UNITED STATES PATENT AND TRADEMARK OFFICE

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

Webinar

Wednesday, September 23, 2020

PARTICIPANTS:

Moderators:

NYEEMAH A. GRAZIER
Patent Attorney
Office of Policy and International Affairs

BRIAN T. YEH
Patent Attorney-Advisor
Office of Policy and International Affairs

SUSAN ALLEN
Attorney-Advisor
OPIA, USPTO

Attendees:

ANDREI IANCU
Under Secretary of Commerce for Intellectual Property
Director of the USPTO

GENIA LONG
Senior Advisor
Analysis Group

ALI SALIMI
Senior Legal Advisor
Office of Patent Legal Administration
USPTO

DAVID E. KORN
Vice President
Intellectual Property and Law
Pharmaceutical Research and Manufacturers of America

DR. GABY LONGSWORH
Director
Sterne Kessler Goldstein & Fox

PARTICIPANTS (CONT'D):

MICHAEL CARROLL
Professor of Law and Faculty Director
Program on Information Justice and Intellectual Property
American University
Washington College of Law

MARK SEELEY
Consultant, SciPubLaw LLC and Adjunct Faculty
Suffolk University Law School

BHAMATI VISWANATHAN
Affiliate Professor
Emerson College

Panelists:

HON. PAUL MICHEL
Chief Judge
U.S. Court of Appeals for the Federal Circuit

STEVEN CALTRIDER
Vice President and General Patent Counsel
Eli Lilly & Company

KARIN HESSLER
Assistant General Counsel
Association for Accessible Medicines

ARTI RAI
Professor of Law and Co-Director of the Center for Innovative Policy
Duke, School of Law

COREY SALSBERG
Vice President and Global Head.
IP Affairs, Novartis

HANS SAUER
Deputy General Counsel and Vice President
Intellectual Property, Biotechnology Innovation Organization

PARTICIPANTS (CONT'D):

HIBA ZAROUR
Head of IP Department - Global Division
Hikma Pharmaceuticals

.

* * * * *

P R O C E E D I N G S

(1:00 p.m.)

MS. GRAZIER: Good afternoon. Thank you for joining this groundbreaking event titled Promoting Innovation in the Life Science Sector and Supporting Pro-Competitive Collaboration: The Role of Intellectual Property.

The United States and Trademark Office and the U.S. Department of Justice have joined forces to create two half- day programs aimed at starting a timely conversation between members of the innovation and legal communities engaged in the life sciences and in the battle to defeat COVID-19.

The presenters and the panelists of this program represent a diverse group of legal, economic, technology, and IP experts. Over the next two days you will hear from prominent members of the judiciary, the private sector, and academia. The program also includes leaders from generic and brand pharmaceutical corporations and representatives from stakeholder groups such as

the Association of Accessible Medicines, the Biotechnology Innovation Organization, and the Pharmaceutical Research and Manufacturers of America.

My name is Nyeemah Grazier, and I am a Patent Attorney in the Office of Policy and International Affairs at the United States Patent and Trademark Office. I am excited to MC this amazing program with my colleague, Brian Yeh. The USPTO will host today's event.

The main issue that we will focus on today is how patents and copyrights impact collaboration and innovation in the life sciences sector. I'm your MC for the patents portion of our program, and Brian will be your MC for the copyright portion.

The Department of Justice will host the second day, which will investigate different ways to expedite the development and uses of therapeutics, diagnostics, and vaccines through competition, collaboration, and licensing. Tomorrow's program promises a dynamic exploration

of these topics from a range of different perspectives.

You will hear from representatives from the National Institutes of Health, the Federal Trade Commission, the Department of Justice, and other stakeholders that promote the advancement of U.S. life science industries.

On a programming note, there has been one change to the agenda. The fireside chat between Director Iancu and Assistant Attorney General Makan Delrahim, was originally scheduled for today. But their discussion will take place tomorrow instead. As a result, please note that tomorrow's program will begin a little earlier, at 12:30, and the fireside chat will begin about 15 minutes later at 12:45.

As for today's program, we will highlight key factors involved in developing businesses in the life science arena. Although we are broadcasting virtually, we welcome and encourage your involvement. We have set aside five minute for questions and answers for Sessions

I, II, and III, and 10 minutes for Q&A for the panel discussions. If you have a question for any of our panelists or presenters, you may submit them by email. Submit it to Lifesciences@USPTO.gov, shown below.

Before we begin it is my pleasure to introduce our opening speaker, the Under Secretary of Intellectual Property and Director of the U.S. Patent and Trademark Office, Mr. Andrei Iancu. Director Iancu provides invaluable leadership to all those who serve at the USPTO and is the government's principle official in all policies related to domestic and international intellectual property.

Throughout the global pandemic Director Iancu has led the development and implementation of new programs aimed at galvanizing American innovation. Under his astute leadership the United States Patent and Trademark Office implemented several COVID-related initiatives. The USPTO also launched the COVID Response Resource Center to provide stakeholders and the

public with access to relevant resources, initiatives, and programs.

Given his round the clock commitment to promoting innovation and protecting American innovation, it is no wonder that he has been recognized for his outstanding legal work and expertise in intellectual property law. He has received countless accolades and honors, including California Lawyer Magazine, Los Angeles Business Journal, Best Lawyers in America, and many others. We truly appreciate his service to our country.

Later this afternoon Director Iancu will moderate the patent panel discussion and he will engage in a very interesting dialogue with the Assistant Attorney General, Makan Delrahim, in tomorrow's fireside chat.

It is my honor to welcome the Under Secretary of Intellectual Property and Director of the USPTO, Mr. Andrei Iancu.

MR. IANCU: Well thank you, Nyeemah, for that very, very kind and generous introduction. And thank you for being one of today's Masters of

Ceremonies. Before I get too far down the line here I want to make sure for my teams that my audio at least is good. Can somebody please let me know that?

MS. GRAZIER: Yes, we can hear you, Director.

MR. IANCU: All right, very good. And if not, please be kind and let me know, and I can switch the source.

So great to have everybody for this event. Welcome to all of you to the first day of our program, which over the two days will focus on ways to accelerate American innovation in the life sciences. Our goal is to enhance collaboration among innovative companies and researchers to solve one of the most vexing health problems we have faced as a country in the past century.

A big thank you to everyone in the Anti-Trust Division at the Department of Justice for co-hosting this program with us at the U.S. Patent and Trademark Office. The collaboration between the two agencies is truly innovative and

it, too, is directed at helping to find ways to end the pandemic as soon as possible.

Over the course of American history innovation in the life sciences have alleviated suffering, cured diseases, and improved quality of life. Since the dawn of the industrial revolution those breakthroughs have almost doubled U.S. life expectancy. From only 40 years in 1870 to 79 years just now.

One example is that before the early 1920s, people diagnosed with diabetes were treated by what they called a starvation diet and were generally dead within two years. But in 1921 scientist Frederick Banting and others discovered insulin, a protein hormone secreted by the pancreas that allowed the body to use glucose for energy. Shortly after the discovery in 1922, insulin extracted from dogs was first used for the treatment of diabetes, with promising results.

By the way, these scientists obtained U.S. Patent Number 1469994, which they promptly sold for $1.00. Almost 100 years later,

scientists are still making advances in insulin therapies, allowing those with diabetes to live full and productive lives.

Throughout our nation's history, American ingenuity and the IP rights granted to inventors have resulted in the creation of entirely new industries that have transformed the global economy. An example is Dr. Marvin Caruthers. Dr. Caruthers is a co-founder of AMGEN, now one of the largest biopharmaceutical companies in the world. Dr. Caruthers told me that without the protections offered by patents, the United States "Would not have had a serious biotechnology industry." He added that patents are the reason inventors "Lay down millions of dollars to start the company."

Today the pandemic has galvanized the global research community into a full-scale assault on the virus. It has propelled the USPTO to create initiatives to accelerate the development and deployment of diagnostic, therapeutics, and vaccines aimed at ending

transmission of the virus.

For example, we are expediting the examination of patent and trademark applications filed by small businesses related to COVID-19. We launched the Patents for Partnerships, or P4P platform to connect innovators with potential licensees who can accelerate the development and application of promising technologies.

We have extended deadlines, waived fees, and eliminated barriers to patenting COVID technologies. And just last week we announced an initiative to encourage the early disclosure of COVID related patent applications on the USPTO website in exchange for the deferral of provision patents' application fees. This action could lead to the sharing of ideas and the collective burst of creativity about solutions to the pandemic.

Our patent examiners and administrative judges have been running at full throttle to keep the U.S. patent system at the forefront of protecting and nourishing the nation's most important asset, its intellectual property.

And we have undertaken major initiatives to renew our economy in the long term by significantly increasing the number of people engaged in the U.S. innovation ecosystem. Last week we hosted the inaugural meeting of the National Council for Expanding American Innovation. Its directive is to help us broaden the population of American inventors to include women, minorities, and millions of potential young entrepreneurs who live far from any of the current technology hubs. We need all hands on deck. And by the way not only to fight and defeat COVID but also to invent America's future.

The patent system remains crucial in this effort. Due to the rigors of the regulatory process it takes years to bring new therapies and pharmaceuticals to market. And depending on the therapy, the cost to bring a new drug market varies from hundreds of millions of dollars to more than $2 billion. The patent system provides the incentives and protections necessary to enable such significant risks and large-scale investments

in R&D. Our patent system also fosters innovation by promoting the disclosure of inventions such that others can learn from them, avoid them where needed, and improve upon them whenever possible.

Without the patent system, seminal discoveries might be kept from the public as trade secrets, stifling breakthroughs and additional innovation. Plus, patents turn intellectual creative into financial and legal instruments that facilitate trade, licensing, and transfer of technologies from lab to market and in between entities.

The bottom line is this. Patents and other intellectual property are critical drivers of innovation and human development. All you need to do is look at one weekly issue of the Official Gazette of the U.S. Patent and Trademark Office to know the huge impact the patent system has and the amazing innovations that come through our office.

We must do everything we can to ensure a strong, reliable and balanced IP system that promotes innovation. The USPTO and the DOJ

Anti-Trust Division are working relentlessly towards this shared vision.

During the course of this conference we invite you to provide us with ideas and actions that the administration can take to even better support innovation and the development of COVID-19 inventions. I look forward to moderating a panel of experts this afternoon on whether changes to patent law could generate additional innovation in the life sciences.

There will also be a session exploring the importance of copyrights for the dissemination and use of leading edge research. We are especially pleased that DOJ will lead the second part of the program, which is tomorrow, to discuss how we can promote partnerships to accelerate the application of new products and processes that can end the pandemic and ward off any future threats.

Additional speakers and panelists will also address licensing strategies, the regulatory and anti-trust issues and risks associated with collaborations and incentives needed to spur a new

wave of innovation in the life sciences.

And I also especially look forward to having a one on one discussion tomorrow with Makan Delrahim, the Assistant Attorney General for the Anti-Trust Division at the U.S. Department of Justice, and a good friend, when we will both delve further into these issues. As a special treat, by the way, Federal Circuit Judge Kathleen O'Malley has agreed to moderate our discussion.

Thank you again for everything each and every one of you do to generate the innovation and nurture the innovators responsible for solving the greatest health threats facing mankind. And now I turn it back to Nyeemah and hope and look forward to a great rest of the conference. Thank you.

MS. GRAZIER: Thank you, Director Iancu for your thought provoking remarks. You highlighted the importance of IP rights and the need for collaborations and partnerships to further promote innovation in pharmaceuticals and biologics. The Patents for Partnership platform you mentioned is one example of a pro-competitive

collaboration. As of yesterday the P4P database contains almost 900 patents and patent applications that are available for licensing options.

Next we will take a closer look at the nexus between patents and the economic value of innovation, specifically in diagnostics, anti-virals, and vaccines. Next slide, please.

Joining us today to explore this topic, we are fortunate to have Ms. Genia Long of the Analysis Group. Ms. Long is a Senior Advisor where she focuses on the economics and business strategy of innovation, particularly the life sciences. She has assisted executives in addressing mission critical research and development, marketing strategy, and financial and business planning challenges, including the impacts of policy and competitive and technological change across all major therapeutic areas and emerging technologies.

Ladies and gentlemen, Ms. Genia Long.

MS. LONG: Such a distinguished group of

later panelists. The later panelist, as the Under Secretary mentioned, are going to cover some very important topics specific to the pandemic contexts, so I've been asked to complement those discussions by very briefly covering some of the essential aspects of the role of patents in biopharmaceutical innovation and where they sit.

That's a very big topic, so I'm just very briefly going to touch on a few specific items. First a little bit of what we know about the connection between innovation and economic incentives, including patents. Namely that innovation drives advancements in longevity and health, as the Under Secretary mentioned, and that it is influenced by economic incentives. So it matters very much what we do in terms of the innovation incentive framework.

Second, because of the features of drug development I'm going to talk about why patents have such an important role to play in drug innovation and how unique to drugs they operate in tandem with statutory IP provisions.

If there's any time left I want to say just a few words about specialists related to that same diagnostics but I know those will also be covered by qualified later speakers. So if I could have the next slide. Thank you.

And the first topic, economists have long recognized technological change and innovation is a driving force in improvements in standards of living and progress in health. The Under Secretary mentioned, you know, doubling of life expectancy, and we'll talk a little bit about that.

It may not seem like a very controversial statement today that there is this link, but it's important that there have been a number of empirical studies by various experts analyzing the benefits and impacts of medical innovation and drug innovation in particular. Listed just a few sample examples here, including the work that, as one example, David Cutler and various co-authors have done dissecting the improvement in U.S. longevity over the past

several decades due to medical innovations. For instance interpretations with heart attack and stroke.

Interestingly, and adding to the observation the Under Secretary made a few moments ago, he and co-authors recently released an updated analysis, finding that real improvements continue to be realized in heart disease and stroke, even after the substantial improvements of the past decade that the Under Secretary referenced a moment ago.

Of 3.3 years in overall life expectancy improvement between 1990 and 2015, about two-thirds, or 2.1 years, they concluded were due to improvements in just systemic heart disease and stroke, of which they attributed 50 to 60 percent of this improvement to pharmaceuticals.

The researchers have looked at a variety of other areas from Hepatitis C to HIV to various cancers, a couple of which are noted here. Next slide, please. Thank you.

So medical innovation leads to

improvements we value in health and length of life, but do we know that if we provide economic incentives we will get more of it? Of course theory tells us that increases in expected market size and value will be associated with increases in innovation, measured as additional new drugs approved and innovation activity measured as additional clinical trial activity undertaken.

But a number of researchers have confirmed that empirically both overall in terms of the number of new drugs or development, as reflected in the first bullet of the examples here, or in specific areas, notably in vaccines and oncology. So looking at vaccines as an example, prior studies have found substantial empirical evidence that the economic incentives reflected in health policies can affect the rate of technological change in medicine.

In the area of oncology, there's an interesting connection with patent policy directly. Studies have found that research investments were lower in cancers where effective

patent life were shorter, the link being that when patient survival is longer, it takes longer to prove a survival benefit, which eats into the remaining effective patent term. However, this correlation disappeared when innovators can use surrogate end points for approval, like time to disease progression, rather than having to wait for patients to die to amass the necessary evidence on survival for approval. Next slide, please. Thank you.

In terms of the second topic, the role that patents specifically play in drug innovation and unique to drugs how they operate in tandem with statutory key provisions. There are some aspects of the economics of drug development that makes patents particularly important.

Because of the scientific and regulatory challenges involved, the process of developing and approving a new drug is particularly lengthy, costly, and risky. More than 10 years from submittal to approval, and few than one in eight drug candidates entering phase one in clinical

trial testing resulting in approval. The costs of development are particularly high and the costs of copying are particularly low. So without patents, few manufacturers would make such investments, and few sources of risk based investment capital, from the venture capitalists community and others, would acquire early stage discovery firms or their assets. Next slide, please. Thank you.

Patents involve two key tradeoffs, one of which was mentioned a moment ago by the Under Secretary. First and most centrally with patents we trade, as with society, a certain limited period of restricted imitative cost-based competition for the same molecule in order to provide incentives for firms to make the large fixed-cost investments that are associated with new, innovated therapy, with new molecules.

So during this period price to the consumer are somewhat higher than they otherwise would be, and therefore some consumption that would take place does not. At the end of the time limited period, vigorous generic drug and

biosimilar competition is encouraged in addition to the vigorous therapeutic competition that takes place during the patent period.

This tradeoff was described in an interesting way, I think particularly interesting way by Craig Garthwaite in some recent testimony as an access today versus an access tomorrow tradeoff as you see in the quote here. Where he compares the tradeoff that's being reduced access today for existing treatments due to somewhat higher prices, versus incentives to enable increased access or created access to treatments which do not exist at all today. The essential rationale for patent protection is that these social benefits outweigh the current period losses for restrictions on imitative cross-base competition.

The second tradeoff the Under Secretary referred to of course is disclosure. The defined right to exclude others comes in exchange for disclosure, which reduces the private benefit of the patent to some degree, but increases its value

to society. Next slide, please. Thank you.

So how do patents operate in tandem with statutory exclusivity periods for drugs? Starting with the blue bar at the top of the graphic, the U.S. patent term length, as we know, is 20 years from the filing date of the patent. So the patent clock begins then. But because of the lengthy drug development process between then and the vertical line marked FDA Drug Approval, however, only a portion of the 20 year life of that patent is available to protect the investment of the drug innovator. A substantial chunk of that period would have been used up long before the drug comes to market, if it ever does.

So the Hatch-Waxman Act recognized this and provided for the period that you see at the far right of the blue bar, the partial patent term restoration, in order to make up for a portion of this period lost. So the resulting period of time between FDA approval and the expiration of the patent is the remaining effective patent life, shown by the red line to the right and below the

blue bar.

But as we know, that's not the whole story. Unique to drugs there is a complementary structure of statutory exclusivity that runs in parallel with patents. And without getting into too much detail, those include the periods of so-called date exclusivity where the evidence used to prove an innovator's drug is not available to the generic applicant.

The patent, however, protects the IP and is subject to challenge in court. Date exclusivity, however, protects just the clinical data that the innovator relied on for approval, it doesn't prevent another company from developing their own set of safety and efficacy data, nor does it prevent therapeutic competition from entirely separate molecules from entering and competing with the drug.

So the main point to take away from this graphic is that the interplay of these provisions that determines what is the key metric for the commercial life of the drug, called the market

exclusivity period. The MEP, so called, is defined as the period between the first sale of the drug, the branded drug, and the first sale of this generic equivalent. So depending on the specific circumstances, the patent might be longer, the period might be longer or shorter, but the point is that they run in parallel and they're going to be based on specific circumstances. Next slide, please. Thank you.

So taking all these individual circumstances into consideration, how do the actual market exclusivity periods compare to the U.S. patent term length of 20 years? According to research conducted together with Henry Krakowski of Duke University, we found that the average market exclusivity period has ranged between 12 and roughly 13 and a half years for all drugs. That's the blue line. And between 10 plus and roughly 13 plus years for drugs with more substantial sales over the past two decades. That's the red line. And by substantial we mean sales of more than 250 million in 2008 dollars

prior to a generic entry.

So what we see on the small molecule drug side is far below the 20 year period of patent protection and market exclusivity periods that have changed relatively little over the past two decades. Next slide, please. Thank you.

At the same time the patent challenge environment, as petitioners who were watching know so well, has changed quite dramatically over this period. So-called Paragraph 4, Patent Challenges to small molecule drugs has increased steadily until three out of every four drugs experiencing first generic entry in 2014 and nine in 10 of those drugs with the more substantial sales that I mentioned, faced at least one patent challenge by a potential generic competitor, that's the blue line, which is up from fewer than one in 10 in 1995. And at the same time those patent challenges come earlier and earlier. Looking at the red line by the right-hand side of the graph, the average time between launch and patent challenge stood at approximately six years for all

drugs on average, and approximately five years for those drugs with more substantial sales. Next slide, please. Thank you.

There are a number of specific issues related to vaccines and diagnostics, but I think I'm coming to the end of my time, so maybe I'll just kind of note here that a key question for vaccines, the experts such as one of the later panelists, Ernie Berndt, who literally wrote the book. The vaccine market is whether existing market based incentives have really been sufficient for promoting vaccine development, and if not, what else can be done?

So I'll stop there.

MS. GRAZIER: Thank you, Mrs. Long. That was very interesting. It appears that we have two questions. All right. Question one, what are the key take aways that are most relevant to the panels that we will hear from today and tomorrow?

MS. LONG: Thanks for that question. I think there are a number of things I would just

quickly highlight before you move on. One is that, as we saw a little bit in the graphics that we took a look at, innovation in drugs is a particularly long-lived process. Innovators, as the Under Secretary noted, are making long-term uncertain investments. So any changes to the core framework elements that we're talking about should be expected really to have a very long tail, a very long-term impact.

And secondly I'd probably say that, as we were looking at in terms of the context of the NEP data, patents are a central component of the innovation system for drugs, but they're also imbedded within a larger and somewhat complex system of rules and incentives which act together to yield market results. So care needs to be given to thinking through how all of these issues and changes may interact in order to ultimately experience a market impact.

MS. GRAZIER: Thank you. We have another question. And it seems we have time for another question. Okay. Question Number 2. If

patents involve a tradeoff, how do we know if we have the right tradeoff? You mentioned tradeoff in your slides.

MS. LONG: Yeah, that's a particularly difficult question. Because the tradeoff is fundamentally a policy decision. And that's what we all give our input kind of into in terms of the both halves of sort of that tradeoff but it reflects our overall priorities as a society. So there's no simplistic, you know, simply arithmetic answer to that question. It really is a question of thinking at a point in time what the balance is that as a society we want to make between those short-term benefits that come at lower prices and the long-term benefits of somewhat enhanced incentives for future therapies.

What we can say is that the rules and the practices that generate the tradeoffs that we have today, that we see today, yields are especially with certain outcome, so changing the rules is likely to change the results.

MS. GRAZIER: Thank you very much. And

was there anything else that you wanted to touch upon? Seems we have a couple more minutes so if you'd like to you could --

MS. LONG: One thing I touched on that might be interesting schematically for future sort of panelist is the oncology and surrogate marker examples that I mentioned before where there were disincentives to the way that the patent system operated in the real world by disadvantaging certain drugs for cancers with longer relative life expectancy. I think it's a kind of sort of subtle impact or not so subtle in the aggregate, kind of impact on the market for drugs that the way that the patent system operates, you know, in the real world, with real innovators kind of making real life decisions on major investments, can have big impacts, you know, kind of on public health. So that was ultimately addressed really by the FDA, you know, adopting surrogates and surrogate end point sort of based approvals, but it had a measurable impact on innovation such as the results.

So it would be interesting to see if other folks have some observations about how incentives that we see playing out on the patent system with an impact on, you know, public health, if that can be addressed in complementary areas.

MS. GRAZIER: Very well. I'm sorry, I think we just lost your audio. Okay. We have you back. I'm sorry, I missed the tail end of your comment.

MS. LONG: All right, we'll see if this -- can you hear me now?

MS. GRAZIER: Yes. Perfect.

MS. LONG: Great. I was just saying, I don't know where I cut off, that the kind of oncology and surrogate markers example that I mentioned earlier where there were disincentives on the ground in terms of the way the patent system operated in the real world, a disadvantage in certain drugs that were developed for cancers with longer relative life expectancy was ultimately really addressed in a complementary way, right, by the FDA adopting guidance and

openness to surrogate endpoint, surrogate based approvals, which had a measurable impact on both innovative incentives and really the results that matter to patients, the approved drugs and therapies that are available.

So I'd be interested to see if other commenters, other panelists, tomorrow particularly, have comparable examples that we might look to where we see the disincentives, you know, kind of in the patent system that in fact can be addressed with supplemental kinds of incentives. And of course we've seen that in other areas as well.

MS. GRAZIER: We just lost you again. I'm so sorry, Ms. Long. I think I lost the last sentence that you said.

MR. IANCU: I'm hearing Ms. Long just fine.

MS. GRAZIER: Okay. Great. Okay. Thank you. Genia highlighted in her last slide special issues concerning diagnostics, particularly patentability challenges. This is a

perfect segue, in my opinion, to Session II, an Update on USPTO guidance on patentability of life science inventions. Next slide, please.

Let's turn our attention to Mr. Ali Salimi for this session, who will discuss subject matter eligibility and disclosure requirements. Mr. Ali Salimi is the Senior Advisor in the Office of Patent Legal Administration of the United States Patent Trademark Office. His responsibility includes providing legal and policy guidance to the Deputy Commissioner for Patent Examination Policy and the Director of OPLA. He has an Under Graduate Degree and a Graduate Degree in Biochemistry and Molecular Biology from University of Massachusetts, and has a JB and LLM from George Washington University School of Law. Please welcome Mr. Ali Salimi.

MR. SALIMI: Thank you, Nyeemah. Can you hear me well?

MS. GRAZIER: Yes, I can.

MR. SALIMI: Okay. Thanks a lot. Can I have the next slide, please?

So good afternoon. As the title suggests, I'll provide an overview of the Section 101 subject matter eligibility and provide an update as it relates to the USPTO's latest guidance, and also briefly talk about Section 112(a), disclosure requirement for life sciences. Next slide, please.

So turning to the statutory language Congress has given us Section 101. And as the plain statutory language indicates, the invention must be useful. So the invention must have a well-recognized utility. Alternatively, the utility must be specific, substantial, and credible. Moreover, the invention must correspond to particular statutory classes of invention. Specifically, the invention must fall into one of the four categories of a process, machine or composition of matter. Next slide, please. Thanks.

Again, invention must correspond to these statutory categories. A process is defined as a series of steps. A machine is a certain

device, manufacture is a manmade means of creating new form or property, and a composition is a combination of two or more substances. Next slide, please.

And meanwhile the Supreme Court has held that the Section 101 excludes certain subject matter from patent eligibility. Namely abstract ideas, laws of nature, and natural phenomenon. The court's view is that these judicial exceptions are basic tools of scientific and technical work, and monopolizing these tools may impede innovation rather than promote it.

Before 2012 the Supreme Court had not really addressed eligibility in the life sciences for several decades. The cases we had were Chakrabarty and Funk Brothers. Next slide, please.

Pre 2012 the PTO's eligibility for life science has focused on human intervention. And claim limitation such as "isolated" was sufficient to establish eligibility. Next slide, please.

So starting with Bilski in 2010, the

Supreme Court showed great interest in patent cases, and in successive years issued opinions regarding patent eligibility. Next slide, please.

In Mayo v. Prometheus, the patent at issue claims to correlation between metabolized levels of thioguanine drug and toxicity. So the recited method steps were rather generic. So the court determine that this step merely instructs a doctor to measure metabolid levels through any well-known and conventional method. So unanimous decision by the court created a two-part eligibility test for claims focused on laws of nature. The Office's response at the time was to update the guidance for process claims. Next slide, please.

In Myriad Genetics the court reasoned that mere isolation of a particular gene is not sufficient to overcome Section 101, and the claimed product had to be markedly different. Office's response was to update the guidance based on Mayo/Myriad precedent. Next slide, please.

In Alice decision, claims at issue were

two products, processes, and computer readable media, that implemented the intermediate settlements on a computer. And the court set forth a two-part test directed to any judicial exception. So more notably known as Mayo/Alice Test, or commonly known as Mayo/Alice Test.

The test asks, is the claim directed to a judicial exception. And if so, analyze the claim as a whole to determine if the claim amounts to significantly more than the judicial exception. Next slide, please.

Meanwhile during this time the Federal Circuit was also active in the eligibility space. In Roslin, the court affirmed Office's application of markedly different characteristic analysis and made clear that Myriad applied to more than just DNA. Similarly in Ambry Genetics, the court relied on Myriad to determine that method steps of comparing sequences were well understood, routine, and conventional. Next slide, please.

So by 2014, following these cases, Office provided a guidance on how to evaluate

claims, and devised the Mayo/Alice Test in a handy chart to be easily followed by examiners and others. Next slide, please.

So since 2014, the Office has issued multiple interim guidances in response to feedback on prior guidances from stakeholders and case law development. USPTO Director Iancu on numerous occasions has explained that reliable patent rights are key to economic growth, providing high quality, efficient examination of patent applications will serve the American economy well. Next slide, please.

So to that end, in 2019 the Office published a new eligibility guidance to increase clarity, predictability, and consistency in how Section 101 is applied during examination to basically enable examiners to more readily determine if a claim does, does not recite an abstract idea. Next slide, please.

So the guidance makes two changes in Step 2a. It sets forth new procedure for Step 2a under which the claim is not directed to a

judicial exception unless the claim satisfies a two-prong inquiry. And abstract ideas are limited to mathematical concepts, mental processes, and certain methods of organizing human activity. Next slide, please.

So the guidance revised only certain aspects of Section 101. For instance, there are no changes to a Step 1 or a Step 2b. Examiners continue by establishing the broadest reasonable interpretation of the claim as a whole, and then work through the flow chart by first evaluating Step 1. If analysis proceeds to Step 2a, then examiners apply the revised procedure from the 2019 guidance. Next slide, please.

As has been stated in the shaded diamond, with respect to all judicial exceptions, the 2019 guidance changes the Office's interpretation of the words "directed to." In particular, the guidance revises the procedures at Step 2a for determining whether the claim is directed to an exception, by creating a new two-prong inquiry. And also groups the abstract

ideas. Next slide, please. Thanks.

So this slide depicts revised Step 2a which applies to all judicial exceptions. Under this new two-prong inquiry, the claim is eligible at revised Step 2a unless it recites a judicial exception and the exception is not integrated into a practical application. Next slide, please.

So let's see how it works. In Prong 1 the examiner evaluates whether the claim recites a judicial exception. If no exception is recited, the claim is eligible, it concludes the individual analysis. If it recites an exception then the examiner goes to Prong 2. In Prong 2, the examiner evaluates whether the claim recites additional elements and integrate the exception into a practical application.

If the recited exception is integrated into a practical application then the claim is eligible. This concludes the eligibility analysis. If on the other hand the exception is not integrated into a practical application, then the claim is directed to an exception. Examiners

are trained to go to Step 2b for further analysis. Next slide, please.

Here are some of the examples of integration into practical application. They include improvements to the functioning of the computer or any other technology or technical feat applying or using a judicial exception to effect the particular treatment for disease or medical condition. This is based on the Vanda case, and Office issued Vanda Memo for the examiners to follow. Next slide, please.

So 2019 guidance does not change the Step 2b. It still requires an analysis of whether the claim provides an inventive concept or so-called significantly more. It also remains true that even if the claim is directed to a judicial exception and requires analysis under Step 2b, it may still be eligible. For example if it recites an additional element or combination of elements that are unconventional. Next slide, please.

Once again, the 2019 guidance does not

change the Step 2b analysis, which still requires an evaluation of whether the claim recites additional element that amounts to an inventive concept. Next slide, please.

So far the Office has created a total of 46 examples covering all types of technologies to delineate the guidance. Next slide, please.

The Office has trained examiners and has held multiple town halls to seek stakeholders' feedback. Next slide, please.

Now let's turn quickly to Section 112(a). Next slide, please.

This slide provide the statutory language for Section 112(a). As you can see, the statute provides that the specification must comply with written description, enabling one skilled in the art to make and use the invention as set forth in this mode for carrying out the invention. Next slide, please.

So for enablement overarching inquiry is, does this specification provide enough information so that one of ordinary skill in the

art can make or use the full scope of the claimed invention without undue experimentation. So enablement is based on the specification at the time the application was filed, the state of the art existed at the filing date of the application, and whether the disclosure is enabling as of the filing date. Next slide, please.

So the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as predictability in the art. The test is not whether any experimentation is necessary but whether the experimentation is undue. Next slide, please.

These are the factors to be weighed in to determine whether the enablement is satisfied as determined In re Wands. You do not have to comply with all these requirements but the majority of them have to be complied with. Next slide, please.

So it is well settled now that beside enablement, the disclosure also needs to satisfy

written description. And written description depends on whether one skilled in the art would recognize possession was achieved at the time of filing. So generally in an unpredictable art, written description of the genus cannot be achieved by disclosing only one species within the genus. Next slide, please.

In Amgen v. Sanofi, the Federal Circuit, in a major written description, determined that disclosure of fully characterized antigen does not satisfy written description requirement for claimed antibodies that bind to the antigen site. Next slide, please.

The courts said a representative number of structural features that are common to the antibodies should be provided. Office provided memo to the examiners based on this decision to follow. Next slide, please.

And the last prong of this Section 112(a) is best mode, which is a two-prong test. The first step has to establish whether the inventor knew of the best mode and secondly,

whether the inventor disclosed the best mode to practice in this investigation. Next slide, please.

In conclusion, these are some of the available resources at the USPTO website that might be helpful. Next slide, please.

Thank you for your time.

MS. GRAZIER: Thank you, Ali. Ali, I think we have time for a couple questions. And I'm going to start off with Question One. Do you think the Federal Circuit places a higher requirement for enablement and written description on bio inventions as compared to other technologies?

MR. SALIMI: I think a number of precedent and opinions the Federal Circuit has issued in bio space speaks for itself. They tend to think because they deem biotechnology as being unpredictable art, so they tend to have a higher bar for inventions in the bio and chemical area. I don't think when you look at some of the claims that are drafted in the computer area or other

technologies, I don't think bio folks can get away with all those functional languages that are employed in the computer area or some of the other technology business methods on other ones.

So I think they view that bio folks have to show more to enable their inventions and make sure that they show possession. So I think the volume of precedent speaks for itself.

MS. GRAZIER: Thank you. We have another question. What has been the impact of the 2019 guidance on eligibility type rejections?

MR. SALIMI: I think it's been well received by the stakeholders for all the comments we've received so far. And also the examiners have been happy with it. So it seems like it has worked well. So we have to wait and see whether it stands the test of time, especially with all the new cases that are percolating at the Federal Circuit, and see where it's going.

But I think the effort was made to make sure to give some clarity to this area absent the legislative effects. I think this was a valiant

effort on the part of the Office to come up with this solution or provide some guidance in this area.

MS. GRAZIER: Thank you very much. Was there anything else that you wanted to touch upon?

MR. SALIMI: No, just thanks for the opportunity to present.

MS. GRAZIER: Thank you again. Okay. Next we will have two speakers. They will touch on the role that subject matter eligibility plays in pharmaceuticals and biologics.

First we have Mr. David Korn. David Korn is the Vice President of Intellectual Property and Law for the Pharmaceutical Research and Manufacturers of America. He focuses on IP and related issues in Congress, the United States Patent and Trademark Office, and the Food and Drug Administration, as well as an amicus brief in cases of interest to PhRMA.

He has degrees in biomedical engineering from Duke and Northwestern. And a JD Degree from Harvard Law School.

Joining Mr. Korn is Dr. Gaby Longsworth. Dr. Longsworth is a Director in Sterne Kessler's Biotechnology and Chemical Practice Group and is the Chairperson of the firm's Diversity Committee. She is sought out by biopharmaceutical companies worldwide for her insight and knowledge of intellectual property and Hatch-Waxman law.

In her practice Dr. Longsworth councils international biopharmaceutical clients in all areas of patent procurement and strategy.

Mr. Korn, Dr. Longsworth, welcome to the program.

DR. LONGSWORTH: Thank you so much, it's great to be here.

MS. GRAZIER: Okay. Mr. Korn, if you would like to begin. Or Dr. Longsworth. I believe Mr. Korn is up next.

MS. LONGSWORTH: Yes, Mr. Korn goes next.

MR. KORN: Just want to make sure you can hear me.

MS. GRAZIER: Yes, we can hear you.

MR. KORN: All right. Thank you for the introduction. As noted, I'm with Pharmaceutical Research and Manufacturers of America, or PhRMA. PhRMA is the trade association that represents the country's leading innovative biopharmaceutical research companies which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

Since 2000 PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone. This includes both drug and biologic treatments as well as vaccines.

2018 NSF data shows that the pharmaceutical industry invested nearly three times more in R&D than either the motor vehicle or aerospace manufacturing sectors, and did most research intensive to any major manufacturing sector.

I am not a representative for any particular company, although some individual

companies are going to be represented on later panels. Genia Long provided some background but I wanted to provide more context for the nature and for this patent protection for pharmaceutical companies. Can I have the next slide, please? And one more, please. Thank you.

This graphic illustrates that the R&D process for new medicines is lengthy, costly, and uncertain, and why patents are important to justify investing in such a process. Discovery of an active compound that could be a potential medicine is just the beginning of the journey. If basic research leads to scientific knowledge that leads to invention of a compound, it's not known whether it will be a successful medicine.

Under applicable laws and regulations, researchers first test the compounds in a lab and test promising compounds in animals. If a compound is still promising, they can file an investigational new drug application, or IND, which is an application required in order to start clinical trials in humans.

As many people are now familiar with given the press coverage of developments of potential treatment and vaccines for COVID-19, Phase One tests are small tests to consider safety in dosage. If a compound is successful it can move to larger Phase Two tests which evaluate at a preliminary stage efficacy as well as safety. If successful, it can then move on to larger Phase Three trials, which can involve thousands of patients across multiple sites to see whether it's both safe and effective for the proposed use or for a biological safe cure potent.

If this is shown in the Phase Three trials, the company can submit a new drug application, or NDA for drugs, or a biologics license application, a BLA, for biologics, to FDA for review. Only after approval of that application is the product ready for distribution for use by patients.

At each step in this process compounds can and do fail. Fewer than 12 percent of potential medicines make it through the FDA

approval process. So for any single FDA approved medicine, there could have been thousands of failures.

We've heard data described earlier, but studies show that this process takes 10 to 15 years on average and costs an on average $2.6 billion when one considers the cost of the many failures.

As Lowe and Pasano noted for science based business startups here, they're are like a rocket mission where everything needs to work perfectly at each stage, something applicable to life sciences as well. Patents allow companies to justify this long-term, costly, and risky investment.

Like for other innovators, patents play the important roles of incentivizing research and development of new products, fostering disclosure of the inventions in the patent applications, and encouraging competition. For our companies we also have the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman,

which applies to small molecule drugs, and the Biologics Price Competition and Innovation Act or BPCIA which applies to biologics. Both statutes balance incentives for innovation and procedures to increase availability of generic copies or biosimilars.

In addition to provisions relating to patents, like the patent challenges referenced by Genia, both statutes also include provisions that protect the data generated to support FDA approval through regulatory data protection, also referred to in some context as data exclusivity.

Those statutes work, as evidenced by 90 percent of prescriptions for drugs being filled with generics upon patent expiration, the growing number of biosimilar products, the utilization of the Hatch-Waxman pathway to challenge patents in court, but also the innovations by biopharmaceutical companies.

Genia mentioned there are also targeted exclusivities. An important one is the Orphan Drug Act. This legislation created an incentive

for companies to devote resources to study products for rare diseases and obtain approval of such products. This incentive is separate from patents and is implemented as exclusivity against approval of the same product for the same orphan designated use. Next slide, please.

So focusing now on patents, there are several broad buckets of biopharmaceutical innovation that can be covered by patents. The one that most people think of may be a patent on the active ingredient or component of a medicine. But just having an active ingredient does not equate with a safe and effective medicine that patients can use.

Other types of innovations can include the dosage form that supplies the active ingredient or compound insupations such as in a tablet or capsule or delivery device. Methods of manufacturing a medicine, like with chemical industries, and methods of using medicine or treating patients, such as using it for particular indications.

When the company develops the medicine into a finished dosage form and develops its manufacturing process it can then seek FDA approval to be able to market it for specific uses for patients upon conducting a sufficient amount of non-clinical and clinical testing as noted above.

As Genia noted, companies typically seek initial patent protection substantially before when a medicine is approved by FDA to help protect the significant amount of time and resources necessary to further develop the product despite the uncertainty involved in development. This means that effective patent life is lost prior to FDA approval, as illustrated by Genia.

Although Hatch-Waxman provided for patent term restoration, only some of that can be restored, and only for one patent. This patent term restoration is based on this production effect of patent life resulting from the FDA regulatory approval process and it's separate from patent term adjustment available because of the

USPTO patent review delays.

But R&D does not stop when a company gets initial FDA approval, and can distribute its medicine for use for patients. Companies continue to learn more about the medicine, its properties, its clinical profile, and potential additional uses for patients. Indeed, such ongoing R&D is important since it benefits patients.

If the COVID-19 situation has taught us anything, it is that we should look to every possible source, including existing products, the products that have failed for other uses when we're searching for medicines to treat disease. Next slide, please.

Medical advances that continue after initial FDA approval can take many different forms and also require additional costly and time-consuming R&D. These advances can include new forms or methods of delivery that can make a medicine more safe or effective, as well as for convenience and improve patience adherence. For example, one could have medicines for patients

with mental health issues that require fewer doses, or even a patch. One could transform a medicine that requires frequent administration by healthcare professionals into one that could be administered by a patient at home. One could lessen side effects of a medicine or demonstrate that it's useful to treat different diseases or different patient populations. One could combine multiple therapies rather than have individual dosages and reduce kill burden and improve adherence.

All of these require research and testing of some sort. All require FDA approval under the same rigorous standards as the initial medicine approved by FDA.

Patent protection is a critical incentive to be able to support such investments. And as Director Iancu has pointed out elsewhere, such inventions must meet the standards for patent protection in order to be able to be granted a patent. Such patent incentivize new innovations for patients. These patents can result from

research and development before or after initial FDA approval of a medicine, based on when the science develops and the invention occurs.

While a new innovation can be patented if it meets the standards, such patent only covers the invention claimed in the new patent and not the original or prior version of the medicine claimed in an earlier patent. And such new patient does not extend the earlier patent. Next slide, please.

I also wanted to build on what Genia said about the importance of patent protections and how they're used. A significant part of this conference is about collaboration. And patents support many types of collaboration. Biopharmaceutical research is part of an ecosystem and there can be other participants in addition to our companies, including NIH, universities or other research centers, startup companies, and even other biopharmaceutical companies.

I understand the print has fallen here, but this is a graph that we have also posted on

our website. There is collaboration by companies working to try to develop a medicine based on a basic research concept that resulted from a government grant to a university. Under the Bayh-Dole Act a university undertaking research under a grant from the U.S. Government can retain title to a subject invention and license it to companies for further research and development into a medicine.

This move away from the government holding title to the invention and instead allowing for research institutions to claim revenues from the licensing of inventions give researchers and their institutions the incentive to seek out partners like the biopharmaceutical industry who can further develop these early stage inventions into useful products. And history before Bayh-Dole taught us that if we don't do this, much of the work can be lost.

There's also collaboration as part of other government research such as cooperative research and development agreements or CRADAs.

And there's also collaboration between companies where inventions can be covered by licenses.

In all of these situations patents lead to disclosure of the invention in the patent application, define the invention and who developed it, and provide confidence in the ability to license the invention for the purpose of the collaboration. Patents are therefore a critical factor not only for incentivizing investments, but also for fueling collaboration.

And in the current context of COVID-19, biopharmaceutical companies are working around the clock and they are screening vast libraries of medicines to identify and test potential treatments. They are also developing new therapies and treatments for those infected by the virus, such as plasma technologies and new monoclonal antibodies, and they're working to develop vaccines to prevent future infections.

IT is a critical incentive and is one of the reasons we have so many potential treatments and vaccines already being tested. Its incentive

for innovation not just for the current pandemic, but also to encourage innovation to counter future pandemics and other diseases.

Thank you.

MS. GRAZIER: Thank you, David.

MS. LONGSWORTH: Thank you. And thank you so much, David, for the really important and interesting overview. I'm just waiting for my slides. Next slide, please.

So as a practicing patent attorney, I will be talking a little bit more about the nuts and bolts and sort of the importance of patents in many different contexts. I think we all know that a company's value is often a mix of knowhow, trade secrets, and patents. All of these elements are important. But for this discussion I'm going to be solely focused on patents, and specifically life science patents.

And why are life science patents important? As we've heard from Ms. Long already about patents encouraging disclosure of the workings of an invention to the public. This is

an advantage to the public and allows one to build upon what's already known and come up with new inventions.

Patents also encourage investment and provide a barrier to entry for those who just want to copy an innovation. So it allows one to recoup some of the investment that was made, as you've heard from other speakers.

If a company does not want to protect an invention by keeping it a trade secret, you can get a patent which will give you, you know, 20 years or so of exclusivity. So having a combination of patents and trade secrets is usually a common way by which companies protect their invention.

While patents of course can also allow and encourage collaboration with other patent holders or just by licensing those patents, which allows, again, one to build a common innovation instead of battling it out in litigation.

And as David mentioned, the process of getting a drug on the market is a very expensive,

lengthy, and risky process. So by getting patents and being able to recoup some of that money that was spent in R&D. Patents also allow patent exclusivity, meaning it allows a company to list the patents that they obtain from their drug in the FDA's Orange Book, which is a barrier to generic competitors, we'll get a bit more on that later, for small molecules, and of course having patents for biologics sort of enables the patent dance and all of the activity that surrounds biologics.

And finally, patents can also serve as collateral for a bank loan or are often sold. So there are many different reasons why life science patents are important. Next slide, please.

So in the United States there are three general ways, which David covered somewhat, that drugs are approved. And these three different ways are highlighted on this slide. So the first one, which is found on what we typically call Section 505(b)(1) of the Federal Food, Drug, and Cosmetics Act is for a new drug application, which

is often abbreviated NDA, and this is got s new molecular entity. You know, a drug that has not been previously approved, a brand new compound, you can get new chemical exclusivity for that, or NCE, and that's one way of filing an NDA.

Other ways of filing NDAs, or if you have a new formulation of a previously approved drug, so for example the first formulation was perhaps an oral formulation and now there is a new and improved dosage, for example. That can sometimes be filed with the FDA as an NDA. An NDA can also cover a combination of two or more drugs. Or it can be a NDA for a new indication for an already-marketed drug. For example a first approved use was for lochia, and whose second approved use is for cancer treatment, you can actually file two separate NDAs for that and get the exclusivity that sort of come with an NDA.

The second type is one that is called a 505(b)(2) application, also referred to as a Paper NDA. This is typically a modification to an already approved drug. And I will go into this a

little bit more in the next couple slides. It relies upon safety and effectiveness of the reference listed drug and it can be marketed as a branded drug or as a generic drug. And importantly, once you file for a Paper NDA the company can actually obtain their own patent and list those patents in the Orange Book. So it builds upon what was already presented in the NDA and allows another way, and it gives the public another way of getting another drug that is a modification of the prior drug.

And then finally there are 505(j) applications which are called Abbreviated NDAs, or ANDAs, which is a duplicate of an approved NDA product. This is typically what generics would file. Generics can also file Paper NDAs as well as innovators of typical generics called ANDA. And this relies on safety and efficacy studies from the NDA. It must have the identical active ingredient, identical route of administration, dosage forms, so for example tablet, capsule, you have to have the same brands labeling and intended

use although some of the inactive ingredients can change. And you have to demonstrate bioequivalence for an ANDA.

So this is sort of the high level review of the three. I'm not really going to address ANDAs at all here, although some generic companies do file patents on their polymers or formulations for new processes of a new factor of the API. Next slide, please.

So prime opportunities for NBA filers. So innovators' goal for an important drug is typically to build a patent state, a patent thicket, to deter competition, to deter a generic. From a generic's perspective it is more difficult to file an ANDA when there are a lot of patents to analyze. It becomes very expensive if there are a lot of claims that need to happen, it makes it more difficult to design around and you either have to invalidate the claims or you have to find another way to get around it.

And from the perspective of an innovator having a lot of patents, it is also very difficult

and more expensive to attack such patents at the PTAB, you know, in a PTR post-grant review proceeding or in an interparty proceeding. So having more patents is typically the goal of the innovator.

And of course another goal is to build a strong blocking patent as opposed to patents that are easy to design around. As an example I recall the Melitin at some point had over 100 patents listed in the FDA Orange Book. So it pretty much, you know, ruled out a lot of competition, a lot of generics that simply were not able to go up against 100 patent state to try to get a handle on the market.

So we look at the different patents and claims that one can obtain for a new chemical entity. You know, typically compounds, novel new compounds are fairly easy to obtain patents on. They get through the patent office fairly quickly, as are polymers, crystal forms of such drugs. Those are fairly difficult for the patent office to find prior art on or typically are not subject

to a lot of, a long execution process, they were fairly easy to get.

As for some impurity patents, and that's usually a very good strategy to, you know, put in with the FDA or the NDA. Put in the FDA a certain spec, you know X percent, less than X percent of a certain impurity that nobody knew existed and then to get a patent on that.

Dosage forms of course are very important. And with dosage forms, the interplay with the FDA is particularly interesting when it comes to directing patent strategy. So what do I mean by that? So for example, for a parenteral formulation, the generic typically has to copy that parenteral formulation exactly. However, in some circumstances the FDA will allow a few changes to that formulation in terms of a preservative, buffer, and antioxidant. So if the patent professional, knowing that, when drafting claims for a parenteral, can make the claims actually fairly narrow, but you don't put in anything about preservative buffer or antioxidant

because if you do that you allow the generic compound to combine around it. So knowing that the interplay with the FDA is super important when it comes to dosage form claims.

Of course there is dosing and titration regime type of patents that can be obtained, method of use. And the claims come in many different flavors. It could be treatment, it could be a combination of dosing and administration or methods of inducing physiological effects. The so-called pharmacokinetic patents are fairly powerful patents to obtain. And you often see claims that have the Tmax, AUC, Cmax parameters in the claims. As well as sometimes you see claims that dropped that are incident to metabolism by cytochrome P450 and you can even see claims to that effect, you know, to adjust the dose if this is a drug that is sensitive to cytochrome P450 as an example.

Methods of manufacturer are fairly standard. Typically methods of manufacturer are not listable in the Orange Book, however if there

is a product by process claim, that kind is listable in the Orange Book.

Sub-populations engage in before a clinical trial, and trials typically provide a lot of data. And so by mining the data there may be a certain sub-populations that have a different profile or a different dosing, where you can also get patents for that kind of subject matter. And we heard from Mr. Salimi there are many examples from the PTO about what is subject matter eligible. And diagnostics, I know the next panel I think will touch on diagnostics, but diagnostics can be tricky, you know, correlations can be difficult to patent and are typically not patentable. However, methods of treatment that employ some sort of correlation typically are.

So this gets you an idea of the many different patents that one can obtain and the patent thicket that can be built. Next slide, please.

For a Paper NDA there are also a number of patents that one can obtain. And for example

if it's a new chemical entity which would be considered a different salt of the prior approved drug or ester complex. There are several examples that I listed here. Those are considered new chemical entities and you can also get patents on those sometimes fairly easily. It depends on what you're claiming. Salts can be difficult if you don't have an expected results or some sort of new angle. Because typically the innovators compound patents have salts claimed, you know, typically you see a claim that says a compound or a salt, compound acceptable salt thereof. And then there's a bunch of salt listed in the specification. So for the Paper NDA filer, you know, if they're trying to get a patent on a different salt they typically have to comment a little bit more.

New dosage forms and regimes brings pretty much a number of those same subject areas that we saw for the NDA, you can get patents on these as well. Next slide.

And to just to round it out for patent

opportunities for biologics, which were mentioned earlier, you know, which are large molecules as opposed to small molecules. There are also a fairly large number of patents that one can obtain to protect these states. And some are a little bit more unique because they're biologics. So nucleotide, amino acids/polypeptide sequences are patentable, hectors are patentable. Modified organism claims can be obtained. For vaccines for example, a live attenuated virus can be claimed. Formulations and method of use. And then the big category, which start are the manufacturers, these are super important for biologics if they're not kept trade secret because they are so many steps in the process of obtaining a biologic and they're all, many of them are very critical, you know, in terms of temperature, in terms of excipient used buffers, you know, all of these different cultures. On a recent biological level, just in terms of manufacturing patents, there were close to 1,000, which is pretty amazing. Of course not all of them will be relevant but it's just to show

that more biologic, the amount of patents that can be obtained are fairly large and being, of course, a giant barrier to competitors would want to file a, you know, a substituted form of the biologic.

So I think this concludes my part. I hope, you know, the overview is helpful. It's a lot of, there's just so many nuances that we could go into, but, you know, not enough time to really do that. So thank you.

MS. GRAZIER: Thank you. Thank you, that was very helpful. We have about three minutes, and I wanted to ask at least one question. We do have two. Okay, the first question is, how are patents on method of using pharmaceuticals enforced? This is for either one of you.

MR. KORN: I could start on that. So I think both of us talked about how innovators can get methods of use patents. We didn't go through the whole patent challenge process and all the nuances of Hatch-Waxman, but innovators can obtain this. They can also obtain exclusivity for a

method of use if its new clinical investigations are essential for the FDA approval. Then generics could not use the labeling, that indication in the labeling.

So there are a couple of questions about how strong the incentives from method of use patents are at practice. For a small molecule drugs whether it's generics. Generics can keep labeling that doesn't include a use, and file a so- called Paragraph 8 application and use what is referred to at times as "skinny labeling."

They could also challenge the patent in a Paragraph certification like we were talking about with other kinds of challenges if they want to include the content in their labeling. But there's another level of complexity here because state laws govern substitution of drugs. So for example if you go to a pharmacy with a prescription for a brand drug, if it is available generic you could end up receiving the generic because of the substitution, and given that this pharmacy doesn't check for exclusivity for patent

protection, it is still possible to get a generic drug substituted for an innovator even if there's patent protection.

Which leads to an even more complex kind of litigation for inducement of infringement. Under a similar dynamic with biologics in that they can also, or a biosimilar, seek approval for less than all the indications. And there could be litigation.

MS. GRAZIER: Thank you very much, Mr. Korn. Thank you very much. And thank you, Dr. Longsworth, that was very exciting and very interesting.

I'm going to try to keep on schedule. It is now 2:29, going on 2:30, so I think it is time for a break. I'd like to thank all of our speakers from Sessions I through III. And at this time we will take a short break. So please grab your favorite beverage, whether that be coffee or tea, and let's meet back here at 2:40, which is in about 10 minutes. Thank you.

(Recess)

MS. GRAZIER: Welcome back. So far we've learned that there is a significant link between economic incentives and innovation. And that patents secure the funding needed for the necessary research and development of medicines, including new and improved uses, forms, and methods of delivery. We also understand that certain life science inventions have faced patent eligibility challenges.

With all of this in mind, there appears to be one question that is ripe for the next discussion. Are changes to U.S. Patent Law necessary? Next slide.

Let's welcome the first panel discussion, which will address the question of whether legal change is necessary to better support innovation in life sciences and the development of COVID solutions.

We have seven impressive panelists. It is an honor to introduce our first panelist, Judge Paul Michel. Judge Michel served for 22 years on the Federal Circuit, and from December 2004 until

his retirement in May of 2010, he discharged the duties of Chief Justice of this National Court.

He judged several thousand appeals and authored more than 800 opinions, 300 of which concern intellectual property law. In 2010 the Los Angeles Intellectual Property Inn was renamed in his honor as the Paul R. Michel Intellectual Property Inn.

In June of 2019 Judge Michel testified before the Senate Judiciary Committee on the state of patent eligibility in America, Part 1. And most recently he filed an amicus brief supporting Petitioners writ in the Athena Diagnostic v. Mayo Collaborative Service Case.

Joining the panel by phone I am honored to introduce Judge Paul Michel.

JUDGE MICHEL: Good afternoon everyone. I hope that I'm audible.

MS. GRAZIER: Yes, you are. Good afternoon.

JUDGE MICHEL: Let me give an overview briefly of my sense of eligibility law. It seems

to me that the case law on eligibility represents a systemic failure on the part of courts to provide either coherent doctrine with reasonable predictability or practical results that work in the economy, in the board room, in the laboratory.

In fact in the testimony that was referred to earlier, I characterized the state of eligibility law as being chaos. And the next witness was former Director of Capos, who used the word "mess." But whatever characterization one likes to prefer, the law is very unstable, very unpredictable. Unpredictable as to results translates into unreliable in the view of business leaders and venture capitalists.

So if patents are seen as unreliable because their validity and eligibility are unpredictable, that means there's going to be less investment, that means less research and development, less commercialization, that translates into fewer new medicines.

We were ill prepared for the present pandemic. If we are going to avoid the same fate

with the next pandemic, the preparation needs to be going on now. And aside from chaotic events like pandemics, most human diseases still lack cures. So there's a vast amount to be done in the human health arena.

I hate to say this, but I think that the case law on eligibility is the deepest rabbit hole since Lewis Carroll wrote Alice in Wonderland. I've studied all the cases in detail, I've written more than a dozen articles, and filed numerous amicus briefs about eligibility law. And despite that and my 22 years on the Federal Circuit, with a given claim I often cannot tell whether the courts will find it eligible or not eligible. If I can't tell, how are business leaders and venture capitalists supposed to decide?

Now I compliment the patent office for issuing the guidance, particularly the January 2019 guidance that Mr. Salimi explained. Unfortunately, the Federal Circuit has disrespected that guidance and gone its own way. And not only is it following the broadest

interpretations possible of the Mayo/Alice regime, but the Federal Circuit has actually made it worse.

So for example, Mayo triggers the two-step process of analysis if a limitation in a claim recites a law of nature or another one of the exceptions. But now, per the Federal Circuit in the American Axel case, even if the claim does not recite an exception, if a law of nature or other exception is invoked, that was the word the court used, that also triggers the regime.

Now it seems to me that the root of the cause is that the standards are hopeless, they're vague, they're subjective, they're undefined, they're undefinable, they cannot be consistently applied by 8,000 examiners or by 1,000 trial judges or by 18 Federal Circuit judges or by anybody else. And to see how much they're like the old saw about the Supreme Court law on pornography is, we know it when we see it, but we can't explain it, we can't define it.

Well that may work in First Amendment

Law, but Patent Law is part of commerce, part of economics, part of corporate life. And to have hopelessly vague standards in Patent Law it seems to me is totally not acceptable.

Just think of some of the key terms. "Significantly more," how much more is significantly more? "Abstract idea," how abstract is too abstract? "Directed to," what does directed to even mean? So these are the root causes, and actually you can trace the switch back to the Mayo case.

Before Mayo, Section 101 was never a problem, rarely raised. After Mayo, it's practically universally raised in every litigation. And what happened was Mayo changed the trigger from Benson and Fluke, which limited the ineligibility to when the exception itself was all that the claim covered. But Mayo, although a unanimous decision, made a huge silent change by switching drawn only to the exception itself to a limitation rarely recites.

So in brief, that's how we got to the

mess that we're in. And the way to get out of it seems to require legislation because the Supreme Court has turned down I think applications for cert to clarify the Alice/Mayo regime. The Federal Circuit has made it even murkier. So I suggest that the only solution is legislation, perhaps guided by the PTO guidance. So I'll stop there.

MS. GRAZIER: Thank you, very much. I think you keyed up a lot of points.

I'm just going to quickly introduce the other panelists. We have Mr. Steven Caltrider, the Vice President and General Patent Counsel for Eli Lily & Company. And we have Karen Hessler. She is the Assistant General Counsel for the Association for Accessible Medicines. We have Ms. Arti Rai, who is a Law Professor at Duke University School of Law, and the Co-Director of the Center for Innovation Policy. Also joining us is Mr. Corey Salsberg, the Vice President and Global Head of IP Affairs for Novartis. We also have Mr. Hans Sauer. He is the Deputy General

Counsel and Vice President for the Intellectual Property for Bio. Last but not least, joining all the way from Amman, Jordan, we have Ms. Hiba Zarour, who is the Head of Intellectual Property at Hikma Pharmaceuticals.

Welcome back, Director Iancu and welcome panelists. I'm going to turn it over to the Director. Thank you.

MR. IANCU: Well thank you, Nyeemah, once again for the introduction. And thank you to all the panelists.

Thank you, Judge Michel, for teeing up a bunch of the issues we're going to be covering during the panel. I suspect there are a variety of points of view on this issue as with everything in the patent system, there are always multiple points of view. And we'll take this hour to explore all of those.

But, frankly, given the global pandemic, this panel discussion could not be more timely. The experts we have here from around the world, as you have just heard, will mostly address

biomedical COVIC-19 solutions but the theme applies much more broadly to all biopharmaceuticals, life sciences, and cultural, environmental, and so many other technologies.

So I thank you all for taking time to be with us today. Let me get right into it. And let me start with Corey. And, Corey, what is, in your view, the role of patents in spurring innovation, in particular by PhRMA innovation? And while you address that, also address the balance that you see that might be needed to respond to certain evergreening concerns involved.

MR. SALSBERG: Sure. And thank you very much, Director, for the opportunity to be here. I want to really turn this discussion a little bit while answering your question, toward the current pandemic because that's what I think everyone wants to hear about, is on everyone's minds, rightly so.

And really on the medicine front, if you think about what we need to get through this pandemic from the medical side, it's really

innovation and collaboration. Those are the two themes, I think they're pretty uncontroversial that these are a key part of the ingredients there.

And the evidence has really been overwhelming that patents are enabling both of these things. And it's happening at unprecedented levels and at record speed.

Starting with the innovation side, patents have given us, as David Korn referenced earlier in his presentation, we have libraries of millions of novel compounds that are ready to test right now. We have a vast array of tools that help us quickly narrow them down, and we have a host of exciting existing technologies that we're able to repurpose, all of which allow us to start tackling this virus at a very advanced stage compared to any other time in history.

And that's exactly what we're doing, just to give you in the audience some statistics. Thanks to patents in just the last few months alone, we've got over 1500 active clinical trials

looking at COVID treatments. We have 35 unique vaccines in clinical trials, and over 145 different vaccines in pre-clinical studies.

And as these figures really demonstrate, if you think about the vast numbers that I just cited, considering it's only been seven months, a huge part of the COVID innovation story is really the story of building on what came before and improving what came before. And if I had a bumper sticker to reflect that point, it would be that innovation is a process, not a product.

And patents are really what keep that process of innovation going because we have to keep innovating through this pandemic and beyond if we want to solve society's problems.

Our founders recognized this, you know, that improvements have been part of the patent system since the very beginning in 1790, patents on improvements. And what I just want to take another minute or two and give you some real world examples from our portfolio.

And one of my favorites is a product

we're working on now for COVID called Alaras. It's an existing drug, it's already in Phase III studies for COVID, and it's a biological drug that's known as an interleukin in one beta blocker. It's currently approved for periodic fever syndrome and juvenile arthritis, which are rare diseases. But it works in large part by blocking certain processes that cause inflammation.

So the story of this drug is that because of its anti-inflammatory properties, a few years ago we started studying this for cardiovascular disease. We started clinic trials, we invested huge amounts of money and time in testing it for this. We got some very promising results. We even sought FDA approval for cardiovascular use. Unfortunately, after all that investment and work, the FDA actually rejected it, even after our submission rejected our application, deciding that more data was needed.

And that is largely the nature of biopharma R&D. Huge failure rates, huge risks,

which is a big part of why we need patents so when we do have the successes we can kind of offset some of this risk.

But the silver lining to that story is we tested this drug for cardiovascular disease and failed, but during those clinical trials we noticed a significant reduction in the instances of lung cancer among those patients in the cardiovascular trials. It turns out that tumors also thrive on inflammation, so now we're in Phase III trials to study this for cancer. And that's also the nature of biopharma R&D.

And the other silver lining, maybe the gold one for the purposes of COVID is that it turns out the culprit behind many COVIC deaths is also a severe inflammatory response, called a Cytokine Storm.

So that's kind of the story of failure but another innovation that comes along the way in the process that gets you to something else you can use your drug for and how innovation is constantly evolving.

For the progress we've made really, you know, developing Alaras for other indications is what put us in this place now for COVID in this instance.

MR. IANCU: So, Corey, let me just ask, let me just follow up quickly on that. So thank you for those insights, and obviously that's so critically important to be able to take existing technology and do additional research and address other conditions so helpful for humanity.

But if you also get additional patents for these new uses, there are folks who argue, well, you're now moving towards "an evergreening" type of a situation, effectively folks argue lengthening the patent term for that particular formulation. How do you respond to that?

MR. SALSBERG: Sure. So a couple of different answers. One is, as I think David mentioned this, but it's really worth focusing on. What I think people misunderstand a lot, is that when you get a new patent it's for a new invention that's separate from the original invention. So

when it's a new use, like I've been talking about here, a new use for a totally different disease, the patent only covers the use of that chemical or the compound or the substance or the medicine, for that new disease. Which means that others, once the original patent term expires, can enter the market and use the drug for any other disease.

A couple other real I think evidentiary points to make on this. The data is clear that the actual time of market exclusivity on average for a drug is at around between 11 and 13 years, depending on which study you look at. So patent terms are supposed to give you 20 years per invention, but overall, with some very rare exceptions, if you look at what medicines are getting, they are getting far less than the 20 years you're supposed to get for an invention. But these concerns that having more than one patent on a product end up giving you more than what you're supposed to get for a patent term, are just simply not true.

And the last thing I'll say on this is

that, you know, as it is, the statistics show that only about one in five drugs that get marketed will actually earn back the return on investment or earn back the cost that it took to invent the drug in the first place. So 80 percent of them aren't even making a profit. And that is because the average time it takes to invent it, well to develop a new drug from the initial invention of a compound, is 10 to 15 years. So if you were only to rely on that initial patent you would never have enough time in almost all cases to recoup your investment at all that it took to actually invent that drug in the first place. And that's why having different aspects protected is so important.

MR. IANCU: Thank you, Corey. Let me now go to Hiba. By the way, thank you for joining us from Jordan. It must be very late at night for you. But it really shows the international interest both of our issues here and really one of the benefits of this technology is that it allows folks to join us from all over the world. So,

thank you.

Now let me ask you, Hiba, you know, as a representative from a generic pharmaceutical company, to address some of the points that Corey made. But maybe you can start by focusing on the question of does the patent system currently sufficiently strike the appropriate balance between supporting innovation on the one hand and access on the other hand. Is there sufficient balance in the system? And if not, what do you think needs to change?

MS. ZAROUR: Good afternoon everyone. I'm very glad to join you all. Thank you, Under Secretary Iancu. Yes, it is a bit late here so it's almost bedtime. I hope I'm coherent in my answer.

First of all I would like to stress for me innovation will happen. I don't think IT means or equates innovation, innovation will happen. Whether innovation is increased by IP or decreased is debatable. We heard from Ms. Long, from David, from Corey, that it increases innovation.

Other studies say that it decreases innovation.

I subscribe to a study that was made by the Swiss Federal Institute of Intellectual Property. What they found that as the protection increases, they thought that the innovation would increase, but they found that it's not an even relationship, actually it is a bent shaped relationship. So innovation increases with protection up to a limit. They call this the optimum protection level or point. And then with that the innovation starts to decrease. I'm not going to debate what is this optimum level for the U.S. because that needs study. It depends from one country to another, but I think we should strike a balance.

One of the things that I would like to sort of suggest is to have a patent's pool whereby a product patent, the first one with the original will have an exclusivity of 15 years on that one, with the PTE. And then we would have to put down the ancillary or the secondary products because I heard from Dr. Gaby that there are products with

1,000 patents, with 100 patents. If these don't stifle innovation, I don't know what would.

So I would put these in a patent pool and people can certainly license them. To me compulsory license is not fair, but (inaudible) license is a good solution. It was used by Gilead for Remdesevir in India, for example. Gilead gave licenses to Indian companies to produce Remdesevir instead of being subjected to a compulsory license. I think it strikes a good balance.

Maybe patent tools are not very common in pharmaceuticals in the U.S. but there is some sort of a patent tool in the U.S. in the realm of electronics whereby they have licenses with Lenovo, they have licenses with Buges, (phonetic) with Motorola, with several companies where they put their patents and their product licensing agreements between them.

But you might ask now why do we need this? We need this because we are coming to the era of COVIC-19, of gene therapy, of complex issues, complex products that really need a

regulatory, there are so many regulatory happens in two parts. And those hurtles, I would rather have the resources spent on attacking those hurtles to prove to get the end quantity than to fight it out, spend millions of the money at court and have nothing.

In the end I would like to go back to your example of insulin. But from a sad point millions of people take insulin from three companies only. One company has 50 percent of the market, the other two companies have around 40 percent of the world market. American lives are lost. Diabetes Type 2 patients are young patients and they need insulin. They cannot take oral anti-diabetic drugs. Those people who are unfortunate to not have insurance and they were laid off from their jobs, they can't afford insulin, so they die.

So one of the first patents on insulin was donated for one dollar to the University of Toronto after almost 90 years since people are dying because they don't have access to insulin.

One of the factors is the evergreening of patents. I think this is a sad thing to happen in this day and age. So I think there should be more balance towards that. Thank you.

MR. IANCU: Thank you, Hiba. Let me ask a quick follow up before moving on to Karin whom I'll ask the next question.

But on the insulin point, Hiba, is the issue patent related? In other words are there current patents on the insulin that you're talking about? And if so, are those patents representative of old technologies or the new innovations that are part of the current insulin products?

MS. ZAROUR: Of course patents are still on new technologies, but the result is the same. And so if we have a patent pool where people could use those and make, you know, more affordable insulins for those people, those lives would not be lost. So it is some sort of evergreening, it was in the end a case the same insulin, maybe not exactly the same but was taken from dogs, now it's

much better. It's synthetic but the idea is the same, people are dying because of the lack of insulin.

So I'm not advocating by any means that we shouldn't grant patents. I think I side with the grant of patents, I think what the FDA and the USPTO are doing is great. But I think we need another angel. We need some sort of voluntary licensing to compensate for compulsory licensing. I don't believe in compulsory licensing, but also the facts that go with the gene therapies, with everything that we are coming to with all the therapy we have, certainly needs more tipping balance towards the public. Thank you.

MR. IANCU: Thank you, Hiba. Let me turn over -- by the way, can you all still hear me?

MS. GRAZIER: I can hear you now.

MR. IANCU: Okay. So Karin, you're the representative for the Association for Accessible Medicines. Let me ask you about balance. How do you see the balances between innovation and access

to medicines, both of which are critically important obviously. So we do have the right balance currently? And if not, what would you do different? Thanks.

MS. HESSLER: Thank you for the question, Director Iancu, and let me just reiterate what my other panelist said. It's such an honor to be here on this panel.

In terms of balance, I do think it's critically important to have balance in this system. And that does involve significant innovation. And just to reiterate something that Corey said, you know, I don't think we would be in the position we are today on COVID-19 with thousands of compounds in late stage clinical trials, going to a vaccine in nine months, which is really unheard of, if we didn't have significant innovation, and that's been innovation.

So innovation is very important. And even though, you know, I represent the generic and biosimilar companies, we have a number of

companies do both generic products as well as innovative products.

I think in terms of where the balance may at times get skewed touches on an issue that Gaby and David Korn touched on earlier. There are some situations where there are a significant number of patents, and I think many of those patents may well be valid on a given product, Gaby had mentioned a situation with 1,000 patents. And I think in that situation, again recognizing quite a few of those patents may be invalid, that definitely does present a concern in terms of that if you just looked at it from a pragmatic perspective, how do you defeat that many patents in terms of designer ideas, in terms of invalidity challenges?

And I think there have been some solutions that have been put forth in Congress that contemplate things like caps on the number of patents that can be inserted in the biologics patent dance, which I think is a somewhat interesting proposal. It obviously entirely

depends on how it's implemented and how it would be workable. But that's something where, you know, obviously a brand company needs to prevail only on a single patent, potentially get an injunction. And that's something that I think from, you know, an efficiency perspective, district courts have been putting in place where you select your best pin patent or even a larger number of patents and proceed on those patents.

So I think those types of solutions could help from an efficiency perspective. And so I think that's something, you know, we try to think of balanced solutions where we don't want to severely discourage innovation because as I said earlier, I don't think we would be in the position that we're in with this pandemic but for having platforms that have been developed over time and significant investment and innovation. And so I think that continues to be something that's critical and that we have to encourage.

But, you know, I think what we would like to see is the balance just, you know, we'd

like to see in this situation that Gaby talked about where there are 1,000 patents. Just some ability for us to really meaningfully challenge those patents.

MR. IANCU: And there's obviously litigation surrounding some of these patents and various products. Do you have a view as to how that litigation is generally going? Is it increasingly more difficult, as some argue, to settle those cases earlier in the process, and why would that be?

MS. HESSLER: Yes, Director Iancu, we believe it's quite a bit more difficult to settle. And what we're seeing right now is that states are increasingly attempting to regulate per state statutes the settlement of patent litigation. And this is a very interesting topic because it's actually one that the Supreme Court spoke to seven years ago in the FTC v. Actavis case.

And in the FTC v. Actavis case, the Supreme Court said that the anti-trust rule of reason should apply to assessing settlements.

That's a more fulsome analysis than other anti-trust tests like the Per Se Test or the Quick Look Test.

California and several other states have begun imposing the anti-trust presumption that the Supreme Court rejected in Actavis when it settled on a rule of reason, and I think that creates substantial difficult for both generic and brand companies to sell patent cases when they're dealing with a patchwork of inconsistent regulations.

One other thing of note that I might highlight in terms of why there's a disincentive to settle, for example the California legislation imposes a $20 million minimum penalty per person so not a party penalty, a person penalty, for settlements that are ultimately being violative of the provisions. And so that's something when we look at it from a generic perspective, about 50 percent of cases settle. And we need to be able to, you know, have that tool available to us on reasonable terms. I mean obviously no one is

looking to do, you know, any sort of, you know, alleged pay for delay deal, and I think we can uniformly agree to that on the panel, but just a reasonable, legitimate settlement agreement. And that's being disincentivized because of the severe penalties and also because we're dealing with disparate regulations across state lines and we just don't really know what the ultimate law.

And there are certain terms in settlements, for example, an exclusive license, which is contemplated under Section 261 of the Patent Act where the California and other statutes are calling those firms which again are expressly provided for under Federal law into question. So it's something that's just giving us a number of concerns in terms of how cases can be settled.

And I think one district court recently recognized the substantial value of settlement. There's some cases where settlements expedite generic and biosimilar access by more than a decade and that would not otherwise be achievable in litigation when you're dealing with for example

an estate of 1,000 patents. This is the one pro-competitive way we have to accelerate access on the market and we think it's an important tool and we want to see, you know, something where that is recognized and that we don't have any hindrances to patent settlement on reasonable terms.

MR. IANCU: Okay. Great. Thank you, Karin. Before I go to Hans Sauer, let me stay on that last point for just briefly, and maybe ask Corey or anybody else on the panel. Corey, from the perspective of, you know, on the part of this, or maybe even Steve from Eli Lilly. How do you see this point about settlements that Karin just addressed?

MR. CALTRIDER: I'll just briefly chime in on that. I mean I agree. I mean I think it's very, very important to be able to settle these cases. There are various reasons why you might want to do that on both sides of the business. And I should also point out that one of our biggest divisions is Sandoz, one of the biggest

generics biosimilar companies in the world. So we understand both sides of the business.

And I think the biggest problem with California's law, frankly is that it's a state law governing the settlement of patent disputes, which are Federal, and of course the nature of settling patent disputes is something that applies to the whole country. So if we were to have 50 different standards for how you can and can't settle a patent case, I think that's highly problematic.

And I also think the Actavis decision pretty much got it right. There are certain things that I think, you know, we can agree are things that shouldn't be done in patent settlements. I think most companies don't do that anymore. If you look at even FTC statistics. And I think the problem is largely solved and the ability to settle is pro-competitive in most cases. So I think we really need to keep all these in mind as we hopefully eventually come up with one set of standards which we would hope would be based on the Actavis standard.

MR. IANCU: Okay. Great. There seems interestingly enough to be agreements, at least conceptually on this issue, from across the spectrum. Sometimes we have the law of learning the consequences here that at least of this result.

Let me turn to Hans Sauer. And, Hans, coming from the Biotechnology Innovation Organization, can you speak a little bit about the role of patents in promoting not just innovation, but also collaboration in life sciences. Corey addressed a little bit at the beginning, the collaboration that's going on now in the industry surrounding COVID. But do you have a bigger perspective, being the head of this large organization with many different entities? What do you see in terms of collaboration, and how is IP helping on that front?

MR. SAUER: Collaboration I think, you know, from bio perspective, and bio being mainly an organization of smaller businesses, right? So I think it's worth reminding everyone and our

listeners that the majority of biotech companies in this country are small. And they're pre-revenue companies that despite their small size hold 70 percent or more of the drug development pipeline generally.

While that is true I think during normal times, it is largely true during times of COVID, and I want to like put my remarks in the context of COVID because I think this is a very interesting setting within which we can discuss pre- existing narratives about access the role of IP innovation and the like.

So if we look at like I think the level of public discourse that we have right now, it is unfolding in a very unusual time. Like mainstream media, for the first time that I can remember, like reports, like Wiki on Page 1, about how clinical trial enrollment is going, how projected end points of clinical trials will be defined. Large segments of the U.S. population, actually the world's population, for the first time experience what it's like to wait for a drug to

treat or prevent a condition for which there is currently no solution.

So this is, I think, new in public discourse. It makes it as much a social phenomenon as it is a commercial phenomenon and a question of science policy.

So in that setting I can say that collaboration and licensing and the transfer of technology between companies has always been a very important characteristic of the biotech value chain. Most of our small member companies that hold early stage technology in that work on validating technology crossing the value of death, adding value to development programs, providing proof of concepts, those companies may never have expectations of becoming the next AmGen or the next Genentech. They for the most part expect to pass on their technology at some point of maturity to another company that is better positioned to advance the product further up the value chain.

A small company that provides proof of concept may not be the best company to conduct

clinical trials. The company that may be well positioned to conduct clinical trials may not be the best company to build a global supply chain to both manufacture and distribution and get a compound across the finish line.

So collaboration I think has always been part, and the licensing it entails, has always been part of the biotech value chain and the characteristic of this industry.

For the most part we believe it's worked quite well in the United States. When Europe used to be the leading region for creation of new drugs, the United States has certainly taken on a leadership role over the last decade. The United States originated more original new molecules and new treatments than the rest of the world combined.

We also know that new drugs and new treatments tend to become available to United States patients often earlier than they become available to patients in Europe by a year or two, and several years earlier than compounds and new

drugs become available to patients in other parts of the world. So new drugs tend to get launched here first.

So these too are patient benefits that rely on licensing. Licensing itself relies on IP, licensing presupposes a level of collaboration between entities, and it has benefits that are not just commercial but these are also benefits that are real life for patients.

Howard Varmus I think put it really well in 1995, then an IH Director of Armis said "Before you can worry about access to and pricing a new drug, you must first have one."

And I think that bring us to, I think the focus of the panel. For COVID I do believe it's fair to say that the industry, in collaboration with publicly funded partners, has never moved as quickly with as much as it has this time.

Corey gave you some numbers earlier but I do want to reiterate that of the more than 700 compounds that we're tracking at Bio, who are in

development for COVID, like 270 of which are in clinical development, 180 of which are vaccines. Of all these compounds and these development programs, when you look at treatments, 90 percent are either repurposed or redirected in development towards COVID. These are pre- existing compounds that have been under study for other reasons. 40 percent of anti-viral drugs are not new but they're re-directed and they're repurposed.

So we are building, I think not just on a foundation of pre-existing technology that has benefitted from the availability of patent protection, but we're also seeing that the companies that are best positioned to work together on advancing COVID solutions are very obviously finding each other and are collaborating towards solutions, sharing data.

It's my conviction that companies are able to draw on their existing experience and existing industry practices of collaboration and licensing because they know the rules under which these collaborations are structured and because

they can rely on intellectual property protections in ways that they're accustomed to.

If we had to invent new ways of collaborating, we wouldn't be off to the running start that we have been through so far.

MR. IANCU: Let me touch just briefly, Hans, on that point because especially now during the pandemic, some argue that it really is not the patent system or the patent protection that these companies have that's enabled this. The incentives to cure the pandemic, the incentives to create enough vaccines for seven billion people around the world, are so large from many other sources, obviously financial, but most importantly just humanitarian, political, and so many other reasons, that you really, you know, the argument goes you could do this without any patents, and in fact it could be that having patents can inhibit distribution and access and all that. What would be your response to that argument?

MR. SAUER: Well my response to that would be that we see really no indication that

that's the case. If I can start first with concerns, understandably, that intellectual property protection may somehow be in the way or be an obstacle. I think this argumentation comes mainly out of attempts to tie current COVID practices to current COVID prices to pre-existing narratives that in some instances are more than decades old.

But COVID is different. Of course it's true that there are huge incentives, like for all actors, including industry to engage in the search for solutions to work really fast. But I think it would be folly to think that companies are engaging in COVID research only out of the expectation that they would gain more IP rights or that they could leverage in the future.

What we're hearing from our companies is however, the availability of patent protection, and especially the need to leverage and maintain protection of their pre-existing technology, manufacturing technology, which would need to be shared between competent manufacturers, that it is

important in the way they structure their partnerships and the orderly dissemination of technology, that companies can rely on IP because a lot of the IP that's at stake, once we've beat this crisis, has applications that have multiple uses that is going to be very relevant in the future for competition in other spaces.

So I do think that despite the urgency of the COVID crisis, patents haven't lost their importance.

The final thing I would say because it is often brought up. It is true that public funders and governments are spending a lot of money to spur the development of COVID solutions, and that private companies, in collaboration with publicly funded partners, have received a lot of support and government support and government funding, to ramp up manufacturing, to boot manufacturing capacity. This, to my mind it's a very rational and very good aspect, a necessary aspect of the COVID response because as I'm being told by our corporate members, companies find it

very hard to use equity capital to build up manufacturing capacity for compounds that have not yet been approved, and vaccines for which we don't yet know whether they will work.

So an unusual level of public/private coordination. And the stepping in of government by assuming part of the risk I think is a very healthy, very instructive and very necessary part. It doesn't diminish the importance of industry contribution to the effort, it is really a societal effort and patents play a role in this just like what Corey said earlier, that they've enabled us to have a foundation of compounds and technology which we can rapidly deploy.

I think patents, rather than inhibit, help grease the wheels to some extent in the collaborations and in the structuring of agreements that is necessary to collaborate as we respond to this crisis.

MR. IANCU: Thank you, Hans. Let me pick up on that last point and turn over to Steve Caltrider who, Steve, you're in the unique

position of not only being Head Patent Counsel at Eli Lilly, but also happen to be a member of the Patent Public Advisory Committee, the PPAC, at the USPTO.

And since the USPTO is the agency in the United States that grants those patents that Hans just talked about, let me ask you, what do you see as the USPTO's role in supporting innovation in life sciences and not just with respect to patents, but IP in general?

MR. CALTRIDER: Thank you, Andrei. Certainly the USPTO has an essential role. I'll step back and really compliment the Office first and foremost, back in March when things were getting locked down in the U.S. and there was a great deal of uncertainty on how to carry out business, the USPTO remained open for business. And that was important because innovation needed to occur not only for COVID, but innovation needed to occur for all the un-pressed medical needs. And the fact that the USPTO remained open for business really allowed the patent system to

continue and the model to perpetuate.

And then more specifically the USPTO has been a tremendous leader in the response to COVID domestically and internationally. Reference was made earlier to the COVID-19 Response Center, the prioritized examination, the waiver and flexibility around deadlines and fees. Small things like wet signatures on formal documents. Internationally the USPTO was a leader in the discussions with the EPO and the JPO, the IP5 offices, Wipro, each leading to maintain the continuity of the system to continue to be available to innovators. And really to provide the confidence the industry needed to continue to make the investment in innovation and patents.

Patents for Partnership was also mentioned earlier, that provided a voluntary form to exchange patents that are directed to the COVID treatment particularly. So all of that contributed to keeping innovation open, keeping collaboration active and available to innovators to work together. Because the problem of COVID-19

in terms of the urgent issue is just as Corey and Hans have mentioned, it's having the confidence the patent system will be available to recoup the investment at some point in time.

But more importantly, knowing the rules and the predictability and the reliability of that patent structure, patent system, allowed us to put in place collaborations at unprecedented level and enabled speed at an unprecedented level. And so it was really the grease that kept the machinery working, and the USPTO was right in the middle of all of it.

So the collaboration and leadership of the USPTO has really made a difference in the treatment and eventual treatment of COVID-19.

MR. IANCU: Thank you, Steve. Let me go back and pick up on a point that Hiba mentioned earlier in the panel discussion where she talked about the concept of potential patent pools when it comes to creating paths perhaps to innovative drugs and the like.

Do you have thoughts about that? I mean

obviously from a company with significant ID assets.

MR. CALTRIDER: Sure. Sure. You know, I'm open minded in terms of patent pools may be applicable in certain circumstances. A medicines patents pool has been a positive contributor in certain areas, particularly to meet unmet medical needs. But it's also you can't throw the baby out with the bathwater.

There are a number of examples, and Corey mentioned one of them today of second uses, third uses, fourth uses of drugs. And those are vitally important. In fact I think we should be having conversations how to enhance the incentive because of skinny labeling and the dynamic that David Korn mentioned, there are considerable limitations on the value of those to support innovation today where I think it should be supported.

But oftentimes the very first use of a compound is not necessarily its best use ultimately. As people get into the clinic and

understand how the drug works and what its biological effects are. And if you don't have a very, very healthy system to support the improvements that need to occur from the time a product is launched through its entire life cycle, you are really leaving innovation on the table and patients are losing out.

And so while I think there's a role for patent pools in certain circumstances, I think you have to be very, very careful not to provide disincentives to study compounds much more robustly when they're available and on the market so that all the innovation and all the uses and all the patients receive the drug to meet their unmet medical needs. Because it's not necessarily the first use that's ultimately the most important. Gaby had several examples and Corey mentioned one earlier today so I won't repeat those.

MR. IANCU: Okay, great. Let me now turn to -- thanks, Steve. Let me turn to Arti Rai, who, Arti, as a Professor you have recently

published a paper that was either pachient (phonetic) or timely. It was titled Knowledge Transfer for Large Scale Vaccine Manufacturing.

So picking up on that, let me ask you, what role do you see for patents playing in the transfer of knowledge so to enable any needed incentivize, as we've heard several speakers today, vaccine manufacturing and distribution.

MS. RAI: So I do think that patents have likely stimulated some of the knowledge sharing that's going on with respect to antibodies in particular, so we'll be talking more about this tomorrow presumably, or at least others will.

With respect to the business review letter at DOJ and FTC put out for a collaboration between Eli Lilly, AmGen, Accelera, Astrogenifin, and a bunch of others, for exchange of manufacturing process information to scale up manufacturing of monoclonal antibodies at a scale that we have never seen before because in addition to vaccines which was the focus of our paper, monoclonal antibodies are also an area where we'll

probably need scale like we've never seen it before. And I have little doubt that the backstop of patents helps with exchange of knowhow and the like, specifically in the context of that business review letter technical knowhow is being exchanged among these firms. I think for purposes of that COVID-19 project that's a very good thing, and I suspect that from the standpoint of these companies they wouldn't do it were it not for the patents.

So I'm a big fan of patents in general in innovation. I will say that the one challenge that I see, and I will now leave the COVID-19 space because I can't say that patents have been anything other than a good thing in COVIC- 19. I think they've been an amazing thing in COVID-19.

The one challenge I see, and I agree with everything Judge Michel said about diagnostics, I think Section 101 is a mess and needs to be fixed. Whether Congress will come up with the magic language I don't know. I think that Helsinn v. Teva may or may not have done

that.

And I think for monoclonal drugs in general are okay. Now whether we say that 13 years is what we're seeing. I've seen a more recent study that suggests 14.4 years. But, you know, in the whole context of things that's a study out of Harvard in clinical pharmacology by Joshua Krieger. We're trying to replicate that study by the way, so we'll see about some monoclonals. But I don't have any big complaint, any complaints at all really about small molecules and what's going on there.

I do think in biologics we have some concerns. So those 13, 14 year figures are coming from small molecules. In biologics we're seeing more like 21, 22 years. 29 biologics have been approved by the FDA, only about two-thirds of them are currently on the market. So when Dr. Longsworth talked about the thousands of patents, those are basically mostly in the biologic context.

And I'm currently doing a study looking

at what patents are being asserted in living patients, biologics litigation. Of the 650 patents that we have looked at asserted in biologics litigation, 260 are manufacturing process patents filed more than a year after the FDA approval. So these are patents that under Helsinn, at least there may be some reason to believe there's some challenges there. And I'm actually proposing in this forthcoming article, Director Iancu, that once an FDA approval has taken place, any subsequent manufacturing process patent that's filed more than a year after the FDA approval be looked at, or has been granted after the FDA approval, be looked at again. Before it will be looked at if it's still in process, be looked at for the first time.

So I'm happy to send that article to folks when it's ready. But I think that for under health, and I'm not sure how you could say that a manufacturing process patent that was filed more than a year after a drug is already on the market has to be infringed in order for a biobetter even

to come on the market, not just a biosimilar, but a biobetter.

And so those are the questions that I have. I think that method of use patents, great. You know, I have no quarrel with method of use patents. I think those are terrific. The quarrel I have is with the subset of so-called secondary patents that I think would not pass the novelty bar, the level on the novelty bar.

MR. IANCU: Well I look forward to reading the study and the proposal. Would it require new legislation?

MS. RAI: No. No new legislation required. In fact, as you might know, Director Iancu, the FDA's supposed to help, if it can, with respect to examination. And you can request their help if you like. So that's the provision that we'll cite to, there's an existing provision in the FDA statute that requires them to help you if you ask for their help.

MR. IANCU: Okay. Great. Thank you. Well as many folks know, we do work closely with

the FDA on a variety of issues and obviously have been in close contact with them for the past year surrounding the current situation.

But given that we are now towards the end or at the end of the scheduled hour, let me end perhaps where we began. And let me just first see, Judge Michel, you're still there?

JUDGE MICHEL: I am. Can you hear me?

MR. IANCU: I can. So you got the first word and you'll get the last word I think. So let me stick to Section 101 which remarkably did not come up a lot during the panel discussion here today even though it is featured so prominently on almost all patent issues nowadays.

You know, there are arguments that the law is just fine and in fact if you make it easier to obtain more patents in the life sciences area through a legislative fix or otherwise, surrounding patentable subject matter, some would argue that that might throw the system out of balance and in fact make it perhaps more difficult for labs and academics and the like to do

additional research and create more innovation, more life sciences products in the future.

What's your view about that, in particular if you could focus on the research question in the lab?

JUDGE MICHEL: Well number one, I think that a Section 101 eligibility fix should certainly include a broad research exemption to protect researchers.

But with respect to the net effect of changing the 101 as the law now stands, my view is that if Section 103 and 112 are properly applied, both in the PTO and in the courts, patents that shouldn't stand will go down. But it will go down under a rigorous analysis. The big problem with Section 101 case law as it exists now is the analysis is not rigorous, it's not focused on prior art, it's too subjective. District judges are guessing based on their gut reaction when they read a claim, and that's no way to run a legal system.

So I'm for clarifying and also

broadening eligibility, but along with that we need to rigorously enforce the conditions of patentability in the other sections.

MR. IANCU: Well thank you very much, Judge Michel, and thank you to all of our panelists for this really truly amazing and informative discussion.

Thank you all for taking the time, and given that we're a couple minutes over time, I will end this panel discussion here and turn it back to Nyeemah. Thank you.

MS. GRAZIER: Thank you. And thank you, Director. And thank you for making the patent section a great success. As the Director mentioned, we are at the end of our time. We will take a 10 minute break. I would like to remind everyone if anyone has questions you can always send it to Lifesciences@USPTO.gov.

When you return you will be accompanied by Mr. Brian Yeh, who is my colleague, and I think the gears will shift over to copyrights. So we have about seven minutes left, if you could please

return by 3:50 that would be great. Thank you.

(Recess)

MR. YEH: I'm taking over the MC duties from my colleague, Nyeemah Grazier, who set the bar quite high by doing such a great job by smoothly running the previous sessions.

So I hope you were able to get some caffeine to prepare for the stretch we're on of this afternoon's program.

We now shift away from patents to talk about copyrights. We will begin with three short presentations that provide an overview of copyrights in the life sciences and how it encourages innovation. Followed by a panel discussion on enhancing access to scientific research content.

My colleague, Susan Allen, will be introducing our distinguished presenters for this session and then moderating the panel discussion. Like myself, Susan is also a copyright attorney in our Office of Policy and International Affairs. She has over 15 years' experience as an

intellectual property attorney and is particularly interested in issues involving copyright and technology, including open access and public access.

Before I turn things over to Susan, I want to remind you all to please feel free to submit any questions for our presenters by email to Lifesciences@USPTO.gov, and we will try to address those during the Q&A portion of the panel discussion.

And now, please welcome Susan Allen to the program.

MS. ALLEN: Wonderful. Okay, good. So it's an honor to be here today and I'm glad you can all hear me now. I want to first introduce the first presenter, and I'll introducer each presenter before their presentation.

It's Bhamati Viswanathan, and she will provide an overview of copyright concepts in the life sciences, the transition from the previous discussion on patents, and set the stage for the discussion we'll have later on. Bhamati is an

Affiliate Professor at Emerson College in Massachusetts and the author of "Cultivating Copyright: How Creators in Creative Industries can Harness Intellectual Properties to Survive the Digital Age."

So welcome, Bhamati, and I'll turn it over to you now.

MS. VISWANATHAN: Thanks, Susan, and thank you, Brian, for having me, I so much appreciate it.

This is a wonderful conference and I'm sure you are all are saying okay, what is copyright and how is it relevant to the life sciences? And I'm here to key us up with our wonderful panel.

It's of course relevant because it in its way promotes innovation just like patents do. And I want to talk about copyright a little bit as a bit of a refresher for some of you and for some of you who are newer to the idea of copyright at all, I'll give you a very quick, quick overview of it. And then I want to talk about the balancing

act that copyright, or balancing acts actually that copyright entails. And then I will touch lightly on the kinds of assets that we're talking about because my distinguished colleague, Mike Carroll is going to address that in greater detail. So I'm going to go kind of fast as copyright's a big ticket issue.

So what is copyright? Copyright is a form of legal protection provided to the author of original work that's Authorship 6, in any tangible medium of expression.

So we all know copyrightable material to be things like books and music and artwork and sodas and so forth, but it also includes software, databases, and compilation.

What's required is that it's an original work of authorship that's a pretty low modicum of creativity that we have. There's no requirement that it be novel or has aesthetic merit. And it must be fixed in a tangible medium of expression. That includes things like dot data and compilations and software and so forth if they

meet those standards.

Works that are not protected or works are not fixed, works such as the government and so forth. We have a dichotomy called the idea expression dichotomy which says that you can copyright an expression, but you cannot create the idea. So of course we want ideas to be in general circulation.

Copyright is really a bundle of exclusive rights. It controls certain uses for the copyright holder and it authorizes things like licensing. So it's a pattern of rights really, it's not one specific rights. And they're secured upon fixation, meaning the moment that you create a work, it's fixed. There's no publication requirement, registration formality is not actually required although if you register you get certain rights, such as the right to file suit in Federal Court, the right to seek statutory damages and attorneys' fees and so forth.

Registration is in fact administered by the U.S. Copyright Office, which is part of the

Library of Congress. And its relative inexpensive, so for your patent attorney it's a lot cheaper and unlike patent rights, because of TRPS, it is worldwide, it's universal in its scope.

And a very small percentage of copyrights are actually refused. So again, unlike patents, its relative easily secured. The term of copyrights is also a lot longer than patent's term, it's the life of an author plus seven years after an author's death, for a natural person.

And the ownership of copyrights vest initially in the author, although many times it's transferred over in an act of writing. And under the Work for Hire Doctrine the employer is the owner of the copyright. More works are created within that scope of employment. So it can be transferred, it can be owned under a Work for Hire by the employer. But otherwise the default is that it goes to the author.

Infringement of copyrights basically means that there's a violation of any of these

exclusive rights or many of these exclusive rights to copyright. And there's different forms of liability which I will not go into, direct or secondary liability, and those of course are morass, as they always are. And there are some limitations and there are some exceptions. Chief among them primarily are the First Sale Doctrine, and certain exceptions for library, archives, teaching, important purposes. Certain statutory licenses, and for reproduction for those with disabilities.

There are a host of remedies in copyright law, as there are in patent law. Actual damages, statutory damages, injunctions, certain costs, and so on.

That is your two-minute overview of copyright law. And I'm always happy to talk more about it at depth.

So what is balancing act? The balancing act, and I called them several acts because they are several. One is really between and among the stakeholders of copyrights. So all the different

parties that in fact, and because we're talking about promoting innovation of course, we have to have incentives for people to invest in copyrightable works. And often their interests do not necessarily align.

Another of course is while we believe in ownership for the rights of copyright holders to get the returns that they are so richly deserving by taking the risk of making copyrightable work, we also want to have access. And access to a variety of users, including people who will take those copyrighted works and create from them. So there's always a balancing of ownership and access concern.

And in order to sort of promote innovation in the life sciences in things like scientific publishing and research, we do want to have the right balance that's struck that is really the way to sort of universally promote innovation.

So, you know, what my colleagues are going to be talking about are the different

stakeholders' rights. Mark Seeley, my distinguished colleague, will be talking about some of the concerns that publishers have when they invest in copyrightable work. And my distinguished colleague, equally distinguished colleague, Mike Carroll, will be talking about some of the assets concerns, you know, how do we sort of state that we want to make works available to people.

As we know in the scientific community, there is a strong norm of sharing and helping each other grow and collaborate together and do the kind of iterative collaborative work that is so important in scientific research and discovery, access is an important part of that. At the same time we have to honor the rights of copyright holders and respect the fact that those who invest in copyright are taking on significant risks and making significant investments, not just in creating the works, but making them available, making them searchable, making them responsibly disseminating them to people, making sure that

peer review is part of the process.

So all of these things compete against each other, of course, in this wonderful marketplace of ideas. And what's most important to understand that in scientific research and publishing we in the copyright world do care about the dissemination of knowledge. We're not just trying to keep it to ourselves because we're greedy or because we feel that it should be propertized. No, part of the process here is making sure that people who do the copyrighted work get the rights that they deserve, get the reputational benefits that they deserve, have their work peer reviewed and taken seriously, and so that it flows into the scientific community.

And that uses six and a half of my minutes. I promised these guys I'd be on time, and I promise you that my colleagues will take this up in a richer and more fulfilling way. But I hope you have a little idea of how important copyright is in this entire process. Thanks.

MS. ALLEN: Well thank you, Bhamati.

And so now you set the bar for courts to think overviews of copyright. Well done.

We're turning next to Professor Michael Carroll, who will present on copyright and open access. Professor Carroll is not only one of the foremost experts on this topic, but he is also a Professor of Law and Director at the Program of Information Justice and Intellectual Property at American University's Washington College of Law. He's the Director of the Public Library of Science, and the Director of Creative Commons.

With that, Professor Carroll.

PROFESSOR CARROLL: That's not my slides.

MS. ALLEN: Could we fast forward and see if those slides are there, and if not we will go to Mark, and troubleshoot while Mark is speaking.

Okay. Mark could we pivot and, Mark, you could present quickly on the role of publishers on licensing non- public content in the life sciences. And we will quickly see what we

can do to get Mike's slides on board. If you don't mind.

MR. SEELEY: And I should probably unmute myself. So it looks like we lost Susan.

I can introduce myself. I was the General Counsel for the Elsevier Science Publishing business for more than 20 years. I retired a couple years ago, I have been teaching at Suffolk University and also doing a bit of consulting.

So the notion of publishing contributions in life sciences innovation is very dear to my heart. The way that I like to think about this issue is that we are living in incredibly interesting times. We're living in this influence of content and data and technology. This can be seen in the amazing power of supercomputing that analyze and categorize billions of data points as in mapping human Geno. Or the ability of new AI applications to identify new relevant and unexpected analytical insights and disparate content.

But I would argue that there are still some constants, informational content, particularly scientific research content, is most valuable, in my view, when it is organized, standardized, updated, and indexed. We can go to the next slide.

So scholarly communication is largely supported through scholarly journals. And the journal article has become a well-organized vehicle for conveying research information. Articles have an almost universal structure, the abstract followed by a description of research methods employed in the research activity. The paper and discussion itself, including some of the charts, graphs, and other data, and of course the extensive references list.

Now publishers in journals have evolved this structure, and although there are some authors chafe sometimes over the confines of that structure, researchers themselves highly value the organization of this information as it improves their efficiency in reviewing the large number of

articles that might be relevant in their projects.

Publishers have in recent decades moved this content online by retrodigitizing earlier journal issues and incorporating such online innovations as reference leaking and through cross-ref and standards in terminology, representations of chemical structures, and the display of formulas. The illustration here is an example of the kinds of standards which eventually get apportioned to the publishing process.

Although authors contribute articles to journals on a royalty free basis, unlike in book publishing, as part of their general work at universities, research institutions or research intensive industries, such as realized in the life sciences, the cost for these innovations and for managing large number, some three million articles are published every year in science, and a lot more actually if you included more of the humanities. And this is being done and organized by more than 2,000 publishers.

It is a submission process also which is

dealing with many millions more of articles. So if you think about that, that's a huge number of articles and processes, including a review process, to manage and coordinate and maintain.

Copyright is fundamental to the business of journal publishing as the vast majority of articles are still published under a subscription model. Although author pays, or under institution pays, all can access, and Michael will address this in his presentation. The economy supporting journal publishing is likely going to be a mixed one or sometime into the future.

In terms of government actions here, in my view the positive thing would be to ensure that research funding also includes publication costs, as is true in many European countries. This would enable a more sustainable real future for government funded research. We can go to the next slide now.

We know or we hear that data is the new currency and life sciences innovation and the urgency of COVID-19 that we've already heard a lot

about today, certainly demand that further work be done to enable the computational research and published articles. As in datamining this is referred to. And on research data itself. The data that represents the raw research results before that data is analyzed, reviewed, and shortened to fit into a journal article. Patents, by the way, are also sources for datamining.

Publishers have established tools for GDM processes. Here the SGM Association with the 2003 declaration supporting non-commercial GDM, which is supported by more than 20 publishers, representing all the major houses, and by offering collective licensing, options to cross-ref, and the copyright clearance center for TDM applications.

These programs offer a normalization methodologies that provide a more consistent database in which to apply those computational queries.

The ULA now permits non-commercial TDM in any event as a copyright exception. Although

there are more limits with respect to commercial activities. Publishers supported the initiative organized by GasCAm Association over the summer, an open COVID-19 content for use by researchers. And as of the end of this summer, we've seen as much as 150 million downloads of articles.

There are also publishers that are particularly active in the life sciences space, including my former employer Elsevier, but also companies like Wolters Kluwer for using these kinds of analytical technologies to support drug development and discovery.

These publishers are providing data about existing drugs but also about potential reactions, relying on chemical structure information and the literature. These products combine published content, patents, with tactical mining capabilities and analytics. And technology companies themselves, such as IBM, through its watching program are also actively innovating in this space. Recently they announced Relno RSN for example.

These new tools are supporting the drug pipeline by focusing on such data as adverse events, reactive data, and the like. And they're intended to replace actual trials of potential drugs that might ultimately be ineffective or even harmful.

What is probably obvious in this discussion is the complexity of research publishing in the life sciences space. Especially given the mix of public data and public emergency, such as COVID with private data and commercial motivations developing new solutions and therapeutics.

One aspect of this complexity is that commercial players traditionally have not always been motivated to publish all of their data, including if you think about data on negative results, for example, which can be extremely helpful and useful, but which are not always actively published.

Even active scholarly researchers in the academic space are sometimes reluctant to publish

this data, and society as a whole really needs to have more data made more public.

The Elsevier Publishing Association again has launched a major initiative this year by launching the research data here and establishing collaborative initiatives with organizations such as the Research Data Alliance. The collaboration with RDA involves new standards on data availability, linking from publication to repositories and working on principles of managing data repositories.

In my view we're beginning to see here the expansion of the traditional publisher role from publishing a journal article to the standardizing capabilities learned from that publishing process. Two things like data curation, building on earlier experiments in a commercial or a scholar such as fixed share, mandala, articles type, all which deals with methods.

Government support for research data management projects would be extremely helpful.

And I think here it would be important to go beyond merely mandating data posting requirements to actually providing direct funding for such research projects.

And with that I think I will stop here. Thank you.

MS. ALLEN: Thank you so much, Mark, I really appreciate it. And, yes, in particular I did not introduce you but just mentioned, you know, we are very pleased to have you on board given, you know, your many years of experience as general counsel for Elsevier and knowledge, deep, deep knowledge of the life sciences industry and work with SPM as well as your current consultant position with us. We are very pleased to have you, and thank you so much for that overview.

I understand that the slides now for Professor Michael Carroll are ready to go, so I'll turn it over to Mike again, and we will see if the slides load. One moment. Mike, thank you for your patients here.

PROFESSOR CARROLL: Thanks. And while

we're doing this let me thank the Department of Justice and the Patent and Trademark Office for hosting us, and glad to see so many familiar names in the participant list. I hope everyone out there is doing well and keeping safe.

Okay. Here we go. Hi, everyone. So in a way the order of Mark's and my presentation worked out pretty well I think because he really talked about the content of the information that we're talking about, that is an important part of the innovation life cycle and the evolution from scientists exchanging substantive letters to, as he says, the structured journal article that tells a story about the research and its output and the role of data in that.

So here's the algorithm. I'm going to talk a little bit more directly about the role of copyright in the distribution of those research outputs and the different modes of distribution within the copyright system.

So here's the traditional algorithm, or here's the challenge that I'm trying to address

when I talk about open access. The internet increases the ability to rapidly disseminate research outputs worldwide. However, copyright applies to those research outputs, even the structures of datasets, although the raw data would be considered facts and not subject to copyright.

Those copyrights are given to researchers who then traditionally under the subscription model transfer those rights to the publisher. And in an online environment, you can't read this, but this is basically saying you're not signed in, you cannot actually access this article. So in effect copyright is giving the effect of access denied.

And the open access movement essentially says wait a minute, this doesn't make sense. We have this internet thing now, let's use it. But to Mark's point, we want to do it in a way that fits with the economics of internet publication, open does not mean free.

The origins of the open access movement

are old, with the Budapest open access initiative which sort of set forth a kind of call to action. Here we have this internet, let's figure out how to realign the publishing system to take advantage of worldwide dissemination.

And within that definition, open has two aspects. It means you can freely access the content on the internet, but also copyrights governance of the terms of use need to be changed through licensing so that you can give the downstream user the right to reuse and repurpose the content. And so the call is as long as you're giving proper attribution you should have those rights, although some publishers also add a limitation on non-commercial use.

And the reason for open access and the reason that open access in innovation promoting is that when it's free to find on the internet, you will get your serendipitous readers who just happen upon a link to an article, who then read the article and get inspired, and then take that inspiration and do great things. Under resource

readers it's not just in the developing world, but even within many higher education institutions and high schools in the United States where there just simply is not the money to pay for these very expensive subscriptions to journals. Science is increasingly interdisciplinary and so, you know, you might have the journals in your discipline, but are you accessing articles in other disciplines in an open access world that's easily done?

International readers, we can see with COVID, science is a global enterprise. And then as Mark mentioned, the ability to do text and datamining to further increase our ability is -- am I driving the slides, because somebody just moved them. All right. Okay.

MS. ALLEN: We're getting. One moment. Yes, they are now being moved.

PROFESSOR CARROLL: You were not seeing them move?

MS. ALLEN: No, we needed you to say "next slide." We can go at the end and go through

them very quickly.

PROFESSOR CARROLL: Did you see that move?

MS. ALLEN: Yes.

PROFESSOR CARROLL: I see, okay. I have a driver's license, this is great. All right.

So the ability then to make research freely available over the internet has basically come in two flavors. There's been a public policy push to at least require for articles published in subscription journals to still eventually make their way to the internet, with some delay. And this first started with the National Institutes of Health, and it's now become a more general federal policy.

In addition, in the marketplace we see the evolution of a new business model in which we move the money from the demand side, i.e., the subscriptions, to the supply side, and have the publishing costs met up front.

So the Office of Science and Technology policy -- next slide, please.

The Office of Science and Technology policy issued a memorandum directing all federal agencies with over $100 million in research funding to develop public access policies. Next slide, please. Next slide.

And those policies need to give the public the right to read, download, and analyze in digital form the final peer reviewed manuscripts or published documents within a timeframe that's appropriate, and also to make these easily searchable. And each of the federal agencies now has such a plan at some stage of implementation. Next slide, please. Next slide.

So in terms of the marketplace, this new financing model for journals, which is sometimes called "gold open access," so the delayed public access is called "green open access," and the full open access is sometimes called "gold," means that once the journal is published it's freely available online.

In addition, the idea that that peer review process has to take place before you make

it available online is even coming under pressure. With the internet, why not make the results immediately available and then subject them to some validation peer review process that then is marked. In the Q&A we'll be talking a little bit more about how in COVID times this rapid dissemination of un-reviewed results is happening at an unprecedented level in the life sciences. Next slide, please.

Now in terms of how you implement the open access model from a copyright perspective, you need a license, and I was part of the Creative Commons organization that developed some standardized copyright licenses that are generally the ones that are used in the open access publication model. Next slide, please.

These standardized licenses offer the licensor some options so you can ask for attribution, you can ask that any downstream users use the same license, a kind of reach through license. And if you take those first two, those are the license terms that Wikipedia uses. You

can also limit reuse to non-commercial reuse or you can simply prohibit any kind of derivative use. Next slide, please.

And these standardized licenses are communicated to the public through icons that once you are familiar it becomes an easy shorthand. Next slide, please.

And there are also ways to completely abandon your copyright by giving it up with the public domain, the one on the left. Or you can simply mark that something has no copyright, with the one on the right. Next slide, please.

So there's a spectrum of reuse rights. Next slide, please.

And the structure of these licenses try to communicate the terms in three different levels. There is a machine readable level that you can put in the website's metadata. Next slide, please.

There's a license deed that is essentially a summary of the essential terms so it tells you up top what you're free to do, and

underneath it tells you what the conditions on your reuse are, generally. And the most open access publishers are using this license, which only requires credit as is indicated by the licensor. Next slide, please.

But of course underneath that is a four-page standardized copyright license that takes care of all of the details that you would expect in a professionally drafted license that has been tested in court and been upheld in court and been properly interpreted in a couple of court cases. So any doubts about this so-called public licensing model where it's a one to many licensing have been laid to rest, and that this is clearly, you know, within the mainstream of copyright law. Next slide please.

I think we're done with that. I think I hit my seven minutes even with the glitches. And I apologize for the glitch. I'm really looking forward to the discussion and any questions that you all may have. Thanks.

MS. ALLEN: Thank you so much. Can you

hear me?

PROFESSOR CARROLL: Yes.

MS. ALLEN: Okay. Good. So thank you all our presenters for this wonderful overview of copyright. And now we'll turn to a discussion of the open, you know, open licensing and how copyright can enhance access to life sciences.

And so the first question, we'll start with Mark, but it's open for all the panelists. Is, you know, we've sort of heard a bit now about on the one hand is open science advocates promote collaboration in the scientific research community, you know, and this idea that we're making research freely available with few and no restrictions. And we've also heard that the publishing community uses these restrictions on copyrights to really invest in systems that can really help target distribution of information and advantages that may happen there. So there's sort of a spectrum in restrictions.

The question is sort of we've seen a response to COVID-19 there's a voluntary release

of COVID related research from many publishers. What are your thoughts about the long- term effects of this? And, you know, what are the trends that we're seeing now, and how may this change how people perceive research? And I again go first to Mark and then open it up.

MR. SEELEY: Yeah, thanks. So I mean 150 million downloads through the summer sounds to me like a lot of downloads. I do worry sometimes that journalists and folks that are sort of looking for advocacy positions one way or the other, maybe they're against facemasks or something stupid like that, might have a tendency to sort of be looking for some type of scientific proof to go along with those concerns. So I have some concerns about how the information is sometimes being used by whom, or with what agenda.

But I think overall it's an unvarnished good. And I think that along with the research that we heard about earlier today in terms of actually looking at therapeutics and prospective drug solutions or many of these issues, the

information mobile content is fundamental in making all those things happen. And to do so in I think in an efficient way.

And I think that both publishers who are managing this content and applying analytic services make it even more effective for those purposes. And, frankly, talented researchers that are in the broader community that are applying similar technologies to this content are lead us to those kinds of new therapies that we're looking for.

In terms of whether it's a long-term model going forward, I think probably not. I mean I think the fundamental thing here is that publishers have made this content available for an emergency. I think that society as a whole is going to need to make a determination as to how valuable that was and for which players. And if in fact it is found to be very valuable, to have this type of data and information more broadly available, though some would argue with that, it was always largely available, particularly to

researchers and research institutions and universities. But to make your argument that by making it more broadly available it leads to even more insights and solutions, if society comes to that conclusion, then I think there has to be discussion about how to make that sustainable going forward.

At the moment open access does represent about 20 percent. I think, Mike, you were going to mention the growth in open access, which is remarkable. It's certainly growing faster than the general subscription access content. But still it represents something like 20 percent of the market. So there is a fundamental question that society will have to address about how to make that go faster if that seems to be the right solution.

PROFESSOR CARROLL: And if I can jump in. I agree, and I think, you know, from those of us who have been making the open access argument for all these years the fact that the publishers recognized there is a difference. There's unmet

demand within the traditional model, and by opening up to the COVID related research there's an implicit admission that this publishing models locks some people out who would want this access. And as you say, the downloads are there.

So I do think this will accelerate the recognition that a move to sustainable open access publishing is probably inevitable at this point. And I think there are still open questions about what financial sustainability looks like, whether it's the current model requires each author to pay a processing charge for each article, which is not necessarily the most efficient way to finance publication. And it has its exclusionary effects as well on researchers who lack the budget to do that.

MR. SEELEY: But actually, Michael, you know, I think a lot of the developments over the last six months or so with flat ask initiative, which is largely an initiative of European funding by agencies with some international engages in there as well. And to the growth of

transformative agreements, by which publishers and universities are reaching deals about how to apply funds and actually to sort of change some of the budget codes from one site to another.

I think we are seeing some initiatives and some evolution there. I agree that merely asking authors to fund $1,000 to $3,000 may not work, certainly for everyone. And it really has problems in some fields of scholarship, I'm thinking of things like mathematics, as well as humanities, where in fact there isn't a lot of research going on that is available at the moment.

PROFESSOR CARROLL: Agreed. Susan, if I can, the other thing that I think we've seen is one of the other barriers to access traditionally within the subscription model, you know, in science priority is key and so the idea of a prior publication would disqualify an article from going through the peer review process and getting published. And the so-called pre-print idea that the author's final draft being posted on line prior to the peer review would be disqualifying.

And that was a traditional publishing norm that has largely fallen by the wayside. It first fell in the physics community where they've been posting their research results, preliminary results, for a long time. And life science has been a more conservative set of disciplines, but this has now changing with the set of so-called pre-print servers like bioRxiv and medRxiv and a lot of this COVID research is being posted there immediately, causing some issues that those of us who've always advocated for this anticipated that, you know, clinically actionable un-reviewed results that then make it into the media can actually be harmful. And so we've seen that some of these pre-print servers are actually dialing back some of the ability for these early postings when there is clinically actionable, you know, implications from those results.

So I think we're all growing and learning from this experience at a faster pace than we would have otherwise, although I think these trends, from my perspective, are fairly

inevitable.

MS. ALLEN: Thank you. Bhamati, do you have anything that you would like to add to that? Okay.

So just building on this is sort of this concept of, you know, there are restrictions that may be necessary for openness at some times, and I think a question for the panel is whether and when these restrictions are acceptable to either add value for sample in the CCDY requiring attribution, or to incentivize value, limiting it to certain terms and conditions.

And do you have any additional thoughts to add to that beyond just the COVID situation for life sciences?

MR. SEELEY: Well, you know, I think there's a bit of a dilemma, I think, with respect to things like text and datamining. And for that matter artificial intelligence. Which is that how do we structure content, and this is something of course that the publishers have traditionally been very good at and they've spent a lot of time doing

these kinds of things, has a great deal of value. In other words, some normalizing data, someone using consistent representations of chemical structures. I mean just a lot of standards is really valuable and is really useful and is very efficient. At the same time, sometimes I think, and I hear, that ingesting a whole lot of content, including a lot of raw content, and allowing some ethological solutions to kind of sort out when there's sort of a connection between this event or this structure and some other event, some other structure, that is more valuable to just kind of have everything in one big database.

And I suppose probably both of those things are true, it's probably the bottom line. It's a little bit like the discussions that I was involved with sometimes with some technology companies as they were remarking on (audio skip) is your content and a lot of you think it's valuable but not as valuable as our ethological capabilities to providing these new insights and solutions.

You know, it's that kind of conflict. Then the reality is that there probably both of those things, technology and content, and with respect to content, well- structured and well organized content in addition to perhaps sometimes big broad datasets, those are both probably valuable, depending on the situation and depending on the research project.

PROFESSOR CARROLL: And if I can add, I think, you know, one of the challenges, particularly in the science publishing is that there is this idea that copyright protects information that has value. But copyrights protection is really designed to protect value that derives from people making creative choices about how to express the information. And if there's underlying information that has value because for instance it is the output of a very creatively designed experiment, the output of that experiment will still be treated as a fact for copyright purposes and not a work of authorship and so won't be protected.

So there's information that has value that requires human inputs, like the research design and the experimental design. But those particular inputs are not the inputs the copyright's looking for. And I think on data and data sharing, this is something I was on a National Academy's panel and we put this in. There's a need for researchers to be able to be rewarded for putting in additional effort to make their data reusable. And in order for data to be reusable another researcher has to be willing to trust it. And I can only trust your data if it's properly structured and properly annotated in a way that I understand where it came from and what the constraints on its reuse might be. And right now there's nothing in the research chain that would reward the researcher for making their data reusable to another researcher. Even if they deposit it, that extra little effort, and sometimes it's not little, but that annotation effort. And we can use technology to speed up the productivity around that.

But to me this is, you know, this is more than just the publishers, this is really the government I think has a real role in helping researchers align their incentives with data reusability, and I think COVID is also really shining a light on that.

MR. SEELEY: Some of the projects that the research data aligns, that I mentioned very briefly, are exactly along those lines of trying to give better recognition where contributions to repositories and establishing standards for data repositories that in fact I think one project is called Trust and it's exactly along those lines.

I wasn't quite sure, Michael, if you were going into a question about the idea expression? I think I agree with your ultimate conclusion, that the mere expression of a fact oriented conclusion from a paper, you know, that this chemical structure breaks down if subjected to heat, that does sound like a fact. But, you know, I think we have to remember, as Bhamati mentioned when she was talking about originality,

the standard for originality in copyright is not terribly high, at least it wasn't intended to be high before they started reading the Feiss decision some years ago. It isn't meant to be, you know, a battle or novelty and I guess we're used to seeing in patents.

I think I agree with your conclusion. I wasn't quite sure about the process points.

PROFESSOR CARROLL: I was thinking more in terms of just like the, you know, an assay or something, just the data that comes off of the machine that, you know. So basically if it's censored data or some other kinds of data that might be quite valuable and might be a significant event data that's, you know, you've captured, like some of the data that's being collected in association with the wildfires in California or something like that. But copyright treats all of that data as fact. You can then get a copyright on the way you organize those facts by selection and arrangement of those but the underlying numerical data, for instance, would not be treated

as copyrightable.

MS. ALLEN: And I think this is a question just that was asked by an audience member as well that has come in just to ask for clarification on what Professor Carroll meant by raw data. And I would say that related to that is the, you know, the idea of what is data. Because especially in the policy context or in the laws, we see data as very broadly worded in the sense of recorded information. So it's not necessarily limited to just that as a fact and maybe sometimes confusion can come up about that.

My sense is that raw, when we talk about raw data, that's essentially synonymous with facts, and that's what we're using, but if anyone has a different opinion feel free to weigh in.

MR. SEELEY: I mean, you know, the traditional chart or graph that appears in a scientific journal article is a representation of at least certain selected facts from the research project that the author finds it particularly relevant for the point that they're trying to make

in the paper.

Authors obviously generally have a lot more data beyond a chart or the graph that they present in the paper. And I think that's kind of what we're talking about, the challenge of all that other underlying data.

Now the chart itself could be copyrightable, probably is if it represents at least a modest amount of creativity in how the information is displayed. But some of the actual elements that go into the chart, so again, if it's about temperature, the fact that this chemical compound does something at this temperature and other compound does something different at a different temperature, those are probably facts. But the way the chart and the graphics display that structure, whether it's horizontal or PI charts or all kind of colors are used, you know, those kinds of things can be copyrightable as part of the article.

PROFESSOR CARROLL: Agreed. Which is why I like a website like FigShare which sort of,

through terms of use, doesn't make you parse that, you know. I mean if you really needed to parse it and say okay, I'm going to take out those numerical data points and reorganize them so I'm not copying the figure as it was published, you can do that if you need to. But ideally there are better solutions and FigShare I think represents one of those.

Susan, you're muted.

MS. ALLEN: Thank you. Another question.

PROFESSOR CARROLL: We can hear you now. No.

MS. ALLEN: Great. No? It's going on and off. But related to this, you know, whether data or this information holds copyright or not, is also related to whether or not something is available to license, right? And I think one of the advantages of this Creative Commons license that Professor Carroll outlined is that it helps create clarity about what can be done with a work, or maybe that isn't always clear when we just go

to the internet or see some things posted. And similarly if we have a subscription to publications it's clear that, you know, spelled out in the terms of use, what we can and cannot do with that, for example. And I'll bring in text and datamining here. You know, there are different type levels of licenses or subscriptions that people can pay for to allow different types of uses.

So if you could share a bit about your thoughts on, you know, the advantages of standardized licensing terms, like Creative Commons or other types of licenses verses sort of maybe the traditional negotiated agreements with respect to data, that would be helpful for the audience. And especially when we're talking about large quantities of data and compiling data for reuse.

MR. SEELEY: Well I think one of the things that Michael was mentioning in his chart that showed, you know, most free or most widespread views is that it goes to one problem

that I think we may have with respect to large datasets, which is that it may be difficult actually to contribute.

If you're really literally talking about millions of data points and if the point of your project, of course, is to combine all that data from several different sources it's not impossible to record attribution information at the level of each data point, but it really adds a lot to the complexity and the difficulty of managing that. I suspect, Michael, you'll say that you should go to zero.

PROFESSOR CARROLL: No, no, no. I mean this is, well the CCzero, yeah, it is. So the problem, we labeled that problem attribution stacking, right. But the problem of having, and if any of you have ever gone to a Wikipedia page and actually looked for the attribution and seen the names of all the contributors to an entry, you know, but you're right. I mean there's a lot of things packed into this.

So let me start with Susan's point about

standardization. I do think standardized terms around information sharing, especially as we see more research collaboration going on, you know, having a common licensing language or at least terms of use language, is just valuable. And I know like with respect to text and datamining, Microsoft has published some draft sort of contracts. They're, you know, we're not sure that they necessarily, it sort of deals with to the extent that there's a copyright here, here's what the license is to the extent that this is just a contract around un-copyrightable data, here what the standard terms are.

So some level of standardization I think is needed or, you know, valuable. And then within those terms, you know, provenance and attribution are important. Like how do we actually trace where this information came from. And lots of people want to know well where did it go, what was the next use. And finding tech tools and other means of being able to trace that, you know, through the research lifecycle is important, and

then marking it with some kind of attribution. And we can use certain amounts of technology and we can use Orcid IDs to identify particular researchers who are involved in these kinds of things, but I agree that the massive datasets that Mark is referring to, there may be cases where, you know, attribution stacking becomes such a problem that we're going to have to just say, you know, in general these are the people who had something to do with this dataset, but we can't say who did what.

MR. SEELEY: And I think, I'm not quite sure that I applaud Microsoft for doing the license. One of the issues that I see in terms of Creative Commons and these kinds of standards licensing is that particularly with Creative Commons, those licenses were designed for a whole huge amount of copyright works. You know, everything from films to music, videos and books. And I think, frankly, I think that the four-page legal license is too long, it's too complicated, and it's probably not specific enough for things

like researchers to figure out what they do.

Do you think it's good that Microsoft had the idea that perhaps something different should be done? I think more collaboration with books out there that are actually working on standards, data standards would be a good idea. Microsoft might say they did that, but I'm not sure that they really did.

PROFESSOR CARROLL: And the great thing about standards is that there so many of them.

MS. ALLEN: Which to pick and how to implement is a different discussion for a different day.

You know one thing to keep in mind here is we are, when we're talking about these state of commons licenses is that legal text does have a disclaimer that it is only addressing copyright and not other types of patents or trademarks or publicity rights.

And so therefore is there a need do you think for a broader one size fits all, all types of rights license that does encompass all of these

rights, or are you aware of any? And what are the pros and cons?

PROFESSOR CARROLL: Well some of the open source software licenses try to address patent, but I find it very difficult to, I mean I think you can do it in the way the open source software licenses have, but from a licensee's perspective, as the user you're not getting the, I mean you know that you won't get sued for copyright infringement as long as you stay within the bounds of the license. But the licensor may or may not have a patent that reads on what you're doing. And so I really think it's hard to mix those two together.

Instead what I've seen is at least with the technology patents there are these sort of patent pools and these kind of creative collective action means of some of the tech companies are engaging in in order to protect themselves from what they see as harassing litigation by non-practicing entities, I think we see less of that in the life sciences, at least to my

knowledge, and that the patent system in the life science really operates differently where there are fewer patents but those patents have greater economic value. And there have been open patent licenses, which is a little odd because you have to spend a lot of money to get that patent. If you really want to be open, just don't get the patent.

But what we've seen is that I want to keep my patent protection in this field of use, but I'm willing to open up use of the patent in these other fields of use. And then I should mention that Creative Commons as an organization is now stewarding the so-called open COVID pledge which is asking patent owners to essentially give the world a pledge that they will not assert their patents that read on a vaccine development or other sort of COVID related, you know, personally protective equipment, at least until the World Health Organization declares the pandemic over.

And there have been some big companies like Intel that have signed up for that as well.

So it's analogous to the way the science publishers have opened up their COVID related research. Some patent portfolio owners are also doing the same thing through that pledge.

MR. SEELEY: You know I think of one of the reasons why the patent issues haven't already been addressed with as much publishing and data and the like is also because of that complexity. So there can be folks working in private research where the company, you know, outside the context of COVID emergency is going to take a very proprietary position. There are universities which have their own IT licensing programs in place which have relied very much on patent rights backing the inventions. So there's a whole host of complexities there about who runs and who is able to actually provide a license and to whom that would cost, which I think makes it more difficult.

PROFESSOR CARROLL: Sorry, Susan, you're on mute.

MS. ALLEN: Thank you so much. This has

been very wonderful. I have one very quick question. We don't have other questions from the audience at this point but just a very quick, you know, thoughts for each of you on maybe what role the government can play in this space, specifically. And then we'll wrap up and turn it over to Brian.

So, Mark, do you want to go first?

MR. SEELEY: Well as I mentioned, I do think that specific funding from government, government research, both in terms of publication but also in terms of data management duration. You know, there's more than just having mandates or policies, there's actually sort of putting, you know, real government dollars behind making those things happen.

I know that the IH traditionally has said, but we do allow publication costs. And it is true that they have some budgeting for things I think for a color charges and other sort of traditional print costs, but they don't specifically have a section or provision for a

goal on the publication side, so unlike some European countries which are doing that more specifically. And then on the data side in addition to simply mandating the data somehow be posted somewhere by somebody at some point, actually providing funding for those repositories to manage themselves more professionally and to do it more consistently would be the right approach.

PROFESSOR CARROLL: I agree with that. My short answer is I was on the study committee of the National Academies of Science Engineering and Medicine that published a report called "Open Science by Design: a Consensus Report of the Academies." And I support the recommendations that are in there, which include some around publishing, and they go beyond. So I would encourage folks out there to really take a look at that.

But I also think some of the points Mark was just making about, you know, within the science funding agencies funding infrastructure, if you will, like for repositories, shared

resources, is not seen as the most valuable investment of the government, and that's because it's a shared resource. So actually being able to show how that resource has changed the world is more difficult to measure until it goes away. And I think in a world where data is the new oil, as they say, you know, the data infrastructure is a necessary research. Both just where it lives but also how it's structured, what the norms are, the training of data scientists in order to really extract and get the best out of those public investments in research, I think that's the next big frontier.

MS. VISWANATHAN: Sorry, I keep trying to unmute. Same problem with you, Susan. So if I may, you know, one thing. I am a qualified fan of initiatives like the OSP paper. I would like to see the government, if possible, do more empirical research on the impact that it has on business models of various stakeholders, including publishers, but also academic institutions and then especially when public/private partnerships

occur, what kind of calculations or what kind of thumb does it put on the scales to insist on a very short window to access or a longer one. I don't think we have enough data to know, and I think that could really make a difference in terms of the viability of some of the companies that sustain scientific research.

So I think there's also some room for some data from within the government to tell us, you know, what's the best way forward in a way that's viable for all entities. That's my wish list anyway. Thanks.

MS. ALLEN: Wonderful. Thank you all for your contributions and your time today, we very much appreciate it and we appreciate the discussion and your presentations.

With that I'll turn it over to Brian for concluding remarks. Brian.

MR. YEH: Thank you, Susan. And thank you all for attending our sessions today that examine how patents and copyrights impact collaboration and innovation in the life sciences

sector. We hope you've enjoyed it.

On behalf of my USPTO colleagues I want to express my appreciation to all the presenters and panelists for contributing to a lively and interesting discussion today.

Please join us tomorrow for Day 2 of our conference, which will be hosted by the Department of Justice. Tomorrow sessions will explore different ways to expedite the development and use of therapeutics, diagnostics, and vaccines through competition, collaboration, and licensing.

Also, as Nyeemah had mentioned earlier, please note that our program tomorrow will begin a bit earlier than today. It will start at 12:30 p.m. with welcome remarks by the Assistant Attorney General of the Anti-Trust Division, Makan Delrahim, followed by a fireside chat at 12:45 between Mr. Delrahim and PTO Director Iancu.

Finally, please know that our conference is being recorded and will eventually be made available for rewatching and later viewing. In addition, the email address,

Lifesciences@USPTO.gov will remain active for some time after this event is over so you may still submit any additional questions you may have about today's subject matter.

Have a very good evening, and we look forward to seeing you all back here tomorrow at 12:30 p.m. Farewell for now.

(Whereupon, the PROCEEDINGS were adjourned.)

* * * * *

CERTIFICATE OF NOTARY PUBLIC

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.

Carleton J. Anderson, III

(Signature and Seal on File)

Notary Public in and for the Commonwealth of Virginia
Commission No. 351998
Expires: November 30, 2020