the way they usually partner up your platform on basis of exclusivity and different therapeutic areas is you do an analysis, you do a landscape analysis of intellectual property, an internal pipeline to big pharma, and then you choose basically the player and the one that has the highest, the widest IP portfolio on that particular indication. So that's something that could be helpful.

MS. DIXTON: Thank you, Luba. We appreciate that. I wanted to turn now unless -- unless anyone has something to add to Luba's remarks, I wanted to move to chat a little bit about our business review letters in this space because they have come up during the day today and you know, one in particular has to do with monoclonal antibodies and getting those to

patients and ways to collaborate to do that. And the letter that we -- the collaboration that we reviewed really had to do with information exchange and a manufacturing capacity in order to facilitate once the monoclonal antibody was approved and safe and effective. You know, how would that manufacturing take place at the large scale? And so we reviewed a proposal on information that would be exchanged between competitors to facilitate information and capacity. And, I wanted to ask Will first and then others, how do you avoid having you know, an information exchange that is -- that is you know, appears to be procompetitive? How do you avoid having any spillover happen? So you now are exchanging information on -- on things that would raise concerns like you know, cost of supplies or customers or you know, other areas where you know, you didn't intend originally to exchange that information but, all of the sudden, how do you avoid getting there and -- and getting on the shelf, as we said earlier? Will, will you outline

and then we can move to others.

MR. DIAZ: Sure. Well first I just wanted to commend the Antitrust Division for agreeing to do these business review letters on an expedited basis. They're extremely useful tools for businesses and for practitioners and you know, during a pandemic to be able to have them in as quickly as seven days or less is -- is great. So we really appreciate that. And -- and -- you know in this specific business review letter that you mentioned involving monoclonal antibodies that could be used for treatment of COVID, there, as you can imagine, you have a situation where we need to have new drugs tested and developed very quickly and have them ready for distribution to patients even before you know if the product is going to be approved or -- or effective. And so that letter in particular, the parties were talking about sharing capacity information. That was critical to that exercise and in (inaudible) that with the restrictions that were put in place on -- on -- on not sharing pricing information,

not sharing capacity information outside of the -- what was you know the COVID related treatment, the DOJ was comfortable with that and you know, and I think that shows you an example of where something that's competitively sensitive information that competitors otherwise wouldn't share but here is relatively low risk and -- and has a very procompetitive purpose. And indeed, you know, Amgen has entered into collaboration with Eli Lilly where you could see that Amgen is willing to provide manufacturing capacity to Eli Lilly as they have a promising -- a product that we -- we know that is going to be a great need for capacity on the actual product. So that's technical collaborations that we're seeing in this space and that I believe are procompetitive.

In terms of what you can do to -- to ensure that -- that these you know efficiency enhancing adventures don't go sour and -- and turn into things that can raise anticompetitive issues, I think there's -- there's a few things in mind. First, you have to have a very clear charter of

what the collaboration is going to consist of, what is -- what's going to be included in it and what's not. And I think Chuck mentioned that earlier, but that's really important that you lay that out at the front end. And you have to anticipate that the -- the membership in the collaboration is going to change over time, and so you want to train the people that are -- that are in it at the moment, but also future members as they arrive on what these issues are so that you have a -- you know, a -- a seamless handoff of the -- of that charter basically.

Number two, I think you should expect that the -- the -- these collaborations will evolve. Things are going to come up that are -- that are unexpected and so you want to ensure that when business people or engineers, technical people are involved, that their working closely with counsel to ensure that they're scoping out any potential antitrust issues so that you can you know, stay clear of them or -- or figure out ways to address them.

Third, I think there's -- there's a, you know, a bit of a -- a mundane issue here, but I think it's having a meeting agenda, you know. These collaborations regularly meet or have conference calls and I think when -- when you can, you should have a (inaudible) that lays out what are the issues that are going to be talked about so that these organizations and the people that are part of the collaboration can stay focused on those issues and not venture off into areas that may -- they may not even realize can create antitrust concerns.

Finally, I would say you should try to scope out as much as you can at the front end potential issues that can arise. And of course, you can't think of all of them, but we've had a lot of collaborations in this space and others where we've seen things that have happened and so if you can think about how you address those at the front end, I think you're going to be in a better -- better place. Things like you know, if -- if one party develops a competing product

outside of the collaboration, what happens? Does that -- does that product become part of the collaboration or does the collaboration end or -- or do firewalls get erected to deal with information flow because now you've created a competitive situation? So trying to think about those things and laying out a framework for how to address them is pretty critical.

MS. DIXTON: Thank you, Will. Anyone else want to make some comments, too? I'll ask Chuck about you know, there -- there were some safeguards not only in the monoclonal antibodies business review letter, but in some of the others that we had issued in this area that have to do with PPE distribution and pharmaceuticals. Now, there were some safeguards that the parties agreed to in those letters, and I'm wondering if you could tell us you know, how these safeguards might apply more broadly outside the pandemic, if they do.

MR. LOUGHLIN: Thanks, Jennifer. First, let me start by -- by echoing Will's point to

commend the DOJ for working so hard to get these business review letters out so quickly. I think they're usually helpful to the industry. And I think when you look generally at the business review letters that came out in COVID, the key lesson that you see is that if the fundamental best practices that have been talked about in this presentation that really do apply and that apply whether you're in COVID or not in COVID. And so, for example, the importance of having well defined procompetitive goals for your collaboration and documenting in your materials those procompetitive benefits, document the procompetitive benefits that you expect to achieve, how you're going to achieve them, why you'll achieve them through this collaboration and why you couldn't achieve them without the collaboration.

Second, be very clear in the documents about what the collaboration will do and what it won't do. So for example, as Will discussed, talk about the information, the types of information that you will share and what you won't share.

That was very clear in the monoclonal antibody letter. Talk clearly about what activities you're going to collaborate on and what you will continue to do unilaterally, and things that you will not collaborate on. All of the letters sort of make those things clear and that gave comfort to DOJ that it was clear what was going to -- what the scope of the collaboration really was.

In that same regard, what you see throughout the letters is the importance of keeping the collaboration tailored to what is necessary to achieve the procompetitive goals. So you see in the COVID examples, you see them all saying that they're only going to apply during the time period of the COVID pandemic, certainly in -- in collaborations outside the pandemic issues you wouldn't have that specific duration, but you would have a duration that is only so long as is necessary to achieve the procompetitive benefits of your collaboration.

Second, I guess, finally, document the benefits you achieved. That's really important to

make sure, make clear that you did in fact do the things you said you were going to do and -- and document them. And then I -- I did skip a line, which is the safeguards. You mentioned, Jennifer, safeguards, and you see throughout the letters the importance of stating clearly the kinds of things that -- that the parties are going to do to minimize antitrust risks. So for example, state exactly how you're going to restrict improper flows of information and then follow through with that. Make sure that you're engaging with counsel and make sure that your parties all understand what it is they can share, what they can't share. I loved Andrew's red, yellow, green example as well. So, those kinds of things giving clear and simple advice and making sure it's very apparent to the parties is really important.

The last thing that comes through clearly in the COVID-19 business review letter specifically is the importance of government involvement in the collaboration and you can see in the business review letters that government

involvement in the activities was important to DOJ and their ability to give the business review so quickly. Certainly, that's not going to be possible probably in all of -- all sort of collaborations outside the pandemic. But it is something to think about if for example you believe that there is some government policy that could be furthered by -- through your collaboration, it's worth thinking about whether some involvement with the federal government would be -- would be helpful, at least in terms of minimizing antitrust risk.

MS. DIXTON: We're nearing the end of our time here. What more the department could be doing you know, other than our business review process, to address uncertainty in collaboration, you know, if -- if there is uncertainty as to antitrust risk? For example, you know, our collaboration guidelines are 20 years old and we heard from Luba that you know, certainly collaborations look a little different today than they did 20 years ago, especially in this life

science space and biotechnology space. I wanted to give our panelist all a chance to tell us you know whether or not or what department could be doing to promote more certainly and whether or not the collaboration guidelines need to be updated given their age? So why don't I start with Luba and then I'll give you all a chance to answer before we conclude today.

MS. GREENWOOD: Sure, I do have also one quick -- quick comment to -- just on -- on some of the things that Will and Chuck was saying. I think it's all great from the pharma company's perspective to be thinking about okay, we need to document -- document this, well we think clinicians and -- clinicians and scientists and engineers should all go together in a room and work together with a lawyer. That is not how biotech companies work (laughter). And I think that's something to you know, just something to think about I think for -- for the legal (inaudible) also those that work with -- in big biotechs. I mean these are large serious biotech

companies and yes, they're worth billions but they're still run like startups. So I think that's just something -- and that's also something that's quite different today than it was even 5 years ago. We didn't have the -- the scheme small biotech companies. So I think you know, if we do want to, one of the things with small biotech companies to look out for is to make sure that they do engage the lawyers, their internal and external lawyers in this process earlier on, right, so that they are -- they're not making mistakes.

In terms of what the Department can be doing, there certainly is more uncertainty, as I mentioned earlier. You know, now you're going into not just the types of deals, but the nature of access is different so now you're more in rare disease and new oncology, and personalized medicine, everybody talks about personalized medicine but how that matters for antitrust is basically what you're doing is you're taking your traditional therapeutic areas and you're

subdividing them and you're getting control over particular smaller more subdivided therapeutic areas. And you see large companies dominating diseases -- certain, you know, disease areas within a disease area and a particular indication, and not just a particular indication but also a therapeutic modality that's supplied to a therapeutic area such as, as an example, you know, you can become number one in gene therapy as it related to hemophilia. So some guidance on collaboration and personalized medicine space would be very helpful. And then also guidance on platforms. Again, as a biotech company you're very proud of your platforms. You lock up all the IP for the use of a particular platform. And from there you can go into a lot of different indications. So I think guidance on that would be helpful and how do you partner that. Again, as I mentioned earlier, there's quite a bit of exclusivity that's usually negotiated in collaborations around those.

There's another area, too, is that we're

also using quite a bit of -- we're doing differentiation based on manufacturing, so a lot of biotech companies come with their own proprietary manufacturing. So and also the use of big data for drug development and sale of the therapeutic. So some guidance on that would be very helpful. And then also we see pharma companies going directly to academic institutions bypassing biotech companies, locking in key patents to establish patent space in a particular modality. So I would think that for -- for them it would be also helpful to see what to do. And I would think just lastly, you know now collaborations include nontraditional players. We see payers are moving into space given a move to value-based care. We see market access becoming much involved earlier to show value of the therapies versus other drugs. And also, we have now large data aggregators in digital companies that are competing with biotech companies that are actually offering pharma companies new ways of discovering medicine. You see AI enabled biotech

companies. So they're quite significant changes in how medicines are discovered and how they're made and sold, so that should be addressed as well.

SPEAKER: I think, sorry, you're on mute, Jennifer.

MS. DIXTON: Sorry. Andrew, I wanted to move to you to see if you had thoughts on whether our guidance needs to be updated in light of the changing landscape in this area.

MR. FINCH: You could -- the competitor collaboration guidelines could use a look and a refresh. You know, it has been 20 years. You know, part of what we've been talking about all day and yesterday has to do with innovation and collaborations and joint ventures facilitating innovation and all of the benefits that innovation can bring. And I think maybe a long look at the -- the competitor collaboration guidelines through that lens to see where they could be improved.

There are some grey areas in the -- in the guidelines. You know, they say up front the

analytical framework is there's the per se rule and the rule of reason. And that all seems very clear and somewhat black and white, but then when you actually get into reading the text, the text says many times over and over again and cites California Dental and says, well, you know, but there may be instances where you know the quick look applies. It doesn't use the word "quick look". And I actually think that, that creates a lot less clarity and it's understandable because when the guidelines came out, California Dental had just then decided the year before. But I think now the agencies might reflect on what they actually do and how often they actually use sort of a quick look, and maybe they can create even more clarity for innovators and joint ventures who want to establish joint ventures, maybe more state harbor, more clear guidance on what's an acceptable duration and what market share is needed when there's information sharing may be borrowing from the healthcare guidelines. So I think it's time.

MS. DIXTON: Thank you, Andrew. Chuck or Will, do you have thoughts to share?

MR. LOUGHLIN: Yes, I have a few. I think it would be helpful to update the examples that are in the collaboration guidelines and consider trying to have sections that are devoted to specific industries so that it would be really helpful I would believe to have some life sciences specific set of examples that people in the industry could look at. I also agree with Andrew about the importance of innovation to this industry and generally to our economy. So I would think that in these examples, try to have more that demonstrate the value of innovation and how that is captured in an antitrust analysis and specific conduct. That would be very helpful I think to industries like life sciences that depend so much on innovation.

And then, and then lastly, I would say one of the examples in the guidelines don't actually tell you how the analysis would turn out and to some degree that's -- that's by design.

They're telling you how you -- how the place would do the analysis, but I think it would all be more helpful that they actually told you this was the -- this would be the result. So I recommend that the DOJ and FTC consider providing results in there as well.

MS. DIXTON: Thank you. Will, do you have any concluding thoughts?

MR. DIAZ: Sure. Just two quick thoughts on -- on the guidelines. First, I think it would be helpful to update them because they refer a fair amount to the merger guidelines and those were updated in 2010, and so they are referring currently to outdated merger guidelines. And in particular, they reference the efficiency section of the guidelines, which were -- you know, had some significant specificity added to them in the -- in the latest update to the merger guidelines. I also think you know, personally you know in terms of getting mergers through, I really thought that the efficiencies are very hard to prove. It's a very high hurdle for them, and so

you know, I would want to see the collaboration guidelines look at whether it's appropriate even to refer to the same types of efficiencies, whether you're dealing with collaborations with more time and scope and maybe don't require the level of you know, the -- the hurdles of efficiencies that are in the horizontal merger guidelines.

Secondly, I think that the guidelines talk a lot about meaningful integration and it slithered throughout the guidelines, and I -- and I think that is important, but I think that's -- it's more important when you have very sensitive issues involving pricing, market allocations, things like that where -- where that integration is critical. I think there are some areas in which parties can collaborate without a significant amount of integration if they don't involve those sensitive areas. For instance, in -- in the biotech space you'll have combination therapies where parties will have their own product and they want to try it in combination

with another one and get approval for it. There has to be some type of interaction with the party that owns the other product just for safety issues, for clinical issues, but they're not really going to have a collaboration to sell the product or develop it or anything like that, so they probably don't need the level of collaboration that's talked about. So it could be useful to have something that addresses those types of situations.

MS. DIXTON: Thank you, Will. And I'd like to thank all of our panelists today for being with us and sharing your thoughts on how to reduce risks in the area of collaboration. And I guess the Department and our colleagues at the FTC will have to think about you know, what -- what you said. So thank you so much for joining us. We're going to just take a two minute break and we're going to be, we'll -- let's reconvene at -- at 4:05 Eastern and we will be joined by our keynote speaker, which I'm really looking forward to and you're so fortunate to have him, Elias Zerhouni,

who will be speaking to us and sharing his insights on innovation in this area. So we'll be back in now four minutes and we'll see you all soon. Thank you.

(Recess)

MS. DIXTON: Thank you. Welcome back to our program. I -- I'm very pleased and I have the privilege and honor of introducing our keynote speaker today, Dr. Elias Zerhouni, who's really a world renown leader in the fields of radiology, medicine, biotechnology. He holds numerous patents himself. He's a native of (inaudible) where he received his basis education and training, and he spent much of his career at Johns Hopkins University. He is currently Emeritus Professor of Radiology there, of Radiology and Biomedical Engineering and he's a Senior Advisor for Johns Hopkins Medicine. He served as Chair -- as the Chair of the Russell H. Morgan Department of Radiology and Radiology Sciences, and Vice Dean for Research and the Executive Vice Dean for The School of Medicine before he became the Director

of the National Institute (inaudible) 2002 to 2008. Dr. Zerhouni also served as a Presidential Science Envoy from 2009 to 2019. He's been a Senior Fellow at the Bill and Melinda Gates Foundation, and from 2011 to 2018 he was President of Global R&D for Sanofi, a pharmaceutical company. He has a number of honors. He is a member of the National Academy of Medicine and the National Academy of Engineering. Among his other honors he's received the Prestigious Legion of Honor of Metal from the French National Order in 2008. He was appointed as Chair of the Innovation College Grant and elected to membership at the French Academy of Medicine. He is a board member of the Lasker Foundation and the Foundation for NIH and Research America. So thank you so much, Dr. Zerhouni for joining us today. We're really looking forward to your keynote speech and I will turn the podium over to you.

MR. ZERHOUNI: Well, thank you. Can you see me all right? Jennifer, thank you for inviting me and I want to thank also Makan

Delrahim for thinking of me as the keynote speaker. I think what you're doing and what I heard in the previous panels run in line with what I think is important. But what I would like to discuss with you is really why is it that competitive collaborations have become so essential to progress in the life sciences as some of you panelists have said. And many have been really launched and are functioning well. From my point of view as an NIH director, I recall launching several public private partnerships in my time at NIH and many others have been launched since -- since that time throughout the world. In Europe, for example, there is an EMA program, a European Union Program for IMI, which has become sort of the standard medium for such collaborations and facilitates in fact the establishing of these collaborations. But what I'd like to share with you, the scientific basis of why are these factors -- what are the factors that are driving us toward great and precompetitive collaboration? Is it industry,

academia, government? And I think as always, you know, the pain points of any field that simply cannot be resolved by any one actor are the main motivators.

A good example with Sematech (phonetic) early for the tech industry where they wanted to address fundamental limits to the -- the creation and design of memory chips and other integrated circuit architectures that no single entity could solve. Well in my sciences, indeed the motivations for collaborations come primarily from a realization really that as we make progress and as we have better tools to understand biological systems, we realize that there are so complex and -- and -- and so difficult to unravel if you will, from a mechanistic standpoint, that it explains why success rates in therapeutics R&D are extremely low, and that new approaches at scales that are commensurate with that complexity are needed. And I used to say that being the head of an R&D organization is an exercise of failure management because 98 percent of the projects you

do eventually fail at any one stage or you know from discovery all the way to approval. And if you really think about it, reducing the failure rate by only 2 percent will double the productivity of the industry. Going from you know 98 to 96 means we go from 2 to 4 percent success rate. So, so the -- the question I think that could share with you is why is it that this is happening at a fundamental level? So let me share with you my simplified sense of the -- of the structure and the magnitude and the complexity that we're dealing with and propose then areas where the main pain points are that will require even more precompetitive collaborations in the future.

So first, let me take you a little bit into biology. Forgive me. First, as you know, the human organisms compose of complex cells. There are organizing tissues and -- and then organs and then all these organs are coordinated as organisms. But all of this really comes from a single cell at conception and at the core of each

cell is DNA, a book of codes of genes, and -- and that underlies the transcription of R&A, molecules that are then the templates for proteins and all the cell constituency, if you will. So DNA itself is regulated by a complex system of activators and repressors, specific to each cell type with a signaling system that regulates their functions either alone or in concert with other or billions of other cells. So to give you a measure of the complexity, cells during development undergo trillions of cell divisions and each one of these cell divisions can introduce some errors of DNA replication, which sometimes explains why a cancer will emerge or another disease will appear. And if you really think about that and the randomness of it, you -- you -- you will imagine that none of us are really a clone of each other. There's no possibility statistically that you will be identical to anyone else in the rest of the world just like your fingerprints are unique, like your iris is unique. And if you go further, you will actually see that even within your own body, we

now know that even in your own brain, a large percentage of neurons contain DNA that is not an exact copy of your original DNA or that of the original neuron. So even for exact twins, two twine, it can be said that their molecular composition is different. And -- and -- and fundamentally, the biochemistry is likely to be different as well. So you can understand from this enormous source of complexity I just described, it urges the fact that each of us is a unique individual, so you have two sides of the coin. You have a very high complexity, but then you need precision medicine at the same time at the individual level because none of us are really identical to anyone else.

So that's why the concept of precision medicine has emerged as we realized that the one size fits all is unlikely to serve all. And so it also explains why our limited knowledge of these systems and their functions as we interact physiologically in health or disease, leads to a high failure rate of research in the life sciences

despite all the advances we've made so far where we've been able to reduce mortality in many areas. And these successes really depended -- were dependent on our understanding of the root causes of disease. So we made great progress in infectious diseases over the past century because bacteria and viruses are foreign to us and could be easily identified and attacked with modern biochemical or immunological approaches such as vaccines, but not so for intrinsic diseases where the causes are still known except in rare diseases where a single gene dysfunctional and even then, finding effective therapies for monogenic diseases has been difficult.

So I did surprise you by telling you that even today we really do not understand the true molecular causes of diabetes, a disease we've dealt with for 100 years now. And even then so, those of newer degenerative diseases like Parkinson or Alzheimer's disease. Do one of the first questions is that the scale of efforts to understand these complex biological systems is

just beyond that of any one company. There -- there's no -- not a single university, a single company, a single country that can really aggregate all of the information needed to sort of get insights into the causes of disease that we can then intervene on with either gene therapy, cell therapy, monoclonal, or small molecules.

And so when we look at this, we as head of R&D and scientists realize that the world of innovation has changed. In the past, you know, if you had a single company, big pharma companies were vertically integrated, everything was within the company just like General Motors was or AT&T with the labs and GE. But these -- these industries have changed their model a long time ago. Pharma has only changed its model in the past 10 to 15 years, and when they realized that there was no way that they could make all the discoveries they needed to make internally, and then because of the Bayh-Dole Act, the creation of multiple biotech companies sort of fragmented completely. The -- the world of innovation and --

and the life sciences is really a network innovation world and the ability to connect is really essential to -- to advance the understanding that we need. And that's really what I call precompetitive although it's clear that the boundary in between precompetitive and competitive can be blurred and blurry as you -- as I heard from the previous panel. And so I have to say myself that I don't have a precise definition and the boundaries clearly defined, but I would agree that it's much clearer earlier in the understanding process where there's no product that exists and there's no manufacturing issues yet or even clinical development issues, but as you go forward in the -- in the history of the development of the product, you obviously have boundary issues.

So what is the definition? I can tell you the one I use that's like the very simple, not legalistic. But whenever I think about creating a consortium and participating in one of them, I've had this little test where I see any activity that

brings together the natural competitors for collaboration designed to enhance the ability of the entire field of possible competitors, not just within the consortium, but around the world, to have a greater chance of success in their competitive endeavor. So anything I can do that will allow more knowledge and more tools to be developed that will enhance the ability of the field is -- is something that I'm interested in. Actually, it's been the subject of studies, you know, Al Truler (phonetic) wrote an article after studying 50 of these collaborations and he offered a way to classify them as to whether they are open or restricted in participation and whether the outputs are open or restricted. And so the more open the participation and more of the access to output is easier. The more precompetitive you can think of that. Those are more restricted. And you were talking about restricted collaborations when you were talking in the previous panel about JVs. Those that are more restricted at both participation where you select who comes in, and

control the outputs with more scrutiny, in my mind. So nonetheless, some collaborations do require significant resources by more than one or two or three participants. Sometimes you'll have to have collaborations across -- around the world. And those can be restricted if it's expensive to do it because you want to avoid the -- the free rider problem and the output may also be temporarily restricted or made available upon contributions to defer the cost to the initial contributors. And so those can be quite large in the life sciences because the amount of data that we're generating is just beyond the capability of analysis of any one player. And as was mentioned before, there are many small companies that are launching efforts in that field.

But the four areas, they're quite simple to understand. I mean, one is the development of standards and tools. There's no question that new tools do bring new insights. But the problem with that is that there are not aggregatable if they're not standardized. And so a lot of efforts that we

have in the field is to try to standardize the tools that the field needs. In clinical trials, for example, a huge cost is the disparate regulations around the world, disparate platforms for clinical research. The sites are really under bombardment from different aspects of the industry in trying to comply with different protocols in different ways. And that increases the cost of clinical research for all. So one of the purposes of these collaborations is to reduce the time, reduce the cost of the discovery and development process.

I -- I -- I can mention to you the entity called TransCelerate, which I helped create in 2011 with five other companies that now comprises over 20 companies. And what we do is reduce the cost and burden by really offering training and platforms to the sites that can make it much easier to fire up the site and participate in clinical trials. There's another example you might know about. It's called the Pistoia Alliance, which is a nonprofit group that defines

a standard that -- that develops a standard ontology called HELM, which is a way of describing complex micro molecules in a consistent manner, in a time when small molecules was easier to do. Not so with micro molecules and not so with the new modalities that we're seeing emerging like cell therapy or gene therapy.

So the generation, the second area where we collaborate is generate and aggregate large data sets in many more patients than any one of us could study on their own. So for example, we aggregated sometimes large data sets of genomes across the world, just like the human genomes started as a consortium around the world. And we've created public/private partnerships, both in Europe and the U.S. For example, we have the Alzheimer Initiative in -- at the NIH that accumulates data on hundreds, 100,000 and more patients with diabetes the same way. That is beyond the reach of any one actor in the -- in the field.

The third area is knowledge creation,

just for the reasons that I told you. We don't understand the biological systems. They are complicated. The assays that we use are not standard. There's a saying in the industry that replication of academic findings is actually not very frequent. You know, over 50 percent of papers are not replicable, and the reason is not that people are not doing it right. They're just doing it with different reagents, different methods, and -- and that's really what you need to do if you're going to really have a body of knowledge around a disease that you can truly exploit essentially creating new innovative therapies. And validating biomarkers for example, to assess a disease process, which is essential to develop a therapy. While you can't do that unless you have also access to a large population of patients, which means that these collaborations are going to be industry, government, and academia typically at a scale that -- that you need to have to have the samples that you need to, to achieve some insight.

I think I would like to join the group here to -- to truly thank the Antitrust Division during the COVID-19 pandemic as the business review letters were mentioned. I really believe that you did a great job because this -- the speed at which the field has moved is really essentially due to the fact that people will be able to collaborate, and you have some example. Imagine, for instance, imagine for instance that the scientists in China or any source would have decided not to publish the sequence of the virus so as to be the only ones developing a vaccine rapidly or if they had published the wrong sequence, which couldn't be verified and didn't provide the virus samples or even methods of culture of this virus were kept secret. These are things that cannot -- cannot be competitive. They have to be precompetitive. So I submit to you that we wouldn't have been able to develop a staff that we did, the engineered antibodies and the vaccines for this unprecedented space at the pace that we're seeing.

We were concerned about the impact of these issues until the DOJ reassured us through the letters that cover the federal government, but there is still the issue of private sector viability. And so that might be something that needs attention because it does scare companies when they say well, I won't have any antitrust issues with the federal government, but I could still have private suits. So that is an issue and maybe the context of the public health emergency space might be a little different. I hope that it's (inaudible).

And then in produce development, that's the fourth area where we need collaboration because when you look at product development will be manufacturing or methods of analytics to control the process of creating the product and you -- you really need collaborations because today all of that is made very, very let's say not very fluid if you will because of regulatory system. Right now with digital technology, you can monitor a patient continuously during the

trial, you can record their response. In terms of manufacturing, we're talking about continuous flow manufacturing. Some of us are experimenting with that but it's all faster. It would be great to have some sort of precompetitive collaboration there, but that's not possible because of the fact that manufacturing is so sensitive to the competition status of the field. But it does take such along time to get it through the regulatory process and to get it approved and get the analytics done that I think this is something that's slowing the field quite a bit and I don't think a single company can do it really effectively. And because of these concerns we -- we shy away from precompetitive collaboration in produce development and manufacturing.

So that was the landscape I wanted to share with you with the vectors, the force vectors that are pushing us into more and more collaborations that are not just nice to have. They are must have. You know, it's -- it's a challenge that we're facing, but the thing that I

wanted to -- two more points I wanted to share with you is based on my experience in academia and government and industry, I've come to realize that the U.S. Patent and Technology transfer system while it has been extraordinarily successful since the Bayh-Dole Act and the Technology Transfer Act, have led to somewhat unintended consequences I'd like to share with you.

They've completely changed the structure of innovation in the life sciences whereby in the past you had major companies and they integrated as I said all the processes. Today, the world is much more fragmented, many more companies, many more academic labs, many more universities are really creating IP and they're mandated to do so. But there's a negative side to it because every university now has a technology transfer office. I used to run one when I was at Hopkins and I was the Dean for Research, and what happens is that it creates a very -- a very difficult market to negotiate. It's a sticky market because today, there isn't a product that is relying on one

patent. They're -- you need a portfolio patent. Today, because things are so fragmented, the portfolio of patents are occurring everywhere and once you start negotiating, every single office and every single entity believes that their patent is the most valuable. And so you end up with this very funny phenomenon of royalty stacking, which can go to 20-25 percent before you even start a project and that's not feasible.

And I think something should be done there to do -- hinge the -- the ability of and the mandate on the university to have their own technology transfer to do what the UK does. In the UK there is a pooling of IPs and creation of integrated portfolios that basically are -- are put at auctions essentially and it's almost like a -- an exchange market. And that makes it much easier to access and to commercialize and to create value. And I think -- I don't know, I'm not an expert, but I've been advocating for some statutory change or other changes, legislative changes that will allow the U.S., creators of IP,

in the field of life sciences to pool their IP and market -- market the IP in a more effective way.

And then the last point I want to make is something that again, it's an unintended consequence of some rules and that's the research exemption. As you know, before the -- the -- the Supreme Court decision in Madey vs Duke University, there was a research exemption that had been there for decades. And so you know, the language says you can -- you can do it for amusement or to satisfy other curiosity or for strictly philosophical inquiry. I'm just quoting here the Supreme Court Language in Madey vs Duke. But that has created a possible block to free competitive collaboration because now you can be basically sued as an infringer if you used any form of IP before you intended to create an IND or go through a product. And -- and that has created the sort of foundation by many parties to sort of create blocking patents that are not even exploited, they're just there to protect in fact someone who has already done something and they

build a mote of IP or reagents or methods or various things, and you as the competitor just can't enter that field because you know that -- that IP can be the source of legal problems. So my question would be, and I know it's hard to do, is there a way to distinguish between patents that are not practiced in the research space to be able to use because they're really there to sort of prevent research use and exploration and investigations that could lead eventually to a product? And if so, obviously the you know licensing should be entertained. So I think patents are made to be produced, not to block others from producing, and any help or consideration there would be good. So I'll stop here. I've used up my time. But I really want to thank again The Division for this perfect work during COVID. Thank you very much.

MS. DIXTON: Thank you, Doctor. Thank you for joining us today. We really appreciate your time. Thank you for joining us. We're going to be moving to our next panel and last panel of

the day. We're going to be exploring academics and economists' views on collaboration and we have Patrick Greenlee from the Department who's also an Economist who will be moderating the panel and I'll let him introduce our very distinguished guests who have I think, have all joined us. Thank you, Patrick.

MR. GREENLEE: Thanks, Jennifer. And thanks to everybody for making it to the final panel here. On this panel, we're going to discuss the interaction collaboration and innovation incentives focusing primarily on how antitrust agencies play a role in assessing that tradeoff. Our conversation is going to focus primarily on mergers, but we can think of it as being similar -- said to be similar considerations for joint ventures or other collaborations which might involve firms that compete against one another in other setting.

We'll break up our conversation in two parts. First, we're going to think about mergers between state firms, so I think it's like a merger

between two big pharmaceutical company. Second half we're going to think about the potentially more interesting and uncertain situation merger between an established firm purchasing a startup. But before we begin all that, I'll provide some very brief introductions on our impressive panel of attorneys and economists. They extensive analyze issues about competition and innovation issues in the life sciences sector and advocated, insulted, and or testified about these issues in various settings. So, without any further delay, we have Rena Conti joining us. She's an Associate Professor of Market Public Policy and Law at the Questrom School of Business at Boston University. We have Scott Hamphill, he's a Professor of Law at New York University. We have Richard Manning who's a Partner at Bates White Economic Consulting. He has prior industry experience working at pharmaceutical firms. And finally, we have Joanna Shepherd who is a Vice Dean and Professor of Law at Emory University.

So I guess before we jump into thinking

about issues that we -- we face with during merger review, let's just think a little bit about the commentary that's been out publicly. There's been a lot of commentary recently suggesting that we have competition problems in pharma or life sciences sector industries, you know, complaints that pharmaceutical prices are too high and that there's less innovation happening now then there has been in the past. So let's first focus on the pricing portion of that concern that's being expressed. Let me just put it out there to my panel. Are pharmaceutical prices significantly above competitive levels currently? Let me start initially with Rena.

MS. CONTI: Thank you so much. Thank you so much for a fantastic day. It's been a pleasure to listen to these panelists. I've learned so much. So to answer this question, let me remind you that really we see with the two pharmaceutical markets, one for which prices are set by competitive measures. Those include the more familiar generic and brand generic

competitive spaces where prices are set on competitive levels although in some of the branded spaces that enjoy competition prices and price discounts and price disciplining if you will, are really expressed in discounts and rebates that might not necessarily trickle down to American consumers.

In the other space, there are places where prices are not set by competitive pressures. I would say the prices are largely set by a very well-known and important economic phenomenon called pudsva (phonetic). Here, we see a set of two concerns. The first is in a small set of innovative products, we see products prices being set where certainly the marginal cost of production matters and many of the products that we've been talking about today, gene therapy, stem therapy, other types of biologics, the marginal cost of production is not zero and it is clear that companies are pricing accordingly. We also see companies pricing based on the innovation that they provide both to patients and those with

clinical benefits in terms of hope and also technological spillover. But it's important to note that there's also other behavior that we observe both in the branded space and the non-branded space where there's no competition, which include anticompetitive behaviors including price fixing.

MR. GREENLEE: Okay, thank you. Richard, would you like to offer your view on the question about pharmaceutical or product pricing? I think you need to unmute, Richard.

MR. MANNING: Sorry. I presume you can hear me now?

MR. GREENLEE: Yes.

MR. MANNING: Okay. So it is an important question and I appreciate Rena's comment there and I actually was reminded about an important concept from Dr. Zerhouni's comments as well that I might reference if we have time. But I think it's important to take a broad look at this question. There certainly are some cases in which prices for patented or exclusive products

are high. Those products also tend to create tremendous value for the patients that use those products. It's a very hard question to ask, are prices high. So certainly during a period of patent, during a period during which a patent covers the product, you wouldn't expect it to be -- you wouldn't want it to be at a competitive level. You'd want it to be dictated by the value that the product provided for patients. You'd want to provide the incentive for people who are actors to discover and develop those new products, so you don't want competitive pricing at those levels. So we shouldn't search for policies that cause those to -- those prices to be placed at competitive levels and we perhaps shouldn't care too much about whether or not those prices are higher in the U.S. than they are abroad. We should care more about whether or not those prices are constrained by the forces of economics that lead to innovation in healthcare and whether they are making people better off in the long term.

I think it's -- you know, it's certainly

-- it's important to understand whether or not the competitive forces are appropriately working in generic spaces or spaces where prices are supposed to be dictated by competition, and I think there's some evidence that there's some insurance companies there. And I think there are -- it's important to make sure that competitive forces are at work there. Another important question that I think is worth asking as you asked whether prices are too high in some sense, is to ask whether profits are too high. I think there's really good evidence to suggest that profits in the industry, certainly those that -- the winners and -- in this market when you develop a grant -- a great new product that provides great value, profits tend to be high. But overall, if you look at profits in the industry, they're not greatly in excess of the cost of capital. So I don't think there's enormous -- there's cause for enormous worry on the point of profitability and pricing in the industry, no.

MR. GREENLEE: Okay, thank you, Richard.

Joanna, did you want to offer a brief comment here or not?

MS. SHEPHERD: Yes. I'll -- I'll just kind of reiterate what Richard was saying with a couple of other facts. You know, it's difficult to think about the too high compared to what. But when we are thinking about pricing during the patent period where obviously prices can be high and should be high because of innovation, it's important to note that you know we've seen changes in this over time and average lifetime revenues for new drugs are lower now than at any point that they've been in the past 30 years, which would suggest that you know, when -- when Richard was talking about like profitability which is obviously very tied to prices, it -- for the average drug, it's been coming down and I think he said this, but pharmaceutical companies that we incentivize to innovate with these profits which flow from higher prices are facing declining financial returns on their R&D compared to where they were again a few decades ago. That's largely

because there's a lot of different factors. We have increased use of generics, which lowers prices for consumers, but also the structure of the industry essentially changed dramatically. And so these days the brand manufacturers who again that we are kind of charging with this innovative -- this task of innovating, are really -- are only receiving less than 40 percent of the gross national spending on drugs and we have so many other players in the supply chain receiving a much larger percentage.

MR. GREENLEE: Okay, thank you. And finally, Scott, did you have a quick comment to make here or --

MR. HEMPHILL: Yes, sure, sure. Let me just end this briefly. Yes, thinking about this as an antitrust, one of the things we very typically care about is how much bang for the buck are we getting? That is how much innovation uplift are we getting for the incremental deadweight loss or loss of access. And of course the patent system is premised on providing some of

that tradeoff that is tolerating some high prices in order to incentivize innovation, you know. I think it's a common place that our state of economic knowledge remains kind of primitive on this as to what the optimal tradeoff is, you know, what the optimal duration of a -- of a patent, of a drug patent, of a semiconductor patent. I think we don't really know much about that and so one place we can look to guidance on this, taking off an economist's hat and put on a lawyer's hat, is what did Congress do? And to some degree, we can think about the statutory duration of the patent, which after all in pharmaceuticals is a little bit longer, they'll fight me about that, than it is for -- for other technology classes, and ask okay, what do we make of you know, conduct or action that reduce access without providing much incremental uplift to the innovations that upset it? If you have to greatly curtail access or you're privately arranged with imagined an extension of duration in a way that costs some money to the company doing it, we could imagine

that the incrementalization incentive might be modest and yet the locked access might be large, and that would be a situation in which whatever the right level is, certain kinds of actions that extend the duration of high prices without much innovation uplift are situations we should be particularly worried about.

MR. GREENLEE: Okay, thank you, Scott. So let's now zoom in on the first hypothetical actual I mentioned, which was thinking about merger to large firms. So, to set the table here a little bit, last year the FTC refused to merger Bristol Myers Squibb in Celgene. This was a 74 billion dollar deal. Ultimately, the merger was approved after securing the vasculature of just one identified price overlap. At the time, Celgene owned the most popular oral treatment for moderate to severe psoriasis and Bristol Myers had a pipeline product that would compete against it. To get the deal through, the parties agreed to devest Celgene's market leading product Otezla, but no other remedies were sought. When The

Commission voted on this, two dispensing commissioners issued statements suggesting that more needed to be done. So along these lines, let me just throw it out there, are there -- should there have been a change in approach to the FTC perhaps taking a more macro approach, not focusing so much on direct head to head competition between products or pipeline products, but instead focused on some more general innovative capability or some other way? So, at that tossed out there, let me first talk to Scott, have him share his views.

MR. HEMPHILL: Yes, sure. So you know, at some level it all depends on the facts, right. That's the first refuge of anybody who does antitrust, I think. Anything can happen. The models can take up any place. We just have to know you know, what's actually going on in a particular situation. Certainly, it's possible in principle that the loss of one major innovator as an independent entity could have a -- a downward effect on innovation. I guess on the fact as I -- as I've seen them to the extent I've looked at

this, that seems relatively unlikely. We still have a large number of big pharma companies who are engaged in profit acquisition and aggressively pursuing new cures. You know, in practice beyond that we also have an enormous number of small entrepreneurs, small outfit that you know, I think is going to drive a major portion of the innovation that we see and where absent some concern about exclusionary conduct arising from the transaction, those incentives should be you know relatively stable. So I think these points tend on the margin to support the conventional overlap analysis.

Two short points that I think are important wrinkles to bear in mind here. You know, one is that you know, critics of these mergers sometimes point to noncompetition concerns that perhaps being the true motivation for the merger. So in the transaction that you mentioned, I think one thing that was pointed to was several billion dollars in tax benefits from the transaction. You know, I don't know the truth of

the matter, but let's imagine that's true. Well, you know, from the antitrust perspective that would be sort of neither here nor there. I think we would think of it as mutual rather than as troubling.

There is a sense in which it might be encouraging, a clearance to the transaction, to the extent that the parties are motivated by a tax angle as opposed to suppressing those competition -- suppressing competition, let's imagine. That's good news, right? Because attempts to displace or update our priors about the likelihood of anticompetitive effects. Now, it might have that sense of similar dampening as to our procompetitive story, but it's not an obvious point against the transaction. And then finally, and I think really important when we think about how mergers effect innovation, is this the nitty gritty bread and butter issue in any merger that the DOJ or in this case, the FTC would be looking at, which is divestitures. Right? It's important, crucial, central, that the divestiture

destination for a set of assets to take care of the overlap, be capable of maintaining the level of competition that would have occurred had the transaction not taken place. And so you want to make sure that when you send that set of assets over to the destination, that they're going to be capable of doing a good job and maintaining the level of competition, in this case, pursuit of innovation. And this is, you know, a major debate in some instances. Thinking of another recent transaction at the Allergen, there was a set of I think a pair of drugs that was divested from Allergen to I believe it was Netflix. And so you know, there was a fight about whether Netflix would have strengths in related areas, but not directly on -- on these pharmaceuticals, would be kind of capable steward on that. And so whether an already approved drug or a drug project, you know, that's something that we have to keep in mind and keep our eye on when we're doing this overlap analysis.

MR. GREENLEAF: Thanks, Scott. Rena,

did you have some thoughts on this question?

MS. CONTI: Sure, so I -- I agree with Scott completely that really in mergers particularly two large firms, the demo's really in the details, but I would just say as a general comment to pick up some of the comments that I mentioned earlier and related as well, is that remember these are multiproduct firms. Some of their assets are in intellectual property, the drugs that they make or they're going to make. But increasingly the other types of assets that they have are labor and also manufacturing capacity are exclusive relationships to raw materials that can make certain types of products. And so when we are evaluating mergers, we largely focus on the product to product definition of competition, but clearly these other assets, most notably the fixed assets of exclusive manufacturing or trade secrets related to certain types of manufacturing could foreclose competition among their large rivals, but also have downstream consequences.

MR. GREENLEAF: So if I understand you currently Rena, that suggest that it's actually, it's -- you're thinking there should perhaps be more investigations for potential vertical theories of harm that a large pharmaceutical firm purchasing some assets, upstream assets or whatever it was, supplies, inputs or such like manufacturing capability, that while there might not be too much head to head concern, that there might be some ability to pursue some raising liable costs or similar exclusion in strategy if you were to combine these assets into a single large firm?

MS. CONTI: That's correct.

MR. GREENLEAF: Okay. Anyone else? Richard, did you want to weigh in here or should we --

MR. MANNING: I do, Patrick. So -- and I'm sorry to you know, just technology makes it a little hard to have the fluid back and forth, but we'll try. And I think all of those things are right and good, but I, you know, as I -- a couple

of things strike me here that I think we need -- that are very important that I think we need to pay attention to. And not to harp too much on the BMS Celgene, but there's a, in my opinion, there is a motivation that is spoken to in those dissenting comments that are not traditionally antitrust. They are -- they're concerned about -- concerns about high prices generally, about things that don't really have antitrust content. If that is the way antitrust is used in the future to assess mergers, and if that then leads to considering things that are not traditionally antitrust related or you know, terms to competition, and if you then look -- if you're forced by that mentality to look for harm in a world where the probability that there won't be any real consumer harm and very low, that may very well have serious problems for the future of complex innovation such as those that Dr. Zerhouni was talking about just before this, about you know, how do you allow companies to get together? Or public/private partnerships, to get together to

solve complex questions of biology and -- and the mechanisms of disease that are ever more difficult and maybe effective or more small parts of the population, but in various serious ways?

So if we allow antitrust to move toward inventive theories of how we're going to worry about things that are not directly related to consumer harm today, but only maybe some day down the future, we open a door that -- that I think we may regret opening and -- and may lead to much more complex analysis, slowing mergers, slowing acquisitions. Maybe this is the big small issue that we were going to move to, but I think that is a very important thing to avoid.

MR. GREENLEAF: Okay. Thanks, Richard. Anyone else have any comments related to this -- the challenges or issues that antitrust agencies face when evaluating proposed mergers of large firms merging with each other? Okay, well, then why don't we gently make way into what Richard was just mentioning passing the moment.

So one of the other concerns that's been

expressed in some commentary about how you know, markets are not performing as well as they could with respect to pharmaceutical pricing, is that, you know, a concern that innovation is declined especially at the large pharmaceutical company. So having listened to a lot of the interesting panels earlier, I think we may have an idea about what the answer here is. So let me just put the question out initially to Joanna to ask, you know, what is the case? Is it the case that innovation has been declining in pharmaceuticals?

MR. SHEPHERD: Yes, so I haven't been able to join the whole day, but I was listening to part of the last panel and I know this was discussed, so I will give my spin on it, which maybe if we have a few new members here it might be something they haven't heard before or maybe I'll just say it in different words. I don't know. So, so no. The -- the -- the short answer is no, there's not been a decline in the innovation. In fact, when you look at new drug approvals, 2018 was a record year. In the last

decade, and the second highest year was 2019, so in fact, you know, new drug approvals are up. What has happened is a shift in where this innovation is happening, and I definitely caught some of this in the last panel. Whereas a lot of innovation used to be internally developed inside the big pharma companies, what we're seeing is that more and more of it is happening in biotech and in smaller companies, and then later there's some sort of you know, a merger or otherwise it's some sort of acquisition of a larger company of the smaller company's innovation.

So you know, the reason, just to kind of put numbers on that, which I'm not sure if that was done in the last panel, so two-thirds of the new molecules approved by the FDA originate these days in biotech and small firms, not in the big pharma companies. And when we look at the global pipeline drugs under development, that percentage is 70 percent, so that's how many are coming out of these smaller companies. So, the reason why this is happening makes -- makes total sense.

It's really as an economist would say, kind of the comparative advantage of these different companies. And so you know, pharma, big pharma companies, they have lots of money. They can -- they have experience. They know how to administer these clinical trials that have become more expensive and more complex over the years. They're also kind of masters of marketing and production and distribution, so it makes sense for them to be doing that piece. But then biotech and smaller companies have other advantages, which makes them better at -- and I won't say in every sense, but in a lot of situations, better at some of the more innovative tasks. They tend to be smaller and have much smaller bureaucracies, which allow for more flexibility and nimble decision making. They have a -- usually have more links to research institutes, to universities where a lot of the breakthroughs originate.

One thing that I've studied, which I think is really interesting, is the financing, the biotech tends to be funded by venture capitalists

or you know, private equity. And that means they're not playing with their own money, which makes them much more able to, you know, to engage in the risks that's required to go through the R&D of the new drug in contrast to a pharma company who is playing with its own revenues and profits. And so -- well revenue, I suppose. So, it gives them a lot more -- a higher risk tolerance, to smaller companies. And because of all of these things, the -- the -- the less bureaucratic cultures, the links to the research institutes, the greater risk tolerance, they often are able to attract the best scientists who are really in the position to develop these innovative new drugs. And the shift really happened in you know, kind of the 80s and 90s. Part of it was the new technology that allowed -- it brought down the -- the prices of the costs of early stage drug development. The computer assisted drug design was part of that, and then also there were some changes in regulations and tax laws, which led to a boom in venture capital, which again is funding

a lot of the smaller companies. It's really interesting between '91 and 2001, that decade, BP funding of biotech increased by 140 percent, so we really did see the boom in that industry, and because of their comparative advantages it makes perfect sense that more and more of the innovation is happening there. So that's a very long way, Patrick, to say no, there's not a decrease, there's just a shift in where a lot of that innovation is happening.

MR. GREENLEAF: Okay, thank you, Joanna. Richard, did you want to elaborate here, or should I turn to Rena?

MR. MANNING: Oh, let me say just a bit. You know, the -- I agree with that, but I do think it's important to understand that there's always been a tendency for bigger firms to license in new products and smaller startups. You know, that's not really entirely a new phenomenon. As Joanna said, it's picked up but it's also I think important to recognize that the -- those who are evaluated the average rate of return on

innovation, that has fallen and so there are you know, careful analysts who care about this who suggest that you know, that might be putting at risk the future, given the rates of return on innovation have fallen.

MR. GREENLEAF: Okay, thank you, Richard. Let me ask the same question to Rena, just sort of the general question about whether innovation is declining or transforming in pharmaceuticals. What would -- what's your view?

MS. CONTI: Yes, thank you. So I agree with my colleagues that we don't see evidence of decline. If anything, 2020 appears to be a better year for investments in bio pharma, so clearly capital is not scared of the type of investments even if they've become riskier or more costly over time.

I think one thing that I am interested in, in this space, is where innovation is not happening. It's clear that there still remains missing markets for innovation that -- where this capital is not flowing. And a great example of

this are products that meet clear public health goals such as antibiotics, antivirals, but drugs to treat substance abuse, and yet we don't see a lot of innovation or competition in that space. I think another fantastic example of that is frankly the world that we are currently living in right now, so much attention is being put -- placed on vaccine for COVID, but the vaccine market has traditionally been a place where the industry has underinvested, and even now with facing a global pandemic for which really our economic laws and our health are intimately intertwined, we only have 19 products, there are 19 vaccines in development, only four of them are U.S. based companies making vaccines in the third engaged in phase 3 trials. That seems low considering that the demand will clearly outstretch demand supplies her for these products, and I would say another signal of that concern to the missing market are the role that we see public institutions stepping into here to assist this market in meeting demand, which include the not for profit investments by --

that were featured earlier by Gates and also by CEPI and also U.S. government and other government efforts to undergird both innovative products in this space, but also in manufacturing.

MR. GREENLEAF: Okay, thanks, Rena. Okay, so let's move now to this perhaps more interesting hypothetical of a large firm merging with a small one. I guess an initial concern as a guy that works at an antitrust agency, is the fear that some of these transactions, the big firm buying a small startup may happen so early or is more importantly, at such a low price that it's not even reportable to the antitrust agency so these things, they turn out to be anticompetitive, just end up going through without any review at all. Is there -- is that a legitimate concern to have, Rena?

MS. CONTI: So, there are clearly some examples of killer acquisitions in this space where new -- where innovative products or companies have been purchased in order to foreclose competition in a space, or promote

monopolies, both in the intellectual property part of this, but also in the manufacturing. There are some good examples, but I would say that (inaudible) example, it's going to be really interesting to see whether we see more evidence of that in the life sciences in the future.

MR. GREENLEAF: Okay, thank you. Richard, did you want to weigh in on the killer acquisition point?

MR. MANNING: Sure, and I kind of alluded to it earlier, but I -- I think you have to be very careful because the probability of success in this sector is, as Dr. Zerhouni was saying, the idea is to manage failure. If you're worried about you know, the true products that might compete with you know, 2 percent probability 10 years from now, you're probably better served spending your time and energy somewhere else. The -- the cost of evaluating every possible potential competitive outcome of a merger in that space just seems astronomical compared to the benefit, and so I would -- I would be very concerned about people

like you being asked to go and look and find every potential merger and do away with all the 40 minutes of the guilt drill that I look at on every single deal. You know, in that world, the collaboration that Dr. Zerhouni was talking about that are vital are just not going to be able to happen.

MR. GREENLEAF: Okay. Okay, thanks, Richard. So then, I guess opening up the question a little bit more given that you can pretense a lot more uncertainty here about knowing what may or may not compete against one another, what may or may not be complimentary. Let me just throw it open to -- for commentary just to talk about how antitrust agency should handle these types of collaborations or mergers when there's so much uncertainty about what might, you know, happen in the future. So for this, let me first have Scott weigh in.

MR. HEMPHILL: Yes, so I mean I guess my starting point is where Richard left off that indeed it's true that the path of future

innovation can often be highly uncertain. You know, we -- we may only attribute our relatively low probability of success to some innovative effort. I do though, you know, I want to sound another caution or maybe even more strongly try to rehabilitate a little bit the idea that even if the likelihood of innovation is low, that it's still something that merits antitrust concern. And this is an issue that has come up repeatedly, both in life sciences and also in tech. You know, those of us who are in antitrust are waiting to see whether the FTC chooses to undo the merger between Facebook and Instagram done years ago now. Our dwelling on this, on this set of issues, but you know, initially, an example that comes up in life sciences, just bear with me for a minute to lay it out here through a live transaction that happened a couple of years ago. And I -- by way of disclosure, I work with the State Enforcement Agency on this matter, is QuestCorp (phonetic) which is, some of the audience will know, the maker of Acthar Gel, a therapy for infantile

spasms. Of course the treatment for which can run 100,000 dollars or more, and in Europe there's been a similar synthetic version of Acthar Gel called cleverly (inaudible), and the owner of U.S. rights to (inaudible) basically made that available for sale and the winner of that low and behold was QuestCorp.

Now, I think there's a couple of things here that are of interest. One is okay, the anticompetitive aspect is pretty clear in terms of maintaining one's ability to charge 100,000 dollars and an alternative is a lot cheaper. I should say this is not a patented product. Manufacturing difficulties -- you can extract from the pituitary glands or something like that. There is potentially a procompetitive kind of complimentary argument that QuestCorp was the very best among all possible at making the most of (inaudible). Again you'd have to look at the facts to work out whether that's true or not. I think there's reason to think that was doubtful. Ultimately, I believe QuestCorp settled the case.

But what I really want to focus on here is what do you make of a situation in which the anticompetitive effect, namely the loss of this probabilistic competition from a competing therapy is highly uncertain? Suppose it's not 90 percent or 70 percent, but 20 percent or 30 percent. Now, I think one way to look at this is to say that a relatively small probability of a very large harm is still pretty large in expected value and I think economists should generally be comfortable moving forward or else they shouldn't be scared of the mere need of taking an expected value of calculating a probability. But you know, there is a strain of legal thinking that says, we can only find liability when things are pretty certain that unless it was more likely than not that competition would have broken out, there's just nothing to be done. Now, I think that gets the law wrong.

MR. GREENLEAF: Thanks, Scott. So you and a colleague have written about how to think about instant competition, which I guess is a term

you could put on established projects, purchasing what maybe is or is not you know going to be a competitor, and that as you say, there's expectation there. It could be a small probability event times a very large benefit. Part of your analysis on instant competition suggesting that the antitrust agencies ought to be more -- consider actually going after mergers after they've been consummated. So you mentioned this briefly when you mentioned FTC and some of the digital things, but could you elaborate a little bit for sort of what the tradeoff there is and how it might relate to how patents get established?

MR. HEMPHILL: Yes, so one important issue that we're currently kind of finding out in various ways thrashing out in antitrust, is what's the right balance of ex ante and ex post enforcement? Now I think this is a familiar idea for people who spend their lives thinking about patents because there we have both ex ante and ex post modalities of patent evaluations. We have

the examination process ex ante, which is a relative -- which though it can be quite thorough, it is not as thorough as litigation. And then we have ex post for some subset patent that turns out to be most valuable and also contested.

Now for people who do patent, it might be a surprise that in antitrust we only really do one of those two things. We have quite robust ante analysis where merging parties under the Hart-Scott-Rodino Act are obliged that the transaction's large enough and important enough to go into the agency and make their case and hope for -- argue for clearance, and if they don't get it, there's litigation and then a lot of those transactions get abandoned and a few get litigated.

There is virtually no ex post enforcement. I don't want to say there is absolutely none. There is even a very occasional Titus case speaking ex post enforcement. So part of the work that I -- that I've been doing with my colleague, Tim Woo, is to you know, rehabilitate

-- let me stop, it's not just us, but strengthen our thinking about ex post enforcement as -- as something worth pursuing, that the optimal amount of enforcement in antitrust or ex post surely is greater than zero.

MR. GREENLEAF: Or a large part motivated by the fact that it's hard to figure out what's going to happen in these really uncertain situations and so much like patents, not necessarily knowing you know --

MR. HEMPHILL: Yes, I mean the details of how uncertainty gets resolved I think are -- are different. You can drive a truck through the distinctions that can be raised between patent and antitrust. I do think in antitrust, there are things that we learn subsequent to the transaction that are legitimate to consider because they do not indulge in hindsight bias. Right? It's not -- oh, these markets were separate and then they became closer. It's more -- we weren't sure whether a firm has the same monopoly power over time, right? So much as we only litigate the

valuable patent. We might let -- if Facebook isn't one among a whole bunch of social media companies, we might well decide in the early 2010s to take a pass on an acquisition that seems to be on the bubble and then upon subsequently realizing that actually they did have strong barriers to entering in monopoly power at the time that we now see that transaction from a few years ago in a different and more negative light.

MR. GREENLEAF: Okay. Thanks, Scott. I understand we only have a few minutes left in our marathon day here today. Let me first ask Joanna if she wanted to weigh in at all on this you know, how to deal with these uncertain mergers or with what Scott said, and then after Joanna, have Rena also add her thoughts. Did you have a quick comment, Joanna?

MS. SHEPHERD: Sure, I me, I'm sure anybody would say this, but you know, I think it's interesting Scott's work in this area and his talking about this. And you know, I -- I just -- I guess I don't know if it's a question or a

statement -- maybe it's a question, but you know when I think about the right place to resolve some of these issues, whether it's in the patent world or the antitrust world, I mean, I think of transaction costs, right? And so it seems like in the patent world, the transaction cost of ex ante figuring out every potential infringer or party on whom you would be infringing are just extremely high. So it makes more sense to do it ex post, but I -- you know, it seems to me like in the antitrust world, you don't have that same issue, obviously. And then you might have a reverse where resolving these potential antitrust issues ex post could have the consequence of you know, a lot of things change when two companies merge, and it -- it may be too difficult to undo some of those changes. And so I just wonder, like how you think about the transaction costs. And I understand that there could be situations where maybe it's been changing in antitrust, about how you think about that.

MR. GREENLEAF: Okay, so in part,

they're taking this ex post approach might be inflicting some costs on either causing firms not to do as much of the decoration for fear that they might get reviewed you know, told to split apart after the fact? Okay, right.

MR. HEMPHILL: Yes, so there'd certainly be the sort of funny incentive effect that Patrick just mentioned. We just -- just thinking more simplemindedly about just a minute, two other points. One is of course ex post you know, break up of mergers could be enormously expensive and lots of remedies to be on the table. And so that wouldn't of course be the only one. To the extent that the parties make the vestiture more difficult through their own conduct, I'd hate to think that we would then credit that as a reason not to be bold since the cost of things that they generate in the hope of avoid enforcement.

The second point, you know, just to bring some of the antitrust back toward patent, is you could take -- this is a very shallow cheap effort to bring patent and antitrust together and

compare them and then say, well, sounds like what that really means is that we need something more like Hart-Scott-Rodino for patent, that our ex ante review of patent isn't sufficiently thorough going enough and that you know even if we think that a big composition of another patent evaluation is more than the average of 20 hours, you know, that we -- that we hear across all -- you know all our areas, it might well be the case that for patents that we can -- patent applications, that we can anticipate in advance are super valuable. That we ought to throw enormous resources at making absolutely sure of the validity of such patents rather than letting them sit on the books, the orange book, show up on docket and get litigated for years only to find out 4 or 5 years down the road that this -- that the patent wasn't actually valid.

MR. GREENLEAF: Okay, thanks, Scott. Unfortunately, I think we -- I've been told time's up, but not until I can let Rena and perhaps Richard have a final word. I promise one to Rena,

so Rena I want you to speak here.

MS. CONTI: I -- I -- I'll go quickly, which is I think -- I think Scott's idea is really interesting and I guess the way I like to think of this is if we are only evaluating mergers in the antitrust space on the basis of price, then what do we do when we're faced with price increases over time, might be an issue. I think the big question for me is not that we have evidence of pricing behavior that might be anticompetitive post merger. It's all the other things that we worry about such as quality, such as access, such as foreclosing competition in the future, and that again, brings us back to the premerger review where we might want to think about doing a more -- doing a little bit more evaluation of price plus these other things.

MR. GREENLEAF: Of the kind of more conduct or vertical issues that might arise from combining firms. You think that's an issue even when it's a large firm purchasing a small guy that might really just have some poor focused biotech?

MS. CONTI: I do. Because again, there are these -- because again, it -- when you -- one is acquiring a firm, one is not only acquiring the intellectual property that its firm owns. They're also acquiring knowledge, trade secret, other types of things that really do matter, and they might have implications for both price, quality, access, and other types of composition in the future.

MR. GREENLEAF: All right, thank you, Rena. I think we will call it an afternoon. So I'd like to thank my panel, the final word here, at least in terms of panels. An interesting discussion sort of about how innovation and collaboration run into each other and how patent law and antitrust also sort of face similar issues. I'll say thank you to all of you and I guess pitch this back, I assume to Jennifer.

MS. DIXTON: Thank you, Patrick. I've learned so much from Dr. Zerhouni and all of our panelists today. It was great that they could all join us today and I want to introduce Rene

Augustine, who is the Deputy Assistant Attorney General in the Antitrust Division, whose work focuses on our international work and also our policy work. And she going to end our program today with a few closing remarks and I just also wanted to thank our PTO colleagues before Rene starts, for posting this Webex and providing all this technical support that went along with it. We really appreciate it. So thank you, Rene for ending our program today.

MS. AUGUSTINE: Thank you. Let me begin by thanking Director Iancu and his extraordinary team at USPTO for partnering with us at DOJ to make this program a success. I also want to thank our esteemed panelists, speakers, and moderators for sharing their insight and particularly former NIH Director, Dr. Zerhouni for his compelling keynote address today.

I think we can all agree that this program has helped us better understand the challenges we face in the realm of intellectual property protection and antitrust in the life

sciences sector. We've been fortunate to hear from leading figures from industry, government, research labs, nonprofit, academia, and the broader legal and economic community. During this workshop, we focused on how intellectual property protection drives value in the life sciences sector. As Dr. Iancu told us yesterday, the patent system is critical to incentivizing development of life sciences based products such as pharmaceuticals.

At the same time, competition as protected by antitrust enforcement, is essential to ensuring an environment that promotes innovation. As Assistant Attorney General Delrahim said earlier today, the antitrust laws are the magna carta of free enterprise, which drives companies to compete. In the biotech and life sciences industries, this sort of competition literally can save lives by encouraging the development of newer, safer, and more effective treatment. The importance of innovation in the life sciences sector can't be overstated. The

COVID-19 pandemic has brought this issue front and center for all of us and as our panelists have noted, pharmaceutical innovations have led to dramatic improvement in both the quality and length of human life.

Great and transformative discoveries of course, do not happen in environments that stifle innovation. The panelists have warned us that we must take care to ensure that innovation can flourish by ensuring proper incentives for taking on the risk of investment in R&D, money, time and energy in the life sciences. These undertakings are expensive and have no guaranteed result. Our panelists reminded us that there is no innovation without risk and investors will not take on those risks without the prospect of reward. So if we are to continue to enjoy the fruit of innovation tomorrow, we must provide an environment that encourages investment and innovation now.

As Warren Buffet once remarked, "Someone is sitting in the shade today because someone planted a tree a long time ago". Our workshop has

allowed us to examine collaboration among private firms, the public sector, nonprofits, and research universities. These collaborations can be instrumental in the development of new therapeutics and vaccines. Our experts discussed the antitrust implications of collaborations and licensing strategies, as well as some of the challenges accompanying them.

We heard from our panelists on what makes the collaboration successful as procompetitive, as well as antitrust concerns that can arise in collaboration and ways to address them. Collaborations of course can have procompetitive purpose and promote innovation, such as those described in The Division's recent expedited business review letters relating to the COVID-19 response. With important safeguards in place, such collaborations can bring lifesaving help to people more quickly and effectively while preserving competition. Other collaborations harm competition, impede innovation, and violate the antitrust laws, the most obvious example being

those that are created with high price fixing. In these cases, antitrust enforcement is essential.

Our panelists engaged in a vibrant discussion on regulation and antitrust enforcement and how they and uncertainty from them can impact competition and incentives for innovation. They also discussed the extent to which regulation and antitrust enforcement are necessary to ensure climate of competition among safe and effective product.

The goal of course, is to identify the proper balance in antitrust enforcement so as to maximize the incentive to innovate while avoiding inadvertently discouraging procompetitive behavior. The challenge in the life sciences sector is to keep up the rapid pace with innovation necessary to confront the problems we face, whether COVID-19 today or a virus of tomorrow. As the Queen of Hearts told Alice in Wonderland, "We must run as fast as we can just to stay in place, and if you wish to go anywhere, you must run twice as fast as that".

Indeed, the stakes are high for making sure the proper incentives exist in IP protection and antitrust enforcement. Innovations in life sciences have the ability to save lives and to alleviate human suffering. Thanks to the contributions of our participants in this workshop, we are better position to get it right.

On behalf of the Department of Justice, thank you for joining us.

(Whereupon, the PROCEEDINGS were adjourned.)

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I, Carleton J. Anderson, III do hereby certify that the forgoing electronic file when originally transmitted was reduced to text at my direction; that said transcript is a true record of the proceedings therein referenced; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and, furthermore, that I am neither a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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