UNITED STATES PATENT AND TRADEMARK OFFICE

USPTO-FDA PUBLIC LISTENING SESSION

Alexandria, Virginia

Thursday, January 19, 2023

PARTICIPANTS:

Held Before:

LINDA HORNER
Administrative Patent Judge

KATHERINE K. VIDAL
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

DR. ROBERT M. CALIFF
Commissioner of Food and Drugs
United States Food and Drug Administration

Session 1: Patient Perspectives:

Speakers:

LESLIE RITTER
National Multiple Sclerosis Society

SNEHA DAVE
Generation Patient

Panelists:

JACQUELINE BONILLA
U.S. Patent and Trademark Office

LINDA HORNER
U.S. Patent and Trademark Office

ZAHAVA HURWITZ
U.S. Food and Drug Administration

DANIEL RITTERBECK
U.S. Food and Drug Administration

PARTICIPANTS (CONT'D):

Session 2: Examiner Training on Publicly Available FDA Resources:

Speaker:

KEVIN WREN
T1International

Panelists:

DANIEL SULLIVAN
U.S. Patent and Trademark Office

DANIEL KOLKER
U.S. Patent and Trademark Office

BETHANY BARHAM
U.S. Patent and Trademark Office

ZAHAVA HURWITZ
U.S. Food and Drug Administration

DANIEL RITTERBECK
U.S. Food and Drug Administration

Session 3: Applicant Statements Made to USPTO and FDA:

Speakers:

PROFESSOR ROBIN FELDMAN
University of California Hastings College of the Law

TAHIR AMIN
Initiative for Medicines Access & Knowledge (I-MAK)

HANS SAUER
Biotechnology Innovation Organization (BIO)

PARTICIPANTS (CONT'D):

SHAINA KASPER
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PROFESSOR ADAM MOSSOFF
George Mason University, Antonin Scalia Law School

CAROL NIELSEN
Nielsen IP Law, on behalf of American Intellectual Property Law Association

Panelists:

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U.S. Patent and Trademark Office

KARIN FERRITER
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MARY TILL
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MARIANNE TERROT
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KRISTIN DAVIS
U.S. Food and Drug Administration

MUSTAFA UNLU
U.S. Food and Drug Administration

DANIEL RITTERBECK
U.S. Food and Drug Administration

Session 4: Patenting Practices in the Pharmaceutical Sector:

Speakers:

PARTICIPANTS (CONT'D):

JULIANA REED
Biosimilars Forum

DAVID KORN
PhRMA

PROFESSOR LIZA VERTINSKY
University of Maryland Francis King Carey School of Law

DR. S. SEAN TU
West Virginia University College of Law

SARAH BOURLAND
Patients for Affordable Drugs

COREY SALSBERG
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Panelists:

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PARTICIPANTS (CONT'D):

DANIEL RITTERBECK
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Session 5: Patent Term Extension and Patent Use Codes:

Speakers:

VICTOR VAN de WIELE
Harvard Medical School

EMMABELLA RUDD
T1International

PATRICIA KELMAR
U.S. Public Interest Research Group (U.S. PIRG)

PROFESSOR JOHN R. THOMAS
Georgetown University Law Center

Panelists:

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MARY TILL
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PARTICIPANTS (CONT'D):

DANIEL RITTERBECK
U.S. Food and Drug Administration

Closing Remarks:

DERRICK BRENT
Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office

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C O N T E N T S

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P R O C E E D I N G S

(10:01 a.m.)

JUDGE HORNER: Good morning and welcome to the Joint Listening Session cohosted by the United States Patent and Trademark Office and the U.S. Food and Drug Administration. My name is Linda Horner. I'm an administrative patent judge here at the USPTO. And I've been working alongside my counterparts at the FDA to lead a collaborative interagency team to advance President Biden's Executive Order on Promoting Competition in the American Economy.

I will serve as moderator for today's listening session. And the purpose of the listening session is to provide an opportunity for broad public input on proposed initiatives for collaboration between the agencies. I'll provide a few announcements shortly. But before we begin, we have two distinguished guests here with us this morning to deliver opening remarks.

Dr. Robert M. Califf was confirmed last year as the 25th Commissioner of Food and Drugs.

He also served in 2016 as the 22nd Commissioner. And immediately prior to that as the FDA's Deputy Commissioner for Medical Products and Tobacco. He spent a good portion of his career affiliated with Duke University where he served as a professor of medicine and vice chancellor for clinical and translational research. He was director of the Duke Translational Medicine Institute and was the founding director of the Duke Clinical Research Institute.

Dr. Califf has had a long and distinguished career as a physician, researcher, and leader in the fields of science and medicine. He is a nationally recognized expert in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care.

Kathi Vidal serves as the Under Secretary of Commerce for Intellectual Property and the Director of the United States Patent and

Trademark Office. As the Chief Executive of the USPTO, she leads one of the largest intellectual property offices in the world with more than 13,000 employees and an annual budget of nearly 4 million.

She's the principal IP advisor to the President and the administration through the Secretary of Commerce and is focused on incentivizing and protecting U.S. Entrepreneurship, innovation, and creativity, and helping American workers and businesses compete and collaborate, especially in key technology areas and across demographics. Director Vidal also is working to expand American innovation for and from all, including serving as the vice chair of the Council for Inclusive Innovation, CI-Squared, along with Secretary of Commerce, Gina M. Raimondo, and the council members.

And with those introductions, please welcome Commissioner Califf to the podium for his opening remarks.

DR. CALIFF: Thank you so much, Linda.

And I do want to note that I have a lot of work to do in D.C. and Silver Spring today so I put on my Maryland bow tie, which you heard I'm a longtime Duke person. It's very difficult to wear a Maryland bow tie. And then on the way over, Emily told me wait a minute, you're going to Virginia. It's not going to be well received there either. But as I meet with many politicians, I'm trying to collect bowties to represent every state so I can be user-friendly as I go.

And also, just in light of this conference, hearing, reminded about my credentials as a cardiologist, I think it is worth a moment just to reflect on the wonders of technology and what can happen when it's used well. I'm sure all of you have followed the saga of the Buffalo Bills football player and if you just think about what happened in that very brief period of time to go from a full cardiac arrest to defibrillation and now a person who's out and about doing fine.

It's just an amazing -- and you think about all the steps that people like you were

involved in going from the idea of a technology of external defibrillation to a defibrillator that can be kept anywhere in the country and used by novices really effectively. I think it's a real testament to what can be done if we do our jobs well in combination with so many creative people in the industries.

So, I am delighted that USPTO and the FDA are collaborating in this joint listening session, as well as in many other ways. And I want to express my gratitude for all that the employees from both agencies who I know have been working for many months to lay the groundwork and prepare for today's meeting. These meetings involve a lot of preparation. So, thank you. I also want to thank the many product developers, representatives of industry, academia, and consumer organizations, as well as the patient advocates, and other stakeholders who are participating today, and for your continuing involvement in these issues.

As President Biden recognized in his

2021 Executive Order on Promoting Competition, our two agencies have distinct authorities and missions. In a number of key areas, however, when it comes to efforts to make essential prescription drugs more affordable and accessible to the patients who need them, we have some important overlapping and complementary interests and responsibilities.

I will note here also having worked in academia and in private industry, matrix interactions don't come naturally in government, I've learned. And so, I'm really proud that this I hope will be a great continuing example of working across agencies in a more effective way on both sides.

So, since the issuance of this executive order, FDA and USPTO have been working together to leverage our combined expertise. For instance, we've begun interagency cross- training to help strengthen our understanding of our respective responsibilities and how we can work together. Today's public listening session is the latest

chapter in this continuing effort designed specifically to provide stakeholders with the opportunity to speak with both agencies at the same time about these vital issues.

As a public health agency, the FDA has the responsibility to use the best available science to review new medical products to determine whether they're safe and effective for specific indications so that the balance of risks and benefits for use of those indications, makes them suitable for marketing. But there's another important related, though perhaps less well-known aspect of our work, that is to encourage the scientific research and development during the long course from concept to determination of approvability to help ensure they're translated into meaningful products that can make a difference for patients.

This responsibility extends for the entire product lifecycle, well beyond the patent life. To this end, the FDA has a number of robust programs to advance the development, approval, and

marketing of high-quality generics and biosimilars. For instance, the science and research program established under the Generic Drug User Fee Amendments, or GDUFA, helps us provide product-specific guidance to support generic drug development. Likewise, FDA has initiated a regulatory science program pilot under the Biosimilar User Fee Act, or BSUFA, that focuses on advancing the development of interchangeable biosimilar products and improving the efficiency of biosimilar product development.

Both programs also have mechanisms for FDA to communicate with applicants early in the process to help clarify regulatory expectations for prospective applicants. These early communications help make product review more efficient by proactively addressing emerging scientific and regulatory issues and thereby reduce a generic or drug or biosimilar product's time in the pipeline from concept to development to market.

We're also focused on supporting the

development of complex generic drugs such as products with complex active ingredients or drug device combination products. These products are critical to the treatment of many medical conditions. But because they can be more scientifically challenging, time consuming, and expensive to develop they often lack adequate generic competition. In addition, there can be greater uncertainty concerning the approval pathway or questions on issues such as proposed study designs or possible alternative approaches.

We know the importance in America's place on affordable prescription drugs. Generic drugs today represent nine out of 10, or 90 percent, of all prescriptions that are filled. What this means is that more patients have greater access to affordable, safe, effective, and high-quality medicines. And that patient access continues to be a priority for the FDA.

While our agency doesn't play a direct role in drug pricing, we can, by encouraging development of generic and biosimilar products,

support increased competition in the healthcare market. This can have a transformative impact by improving affordability and increasing access to these essential medicines.

On a personal level, I'm certainly glad I get important medications I need for things like blood pressure and lipid control in a generic form. At age 71, like most seniors, I'm on a number of medications and it's really good to have these low-price generics that I can have confidence in. And I think it's a fair deal to have access to low-cost versions of these medicines after a defined period of protection.

And that's the crux of the matter. Our laws and regulations provide drug developers with protection from competition for a specific period of time. The reason for this is that these companies do necessary and important research in support of their development of essential and often lifesaving treatments. Consequently, they should be allowed to recoup and benefit from their investments. That code of fairness is why these

principles were written into law.

At the same time, however, delay in competition must have limits and involve a balance between innovation and access. The just rewards that come with investment in R&D must be balanced with legal and regulatory pathways that allow for and encourage generic drug and biosimilar product manufacturers to enter the market. This helps increase competition and drive down prices, thereby making these essential drugs more accessible and affordable and lowering healthcare costs. Moreover, by enabling a path for competition, we provide developers and innovators with added incentive to invest in further research that will lead to the discovery of new drugs that can deliver additional benefits for patients.

As you're probably aware, there are significant savings to consumers from this kind of competition. In 2022, the FDA estimated the cost savings from new generic approvals from 2018 to 2020 amounted to $53.3 billion a year. It's worth noting that first generic approvals accounted for

about one-third, or exactly 29 percent, of these total savings. First generics are especially important because they are the first approval by the FDA that permits an application holder to market a generic drug product in the United States.

While this system is sensible and straightforward, the road to competition requires sponsors to navigate both the drug approval process and intellectual property issues before generic and biosimilar products can be brought to market. For example, under the Hatch-Waxman law, many first generics only obtain final approval after they have challenged a patent listed in the Orange Book for the brand product based on the generic applicant's opinion that the patent is invalid, unenforceable, or will not be infringed by the generic product.

Unfortunately, we also have seen gaming tactics by some brand companies who attempt to impede or undercut competition from generics and biosimilars. We put in place multiple

comprehensive initiatives, many of which are outlined in the Drug Competition Action Plan and the Biosimilars Action Plan, aimed at reducing the so-called gaming of FDA regulations that attempts to extend brand monopolies beyond what Congress intended with Hatch-Waxman and unfairly delay market competition.

These plans also include policies that improve the efficiency of the FDA's review of marketing applications for generics, biosimilar, and interchangeable products, increased scientific clarity, and regulatory certainty for manufacturers and other stakeholders, and help educate stakeholders about interchangeable products. The objective of our two agencies' collaboration under the executive order is to ensure the patent system is not used in ways that unjustifiably delay generic drugs and biosimilar competition beyond that reasonably contemplated by law.

While FDA only has a ministerial role when it comes to patents and their listing in the

Orange and Purple Books, collaboration between our agencies remains important. We're committed to working with PTO on the initiatives and topics outlined in our exchange of letters, as well as to working with other federal partners like the Federal Trade Commission to advance competition and ensure enforcement of the laws.

There's one other important point I think worth noting that's increasingly been coming to my attention. That's the potential problem of prices being driven too low to give manufacturers incentives to continue to produce drugs for certain markets. We know, for instance, that when more than 95 percent of the market for a particular product is filled with generics, that saturation can result in manufacturers leaving the market.

This is not an issue related to patent law as these products typically have been off patent for a long time. But what it makes clear is that the problem of access to affordable medications in the marketplace will not be solved

simply by encouraging and introducing competition. It must also include consideration of other issues, including how to provide incentives for manufacturers to continue to supply less profitable off-patent drugs in the long term. We need to ensure that market competition and the resilience of the supply chain are promoted and sustained even after generics and biosimilars are on the market.

The USPTO and the FDA will continue to collaborate in the development of policies aimed at protecting and promoting U.S. innovation, advancing competition, and lowering prescription drug prices for all Americans. We must achieve the appropriate balance that encourages meaningful innovation of drug development, while not unduly delaying competition that provides relief from the high costs of medicines.

I want to thank you again for your engagement and we look forward to your comments and questions today and going forward. I wish I could be here for the whole meeting, but there are

a number of other issues I have to attend to and we have so many FDA people, I'm sure I'll get a complete report of what was said and much appreciate the chance to be here.

DIRECTOR VIDAL: Thank you, Commissioner Califf. I will say that one of the first things I noticed when the Commissioner came in here was his bow tie. I asked him if he has a Virginia one. He does not. He said it's hard to find. So, I'm going to go set forth trying to find him one.

I want to thank you for all the work that we're doing together, both with your staff and the work that you and I do together directly, and for being so accessible when we have issues we're trying to resolve and it requires us to have a one-on-one conversation. So, I appreciate that.

And I do want to thank your staff. I want to let everybody here know that we do have staff both from the USPTO and the FDA. Can the staff from the FDA raise their hand or identify themselves so people can see where you are? Wonderful. Thank you so much for all of your

collaboration with our teams and for all the great work you're doing.

I also want to thank Linda. Thank you for your opening remarks. And thank you for leading the initiative at the USPTO. I know that you're working tirelessly on these issues. I know the entire team is. So, I want to thank you and our team. If the USPTO representatives could raise their hand, that would be great. A lot of enthusiasm there today. I think we maybe need to refill that coffee.

So, I also wanted to take this opportunity to introduce the USPTO's new Commissioner for Patents, Vaishali Udupa. Because the work that she is going to be doing is going to be critical to everything we're discussing today. So, Vaishali, if you could stand and actually, maybe come up on stage just because I know we have so many people attending remotely.

Commissioner Udupa was just sworn in two, three days ago?

COMMISSIONER UDUPA: This is day three

on the job.

DIRECTOR VIDAL: This is day three on the job. She has a technical background and is a nationally recognized leader in intellectual property with over 20 years' of experience in strategic IP advisement and complex litigation. The best story about her that I love is she applied to be a patent examiner 26 years ago. This is where she always wanted to be. At the time she happened to not be a citizen yet. So, we couldn't take her on then. But she's been working hard to be in the USPTO ever since. So, just that dedication, that commitment to public service, and to working on behalf of the country as the ultimate client is just phenomenal.

She has a wealth of experience in patent prosecution, licensing, and litigation, including developing patent and trademark portfolios, national and global IP policy, and diversity, equity, inclusion, and accessibility. And like me, when we talk about inclusion, it's everybody. Commissioner Udupa is going to be working with me

this week on our Robust and Reliable Patent Initiatives. That was one of the initiatives that we mentioned in the letter that I sent to Commissioner Califf.

We have already released one request for comment on the Robust and Reliable Patents. If you haven't seen it, comments are due February 1. And we are working on a second one that the Commissioner and I will be working on. So, on behalf of everyone at the USPTO, and I'm sure everybody in this room, we want to welcome you to America's innovation agency. Thank you.

COMMISSIONER UDUPA: Thank you.

DIRECTOR VIDAL: Accessibility to medicine for all Americans is a top priority of this administration. It is not only a moral imperative; it is a national one. The U.S. is a leader in innovation in the pharmaceutical space in large part because of our patent system. The patent system plays a critical role in the development of new and innovative medicines. It incentivizes the research and development that is

necessary to bring these products to market. And it incentivizes the disclosure that is necessary so that others can build on innovation.

And the generic market relies on that system because as we get products out there, people can continue to build on them. I'm often asked what my views are on the pharmaceutical space. And I don't think I articulated it any better than the letter I sent on July 6 to Commissioner Califf. So, I just want to read a few short lines from that. I would also encourage everybody here if you have not read the letter, it really outlines a lot of the work that the USPTO is doing in this space and the work that we're doing in collaboration with the FDA.

So, from the letter. The patent system was developed to promote economic growth and a higher standard of living for all. The United States is a global leader in new drug development due to its strong system and the ecosystem envisioned by Congress with the Drug Price Competition and Patent Term Restoration Act. As

you all know, the Hatch- Waxman Act of 1984, and more recently the Biologics Price Competition and Innovation Act.

Though patents play a critical role in incentivizing and protecting the investment essential for bringing lifesaving and life altering drugs to market, we must make sure our system as a whole does not unnecessarily delay generic, biosimilar, and more affordable versions of those drugs getting into the hands of Americans who need them.

In addition to all of the different ideas that I outlined in this letter, with the help of Linda and our entire team, the USPTO has several programs to try and incentivize investment in the medical space. We have a COVID-19 Prioritized Examination program that will continue until there is no longer a crisis. That allows us to expedite patents in that space so we can get products to market more quickly. We also have a Cancer Moonshot Expedited Examination program that will be starting on February 1.

We also recognize that improperly issued patents extract a cost on society. At the USPTO, you can come back and challenge patents that we have issued through our Patent Trial and Appeal Board. As soon as I came onboard, I tried to clarify some of the rules on when we would take on those challenges and when we would, under the Director's discretion, deny -- discretionarily deny those challenges. And one of the first changes I made was to institute a new standard of compelling evidence of patentability because there were some concerns that we were discretionarily denying strong challenges that we should be looking at.

I've issued guidance under this. We are going in 2023 to work on rulemaking. So, I would encourage you to stay apprised of that. Please provide your comments as we move forward because we're looking forward to making the system work for everyone. I'll also note that in one of my many roles, I also comment on Supreme Court cases. And sometimes I pick up the phone or email

Commissioner Califf on some of those where the cases intersect the work that we're doing.

I was asked recently if it was worth providing -- I was asked I think this week, on whether it's worth providing comments on our RFCs, and submitting amicus briefs, and doing all that hard work. I will tell you it's incredibly important to the work that I do. I do need to hear from everyone. Our team summarizes comments, but I go back through and read a lot of them individually. And any time I go to make a decision, whether it's collaborating on a position the U.S. should take on a Supreme Court case, or whether it's on regulations that we are going promulgate within the USPTO, I always go back and read dissenting views to make sure that wherever we're landing the plane, it's in the right place.

Now, we recognize that our agencies do not have all the answers. I think you heard some of that from Commissioner Califf. But we're doing what we can within our power. That's why we're excited to hear from all of you today. I want to

thank all the speakers who have taken the time. I want to thank all of those who submitted comments. I know it's a lot of work. I know especially when you work within companies and organizations, there's a lot of vetting, a lot of back and forth. And I can only imagine the immense effort you committed to today.

We will hear today from patients, from public interest advocates, from academics, from industry groups, from brand pharmaceutical, and generic companies, and brand biotech, and biosimilar companies. So, thanks to all of you and thank you to everybody who's tuning in today. We will also hear from subject matter experts from the USPTO and FDA that you heard from recently.

Through all of your hard work, we are going to take the input that you're providing both through your comments and through the work that you're doing with the submissions to create positive impact on accessibility to lifesaving and life altering medications. So, thank you for being here. And with that I will turn it over so

we can begin our discussion. I will note that I plan to listen in to all of this from my office. I may come down during the breaks. But I'm looking forward to hearing from all of you directly. Thank you.

JUDGE HORNER: Thank you, Commissioner Califf and Director Vidal, for being here today and for your remarks and leadership. Your insights will frame the discussions that are to follow. We know you have busy schedules and we're going to let you get on with the rest of your day.

I'm going to take a moment just to relocate myself to this head table. This is where the rest of the remarks will be today in the question-and-answer period. And so, I'll go ahead and relocate there and then make a few announcements before we get started with our first session.

Okay. Hopefully, everyone can hear me okay with my mask on. I'm going to try to leave it on while I'm at the table here. I wanted to make a few announcements before we get started.

First, if you'd please silence any cell phones or mobile devices so we don't have interruptions during the day. Second, we ask that all attendees, and especially speakers, if you haven't done so already, sign in at the registration table so we know you're here. And third, if you're looking for restrooms during the breaks, they're just outside the door here, down the hall past the coffee kiosk.

We are recording this event and it's being transcribed. And we'll post the recording and the transcript a few weeks, two to three weeks after the event on the USPTO webpage. I know we have a few members of the media here today. If you have media inquiries, Paul Fucito at the USPTO is our press secretary and you can direct any media inquiries to Paul. If any members of the media are here today, please make sure you sign in so we know you're here. And because the listening session is intended to give our agencies time to hear from the public and the panelists, the panelists and other USPTO and FDA members are not

available today to speak with the media or make statements.

Here are some procedural rules for today. We have 20 speakers today. We've divided the speakers into topical sessions based on the primary topic of interest that they indicated in their registration. Although each session focuses on the speaker's primary topic of interest, they are free to comment on any aspect of any of the inquiries in the Federal Register Notice.

No participant can interrupt the presentation of any other speaker and only the USPTO and FDA panel members seated here along this side of the table will be allowed to question the speakers. At the start of each session, we invite the speakers for that session and the USPTO and FDA panel members for that session to move to this head table and be seated in front of the tent card with their name on it.

I will note here and it's marked in your agenda, we have a few speakers today appearing virtually due to requests for special

accommodation. And these speakers will appear on the large screens in the front of the room. Each speaker will present in the order listed on the agenda and each will have seven minutes to present their remarks. After each speaker presents, our USPTO and FDA panel members will have three minutes to ask questions of the speaker.

If the speaker finishes early or the panel does not use the full three minutes, we'll move on to the next speaker. And we will plan to keep to our scheduled breaks as set out in the agenda. And for the speakers, we have timer lights here to guide you. So, green when it's time for you to speak, yellow when you have one minute left, and red when your time is up. If you've not concluded your remarks by the time the light turns red, I apologize in advance, but I may interrupt you and tell you your time is up.

Please remember that the listening session is being transcribed and recorded so, when you come up to speak, use the microphones at the head table here. You would push the button to

talk and you'll see it will light up red when the mic is hot. And then please turn your mic off after you finish.

Speakers have already submitted their remarks to the docket on regulations.gov. So, if you go on that site you should be able to see all the speakers' remarks. We do invite the speakers, you're welcome to submit any other thoughts or input that you have using that same portal. And the Federal Register Notice has details on how to submit comments and anyone listening today if you wish to submit written comments, the docket will remain open until Monday, February 6th.

This hearing is being webcast live. However, it is not interactive. So, webcast viewers you won't be able to comment or ask any questions. But, of course, you can submit written comments to the docket.

So, we're going to start with our first session. Thank you all for coming. We're already seated here at the head table and we will have one speaker today that's virtual. But before we turn

to the first speaker, I'd like to ask the USPTO and FDA folks to introduce themselves with their name, title, business unit, or department, and then agency.

MS. HURWITZ: Good morning. I'm Zahava Hurwitz. I'm the Director of the Policy, Engagement, and Coordination Staff in the Office of Policy. It's in the office of the Commissioner at FDA. And our division is the Office of Policy, Legislation, and International Affairs.

MR. RITTERBECK: Good morning, everyone. My name is Dan Ritterbeck. I am a regulatory counsel in CDER's Office of Regulatory Policy at the FDA.

JUDGE BONILLA: Hello, good morning. Thank you, everybody, for coming. My name is Jackie Bonilla. I am at the USPTO at the Patent Trial and Appeal Board, Deputy Chief Administrative Patent Judge there. And I have a background in pharma as well.

JUDGE HORNER: Great, thank you. Our first panelist is Ms. Leslie Ritter from the

National Multiple Sclerosis Society. Ms. Ritter, you can begin with your remarks.

MS. RITTER: Thank you. Good morning. And thank you for hosting this important listening session. My name is Leslie Ritter. I am the Associate Vice President of Federal Government Relations at the National Multiple Sclerosis Society. And my goal this morning is to detail how the misuse of patents and gaming of the regulatory system ultimately hurts the people who rely on them the most and make recommendations on how FDA and the USPTO can work collaboratively to end these practices.

MS is an unpredictable disease of the central nervous system. Currently, there is no cure. And symptoms may vary from person to person and include disabling fatigue, mobility challenges, cognitive changes, and vision issues. An estimated 1 million people live with MS in the United States. And it is also a highly expensive disease. The total estimated cost to the U.S. Economy is 85.4 billion per year.

Early and ongoing treatment with an MS disease modifying therapy is the best way to manage disease course, prevent accumulation of disability, and protect the brain from damage due to MS. There are now more than 20 MS DMTs on the market and these medications have transformed the treatment of the disease over the past 30 years.

Unfortunately, these DMTs are incredibly expensive. And competitions amongst the brands have driven prices up rather than down. People with MS stay on these medications for years with the annual cost for individuals ranging from $57,202 to $92,719, depending on a person's age or gender. Although there are now lower cost options, including generic options for some MS DMTs, they are still relatively new to the MS market. And there is currently a submission for the first MS biosimilar before the FDA.

People with MS have waited a long time for these generics. The first non-biological medication for MS came on the market in 1997, and a generic was not available until 2017. This

delay in availability of lower cost options and the high prices of MS medications has a real impact on people's lives.

In a 2019 the National MS Society survey of people with MS, 40 percent had altered the use of their DMT with some due to cost, with some skipping or delaying treatment altogether. And more than half of those surveyed said that they were concerned about being able to afford their DMT in the next few years.

People affected by MS have benefited from and support innovation. Innovation is what ultimately will get us to a cure. We believe that it is critical that the U.S. maintain an environment that allows for the risk needed to drive research and development of life changing therapies and innovators should be rewarded and compensated fairly.

The Hatch-Waxman Act provides the framework that has allowed the U.S. to remain a leader in medical innovation and works well to address the multiple goals of innovation,

affordability, and promoting competition. Yet, practices being discussed here today seem to be at odds with the intent of the Hatch-Waxman Act and hinder patient access to lower cost therapies.

We have seen tactics discussed today used in the MS market. Brand companies patenting FDA required brand safety programs and methods used to monitor a safe therapy engage if it is working. Some MS DMTs have upwards of 20 patents associated with just one therapy, often extending protections from generic competitions for decades. And brand manufacturers of MS DMTs have made small tweaks or modifications to drugs already on the market, thereby extending the patent life of older products. Then they obtain approval for those products and move people with MS to that new product right before the entry of a generic version of the older drug into the market.

These practices do not promote innovation, competition, or affordability. Nor do they move the needle improving health and health outcomes for people with MS. Instead, they are

utilized to protect profitable revenue streams far past the timeframes which manufacturers need to recoup investments and build profits to drive further innovation.

It is with this background in mind that we make the following recommendations. Applicants should be required to certify that the statements made to both FDA and USPTO are consistent when they are seeking regulatory approval for a new drug application. Lengthy patent protections or extended market exclusivity for minor tweaks to existing products should not be granted. Further, USPTO should end the use of terminal disclaimers to overcome obvious-type double patenting. Or require a binding admission within the terminal disclaimer that claims are not patentably distinct from previously granted claims to which there are obvious variations.

USPTO should help provide transparency by updating its centralized listing of PTE applications to include the terminal disclaimer language and/or all patents that are associated

with the original patent. Both the USPTO and the FDA should work collaboratively with the Federal Trade Commission to establish what actions do and do not constitute gaming of the system, and have those actions be publicly available. Examine the patentability of REMS programs and engage all stakeholders in meaningful dialogue including patients.

Relatedly, the USPTO should engage patient and patient advocacy groups as members of the Patent Office Public Advisory Committee. And both agencies should work closely with congressional leaders to assure they have the authorities and resources necessary to effectively engage in and act on their collaborative work.

Thank you for the opportunity to provide feedback and recommendations here today. The Society's full comment has been submitted to the docket and we look forward to working with you.

JUDGE HORNER: Great, thank you, Ms. Ritter, for being here today. For sharing the insights of patients and the perspective from

patients and for the recommendations that you've provided. I'll turn to the panelists and see if we have any questions from the panel.

JUDGE BONILLA: I had one question. One of your recommendations was that the Patent Office do away with the terminal disclaimers in relation to obviousness-type double patenting. Patents that are issued that have this terminal disclaimer they expire on the same day as the patent which they're doing the terminal disclaimer. Does that alleviate some of your concerns? Or are there additional concerns about the terminal disclaimer situations in patents that are worth sharing with us?

MS. RITTER: I'm sorry, it was a little mumbled in the middle. Can you repeat that?

JUDGE BONILLA: I apologize. It was the mask. I'm going to take it off. On patents that have the terminal disclaimer based on a patent that issued earlier, those patents expire on the same day.

MS. RITTER: Mm-hmm.

JUDGE BONILLA: I was just curious as to -- because you're suggesting to do away with terminal disclaimers, if you had additional concerns since the issue of when they would expire, they would be on the same day.

MS. RITTER: Right. I think our concern is when you have -- I think that would alleviate some of the concerns. I think that when you have -- our concern is when generic competition is looking for patents to challenge, often it is impossible to address the multiple patents that are associated with the product. We're looking really to end that practice because patients really look at what is the patent end date? When can I expect a generic to come on market when they're looking for affordability. Anything to improve that process and make that process seem more fair, and move more quickly, and within the intent of Hatch-Waxman would be an improvement that we would like to see.

JUDGE HORNER: I have a question following up on that. Does the listing of the

patents in the Orange Book help in that regard for companies to know which patents cover the products? You may have 20 patents on a product, but only a lesser number in the Orange Book listing.

MS. RITTER: Yes, I think that you highlighted one of the challenges. I think the challenge that we most see is looking at what patents are associated that kind of protect around the thicket. So, you may have some patents listed in the Orange Book, but the ones that are actually being used to kind of deter generic competition are not necessarily listed or are listed in other places. So, it's very hard to kind of keep track of what patents are actually being challenged and are providing the challenge to the system and in what status those are in.

JUDGE HORNER: One last question before we run out of time.

MS. RITTER: Yes.

JUDGE HORNER: On another recommendation you mentioned about using patients and patient

advocacy groups --

MS. RITTER: Mm-hmm.

JUDGE HORNER: -- to provide input. Has your organization been involved in similar advisory groups for other agencies? And how has that worked? And what sort of model has it followed?

MS. RITTER: Sure. And I'll try to be very quick because I know we're running out of time. The FDA has a patient panel that could actually serve as a good model for this. They routinely engage patients. There is a process by which the patients apply, have to be kind of vetted through the system, and sign on as I think they're contract government employees for that period of service. But we think that's a good model that the USPTO could utilize to look at this.

JUDGE HORNER: Great. Thank you very much.

MS. RITTER: Thank you.

JUDGE HORNER: And now if our conference

services folks can have our next speaker appear on the screen, Ms. Sneha Dave, from Generation Patient.

MS. DAVE: Yes. Can you all see me okay?

JUDGE HORNER: We can, yes, we can see you. Welcome. Welcome.

MS. DAVE: Amazing.

JUDGE HORNER: So --

MS. DAVE: Okay, great.

JUDGE HORNER: -- please go ahead and deliver your remarks and then we might have a few questions.

MS. DAVE: Great. So, my name is Sneha. I am 24 years old and I was diagnosed with a severe form of ulcerative colitis when I was six years. I created what is now Generation Patient around 10 years ago when I felt like there was not enough support for adolescents and young adults with chronic conditions.

Generation Patient is still entirely led by young adult patients and we focus on peer

support, higher education, and health policy. Over the last two years, we have done over 400 peer support meetings and developed novel programming and advocacy related to higher ed avenues. But our work in health policy is extremely important to me because I have seen firsthand the disparities in our community that are often fueled by the high prescription drug costs that we need to survive.

Early on, we at Generation Patient made the decision to decline all funding from the pharmaceutical, insurance, hospital, or related healthcare industries to keep the integrity of our work. Through our only disease-specific programming, the Crohn's and Colitis Young Adults Network, we work to empower adolescents and young adults with inflammatory bowel diseases.

Humira is a medication that I was on for a number of years and one that is needed by many in our community. And it has been granted over 166 patents and has delayed biosimilar entry until 2023 in the United States. This is just one of

the many examples which illuminates and which is why it is so exciting to have this USPTO and FDA collaboration.

The following points that I make are going to be divided into sections based off what we feel like is most important to address. So, the first is to engage patient stakeholders. Patient stakeholders are critical, but often underrepresented at its equal stakeholders and policy and regulatory discussions. The USPTO and FDA must have accountability to those most impacted in all aspects of the collaboration.

We recommend the development of an independent public advisory committee, inclusive of patients who represent areas from chronic to rare diseases, different age groups, and more. This independent public advisory committee should play a critical role in advising on public dissemination of information, best practices for engaging public and patient stakeholders in ways in which this collaboration could be even more patient centered.

We commend that the FDA already has a variety of existing patient engagement opportunities of which I am a part of. Rather than just also having patients serve on separate patient councils, we encourage the integration of patients in all core activities of this collaboration. We also wish to encourage the foremost engagement of individuals in organizations that are independent of pharmaceutical industry funding. Further, as part of an advisory council, we uphold that patients must be compensated for their time and experience to ensure that there is an equitable representation of who can provide this insight.

The second point is this idea of value-based patents. Before a patent extension is granted, it is important to understand what benefit the drug actually has on patients. Does a secondary patent meaningfully increase the clinical benefit and post a transformative impact on patient quality of life?

Modifying a drug without a meaningful

impact on the utility proves unnecessary in improving patient lives. It should not warrant a new patent that allows drug manufacturers to continue escalating the cost of lifesaving drugs for patients. As patients, we need novel medications, not the ones we have already tried and which have not worked for us.

When we reward pharmaceutical companies with new patents on old drugs, we remove the financial incentive (audio skip) establish channels for sharing information about an applicant. Patent examiners should have access to a wide array of information when conducting prior art searches such as including updated information from the Purple and Orange Books, FDA decisions, and scientific information.

We also recommend that when considering these additional patents, sponsors can be held accountable to share robust evidence, diversity in trials, and adequate documentation of safety data earlier on.

The last point is that this

collaboration is a unique opportunity to place an emphasis on pediatric adolescent and young adult patient populations. These are populations that have been historically left behind within clinical research. We encourage novel ways of thinking to incentivize pharmaceutical companies to truly innovate to develop drugs for pediatric populations.

Further, there must be better incentives for evidence generation earlier on, rather than nearing the end of an initially granted patent. For example, a study showed that approximately one in 10 pediatric trials ended early and that the results of the majority of these had not been published even three years later. We feel that the incentive is low for actually completing pediatric studies. Rather, it feels like there is simple encouragement of earlier pediatric research without the actual timely completion.

We suggest a sense of urgency for creating a collaborative system in which there is a true incentive to bring pediatric-approved

1 therapies to market rather than creating
2 opportunities to delay generic and biosimilar
3 competition.
4 We also wish to note that when the
5 patent system is misused and when me-too drugs are
6 created, our demographic of young people with
7 chronic conditions are disproportionately
8 affected. We run out of treatment options quickly
9 and we have a lifetime ahead of us. We need novel
10 innovation fairly priced.
11 We welcome continuing to partner with
12 the USPTO and FDA to include patients at the
13 forefront of all actions taken through this
14 important collaboration. Thank you.
15 JUDGE HORNER: Thank you very much, Ms.
16 Dave, for your work. It's impressive what you're
17 doing with your group. I did want to ask on the
18 idea that you mentioned, the suggestion you
19 mentioned of this independent public advisory
20 committee. Have you been involved or has
21 Generation Patient been involved in those kinds of
22 groups before? And again, what kind of model do

you think works best to get patient input and patient involvement?

MS. DAVE: Yes. So, we've been on a number of -- or I have represented and some of our community members have represented Generation Patient on the FDA Patient Engagement Collaborative and a couple of other like opportunities through ICER and some other sorts of non-profits and other organizations. And we really feel like a lot of times the patients that are included in these discussions are not the patients that, you know, reflect our community on a grassroots level. And so, I think a huge problem is that there is often not opportunities for compensation for patient time.

I think also a lot of times with agencies, there's a lack of plain language to really ensure that all patients can understand information in an accessible manner. I mean, even for us as a non-profit group, it takes us a lot of time to look into information. And we ask people so many questions because a lot of this language

is not done in like plain language concepts. And so, we really believe that an advisory council like this or at least adding patients to existing ones could increase opportunities for dissemination of a lot of this material.

JUDGE HORNER: Great, thank you. Any questions from our other panelists?

JUDGE BONILLA: I have one question. And first, I wanted to start out by saying how incredibly impressive it is that you are doing this at such a young age and sort of making lemonade out of lemons of your personal situation. So, thank you so much for doing that because I think hearing from you, especially on the pediatric side, I think is so valuable for us to hear.

I did have a question. And one of your recommendations had to do with patent term extension and, you know, taking a look what benefit it actually has for patients. I know some of the things that we hear on some of these what they're called secondary patents is they actually

are pretty significant improvements of the existing -- the way the existing, you know, medicine is, you know, for example, could be, you know, lowering side effects, or stability, or, you know, things like that. Do you consider those to be sufficient to be taken into account even when it's a secondary patent on the same drug?

MS. DAVE: Yeah, again, I think it depends on what the actual patent is for. So, if it's something like side effects, I think that's incredibly important. But we've also seen other things like very basic things that may not actually warrant a patent extension and may not actually have a benefit to where it's worth to have an additional, you know, couple of years or however long it is. So, I think that's where it's also really important to have patients involved in determining some of these like what is the value of the actual added benefit, so.

JUDGE HORNER: Other questions? I'll just have one more of a comment but just for awareness. So, one of the suggestions that you

made dealt with what patent examiners have access to in terms of searching. And I will say that we've done some cross-training already on patent examiner searching with the FDA. We've done training and looked in depth at what resources examiners already have.

And they do have quite a number of resources outside the USPTO patent database. They also search Orange Book and Purple Book information. They have access to public information available through FDA databases. So, their searches are very comprehensive but we're still working together to look and see if there's any other information that they don't have ready access to or aren't familiar with that they might want to consider searching. So, we'll certainly keep looking at that issue as we move forward.

MS. DAVE: Great, thank you so much.

JUDGE HORNER: Thank you for being here today, and for speaking, and for providing us with a great perspective from a patient advocacy viewpoint. So, thank you.

MS. DAVE: Thank you.

JUDGE HORNER: Okay. That concludes Session 1. We're going to move to Session 2. And we have one speaker for Session 2, Mr. Kevin Wren from T1International. So, if we have Mr. Wren already available online, we can go ahead. And as we're waiting to get him up on the screen, we'll have our panelists come and get seated. Dan, you can sit right here. Dan Kolker and Bethany, please. Thank you.

I'll have the panel do introductions in just a moment but I want to make sure Mr. Wren is connected first. So, we'll give him just a moment.

MR. WREN: Thank you.

JUDGE HORNER: Yeah, there you are. Hello, Mr. Wren.

MR. WREN: Hello.

JUDGE HORNER: We're going to have our -- hopefully, you can see our panel and we're going to have them introduce themselves and then you can deliver your remarks.

MR. WREN: Thank you.

MS. HURWITZ: Good morning. I'm Zahava Hurwitz, the Director of the Policy Engagement and Coordination Staff in the Office of Policy, Legislation, and International Affairs in the Commissioner's office at FDA.

MR. RITTERBECK: Good morning, Mr. Wren. My name is Dan Ritterbeck. I'm a regulatory counsel in CDER's Office of Regulatory Policy at the FDA.

MR. SULLIVAN: Good morning. I'm Dan Sullivan. I'm with the USPTO. I am Director of Technology Center 1600 where we do examination of most of the pharmaceutical inventions.

JUDGE HORNER: And, Mr. Wren, I'm Linda Horner. I'm an Administrative Patent Judge at the Patent Trial and Appeal Board at the USPTO.

MR. KOLKER: Good morning, Mr. Wren. My name Dan Kolker. I'm a supervisory patent examiner. So, I have direct oversight of 17 patent examiners in the antibody and immunology area in the USPTO.

MS. BARHAM: Good morning. I'm Bethany Barham. I'm a supervisor patent examiner in Art Unit 1611, which we examine small molecules, cosmetics, as well as drug formulations.

JUDGE HORNER: Great. And that's our panel. And, Mr. Wren, you're welcome to deliver your remarks.

MR. WREN: Thank you. My name is Kevin Wren and I was diagnosed with diabetes over 20 years ago. Over that time, my insulin prescription has remained relatively unchanged as new monitoring and delivery technologies have emerged. I live in Sacramento, California and I advocate with Insulin for All because no one should have to ration the insulin that they need to survive or the best treatments and technologies available. My colleagues Shaina Kasper and Emmabella Rudd will show more later about who we are and the work that we do.

Life with diabetes is complicated but at T1International, we believe that access to vital insulin, diabetes supplies, and medical care

should not be. I am grateful to have the latest insulin pumps and continuous glucose monitoring technologies and insulins, but I question whether the patent system as it exists today helps or hinders the innovation needed to get these technologies into the hands of patients.

The patients on these drugs and technologies need technology to protect their innovation are essential. My continuous glucose monitor, the Dexcom G6, reads my blood sugar levels every five minutes and gives me alarms when it is too high, too low, and going up or down too fast. I can access the readings on my phone and they connect to my insulin pump. However, these technologies are not available to everyone. I only have access to these new innovations because I live in poverty and I am able to access Medicare and Medicaid.

These are less widely used by the many people and Black, Indigenous, and People of Color who earn too much to qualify for Medicaid but too little to afford it. I am testifying today

because I have experienced rationing insulin and supplies and I believe that no one should have to do that. We should have access to vital medicines, care, and supplies due to where they live or what they do or how much they earn.

And because of manufacturing and patent manipulation and exploitation, combined with the lack of time and training on what is innovative, too many patients -- too many patents are being awarded for things that are not new, leading to rationing and serious health outcomes. I think that three things can be done today to improve training: More time, more training, and patient consultation.

First, patent examiners need more time for more examination. It may only take several years from filing a patent application for an applicant to receive a final patentability decision from the patent office. However, on average, an examiner spends only 19 hours reviewing an application. This can include a lot of different important and detailed work including

reading the patent application, searching for prior art, reading the prior art, and identifying the most pertinent references, comparing the prior art with the patent application, writing a rejection, responding to the patent applicant's arguments, and often conducting an interview with the applicant's attorney. That's a lot to do in not much time. Patent examiners need more time.

Second, patent examiners need more training and resources for patent examiners. Training should be inclusive of both FDA reviewers and PTO examiners so both parties have consistent understanding of products under review.

Finally, patients need to be more involved in the process and patients should be involved in the training. As patients, we are the experts in living with diabetes and these conditions. And we should have the opportunity to consult and offer our expertise on technologies and innovations, including the state of art in diabetes care. Examiners listening only to pharma's lawyers everyday about what they think

the state of the art is, is leading to bias. Having only training from pharma is leading to bias.

For too long, drug makers like insulin manufacturers Eli Lilly, Novo Nordisk, and Sanofi managed to manipulate the patent process and the lack of time allocated for the reviewing process allowing them to evergreen patents and exploit flaws in the system. We, the patients, see the true impact of these innovations, yet we are left out of the conversation and the process that impacts our health and the lives on a constant basis.

We should be included and addressed as part of the patent examination process for drugs. We can see the blind spots and can help ensure that a patent fulfills its promise to help us manage our chronic conditions. This hearing underscores the importance of independent patient and consumer group perspectives.

I am able to speak remotely due to ACA accommodations because I am a patient. However,

the PTO's decision to prohibit remote speaking silences a lot of voices, including members of the T1International's Families United for Affordable Insulin who didn't feel welcome to come despite having lost loved ones due to insulin rationing due to cost.

The technologies that I have should be accessible to everyone. Racial healthcare disparities is very persistent in diabetes care. A study recently published in Diabetes Technology and Therapeutics found that even though use of insulin pumps for type 1 diabetes has grown in the past two decades, there was no improvements in racial gaps.

In order to fulfill its promise of equity and inclusion, the FDA must prioritize patient voices within the review of a patent. To that end, the FDA must give space for Black, Indigenous, and People of Color, as well as those in the LGBTQ+ community, in order to fully understand the impact of patients -- of patents on marginalized groups.

PTO and FDA include patients, patient groups, and patient coalitions because we live with the conditions consuming these drugs. Patients must be at the table and our voices must be heard amid the examination process. If the process is to be equitable, then it must include those who are most affected. The disproportionate lack of access among BIPOC communities to emerging technologies, like my continuous glucose monitor and my insulin pump, means the system is racist. If we are not given a voice within the process, then you are allowing inequities to persist and fester. If we are not given reasonable accommodation to be part of the process, the system is ableist.

Only by centering the examination processes for drug patents on patients can the FDA fulfill its commitment to protect public health. New drugs and technologies can be lifelines for those struggling and we must include patients within the examination process because this is truly life, death, and good health. Thank you.

JUDGE HORNER: Mr. Wren, thank you for being here today for taking the time to prepare these remarks and share your story and your perspective, and we value your input. I'm going to turn to our panelists to see if we have any questions from the panel.

MR. KOLKER: So, one thing you mentioned was the amount of time it takes for a patent application to be reviewed and a patent applicant to get a final decision, as well as the relatively small amount of time, you cited 19 hours that an examiner has to look at a patent application. And I feel like this is a tension that the USPTO is always dealing with that we want to give examiners time and yet we want to get decisions to applicants more quickly. And so, what would be your recommendation for where we should swing between looking at more applications versus spending more time per application?

MR. WREN: Yeah, I think the system is geared towards the patent applicants not the patients that are receiving the care. So, I think

in trying to move efficiently, you ignored simple aspect of the process, and that's patient voices. I think, I mean, just given the sheer number of patents that are being reviewed, it makes sense that it should be like a just like a factory model where you're just getting it through.

But some of these have real dire impacts on people's health. And I think 19 hours is not nearly enough. You ask anyone who has any idea of what a patent application might be, we need way more time to review these things and include patient voices. I don't have a set number of time that you should increase it by, but I think the process itself should be reexamined and completely redone.

MR. KOLKER: Thank you. And then I'd like just to make a comment as well just so that you and your community are aware of it. You said that there needs to be more voices and that we need to understand the patient's perspective. And I'll just point out that there is a mechanism already in place called a third-party submission,

which allows someone to submit things that they think might be prior art. And I'm not going to get into the details of it, but it's called a USPTO third-party submission. And that does exist already and it's open to members of the public.

MR. WREN: Thank you.

MR. SULLIVAN: So, yeah, thanks for your comments. So, there was some earlier discussion about, you know, patient group advisory committees as a means for giving, you know, patients access to the agencies. And I just wanted to know if, you know, you're involved in those or aware of those, and is that something that you think addresses the concerns that you have about access to the agencies? Or are there other ways that you think that patients should be -- or other ways that patients could have a voice in what the agencies are doing?

MR. WREN: Yeah. I think Sneha said it pretty well. But I mean, just an example from my own life. In Washington State we have a Total Cost of Insulin Work Group where we looked at the

total cost of insulin and why it's so expensive and ways to make it more affordable. And from my testimony, we were able to establish five positions for members of the public who have the disease to balance voices from pharma, the hospital industry. I mean, without my testimony and without us like fighting for it, we wouldn't have gotten a seat at the table.

So, I think too often we're having to fight for these seats and they should be made available just as like a basic concern. I mean, this should be built in. We shouldn't have to have like fight and struggle just to get our voices heard. I mean, just appearing today in this room like I had to wake up at 7:00 a.m. I had to do a whole of stuff to get prepared. And a lot of patients who are suffering with chronic conditions, don't have that kind of time or resources. So, I think you say the process is open, but it needs to be made way more open.

JUDGE HORNER: Any other questions from panelists? Dan?

MR. RITTERBECK: Yeah, thanks again for your comments. I just wanted to make a quick distinction that I think is important. There were a couple statements in your comments that seemed to suggest that FDA is involved in the examination of patents and I just want to make sure that you and your community are aware that FDA does not examine patents. We're tasked with reviewing drug applications. And so, I just wanted to, you know, make sure we were clear about that. That's all.

MR. WREN: Sorry for that misconception.

MR. RITTERBECK: No, no, no problem. I just wanted to make that distinction, thanks.

MR. WREN: Thank you.

JUDGE HORNER: And, Mr. Wren, I'm intrigued by the idea of examiners having an opportunity to hear from patients about state of the art because you're the ones using the products. And so, you know, we do have a program at the USPTO that allows examiners to make site visits or to get training about state of the art from industry. And I think, you know, that's a

suggestion we'll take back and think about is whether that could be expanded to include patient groups so that examiners get that perspective as well. So, thank you again.

MR. WREN: Thank you so much.

JUDGE HORNER: Thank you for your time. This concludes Session 2. We're going to take a break. We'll reconvene at 11:30 for Session 3.

(Recess)

JUDGE HORNER: So, if everyone could take their seats. All right, welcome back. So, we have a full Session 3. We have six speakers. Our fourth speaker will be virtual. So, we'll take a little break from the room and see our virtual speaker. Our first speaker is Professor Robin Feldman from the University of California Hastings College of the Law. Professor Feldman, you may deliver your remarks.

PROF. FELDMAN: Let's see. There we go. Thank you. It's an honor to be here but I'm not sure that my mic is working. Thank you. Ah, that's so much better. Okay. Thank you. It's an

honor to be here.

A few years ago, my coauthors and I published a piece in Nature Biotechnology focusing on patents for a cancer drug that unfortunately protect excessive does of the drug. Those patents thereby encouraged treatment at unnecessarily high doses. Discussing these and other concerns, we suggested greater coordination between the FDA and the PTO to ensure that each agency would know what the other is doing and to avoid the possibility that applicants could say different things to each agency. I am, therefore, heartened to see all of the efforts going on today.

I do want to be clear that I believe the problem goes beyond the potential for directly inconsistent statements because patent examiners normally are not clinicians. That is, they are not physicians or pharmacists. And they're also not normally pharmaceutical researchers. Input from the FDA can fill that knowledge gap helping patent examiners determine whether a pharmaceutical application represents a true

innovation or rather something that is obvious to physicians or obvious to the FDA itself. It's where to look in the vast amount of information that's out there.

Such communications can also help the PTO determine whether the claims are based merely on routine optimization or even an action requested by the FDA. With that in mind, I'd like to offer a few examples of reasons why lines of communications could be helpful.

So, first, a company shouldn't be able to tell the FDA this drug product is essentially the same as what we have out there. So, no further testing that's needed. And then go to the FDA -- go to the PTO and say the product is entirely new. Either it's new, it's the same, or it's not. One or the other. It can't be both new and the same at the same time.

Similarly, if the FDA is not convinced by the clinical data, then that data shouldn't be the basis for a patent claim. Suppose the FDA doesn't allow a comparative clinical study in the

product information. In other words, the company won't be allowed to say our drug causes fewer headaches than what is currently on the market. In that case, the company shouldn't be able to get a patent by claiming that the drug causes fewer headaches.

From another perspective, if the FDA is telling a drug company to take an action or investigate an aspect of the drug, the company shouldn't be able to patent the results of that investigation. If the FDA directs your action, then it isn't novel and it was certainly obvious to try. This is not to impute nefarious motives to pharmaceutical companies. Rather, it is unfortunately too easy and perhaps just human nature for companies to emphasize for the FDA little is new, nothing to worry about, no data needed. And yet, to emphasize for the PTO that the drug product is wonderfully different and innovative.

Applicants are speaking to their own interests at each agency. But society has a

larger interest and that's to get to the truth of the matter and make sure each agency has the full picture. I'd like to suggest some steps that could help ensure consistency.

First, consider specifying that if an applicant makes a representation to the FDA and the issue is relevant to a patent application, the applicant should disclose to the PTO the same data analysis and conclusions as those submitted to the FDA.

Second, establish more formal communication inputs for the agencies regarding applications. One could begin by communicating about a smaller subset of patent applications such as those that include method of use or formulation claims. A group of patents more likely to be subject to litigation. Smaller steps like these can help work out the problems in the system and the effort could expand to other types of secondary or tertiary patent applications.

A key time for patent examiners to avail themselves of experts at the FDA would be when

reviewing applicants' responses to patent office rejections, particularly if the applicant responds with affidavits attesting to specific clinical or pharmacological findings. In this context, the PTO could obtain information from FDA employees that may support examiner findings and could also access the documents submitted to the FDA. Again, the issue isn't the vast amount of information that's out there sometimes. Sometimes the innovation isn't out there. But it's a question of knowing where to look and what matters to those who are on the ground in the field.

It's possible that the relevant information should not yet be released to the public. Consider information existing prior to drug approvals, such as a request for permission to test the drug in humans. If so, perhaps there could be a separate file wrapper in which the information remains sealed until the appropriate time.

I am concerned, however, about some of the things that are happening in the context of

confidential information just in general. Trade secrets, claiming trade secrets, a broader category than confidential information, has become like a magic wand. People waive it and everyone backs off. Trade secrets do play an important role in the pharmaceutical industry. However, there is quite simply considerable overreach with trade secrets at the moment. Federal trade secret law does not preempt the Patent Act, nor does it preempt the Hatch-Waxman Act or the Biosimilars Act. State trade secret laws don't preempt any of those either. So, patent and regulatory disclosure processes should not simply fold in the face of trade secret claims. They need to be looked at more carefully.

I would close by saying that thanks to the work of PTO directors and staff in recent administrations, both Republican and Democrat, we now have enhanced mechanisms for the PTO to receive advice and information from counterparts in foreign countries and from industry. I believe it would be helpful for the PTO to also enjoy the

expertise of its own sister agency right next door. Thank you very much.

JUDGE HORNER: Thank you, Professor Feldman. I'm going to open it up for the panel. And we'll just start down on this end if you have any questions for Professor Feldman?

MR. RITTERBECK: Hi, Professor. I had a question for you. You had mentioned the -- you coauthored a published piece about a patent that protected excessive doses of a particular treatment and you said that that encouraged treatment with those excessive doses. I'm just curious, has it been your experience that healthcare providers or patients are relying on patents in order to inform treatment decisions?

PROF. FELDMAN: No, patents don't inform, but they do inform what product gets to market. And that matters for what's accessible, what's available to the parties. So, in that case that you're referring to, the FDA specifically encouraged and noted its concern about the excessive dose. Encouraged the folks to test it

at lower does, to look for that product. That's not going to happen because lower doses weren't patentable.

In the case you're describing, the companies picked the one tiny slice that was available among all of the patent rights that existed and other types of information of prior art to patent. That was helpful for getting a patent. It's not necessarily helpful for patients.

MR. RITTERBECK: Thank you.

JUDGE HORNER: Any questions from this end of the table?

MS. FERRITER: I'll ask a question. You mentioned that comparative claims that are not substantiated before FDA should not be patented. On what statutory basis would PTO be able to rely on to reject such type of claim? And then since that FDA submission would typically be well after a patent application had already been on file and likely examined, how would the applicant then be able to address that issue?

PROF. FELDMAN: So, let me see if I can address the second one first then I'll go back to the first. And that is if you think about a biosimilar application, yes, there's a great deal -- and I'm talking about applications in either agency -- yes, there's a great of time that passes. But there are also obligations to update information if there are changes made to the drug. So, you have information that is coming into the PTO.

There is certain -- I'm sorry -- that's coming into the FDA. There is certainly an issue in which the FDA gets its information well after the PTO gets its information, which I think is what you are talking about. However, if you have proper disclosure of information by both agencies along the way, and you have file wrappers when it's appropriate for that information to become public, and you have the FDA disclosing the information at the time that it becomes public, then it becomes possible for others to challenge the patent and to understand and to put the pieces

together. So, I think that's a piece.

You are right that I think there's a problem with how early we grant rights in some of these areas. And I think that is something worth looking at. But it's not the subject of today's hearing.

The first you asked -- the first question though you asked about is what is the statutory basis. So, for any -- and I -- you know, you and I can talk about the, you know, the five elements of patentability. But I think what you're saying is that it's difficult to rebut a claim particularly a claim that's made in an affidavit by a patent applicant. But a patent examiner can look at any information that exists out there for making a determination of whether something is novel or would be obvious to those in the field or a claim that's simply doesn't have validity.

That's why in an office objection, one can challenge the question of the assertions that are made by the applicant. The applicant in that

case may come back and just put an affidavit in. But it can be useful if an agency that actually knows something can say either that affidavit is problematic based on what the applicant has told us. That is something that can be useful. I agree with you that timing's a problem in this area.

JUDGE HORNER: Thank you, Professor Feldman. Unfortunately, we're out of time. I'm sure our panelists have more questions. But for the sake of keeping this moving and keeping to our time allotted, we're going to move ahead to our next speaker.

PROF. FELDMAN: Thank you. And I would welcome other questions if folks want to follow-up. I also note that with my apologies your staff was kind enough to give me the first slot here because I do have a plane to catch. So, I will disappear from the panel at some time, but with great respect to those who are speaking after me. Thank you so much.

JUDGE HORNER: Thank you. Our next

speaker is Mr. Tahir Amin from the Initiative for Medicines, Access, and Knowledge, I-MAK.

MR. AMIN: Thank you, Linda. And thanks to the USPTO and FDA for hosting this listening session and for allowing me to make some remarks.

My comments are specific to the FDA guidance on polymorphic forms and the patenting practices around them. In 2000, the FDA published a guidance document, which is available in my comments. And in that guidance the FDA sets out how polymorphic forms should be monitored and controlled by companies for new drug substances and products.

As the guideline states, some new drug substances exist in different crystalline forms that differ in their physical properties. In cases where differences exist that are being shown to affect drug product performance, such as bioavailability, stability, then the appropriate solid state should be specified. The guidance then provides how physiochemical measurements can be obtained and these are various sort of

techniques, which are commonly practiced in the industry, such as hot-stage microscopy, solid state IP, x- ray powder diffraction, and so on. I won't reveal the whole list. But these are common practices that the industry uses.

There's also in the guidance a decision tree, which sets out how drug applicants need to go about testing for these polymorphs. And related to that there is what we call the investigation of a new drug application. Now, current federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship an investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. And the IND is the means through which the sponsor will do that.

Now, it's important to recognize the IND application must contain information in three broad areas: Manufacturing information pertaining

to the composition, stability, which is very relevant to polymorphs, and controls used for manufacturing the drug substance and the drug product. This information is assessed to ensure the company can adequately produce and supply consistent batches of the drug.

So, accordingly, the FDA requires polymorphic screen data to be submitted by a company seeking to bring a new product to market in its original IND application before Phase 1 clinical trials. Therefore, polymorphic data on the new drug can be available to the FDA anywhere between three to six years before the drug is finally approved.

So, how does that affect polymorphic patenting and practice? Despite the FDA guidance for routine testing for polymorphs, I refer to that decision tree, and that such information is provided to the FDA as early as the IND application stage where is applicable, our review of patent filings for polymorphic forms for a number of drugs shows that they are often filed by

companies considerably later. So, while it is recognized that information on polymorphs are provided through an IND to the FDA is treated as confidential information, it appears companies are using this confidentiality to delay the filing of the patents on these polymorphs in order to stretch out their patent protection for as long as possible.

In essence, companies are being allowed to protect the polymorphic data they provide to the FDA as a trade secret until they conveniently decide that the relevant polymorph patents for the purpose of meeting the listing requirements on the U.S. FDA Orange Book, as required by Hatch-Waxman, or simply for defensive litigation purposes.

I just want to illustrate this with the example of the drug Revlimid, which is a cancer drug to treat multiple myeloma. The main compound patent of the drug lenalidomide, which is what constitutes Revlimid as developed by Celgene, is U.S. Patent 5635517. It was filed on the 24th of July in 1995 and expired on the 4th of October

2019. According to a source at the Mayo Clinic who worked on the preclinical trials for lenalidomide, it is understood that the drug was under clinical investigation in 1999 and 2000, which would have required an IND at the submission of relevant polymorph data and the submission of relevant polymorph data to the FDA as I've described.

However, Celgene did not submit its patent application for the polymorphic form of lenalidomide until the 3rd of September 2004, which is U.S. Patent 7465800, which expires on 27 of April 2027. That's roughly four to five years after clinical investigation commenced and adding another eight years of patent protection be on the main compound patent.

Furthermore, between 2008 and 2020, Celgene then applied for several other patents covering polymorphic forms of lenalidomide. Many of them were divisionals but also -- so, it didn't extend the actual expiry of the patent, it didn't extend the protection of the patent -- but also,

there was completely new patent application for a different polymorph, U.S. 9808450, which was filed on the 25th of March 2014, expiring 25th of March 2034.

Now, this patent data is available now at Drug Patent Book, which you'll probably hear a lot about today where people believe it's misleading, but I think it's important to recognize the universe of patents that you see on the Orange Book is not the universe of patents that corporations actually apply for and use in different various ways.

So, Celgene has entered into settlements with a handful of companies, which only allows for limited generic volume launch. So, only after 2026 will the U.S. market see full unfettered competition, and that's because of these polymorph patents that they've delayed deliberately.

So, given the FDA guidelines on polymorphic screening and the routine testing that's required, I've got a couple of quick recommendations. I think first of all, the courts

currently see polymorphs as unpredictable, despite the routine testing. However, given polymorphs are inherent in the original compound and the FDA requires companies to find them as a matter of experimentation for the purpose of marketing approval, shouldn't it be the case that the USPTO revise its examination practice on polymorphs as being prima facie obvious?

Secondly, where companies are filing patents for other polymorphic versions much later than the first polymorph patent, even if it's a continuation or divisional, that does not extend the expiry of the patent and claiming surprising or unexpected advantages, such as stability, flow, or bulk density, these patents should be refused if the FDA had knowledge of these other forms at the time of the IND.

And finally, alternatively, and without prejudice to the recommendations above, once a company has submitted a polymorph screening to the FDA as part of its IND, it should have 30 days to file its patent applications for all polymorphs

identified to the USPTO. Failure to meet that requirement means the USPTO should refuse the application because otherwise they're using it to deliberately extend the patent. Thank you.

JUDGE HORNER: Thank you. I'm going to start at the other end of the table this time and see if we have any questions on this side.

MS. FERRITER: Sure. Thank you very much for your having made the written comments and for your appearing today. We really, really appreciate all of your engagement. I realize I-MAK has made a number of PTAB challenges in the past and one point you didn't exactly address today was your experience there. I'm wondering if you have any comments on whether you believe that the scope of patent challenges that can currently be made to PTAB are sufficient or would you recommend being able to bring in any additional grounds for rejection?

MR. AMIN: I think first of all the PTAB is it's very prohibitive for groups or people who are outside of the commercial sector to afford to

bring those challenges. We were fortunate enough to have the limited funding to bring those challenges. And I think the first step is certainly for non-profit groups or actors who are not in the commercial space should have some kind of lower fee structure to be able to do it. I think there may be something like that even when applicants file patents they have a different fee structure. I think for groups who are like whether they'd be patient groups, or consumer groups, or whatever, there should be a lower fee.

I think in terms of the institution of the challenges that we made, we didn't get any instituted. And I felt in some ways that we were almost prejudiced against because we were actually challenging the patents as a group who has actually voiced a lot of concerns about some of the patent abuses. I'm not saying -- I'm not implying intention there, I'm just saying that's how we felt because when Gilead actually responded, the first thing they did was to attack our expert and saying that he's anti-patent. And

I think that doesn't help the conversation. So, I would just kind of leave those two comments there in terms of our experience.

MR. SALIMI: Hi. One quick question on the polymorphs. If the jurisprudence hasn't changed, under what authority does the U.S. have to find these polymorphs prima facie obvious?

MR. AMIN: Yeah, that's a good point and I recognize it. But I think it should actually be recognized within the context of what the FDA requires. So, I think there should be some change in practice there. Whether that be done from the legislature, whether it be due through the USPTO and FDA to change the guidance of how they work. I do recognize that current jurisprudence is --

REPORTER: Could you turn your mic back on, please?

MR. AMIN: -- that current jurisprudence is debatable. But I think actually it's important to recognize if you look at the roster of experts who testify on these cases, most of them are making a handsome living testifying about

polymorphs. And so, the question then remains is that really true independent evidence experts, which is a different issue. But, you know, the idea that jurisprudence is correct on this, you know, if we had independent experts outside of whichever actors involved in the litigation, we may have actually a different assessment of this.

JUDGE HORNER: Okay. I think we're going to have to leave it at that unless our FDA folks have any questions?

MR. RITTERBECK: I just have a few questions.

JUDGE HORNER: Go ahead.

MR. RITTERBECK: Thanks. I'm looking at your suggestion number three, your recommendation number three, and I'm just curious, the last line says this would require FDA to share the IND materials with the PTO. Why would it require FDA to share the materials with the PTO as opposed to that onus being on the applicant itself?

MR. AMIN: Well, unless there's -- because I don't think the applicants in the

current, they will try and delay and if the PTO has no idea about the polymorph testing that's happened and what's actually what they found as a result of in their ability to get the IND, how will the PTO ever know?

MR. RITTERBECK: Okay, thanks.

MS. TILL: Can I follow --

MR. AMIN: So, it's a way --

MS. TILL: Can I --

MR. AMIN: -- it's a way to just sort of it's an alert system in saying, you know, we have received this information about this kind of polymorph related to this drug or this, you know, and then it kind of puts the onus on the applicant to kind of show up.

MS. TILL: I just wanted to follow-up on that. So, if the polymorph information has been submitted to FDA as part of an IND and it's held in confidence, what statute or provision requires that applicant or that marketing applicant or that potential patent applicant to immediately file their patent application?

MR. AMIN: There is none. And I think that's the gaping hole in this issue and that's what I'm trying to raise.

MS. TILL: All right, thank you.

MR. AMIN: To use a lawyer speak, we found a loophole. You know, I did this as practice for 10 years, so.

MS. TILL: Thank you.

JUDGE HORNER: Our next speaker is Mr. Hans Sauer from the Biotechnology Innovation Organization, BIO. Mr. Sauer.

MR. SAUER: Thank you, Judge Horner, at the Patent Office. Good morning. I'm pleased to offer remarks this morning.

Most of BIO's members are small development stage companies that do not yet have a product on the market and that rely on robust IP rights in order to access capital, engage in partnering and licensing, and advance innovative health solutions through the development chain. The chances of successfully developing a new therapy are less than 10 percent at a cost

exceeding $1 billion over an almost 10-year development process. Robust and reliable patent rights are crucially important if private investment in healthcare innovation is to be sustained in the face of such costs and risk.

Thanks at least in part to a robust and principled U.S. patent system, more new therapies are invented and developed in the United States than in the rest of the world combined. It is unsurprising that questions about how to sustain the biomedical innovation engine in the United States would eventually come into political focus. In order to execute on the President's drug pricing agenda, the PTO has issued multiple Federal Register Notices seeking comments on a great diversity of proposals to change the way patents would be examined, reviewed, and enforced. Proposals range from changing continuing application practice, to terminal disclaimers, to PTAB proceedings, patent term extension, information disclosure statements during patent prosecution, restriction practice, Orange Book

listing, use codes, skinny labeling, and so on.

While it is clear that these proposals are responsive to political narratives and concerns, the scope and contours of the underlying problems are subject to debate and poorly substantiated at this stage. For example, you have heard that biopharmaceutical companies procure unusually large numbers of patents. They do not. In fact, normalized to R&D spend biopharmaceutical companies procure fewer patents than comparable businesses in other technologies. By some accounts patenting intensity in the biopharma space is around 1/10 of that in high-tech or communication technology, for example.

Nor are biopharmaceutical patents of doubtful quality. In fact, pharmaceutical patents are invalidated less often in litigation, around 25 percent of the time, compared to 40 to 45 percent across all industries.

Patent counting exercises are frequently referenced in public debate but we believe they

are neither particularly accurate nor particularly relevant. Biopharmaceutical companies do not accumulate unusual numbers of patents associated with individual products. There are golf balls with 60 patents on them. Vacuum cleaners with hundreds. Even cream cheese with seven patents. Biopharmaceutical products and advanced therapies are no different from other complex products in other technologies in this respect.

The average number of patents for new chemical entity drugs in the Orange Book is around five, not hundreds. The median number of patents that have been litigated in biosimilars disputes is less than 10, not hundreds. And importantly, narratives of everlasting patent monopolies have consistently avoided looking at actual dates of generic and biosimilar entry, even though this information is available and has been studied.

A published assessment of the UC Hastings so-called ever-greening database, for example, found many innovator drugs that are listed as supposedly still under monopoly, when

they in fact, have had generic competition for years. The purported innovator monopoly periods were found to be off by an average of seven years relative to the dates of actual generic market entry.

If claims to pervasive so-called ever-greening are correct, we would expect to see increasingly long periods of market exclusivity and increasingly later entry of generic competition. This is not the case. The empirical period of actual pharmaceutical market exclusivity from approval of a new chemical entity to the date a generic enters the market has been studied since the 1990s and has been found be stable at around 12 to 13 years, not decades. It would be a fallacy to say that patenting data proved the emergence of ever- expanding pharmaceutical monopolies at the need for expansive policy change.

BIO looks forward to engaging with the PTO and the FDA on the empirical evidence. BIO's members welcome and support agency collaboration

that helps agencies better do their jobs. On the topic of FDA-PTO collaborations, specifically, we understand that FDA already has authority to inspect PTO records for purposes in enforcing the FDCA. And the PTO in turn has the ability to request full and complete information from the FDA relating to questions raised by any drug patent application and even to have the FDA conduct additional research into such questions. Patent examiners are able to require such information directly from applicants if they deem it to be reasonably necessary to the examination of an application. And applicants are under a duty to disclose material information under Rule 56.

Given these tools already being available to the two agencies, it would be helpful to better understand what it is in the FDA record that the PTO would expect to find. We know empirically that FDA regulatory dossiers are not very efficient or fruitful sources of prior art that cannot be accessed from other sources. Well-heeled and sophisticated litigants in patent

litigation have reviewed their adversary's regulatory filings for decades with few instances of finding killer prior art.

And even with respect to inconsistent statements the PTO points to two cases, not more, a 30-year-old case of a 510(K) medical device applicant and a more recent case of a 505(b)(2) new drug applicant. In each instance, those applicants relied for FDA approval on prior art predicate devices or reference drugs that had been withheld from the PTO. These are hardly typical scenarios in the innovator biopharmaceutical industry and we think they are a thin reed for instituting systemic change.

Nonetheless, the PTO should, of course, have access to material information. There may indeed be instances where the FDA could assist the PTO in finding prior art, perhaps non-patent, non-publication prior art that may not be identifiable from other sources. Like, for example, the specifications of the predicate devices or the reference drug at issue in the

Bruno and Belcher cases that are cited in the Federal Register Notices.

We caution, however, against witch hunts for seemingly inconsistent statements because consistency or inconsistency is going to be extremely difficult to assess given the varied standards between the two agencies. Something may be non-obvious under the PTO's standards, but still qualify as a predictable, reliable, safe, and effective outcome in support of a drug applicant. Sorting through all of the FDA's written materials would be an enormous burden on agency staff and applicants, causing much delay while unlikely to prove new or additional information relevant to patentability in the aggregate. Thank you for your attention.

JUDGE HORNER: Thank you very much for your comments. I'll open it up to the panel for any questions. Any? Yes, go ahead.

MS. DAVIS: Thank you for your remarks. I have actually a request instead of a question. I saw you submitted your written remarks, but if

you have anything additional you can submit to the docket about some of the figures you cited like average numbers of patents, that would be really helpful. Because that's different than what I think we've seen in our own analysis. So, it would be helpful to see how you looked at it and where that figure comes from.

MR. SAUER: Yes.

MS. DAVIS: Thank you.

MR. SAUER: Thank you.

MS. TERROT: Hi. I had a question. You mentioned that there's been tracking of the average time to generic entry and that it stayed relatively stable. Have you studied the litigation costs relative to other development costs? Or, you know, has the number of patents asserted in Hatch-Waxman litigation evolved? Or have you studied how, you know, how much of a relative financial burden the litigation is to getting a generic to market?

MR. SAUER: Okay. So, on the financial burden, I don't have that information. We did

look, however, over the years at how many patents are listed in the Orange Book for, in particular, new chemical entities. That's not just us. I mean, this has been studied a number of times over the years. I do think it's true that over time there's been a moderate increase in the number of patents that appear in the Orange Book. So, 20 years ago the average number may have been something like three patents per drug, and it is now more around five. So, there has been an increase over time.

The time to a generic entry has stayed similar, as I said. What has also changed is the frequency and the timing of generic challenges, and particularly a paragraph 4 challenges, which now occur earlier than they did 20 years ago. So, I think one way to look at this would be to say that both sides of the industry, at least in the Hatch-Waxman context, have over time evolved their strategies. And the net effect on the timing of generic entry as a result has stayed the same. That would be our interpretation of the data. But

that too will be something that would submit on the 6th when the time comes for written comments.

MR. SALIMI: I guess I would -- I appreciate the fact that you said the difference -- there has been some decade between the Bruno and Belcher case. So, that means the system is somewhat working. But do you have any new ideas for private practitioners to have a better communication with the regulatory side and the litigator side so there won't be any Belcher case?

MR. SAUER: Yeah. Do I have ideas? I think those will -- the way this would be implemented -- well, first of all, I think you're right. You know, we haven't seen a lot of case law, but we do know that defendants in litigation have been looking for exactly this kind of scenario for a long time and it doesn't appear often. In my personal opinion, I think the Belcher and the Bruno cases are examples where the system worked. If this were to happen routinely, we would have heard about it more often. And so, these cases I don't think are tips of an iceberg.

They are more signs that the system can actually work if you have motivated litigants. No, not everything will have been caught over time.

With respect to implementing practice changes in the industry, I hear a lot from our member companies who are wondering about the Federal Register Notices, the scope of the obligations and duties. Companies are different in size and organization. Belcher, I think, was a very small company. You could see from the record that the people involved with the prosecution of the application had an unusually strong input in the FDA. They even shared jobs and responsibilities. That is often not the case in pharmaceutical companies.

So, I can tell you when I worked in-house as a patent lawyer, I had some patent lawyer colleagues and I would sit in on product development teams. But I had no line of sight into what everybody else in the team was writing or communicating to colleagues at the FDA or frankly others like clinical investigators because

why stop at the FDA record?

So, to expect that the patent people in the company have a line of sight into what some medical writer communicates to another colleague in their space or maybe a clinical investigator sometimes it's very hard to expect of a company to be able to do this and to control communications. But we are certainly thinking through these questions. We agree that there shouldn't be inconsistent statements. But we also think that finding prior art, rather than inconsistent statements, I think prior art is the more important of the two kinds of information to find. And then I'll stop.

I will say what we've seen when we looked in litigation records for typical scenarios, what seems to be common is that prior art is usually sourced elsewhere. It emerges somewhere in the litigation. And then defendants want to know and want to access the FDA record to see not the prior art, but they want to know what the patentee said about that prior art. So,

finding the prior art is one thing. Wanting to know what was said about it is a different question. And that's not always relevant to patentability.

JUDGE HORNER: Thank you. We're going to move on to our next speaker who is a virtual speaker, Ms. Shaina Kasper, from T1International. And while we're waiting for her image to come up, I want to make a shameless plug for an event that we're planning on February 23rd. We're going to be doing a panel discussion. It's going to be moderated by the vice chair for the AIPLA Food and Drug Committee. And we'll have panelists from the Office of Patent Legal Administration and the Office of Enrollment and Discipline to talk about the Federal Register Notice that the Office issued on duty of disclosure and duty of reasonable inquiry.

So, we're fielding questions now from the public that we could provide to that panel. So, if you have questions, specific questions from members of your group that you want to pose to the

panel, we're collecting those questions now.

All right. And hopefully we will get Ms. Kasper.

MS. KASPER: Can you hear me okay?

JUDGE HORNER: We can hear you. We can't see you yet. Yes, there you are, wonderful.

MS. KASPER: Great. My name's Shaina Kasper. I'm a patient living with type 1 diabetes, insulin dependent. I'm also the policy manager for T1International. And I'm apologize I'm not able to appear in person as planned. It seems that while I don't have COVID, I have been taken out by the common cold.

So, I want to start off just by sharing a little bit about our organization. T1International is a global diabetes advocacy organization led by people with diabetes, poor people with diabetes. T1International believes in a world where everyone with diabetes no matter where they live has everything they need to survive and achieve their dreams. We accept no funding from pharmaceutical companies and provide

advocacy training and support to all Insulin for All advocates.

In the U.S., T1International has 41 state-led Insulin for All chapters and growing, and we have three working groups with national membership. Communities of Color Working Group focuses on ensuring Insulin for All is for all and part of our organizational efforts to seek and learn from and incorporate the lived experience that has historically excluded communities at the center of our organization and our work.

Families United for Affordable Insulin is both an advocacy and support group for advocates with lost loved ones due to insulin rationing. And the Federal Working Group is focused on addressing the insulin price crisis through legislative and administrative policy changes.

So, I want to start off by sharing some about why patent review reform is a priority for T1International's Federal Working Group. One hundred years ago this week, in January of 1923,

the discoverers of insulin sold the patent of insulin for $1 saying insulin does not belong to me, it belongs to the world. Rather than the gift it was intended to be, their discovery has become the poster child for pharmaceutical price gouging.

Over the past 100 years, while insulin has improved incrementally, many of the newest insulins are still decades old. So, one example of the many reasons why long-acting insulin chloroquine prescriptions have been so expensive is because Sanofi had filed 74 patent applications on the drug Lantus, effectively blocking generic competition for 37 years. This example has been written on extensively including with an I-MAK report published in 2018 on the topic.

Unfortunately, it is not unique among the insulins or among other pharmaceuticals. Pharma has created big thickets of patents around them allowing them to maintain a monopoly. And this patent thicketing, along with the pay for delay set of patent settlement dispute agreements and more, has hindered true competition and thus

lowering the prices of drugs.

The PTO has made mistakes, I believe, by allowing for additional patents for trivial obvious variations on older drugs and enabling companies to maintain these monopolies. These unfair extensions of monopoly protections have been keeping prices high. The PTO must share information with the FDA to stop new patents on trivial obvious variations on old drug.

Lantus insulin patents are a good case to be for why this is important. The priority claim on Lantus was in 1988, with a first patent filing for Lantus in 1994, and approved by the FDA in 2000. Lantus was revolutionary when it came out and dramatically changed patient care. And if the PTO had talked with the FDA back then, I think they would have agreed this was an innovative, and non-obvious, and medical benefit. And rightly, Sanofi secured monopoly protection for Lantus in the U.S. for years just on the basis of that primary patent, which expired in 2015.

However, Lantus wasn't just covered by

one patent. Almost 95 percent of the total patent applications, 69 out of 74 on Lantus, were filed after the drug was approved in 2000. One exemplary patent filed when Lantus was first approved covers a supposedly new and improved delivery system for the insulin patent, the dose style sleeve between the housing and the piston rod with helical grooves. This patent's effective filing date was 2004, but the patent doesn't expire until 2027 or 2028. This patent helped Sanofi force Merck, a would-be competitor, to give up on its lower cost insulin Glargine products back in 2018. So, this patent seems to have played a role in preventing competition and protecting Sanofi's monopoly.

Before going on, I must note that there are now lower cost biosimilar alternatives to Lantus on the market, including the form of Viatris's assembly product. Although the product isn't available everywhere. Merck gave up but Viatris, formerly known as Mylan, kept going and ultimately did get to market. But this patent

helped Sanofi protect its monopoly, delay competition, and keep one would-be competitor off the market altogether. All of which serves to keep Sanofi's profits high and profits high.

I am not a mechanical engineer so I don't feel I'm really qualified to opine here. But the patent invention of the dose style sleeve between the housing and the piston rod with helical groove does not appear to me to be a radical step forward in insulin delivery technology. I don't have an insulin -- a Lantus insulin prescription anymore. But here is my Levemir dose style sleeve with the helical groove. Pretty similar to the Novalog pen, as well as the reusable Novalog pen here as well, as well as this mechanical pencil, as well as this Chapstick that are also all purchased at CVS.

It is not clear to me as a patient, what medical benefits, if any, Sanofi's patented delivery device system does provide to patients. These patents do not constitute a novel innovation to me.

We need consistent representation between the FDA and the PTO to ensure that PTO examiners are trained on what FDA documents to review when examining patent applications for situations like this. When Sanofi made small modifications to its patent, did it characterize these modifications to the FDA? PTO should update its regulations to make it really crystal clear to patent applicants that those applications have an ongoing duty to disclose what they've said to the FDA about their products.

This example also highlights the importance of independent patient and consumer group perspectives in these processes. Had there been an opportunity for independent patient perspectives on the Lantus example, we could have shared back in the '90s that having this long-acting insulin like Lantus is non-obvious, novel, innovative. And had we been consulted about the groove improvements we likely could have shared that this was not a non-obvious. It was not a major advance. It did not have a clear

medical benefit to patients like me, as my colleague Kevin Wren shared earlier.

A few years ago, because of this patent thicketing and Sanofi's high prices, I went into the pharmacy to pick up my prescriptions and had to turn around without filling these prescriptions. Before I hit my deductible usually in February, I've had to pay that full cost of Lantus. Had to pay that full cost of the patent thicketing, which has cost me money, but also my time, my stress, anxiety, and led to insulin rationing, with serious health consequences.

Insulin patents provide a clear case study on the important need for constituent representation between the FDA -- and for consistent representation between the FDA and the PTO, as well as constituent support. And I hope this will provide some real-world grounding and ongoing and further conversations. Thank you so much for your time.

JUDGE HORNER: Thank you, Ms. Kasper. Do we have any questions? I think we have a

question on the end.

MS. FERRITER: Thank you very much for your testifying today and the time that you took to write the written submission. The USPTO, as has previously been mentioned, does have a process by which we welcome third-party submissions related to patent applications. And I'm wondering if you or your organization has ever taken advantage of that process?

A few years ago, we changed the process to eliminate the fee. And right now, we have a really handy tool where you can go online and make the submission. And we would really welcome the information that your organization could provide related to novelty and non-obviousness. Thank you.

MS. KASPER: Yeah, I think in order to really get more patient perspectives and voices involved in the process, there needs to make -- the process needs to be even more simplified and easy to use. I think the third-party submission process is still extremely complex and easy to

use. You know, we are not attorneys. We are not mechanical engineers. We are patients with chronic conditions and being able to access and use these submission processes by, you know, being able to share our lived experiences and stories is -- doesn't feel welcome in the current submission process.

And I can provide more in additional written comments including our patient -- oh, my gosh, what's it called -- our -- at T1International, we have a ethical patient engagement principles that I can also share that could be helpful for this. And would love to continue the conversation of how to potentially improve that process, as well as updating additional processes for improvement.

JUDGE HORNER: Sorry, thank you. I have one more question. You mentioned a couple of times when discussing about patentability that it should have medical benefits for patients. Are you proposing that, I mean, the standard for patentability is novelty and non-obviousness. But

the patentability standard does not require an examination of whether the claimed invention has medical benefits per se. Is that something your group is advocating for that you think the law should be changed in that regard?

MS. KASPER: Yeah, I do not -- I'm not making a request to reopen the law. I know that has been in discussion and I recognize this is not the audience for that, as well. I do think medical benefit is the primary novel reason for looking at patents and that should be under consideration as well. But, no, I'm not. I'm not --

JUDGE HORNER: Okay.

MS. KASPER: -- suggesting that we reopen the law, the legal framework.

JUDGE HORNER: Thank you. Thank you. All right. Thank you for your time today.

MS. KASPER: Thank you.

JUDGE HORNER: And we'll go to the next speaker. Our next speaker is Professor Adam Mossoff. He's with the George Mason University

Antonin Scalia Law School. Professor Mossoff.

PROF. MOSSOFF: All right. Thank you. Thank you for this opportunity to speak at this listening session today on USPTO-FDA collaboration initiatives. Now, in my brief remarks this morning, I'd like to emphasize the importance of evidence-based policy making when it comes to any new proposed regulatory initiatives in the patent system.

As economists and historians have shown, the patent system has driven the U.S. innovation economy for over 200 years. And this is dramatically evidenced in the pharmaceutical and biotech revolutions of the last 100 years. Well over 1/2 of all new drugs are invented in the United States. And a significant majority of R&D funding of the biomedical research that creates these new drugs is private, not public.

Thus, anyone proposing new regulations that would impose costs on all innovators who use the patent system has the burden to prove the necessity for these regulations by evidence-based

studies that follow rigorous norms of statistical or scientific analyses. Without this evidence, we risk creating unnecessary and costly regulatory barriers for all innovators who rely on effective and reliable patent rights to recoup billions in R&D investments and who also rely on these same patents to facilitate the licensing and other commercialization activities that are necessary to translate new drug discoveries into real-world therapeutic treatments that save lives and improve the quality of daily life for everyone.

Now, with this policy and evidentiary principles in mind, I am concerned that the policy debate over drug patents that is driving the calls for these new regulatory initiatives between the USPTO and FDA has been defined largely by ill-conceived rhetoric like patent thickets and ever-greening. Now, I call these terms rhetoric to distinguish them from proper conclusions carefully derived from rigorous evidence- based analyses and statistical studies of the patent system generally and of drug patents specifically.

Now, I detailed this concern recently by identifying significant and unexplained discrepancies in the claims about drug patent numbers in a policy brief I published last year titled, Unreliable Data Have Infected the Policy Debates Over Drug Patents. Now, in this policy brief, I identified discrepancies by orders of magnitude between some of the total drug patent numbers that are asserted by I-MAK in its studies and publications over the past several years, and those found in public government sources like the FDA's Orange Book or in court opinions.

Now, I don't have time to review all of the examples and so, I'll only give one or two to illustrate these profound empirical concerns. Now, one example addresses Lyrica, a drug produced by Pfizer to treat pain caused by nerve damage from diabetes, shingles, or other injuries. Now, I-MAK claimed in its 2018 report that 68 patents cover Lyrica. But when you look at the Orange Book, it identifies four patents. In fact, only three really in reality because one of those

patents is a reissue patent and so, it's not even a separate patent.

Now, I-MAK also asserted in that same report that Pfizer will retain exclusive rights over Lyrica until 2038, a whopping 10 years beyond the expiration date of the patents listed for Lyrica in the Orange Book. But the main patent on the active ingredient in Lyrica expired in December of 2018, the same year that I-MAK released its report. And the FDA approved nine generic versions of Lyrica the following year in 2019. As one media outlet reported in 2019, the "patent cliff is here" for Pfizer's Lyrica. Yet, I-MAK claimed that Pfizer has exclusivity in Lyrica for another 20 years after entry of multiple generic versions of Lyrica.

Now, another example that I identified in my policy brief concerned the drug Eliquis. Now, Eliquis is a drug produced by Bristol-Meyers Squibb and Pfizer that reduces the risk of life-threatening blood clots caused by irregular heartbeats following surgery. I-MAK has asserted

in its various reports that there are somewhere between 27 and 31 patents covering Eliquis. It doesn't explain the differences or how it derived the basis for these different numbers of patent numbers but it's somewhere between 27 and 31. Again, when one looks at the FDA Orange Book, one finds three patents covering Eliquis.

Now, these are just a few of the examples of vast discrepancies in numbers. And again, these are unexplained discrepancies by orders of magnitude. These are not mere rounding errors that one might find as a result of dealing with significant numbers. Now, last year Senator Tillis prompted by my policy brief and other studies and reports, sent letters to the USPTO, to the FDA, and to I-MAK.

Now, in addition to concerns expressed about the quality and reliability of I-MAK numbers, Senator Tillis also identified serious concerns about the evergreen drug patent search database that's at UC Hastings. One example that he referenced is that this evergreen drug patent

search database, that's its official title, has listings for aspirin, despite aspirin being available in generic form for over 100 years.

Now, one very important revelation that came out of Senator Tillis' letters and I-MAK's responses is that I-MAK has been counting both pending and abandoned patent applications in its total patent numbers. And this is not something that it has always acknowledged in its annual reports. Yet, all drug companies, generic and branded drug innovators, and patent lawyers know that abandoned or even pending patent applications are not the same as issued patents. They do not confer exclusivity.

Just as any patent -- and by the way, this applies just as much to claims about continuation practices -- any patent lawyer and any drug company knows that a continuation does not extend a patent term. And yet, we're seeing similar repeated claims about continuation practices now as we have heard in the context of patent thickets and ever-greening.

So, in sum, and in my brief time this morning, I really would believe and I hope I have highlighted two key points that should guide policymaking by government officials. First, the evidentiary burden for proving systemic problems requiring systemic changes via regulatory initiatives to the patent system is on those proposing the systemic changes. And second, the data claims about drug patents driving the policy debates are rife with serious questions about their veracity. The patent system is too important for inventors, the U.S. Innovation economy, and the enumerable people who benefit from innovations in healthcare.

Alan Marco, former chief economist at the USPTO, when he was chief economist, argued repeatedly that we need to ensure that there is evidence-based policymaking as opposed to what he referred to policy-based evidence making. And this is a very serious concern. Or to invoke the more simple point made in the healthcare context, we should follow the maxim, first, do no harm.

Thank you.

JUDGE HORNER: Thank you, Professor Mossoff. I have one question to start out and then I'll open it for the rest of the panelists.

PROF. MOSSOFF: Sure.

JUDGE HORNER: The idea of counting patents and looking at patent term, is that a sufficient way to look at a patent landscape of a product without consideration of patent scope? Or is patent scope an important part of an examination of a patent landscape for a product?

PROF. MOSSOFF: That's a great question. And as a general matter, just patent counting as such has been repeatedly identified as extremely problematic by economists. There are numerable confounding variables that would apply in patent counting. By the way, assuming you're counting actually issued patents, not abandoned patent applications and/or pending patent applications. Because there are many reasons why people obtain patents. Patents have different scope. They apply to different types of products and different

types of inventions. Some are methods, some are on, some are products, right? Some are compositions of matter.

And so, you know, there's a real concern with just saying, well, here's a list of patents that we found. And yet, those are easy to understand numbers, especially when they seem to be very large. And they have a hold on people's imagination. And that's why I think we see people easily invoking those numbers that we've heard today and we've seen even on the Hill and even among some professors, unfortunately.

JUDGE HORNER: Thank you. Do any other panelists have questions? Karin.

MS. FERRITER: So sort of building on that, do you think that counting patent use codes is at all useful proxy, or does it have the same problem that Linda was alluding to of not necessarily understanding scope?

PROF. MOSOFF: Yeah. That's an interesting question, I hadn't thought of it, which I'm thinking about your question. I think

it still kind of relates, it could still relate to some of the underlying concerns although might provide some more granular assessment of what types of patents you're counting. But I think you'd still end up with some of the similar concerns and related concerns about why those patents were being obtained, what their actual function is and what their role is actually in the specific art in which they're being deployed.

JUDGE HORNER: Thank you. And now we'll move to our last speaker, Ms. Carol Nielsen from Nielsen IP Law, speaking on behalf of the American Intellectual Property Law Association. Ms. Nielsen.

MS. NIELSEN: Hi. I am Carol Nielsen, and I am of Nielsen IP Law, but I am here on behalf of AIPLA and making the statement on behalf of AIPLA, not my law firm or its clients.

I've been a patent practitioner, well I've been a lawyer for over 30 years, and I think I got my registration number, I was trying to remember but it's '93 or '94. And my perspective,

and many of our members, is as a patent practitioner.

The American Intellectual Property Law Association is a national bar association of approximately 7,000 members who are engaged in private or corporate practice in government service and in the academic community. AIPLA thanks the offices for the invitation to comment on issues relating to pharmaceutical patenting and for the opportunity to be heard in this listening session.

AIPLA intends to submit written comments that address a number of the questions presented by the patent office but today we'll speak primarily to Question 2. That is what mechanisms could assist patent examiners in determining whether parent applicants or owners have submitted inconsistent statements to the USPTO and the FDA. And whether such mechanisms present confidentiality concerns.

To be clear, AIPLA, like the USPTO, believes that a patent examiner needs to know

about inconsistent statements. That is, statements that can affect his or her determination that a patent claim is allowable and that a patent can be granted on that claim. However, AIPLA is not aware that inconsistent statements are a wide-spread problem or that inconsistent statements have resulted in any significant number of patents being granted that should not have been granted. AIPLA believes the existing duty of candor to the U.S. Patent Office provides a substantial deterrent not to make a material inconsistent statement.

But in answer to the question, one mechanism to be considered could be to permit the patent office, the U.S. Patent Office, to make direct requests to the FDA regarding specific inventions and to request information that may be material to patentability. The request could come after a specific issue comes to light during patent prosecution or when a patent examiner is aware of documents containing information material to patentability that are on file with the FDA.

While it's already possible for the patent office to ask applicants for information under Rule 105, a request for specific information could be made to the FDA in a similar manner as requests are made to applicants.

The authority under which the patent office, U.S. Patent Office, and the FDA work however, are completely different, Title 35 versus Title 21. Information brought before the USPTO is related to an invention defined by claims whereas the FDA is concerned about drug, safety, and efficacy. Therefore any mechanism requesting information sharing between these agencies raises questions about the scope and implementation of such requests for information.

For example, what issues raised in patent prosecution will mandate the need for additional information from the FDA? How will the FDA determine what information to give the patent office and/or what kind of information can be subjected to USPTO review? How will trade secret information submitted to the FDA be handled to

avoid public disclosure? Will the patent applicant be involved in this process? How will the review of confidential information by the examiner be documented in the file history, if at all?

AIPLA would appreciate a better understanding to the answers to these and similar questions before providing additional comments on the feasibility of this possible mechanism. Generally AIPLA is concerned that any attempt to share information between the agencies, regardless of the mechanism, will create significant burdens on both agencies and applicants. We're further concerned that confidential information will be disclosed which will put trade secret protection at risk and will result in a disincentive to innovation.

While avoiding inconsistent statements is a valid concern, AIPLA believes that the current duty of disclosure rules work. AIPLA believes that the duty of disclosing information to the USPTO that has been disclosed to the FDA

are required by the current Rule 56, and it is clear the law requires that every individual involved with a patent application be candid with the USPTO. This duty of candor requires anyone associated with the prosecution of a patent application to disclose to the United States Patent Office information that's material to patentability, including that information that's on file with the FDA.

The effect of not abiding by these rules, the deterrent, is very serious, unenforceability of any subsequently issued patent right. AIPLA believes that the obligations associated with the duties of disclosure, candor, and good faith are clear and are diligently implemented and administered by the USPTO and further supported by the judicial branch. Through the enforcement of associated regulations the U.S. Patent Office encourages patent applicants to provide it with accurate and material information. Inconsistent statements made to the FDA and the USPTO pose a substantial risk to enforcement of

potentially very valuable patent rights. Prudent applicants thus have a strong incentive to take precautions to avoid the risk of making inconsistent statements.

On behalf of AIPLA I thank you for your time and your consideration of these views. And I also note again that we will continue to consider these issues and will supplement these comments with a written comment letter.

JUDGE HORNER: Thank you, Ms. Nielsen, we appreciate AIPLA's involvement in this discussion and their remarks. Do the panelists have any questions? No? Everybody's hungry.

MS. TILL: The only question that I have was about if information that is provided to PTO from FDA records and it is confidential type of information, currently there's no process in place at PTO to address keeping it confidential, using it in some type of rejection of a patent application. Are you suggesting that the examiner could review that information and have that knowledge in order to leverage it in say a request

for information from the applicant?

MS. NIELSEN: That's not our suggestion per se, as I understand it. But our concern is, well one of them are how are you going to document that? Once the examiner has confidential information subject to trade secret protection and is using that either to say the claims are allowable or not allowable, then, you know, where does that information go on the freedom to operate side on the infringement analysis, which I do as a practitioner, I will have no idea knowing what the examiner looked at if that information doesn't become public in some way and therefore it's kind of circular, right? I mean what do we do about that?

MS. TILL: Yeah. I think what you are saying is how do you know what was in the examiner's head when they made the determination.

MS. NIELSEN: Well yeah, and I have to tell you as a patent practitioner we live and die by the file wrapper. It's very important to us.

MS. TILL: Un-huh.

JUDGE HORNER: Great. Thank you. Any other questions?

MR. SALIMI: Yes. Ms. Nielsen, in your experience when there are like two firms, one handling the prosecution, one handling the litigation or before the FDA, these two firms, do they really communicate with each other or the materiality of the information to the PTO, or is there a what they might call like a Chinese Wall between these two firms? And if that's the case, is there a better way to communicate between the two entities?

MS. NIELSEN: Okay. I'm here on behalf of AIPLA and we have not addressed that. But, you know, who handles what in the patent world, it can be the same firm that does the litigation and the prosecution, if that's what you mean law firm, it can be both. They can do it, it's not always advisable but both, the same law firm can handle both. And then usually there's a regulatory expert. And that's all really I know. I don't know how the paper flow would go between a law

firm environment if that's what you're asking me.

MR. SALIMI: I was thinking like if a firm handles the prosecution side and then there's another firm that handles the regulatory or if there's a litigation going on, is there a line of communication between these two?

MS. NIELSEN: No, I would not think so. And that's my opinion, we haven't discussed amongst our group at AIPLA.

JUDGE HORNER: Thank you, Ms. Nielsen. We're going to take a break for lunch, we'll reconvene at 2:00 o'clock for Session 4. If you haven't already grabbed information out on the registration table we have some information about nearby restaurants and also the cafeteria here at the USPTO is open.

(Recess)

JUDGE HORNER: I'll go ahead and get started, it's about 2:00. So a couple of administrative things. One, for the speakers and panelists, when you're speaking try to keep close to your microphones because with these masks

sometimes it's difficult when you're far away to understand and project what you're saying.

Also it was called to my attention I neglected to allow the panelists to introduce themselves for Session 3, but most of the panelists for Session 4 are the same so I'll allow them to introduce themselves. With the exception of two speakers, or two of the panelists from the Patent Office for our last panel were Ali Salimi and Mary Till, they're with our office of Patent Legal Administration. I apologize to them for not allowing them to introduce themselves.

But before we get started on Session 4, I'll just start at the end of the table, panelists if you can introduce yourself with your name, title, affiliation within the Agency and then your agency.

MR. UNLU: Hi. I'm Mustafa Unlu, I'm with the FDA Center for Drug Evaluation and Research, and I'm at the Office of Therapeutic Biologics and Biosimilars.

MS. DAVIS: Hi. I'm Kristin Davis, I'm

the Director of the Office of Generic Drug Policy in the Office of Generic Drugs in the Center for Drug Evaluation and Research at the FDA.

MR. RITTERBECK: Hi everyone. My name is Dan Ritterbeck, I'm a Regulatory Counsel in the CDER's Office for Regulatory Policy at FDA.

MS. TERROT: Hi, my name is Marianne Terrot, and I'm an Associate Chief Counsel in FDA's Office of the Chief Counsel.

JUDGE HORNER: I'm Linda Horner, I'm an Administrative Patent Judge at the Patent Trial and Appeal Board at the USPTO.

MS. MOEZIE: Hi, my name is Minna Moezie, I am a patent attorney in the Office of Policy and International Affairs, USPTO.

MS. FERRITER: Good afternoon, my name is Karin Ferriter, I am on detail from the Office of Policy and International Affairs to the Office of International Patent Cooperation, we're working on a number of different issues. So it's exciting to be here today. Thank you.

MS. EVANS: Good afternoon, my name is

Robin Evans and I am one of the Deputy Commissioners for Patents in Patents.

JUDGE HORNER: Thank you everybody. We will begin Session 4 hearing remarks from Ms. Juliana Reed from Biosimilars Forum. Ms. Reed.

MS. REED: Thank you. And thank you very much for this opportunity and for accommodating my crazy schedule, you guys are great. So thank you for that.

So the Biosimilars Forum, as I mentioned, we're very grateful for this opportunity, it's a very unique collaboration and the Biosimilars Forum being a very unique and new industry has a lot of recommendations that we will be formally sharing in more detail by February 6.

But a little bit about the Forum. The Forum is the Nonprofit Trade Association representing the companies in the U.S. developing biosimilars. And we also develop globally as well. So our companies are very familiar, not only with U.S. patent laws but also those around the world in highly regulated countries.

Our members include Biogen, Boehringer Ingelheim, Coherus Biosciences, Fresenius Kabi, Pfizer, Organon, which was the spin-off from Merck, Samsung Bioepis and Sandoz, which is part of Novartis. Our comments today represent the views of our members, all, as I mentioned, manufacture and market biosimilar products in the U.S. as well as other parts of the world.

I think it's also important to understand our members not only manufacture and develop biosimilars but generics, small molecule generics, in innovative drugs and therapies as well. So we have a very global perspective of this space and of the IP around it.

Biosimilars, as I think all of you know, have the potential to provide significant healthcare savings in the U.S. Without robust competition, innovator biologics will continue to represent approximately 40 percent of the total prescription drug spending while they represent only 4 percent of the medicines prescribed to patients.

While U.S. patients have the greatest access to innovative biologic medicines in the world, this has also resulted in the U.S. having the highest expenditures for these important medicines. Biosimilars has successfully provided competition to lower the cost of biological medicines not only here in the U.S. but again, as I mentioned, around the world.

The Forum greatly supports this collaboration initiative. In the goal to ensure that the patent system promotes research and development and protects key innovations while not incentivizing protecting or permitting activity that will improperly or unnecessarily delay access to low cost medicines such as biosims. We believe in robust and reliable patents. Such patents are needed, as we all know, to incentivize and protect the immense R&D that is essential to bringing lifesaving and life-changing medicines. And critically, we must bring innovation to impact the healthcare system for all Americans.

We're very pleased to see the PTO and

the FDA collaborating on this important work revising patents. We look forward to working with you to provide our comments and any expertise you need from industry, the biosimilars industry, on revisiting patent term extensions, clarifying skinny labels, which is very important for our new industry to receive clarity, examining patents thickets which have been profound and very detrimental to the launching of biosimilars in the U.S, improving procedures for obtaining a patent so that we also get robust and reliable patents, which is important. And conducting, as I mentioned earlier, with our members' global experience. We're very happy to work with you and to provide any information and experience we can as you conduct the comparative analysis of the U.S. patent system versus our experiences with other highly regulated countries around the world.

Biosimilar developers in this is a very critical challenge and costly challenge for our members and when we have to challenge an innovator's patent in order to be able to come to

the market. With new Medicare policies being implemented through the Inflation Reduction Act, challenging patents and getting the biosimilars to the market as early as possible after approval is critical. And the work this group is going to be doing is going to be critical to the long-term sustainability and success of the competitive lower cost biosimilar industry.

The initiatives the PTO collaboratives have outlined will result in improving patient quality in providing the much-needed clarity and guidance to the collective industry here present today. We support the initiative, we look forward to participating in the process. And we're looking as always to Biosimilar Forum looks for common-sense solutions that protect innovation but also promote competition.

So again, thank you very much for the opportunity to be here today, and we look forward to working with you however you need us to do that. Thank you.

JUDGE HORNER: Great. Thank you, Ms.

Reed, for your comments and for being here today. I'll open it up to the panel for questions. Go ahead.

MR. UNLU: You said you wanted somebody to clarify skinny labels. Can you say a little bit more about that and how would we do that?

MS. REED: Yes. And I also rely on my real patent expert to help me answer this. But what I think what we're looking for on the skinny labels is the ability and how do we carve out and continue to carve out so that we can bring a biosimilar to the market for less indications or other indications that may still be patent protected.

So and I think you know, I mean and we work with your group very closely, it's very important as we do our education and position with package inserts and everything else to have that really good clarity both from the FDA and the skinny label, but also the PTO. So that's where we're looking for so that we can again develop and bring a product to market as quickly as possible.

MR. UNLU: Thank you.

MS. REED: No, thank you.

JUDGE HORNER: I have a question. Can you describe sort of the size, typical size of member companies within your organization? And do they use the Patent Trial and Appeal Board proceedings at all?

MS. REED: Yeah.

JUDGE HORNER: Has that been an effective tool for them or are there ways to make it more effective?

MS. REED: So the preference is to go through PTAB and IPR and deal with that. One of the key things, so going back to the first part of your question, the size of our companies and members. As you can imagine, Pfizer being one of the largest pharmaceutical companies in the world down to Coherus Biosciences which is a small startup, biotech startup in Redwood City, the Bay Area. And they only have a couple products. So I think that's really key.

But the PTAB and IPR is very important.

But you also have to look at the innovator side of this. And what's really important to us is when we see patents that give significant patent estates that are created, unfortunately created just to prohibit competition. And this is prevalent in the biologic space. Where there's products that are biosimilars that are approved and on the shelf for another 10 years because of a submarine patent. And the innovator product has been on the marketplace for over 20 years so it has no competition, submarine patent comes up, it has another 10 years of market monopoly. So what is so important and we expect to see and need to see is ongoing. The litigation cost for over 100 patents is cost prohibitive to development of a biosimilar. Development of a biosimilar right now with the FDA is I think six to nine years and it's rounding up to close to $200 million. So it's not anything near a small molecule generic. And the patent estates is another $100 million, it could be because that's through PTAB, right? It's at least a million dollars per patent so it depends

on the patent dance and where we're going to go. And I could talk all day so my apologies.

But I think we're also looking for and want to continue to educate in is the need. Because of the prohibitive cost of the patent estates and the amount of time and money it could take biosimilar, regardless of the size of the company. So Pfizer, Coherus, Fresenius Kabi, all of our members face the patent challenges and the cost.

Patent settlements are very important to the biologic biosimilar space. It gives us timely and actionable launch dates. It's going to be very important moving forward under the CMF Inflation Reduction Act because if an innovator wants to have a delay in any pricing negotiations, biosimilar must launch. So it's a complicated answer to a complicated question.

But biosimilar patents and challenges and what we need to do, this collaborative is so important. Because one, clarity on what the patent term extension, clarity on what's the real

innovation so that we can start to see patent estates protecting innovation versus market access and competition. That's really important to us.

And then our goal is to shorten the amount of time to develop a biosimilar in the future. We're very grateful for FDA to work on that with us. But also to shorten the amount of time and money it costs for a patent challenge. And then I think you'll see that we'll be able to get more biosimilars out on the marketplace faster.

JUDGE HORNER: Thank you.

MS. REED: Sorry to take all the time.

JUDGE HORNER: No problem. Okay, we'll go on. Thank you for your comments.

MS. REED: Yeah, thank you.

JUDGE HORNER: We'll move on to our next speaker, Mr. David Korn from PhRMA.

MR. KORN: Thank you for holding this meeting and inviting views of the public. I'm David Korn, Vice President IP and Law at the Pharmaceutical Research and Manufactures of

America.

PhRMA represents leading innovative biopharmaceutical companies whose mission is to research and develop new and improved medicines for patients. Intellectual property provides critical incentives for biopharmaceutical innovation given the unique nature of the biopharmaceutical research and development or R&D process, which is lengthy, costly, and uncertain. It takes 10 to 15 years and costs on average $2.6 billion to develop a new medicine. In 2021 PhRMA members alone invested more than $100 billion in researching and developing medicines. IP protection supports such continued future innovation in the long term.

PhRMA supports the important role of generic and biosimilar products for patients. The natural evolution of medicines is that after an innovator undertakes the time- consuming and expense of development process and obtains FDA approval, it enjoys an appropriate period of IP protections, following which a generic or

biosimilar version may become available for patients. This is the cycle that Hatch-Waxman and the BPCIA contemplated for generics and biosimilars.

Hatch-Waxman has fostered competition through the timely entry of generics. Today 90 percent of all prescriptions for drugs are filled with generic products and the biosimilar market continues to grow. Both have led to cost savings. Post-approval innovation such as new dosage forms and routes of administration is a critical part of pharmaceutical development, producing important treatment benefits for patients. R&D does not stop and should not stop with initial FDA approval of a medicine. A medicine's safety and effectiveness are not determined solely by its active ingredients. And its therapeutic usefulness is not limited to its first approved disease.

Post-approval changes can improve a medicine's tolerability, effectiveness, adherence, or convenience, and support its approval for new

diseases in patients with unmet medical needs. Such post-approval advances benefit patients and the public health and should be incentivized by the patent system rather than discouraged.

U.S. continuation practice helps provide the incentive for innovators to develop the many types of patentable inventions at different stages of a product's life. The availability of continuation applications helps foster the patent system's goal of promoting innovation and earlier disclosure in the original application of the underlying research that resulted in the innovation.

The original application provides the public and competitors with notice of the applicant's inventions and thus what can be claimed in its continuation applications. This framework is fair and strikes the right balance between protecting innovators and providing society of its benefits. Such a system differentiates the patent system from other means of IP protection such as trade secret protection

by rewarding innovators who disclose their inventions.

Limiting continuing practice would not promote innovation and progress in science. Inventors would be disincentivized from robustly disclosing their inventions if there were uncertainty around whether they could receive the benefit of patent protection for the full scope of its disclosed innovation.

Indeed, the negative rhetoric regarding patents on post-approval advances more broadly, including on manufacturing process patents, is concerning. Providing IP protection for such innovation does not negatively affect access to generics or biosimilars. Once IP protections on an original drug product have ended and provided there are no safety issues, copies of that product may be approved. Healthcare providers and payers can then decide whether clinical benefits offered by the improved branded products are more important than the cost savings available through use of less expensive generics or biosimilars.

And generic or biosimilar applicants can often design around certain patents and carve protected conditions of use out of their labeling, allowing generic or biosimilar products to enter the market prior to the expiration of all patents or exclusivities covering a product.

We've seen letters that suggest more direct collaboration between FDA and USPTO is warranted due to concerns about potential inconsistent statements made to the agencies by pharmaceutical innovators. We've also heard theoretical concerns about manufacturing process patents. Proponents of the inconsistent statement narrative cite a single drug case, Belcher v. Hospira. One case is hardly indicative of a systemic problem. And in that case the court imposed a severe penalty, the patent was held unenforceable.

Indeed, there have been 4,696 Hatch-Waxman cases file in U.S. District Courts between 2008 and 2022 and we have seen no evidence of a wide-spread problem of inconsistent

statements to FDA and USPTO.

Moreover, increased information sharing across agencies raises confidentiality concerns. The agencies have different practices for handling confidential information. The USPTO's general position is that information material to patentability must be disclosed to the public. Whereas FDA is subject to specific statutory restrictions on sharing proprietary information.

Accordingly, PhRMA is concerned that materials that are confidential at FDA will not be treated as confidential by USPTO. Any policy changes to the U.S. patent system, including increased collaboration between these two agencies, should be based on evidence of the need for the change. This is especially the case when the collaboration could put trade secrets and confidential commercial information at risk.

Similarly, PhRMA's aware that there are alleged concerns about the number of patents per product. Reports on this topic are inaccurate and the validity of the numbers of patents and

protections reported have been called into question. Further, this is not a useful measure for policymaking. Many of society's most innovative products embody numerous inventions protected by multiple patents. The U.S.patent system should celebrate and encourage such a complex innovation.

The United States has historically been a science and technology innovation leader in the world. To maintain this standing in the 21st Century policy leaders must ensure that our laws continue to support innovation. PhRMA plans to submit written comments and looks forward to working with the agencies on policy issues to improve the biopharmaceutical ecosystem. We need a policy and regulatory framework that fosters the continued innovation necessary to address the world's most challenging diseases.

JUDGE HORNER: Thank you, Mr. Korn. I will submit that to the panel for any questions. No questions?

I have one question. Could you go into

a little bit more detail, you were talking about continuing R&D post approval. Can you go into a little more detail on what kinds of R&D happen post-approval and if you have information on sort of the breakdown of the statistics of, you may not have this, I understand, but what percentage of your investments, your member companies investments in R&D go into post-approval R&D versus pre-approval R&D? What kind of things happen after approval?

MR. KORN: I don't have those statistics, and we couldn't address the question in the comments. But it's both from the technical perspective of improving the product and how it's presented to patients, how it's delivered, as well as the diseases. There could be new diseases, new ways of treating a particular disease, new patient populations. And all of this is happening after the original approval.

JUDGE HORNER: Yes. Karin.

MS. FERRITER: Thank you very much for your comments and for testifying today. A lot of

people really appreciate the Orange Book because it provides a listing of the drug products and method of use part of patents that are relevant to a specific drug. And it's really a useful reference tool. However, it doesn't list, as you know, method of manufacturing patents. Could you, for the benefit of our analysis, talk a little bit about why it doesn't and just explain why or whether it should or should not in the future be changed to list such patents?

MR. KORN: Thanks for the question. So when Congress was looking at developing Hatch-Waxman the question was what patents are relevant as far as the particular product. And manufacturing is not something where there's a standard that a generic company needs to produce the same product in the same way. There's the same active ingredient standards, bioequivalent standards, same labeling, but not same manufacturing process.

So it is something where generics are free to use different manufacturing processes to

come up with the same bioequivalent product in the end.

MS. FERRITER: If I can just follow up a little bit. So we have the Orange Book process for drugs that we've just described, and then the Purple Book processes evolved to be quite different. Can you at a super high level describe whether we're in a good place for the Purple Book or should it be changed to be more like the Orange Book, or is it because of the importance of method of manufacturing processes being different that we probably will continue to have different procedures?

MR. KORN: I think manufacturing process patents are an element of it, and the nature of the process in the BPCIA for patents, it's focused on patents relevant to the biosimilar, not patents relevant to the innovative product. And the Purple Book now reflects that whole process overall and the development of biosimilars.

MR. RITTERBECK: Thanks for your comments. I just had one point that I wanted to

clarify. In your comments you mention that any policy changes, including collaboration between the PTO and the FDA need to be based on evidence for, you know, needing a change. I just want to clarify, is it PhRMA's position that there is no evidence that there's a need for change as it relates to the collaboration between the PTO and FDA, vis-à-vis drug pricing and competition?

MR. KORN: I think it's up to the policymakers on that. There certainly have been people who have called for a degree of change and the office, the two agencies, are already working on training and the like. We don't see a need to have further policy changes, but we can address that more fully too. Thank you.

JUDGE HORNER: Thank you, Mr. Korn, for your comments. We'll move on to our next speaker. Professor Liza Vertinsky, University of Maryland Francis King Carey School of Law.

PROF. VERINSKY: Thanks for this opportunity to speak with you today. The USPTO and FDA have announced a joint initiative designed

to ensure that "Our innovation system strikes the appropriate balance encouraging meaningful innovation in drug development while supporting a competitive marketplace that can promote greater access to medicines for American families."

I'd like to suggest that as part of achieving this balance USPTO and FDA have a crucial role to play in ensuring that public funding and public participation in the innovation process is given greater consideration.

My remarks today focus on the opportunities to augment the public role and the initiatives included in Director Vidal's July 6 letter.

Section 1(d) of the letter address the issue of disclosure. The USPTO could do a lot more to incentivize and enforce the disclosure and reporting obligations of patent applicants who have benefitted from federal funding of research that's led to their inventions.

Doing so would serve the public interest by promoting transparency and accountability in

the development and use of publicly funded inventions. It's also allowing the government to more easily determine whether and when it might need to exercise its retained rights to ensure reasonable access to the patented inventions.

The Bayh-Dole Act allows recipients of federal funding to receive title to inventions developed using federal funds. But in return, the Act grants the government automatic non-exclusive fully paid-up licenses to inventions developed using federal funding. As well as the right to use these inventions under specified circumstances.

In addition, the Act imposes specific disclosure and reporting obligations on recipients of federal funding regarding the rights retained by the government in the inventions to which they have retained title. These obligations include a duty to disclose the inventions to the federal funding agency within a reasonable time and to make periodic reports on how the inventions are being utilized.

But more importantly for our current discussion today, the Act requires recipients of federal research funds to include a statement in their patent applications that their inventions were made with government support and they're subject to government retained rights.

Enforcing patent applicant's obligations to make these statements and to do so accurately is critically important because it could create opportunities for third-party oversight that can serve as additional checks on improper use of patents covering government funded inventions.

The Act's disclosure and reporting requirements and reserve government rights are important public policy levers designed to ensure the appropriate balance of public and private interests in inventions developed with public funds.

However, research has shown that patent applicants regularly under report government rights in federally funded inventions and that government efforts to enforce these reporting

obligations are lax at best. A recent salient example involves Moderna's failure to disclose federal funding in patents on the technology underlying its COVID vaccine. Moderna's COVID vaccine received substantial funding from both the NIH and BARDA and yet Moderna has failed to disclose government funding in its patent applications and patents. Accurate disclosure, again, is crucial because, as I already mentioned, there are important public rights attached to these inventions.

While the federal funding agencies have the primary responsibility for the enforcement of the Bayh-Dole Act disclosure and reporting obligations, I think the USPTO and FDA can play important supportive roles in enhancing compliance and improving the accuracy of disclosure.

To give you a few examples or ideas, Section 1(d) of the letter specifically mentions exploring initiatives to require patent applicants to provide relevant information to USPTO that has been submitted to other agencies and to remind

patent applicants of their disclosure obligations and the ramifications of failing to disclose required information.

As part of this effort the USPTO could include specific requirements for the reporting of federal funding and attach meaningful consequences to the failure to report. Reporting federal funding could be regarded as information material for patentability, for example, and subject to the same duty to disclose as other material information. Delays in disclosure should be penalized where the applicant should have known at the time of filing that the admissions were subject to Bayh-Dole requirements in order to avoid strategic behavior by patent applicants.

The USPTO should also consider ways to facilitate greater public access to information about the public funding, particularly those covering inventions in the biomedical areas.

Section 2 of the letter explores ways of improving procedures for obtaining patents. Efforts to enhance information disclosure

statements discussed in Section 2(d) along with the development of resources such as the design of an amalgamated tool for patent examiners, could also include required disclosure of public funding along with the identification of prior art. And in addition, patent examiners ought to receive more time and resources for the examination of patent applications covered by biomedical inventions so they can investigate effectively compliance with government funding disclosure obligations.

Finally, in addition to the focus on enforcing existing Bayh-Dole obligations, the FDA and the USPTO have an important role to play in developing best practices for awarding patents and regulatory exclusivities where public/private partnerships are involved. Effective collaboration requires a balanced approach to patenting and data sharing practices that incorporates both private incentives to participate and public interest and access to the knowledge generated in the products that results.

When developing best practices the Bayh-Dole obligations should be considered as minimum requirements. They should continue to be incorporated in future federal funding agreements, including those involving high profile public/private partnerships such as ARPA.

Thanks so much for your time.

JUDGE HORNER: Thank you Professor Vertinsky. Do we have any questions from the panel? Robin.

MS. EVANS: I have one. Thank you so much for your comments. You mentioned that the USPTO could incentivize making such disclosure statements. I was wondering if you had any other comments or what those incentives you think might be?

PROF. VERTINSKY: And I'm currently working on some other ideas but the one that I mentioned today was it would require sort of a change in regulations but to treat disclosures of public funding in ways similar to the ways we treat disclosure of material information for

patentability, right. And so if you don't disclose information material to patentability there's significant consequences to that. Not so much with failure to disclose federal funding, that's typically left to the federal funding agencies, but that sort of oversight hasn't worked well so far.

MS. EVANS: Thank you.

MS. FERRITER: And thank you very much for coming here today and talking about this really important topic. There has been a lot of interest as you've noted in this aspect of Bayh-Dole. Because these disclosures, when we do receive them, are part of the published patent application, I'm wondering how often you as a researcher try to analyze that data and is your ability to use the patent database sufficient for your work?

PROF. VERTINSKY: So there's actually been researchers, Heidi Williams and her co-op is for one, I've referenced those in my submitted remarks. And they describe in their paper the

difficulties of trying to match and identify the public funding to particular applications.

And just a little bit further along that, something that they don't include, they discuss their methodology and their work really well I think. But one of the reasons I think there's an opportunity for the USPTO and the FDA to work together is the FDA works with companies on a repeated basis over long periods of time. So they have sort of an understanding of the different actors, public and private involved. And they're also often involved in these public/private partnerships as well. And so there's information that they might have about the public funding that might be useful in this cross fertilization. And again, that's not something that researchers could access or map easily onto without help.

MS. DAVIS: Thank you very much for your presentation. Could you talk a little bit more about the suggestion that we develop best practices in the context of awarding regulatory

exclusivities for considering whether public/private partnerships were involved. We already consider under the law whether a relevant clinical investigation was conducted or sponsored by the applicant. Do you have thoughts for modification to current practice, or is it more making best practices more transparent to stakeholders or if you can give any further context on what you were thinking along those lines, that would be helpful.

PROF. VERTINSKY: So the area that I have looked at most is on the contracting side. And I know that the FDA is not directly involved in what those contracts between the public and private actors look like. So what I was sort of suggesting is in this sort of whole of government approach, which I know has been a theme of these hearings, that you're the knowledge, you have sort of the combined knowledge experts of this process and have important roles to play in for example maybe pushing back against this tendency towards using other transactions authority to reduce the

public rights in the products that are being developed.

And so I see the role more as this whole of government approach in which you have the knowledge to discuss with the people who are writing the contracts about the importance of, for example keeping the Bayh-Dole Act in place because of its role in maintaining that balance. So it's an indirect role. There may be other roles but I'm confined by, I serve my best in transactional IP, so that's what I know more about.

JUDGE HORNER: Thank you for your comments today and for taking the time to be here.

We're going to move to our next speaker, and he is virtual. Dr. Sean Tu from West Virginia University College of Law. Dr. Tu.

DR. TU: All right. Can you hear me?

JUDGE HORNER: We can hear you and we should be able to see you in just a moment. We see you now. Please go ahead.

DR. TU: So I wanted to thank the PTO and FDA for organizing this event. We have some

really smart people here who have thought long and hard about these issues surrounding patenting in the pharmaceutical area.

I am an academic who has been studying the patent system for about two decades at the West Virginia University College of Law. So I wanted to start by saying that I love the patent system and I think it's made the U.S. stand out as one of the most innovative countries in the world.

The patent system was designed to reward and inspire innovation, and when it works it works really well. The problem for me is that I believe that the patent system is being manipulated to extend monopoly power and to unethically prioritize the profits of the few over the well-being of the community, including those patients and those who are suffering from life-threatening diseases.

So I think it's clear that one of the most effective ways to lower high drug prices is to let the free market do its work and lower drug costs. When generics and biosimilar competitors

enter the market, market prices go down. However, when they are unreasonably prevented from entering the market multiple parties are harmed. Patients end up having to pay higher prices and face worse health outcomes, employers end up paying higher insurance premiums, and taxpayers shell out more to cover higher Medicare and Medicaid costs.

Although the patent system was designed to allow inventors to profit from their inventions, this type of drawn- out profiteering is really not what the patent system was created to do. So I'm going to focus on just one area where I think gamesmanship is occurring, namely the creation of patent thickets and continuation practice.

So patent thickets are just a whole lot of patents connected to the same product. Generic and biosimilar firms must challenge scores of non-patentable distinct patents before getting to market. This may be why firms settle instead of litigating to a final decision.

Additionally, IPRs don't work well

because IPRs are instituted on a patent-by-patent basis which is maybe why we see fewer firms using IPRs compared to a decade ago. Thus competitors really face an uphill battle in terms of time, cost, and clarity even when going after what some would consider weak patents. Our continuation patents, or Cons, are a key component of patent thickets because they allow drug companies to build large patent portfolios comprised of lower quality patents. Cons are typically narrower than their parent applications and are usually linked to each other via terminal disclaimers.

Cons are easier to file and can move through the patent system quicker than a typical application because one, they're usually were given to the same examiner so that examiner should already be familiar with the invention and the prior art. And two, there are avenues for traversal that are not present in other applications, namely terminal disclaimers.

Finally, the PTO may be unwittingly helping to create these patent thickets by

incentivizing examiners to handle Cons. Patent examiners love Cons because it allows them to meet their hourly, or their quarterly quotas with relatively minimal effort, all right?

So my research has shown that there's been an overall increase in the patent intensity in the pharmaceutical field. So from 2001 to 2019 there has been a three-fold increase in the number of patents associated with each active ingredient listed in the Orange Book. And that's public data from Heidi Williams in her NBER data.

Correspondingly there's been a six-fold increase in the number of use codes that is associated with each active ingredient, from about 1,200 to over 8,000. So pharmaceutical firms really seem to be relying more and more on these lower quality patents to protect their products.

To examine the role of Cons in these thickets I analyzed every patent that was issued since 1980, about 7 million patents, every litigated patent since 1980, about 46,000 patents, every Orange Book patent, and every litigated

Orange Book patent since 1984. We find that the pharmaceutical industry relies on Cons more than any other industry. You know, Cons, as I said earlier, that Cons are used by industries, other industries, and that's true. However no one litigates Cons like the pharmaceutical industry. 55 percent of all litigated Orange Book patents are Cons. I note that very few industries rely on Cons. In fact the top 15 CPC codes account for 46 percent of all filed Cons and 55 percent of all litigated Cons. These correspond to the software, semiconductor, and pharmaceutical industries.

So in addition to that I've looked at the prosecution histories of all of these Orange Book patents, about 4,000 patents, and I found that Cons really don't disclose very much that's new but are simply narrower versions of the original patent. I say this because I've looked at the number of words in the claims for each independent claim in the patent. And you can see that with each increasing generation, the number of words in each claim increases pretty

dramatically when you reach like the fifth generation, which is the great, great, great, great grandchild of the original patent.

Unsurprisingly, there's also a linear decrease in the amount and type of rejections you get as you move down the Con chain. So when you have more and more generations you get fewer and fewer 102, 103, 112(a) and 112(b) rejections. The only type of rejection that increases is the ODP rejection, and that goes up from 20 percent to 70 percent as you move up the chain.

These data argue that with more Cons, that conversation between the examiner and applicant is less and less useful. Likely because there's really no change in claims scope between the second and fifth generation of the patent.

So what do we do about this? Cons are not a new problem, right? However, previous attempts to deter Cons have really been met with heavy industry resistance. There are several possible solutions that I've written about that may not require conventional intervention. Some

may require it, depending on how you interpret the law.

First the PTO should require applicants to identify their patents as potential Orange Book patents so that the PTO could give them to a special art unit that uses team examination with added support. We know these patents are important and thus should be given detailed review necessary to grant high quality patents. This might also help with flagging these patents for patient inputs as they may have a harder time kind of defining which patents are relevant.

Second, the PTO and FDA should collaborate to verify the information that's submitted to the FDA for Orange Book listing is correct.

Third, the PTO should increase the fees associated with serial Cons. Just like we increased maintenance fees from years 3 to 7 to 11, we should increase the fees associated with the second, third, fourth, and subsequent generation Cons.

Fourth, the PTO should pay closer attention to these large patent families that would require significant numbers of ODP rejections. As part of the solution I think the PTO could abolish the use of terminal disclaimers and require applicants to explain how their Cons are patentably distinct from the claims that are already present in the family.

Fifth, the PTO could allow IPR challenges, not to apply on a patent-by-patent basis but via the whole Con family.

And finally, the PTO could limit the number of Cons to just two and limit it to broadening Cons to two years after the notice of allowance of the original patent.

JUDGE HORNER: Thank you, Dr. Tu. Going to open it up for panel questions. Robin.

MS. EVANS: Yes, thank you. Thank you, Dr. Tu. I was interested in hearing, to see if you could tell us a little bit more about the team review and how you think that would help the process.

DR. TU: Yeah. So I wrote a paper recently with Mark Lemley about this, published in the Washington Law Review. You know, Lisa Lett from Stanford has also written about this. And they did this actually in the rubric of food inspections in New York. And they found that when you get two food inspectors instead of just one food inspector and they work together, you get actually better quality examination of restaurants and more consistent review of restaurants who may or may not pass that inspection.

And I think we could have a similar system where we could have two or three examiners, one of them, you know, very few examiners right now have medical degrees or are trained in both examining FDA information and medical information. I can imagine a system where if you have at least one person in that team, you would have better examination.

I think everybody wants higher quality patents. And this I think is one way we can get to that without really having to just simply add

time for examiners. To be honest, I don't think adding time for examiners is going to help all that much. I've seen that when examiners are given Cons, like what do they do, they cut and paste from one family to another. So they have more time but they're not using that time. And it makes sense the way our count system is based really on quantity and not so much quality. And, you know, like it makes sense that you would give similar rejections to cases that look pretty much identical.

So I don't blame them for doing what they do right now, but I think having more input, more perspective, would get us better examinations and stronger patents in the long run.

JUDGE HORNER: Marianne.

MS. TERROT: Hi, Professor Tu. I have a follow up question on this idea of flagging potentially Orange Book listable patent applications. Were you envisioning, what would you consider needing to be flagged, like that there is an active ingredient that's already in an

approved NDA or flagging that there's a pending NDA -- how early? Because otherwise some art units, I think everything is potentially --

DR. TU: Well first of all I've done the analysis and, you know, when it comes to Orange Book patents it's mainly 1611 and 1612 I think have like the lion's share of Orange Book patents. 1643 and 1644 have the lion's share of biological patents. So it's already kind of self-selecting.

But the way I imagine it is the applicant, if they submit the patent as filed, if those claims were allowed, if they were going to file it in the Orange Book, it would be self-identified by the applicant. If the claims as published or as submitted would be filed in the Orange Book then it should go to that argument.

MS. TERROT: You mean if there is an approved product that those claims as filed, if the product is already approved then.

DR. TU: No, that would be an ex-post kind of review. You would want it an anti-kind of review. So if the claim would go to a product, it

would have to be much earlier, right? So again it would be kind of a thought experiment for the applicant, but I don't think it would flood the system with this art unit going, you know, having a ton of patent applications go to it.

JUDGE HORNER: All right. Thank you, Dr. Tu, for your remarks and for your suggestions. We're going to move to our next speaker, Mrs. Sarah Bourland, Patients for Affordable Drugs.

MRS. BOURLAND: Thank you for inviting input on USPTO and FDA joint initiatives. My name is Sarah Kaminer Bourland, and I represent Patients for Affordable Drugs Now, the only national patient group focused exclusively on policies to lower drug prices.

We are bipartisan and do not accept funding from any organizations that profit from the development or distribution of prescription drugs. I lead PFAD's policy and legislative work as Legislative Director. I am also a Registered Nurse. And as a nurse I've spent much of my career treating patients for illnesses that could

have been prevented by better, more effective policy, including those that promote lower drug prices.

The FDA and the USPTO have missions that directly impact the health of patients and communities. The FDA promotes safety and protects consumers by regulating and granting market exclusivity to pharmaceutical products. And the USPTO facilitates commerce and fosters innovation by granting patents.

Since both agencies confirm monopoly rights you play a critical role in competition and in the prices paid by the millions of people who take medications every day. For this reason we welcome the collaboration between your agencies and urge you to center patient and consumer interest in this work.

Today I will discuss three key initiatives we hope your agencies will continue to collaborate on in order to better facilitate competition and lower prescription drug prices.

First, it's important that your agencies

work together to alter incentives and increase oversight of data provided by drug corporations. The current system encourages brand name companies to present different and often conflicting information to the FDA and USPTO about the same drug.

Today drug companies are incentivized to make false statements or omit statements to the USPTO about a drug being novel or non-obvious enough to patent while simultaneously telling the FDA the drug is so similar to a product on the market that additional clinical tests are unnecessary.

Gaining approval of these two agencies in this deceptive manner enables brand name drug companies to engage in product hopping behavior, a strategy used to switch patients from an older medication to a newer version of the same product that has longer monopoly protection. Product hopping blocks generic competition, keeps prices high, and undermines true innovation. We submitted an example of this phenomenon in our

written comments.

Increased oversight, communication, and collaboration between your agencies is integral to cracking down on behaviors like this. We welcomed USPTO's commitment last year to the FDA to examine the consistency of statements provided to the two agencies and to explore initiatives that would require applicants to provide to the USPTO relevant information that was submitted to other agencies about the invention under consideration.

Second, we believe that prioritizing quality over quantity in the examination and awarding of patents would contribute meaningfully to improved health for patients. Too often patients in our community cannot afford their needed medications because a pharmaceutical company has obtained an excessive amount of patents in order to block competitors and maintain their monopoly prices.

According to a recent investigation by the House Oversight Committee, the 12 costliest products to Medicare are protected by over 600

patents designed to inflate those drugs from competition that could lower prices and save patients and taxpayers money. A noteworthy example is AbbVie's filing of 165 patent applications on it's block-buster cancer drug, IMBRUVICA, with more than half filed after FDA approval.

Opponents of reform point to litigation records to say that patent thickets are not actually thwarting generic entry. Secondary patents do not need to actually be asserted to deter competition. The mere presence of excess patents is often enough to deter a company from pursuing the development of a competitor at all.

Thorough scrutiny of the multitudes of patent applications that come before the USPTO is essential to ensure the patent system promotes innovation effectively and equitably. We realize this creates a significant administrative burden for the agency and that patent examiners who carry out the task of scrutinizing these applications. But prioritizing the quality of examination over

volume of patents is the only way to ensure the patent system incentivizes the creation of novel and non-obvious inventions.

To facilitate this we agree that patent examiners should be provided with additional time, education, and resources as necessary for reviewing the inherently complex pharmaceutical patent applications.

Third, we believe the FDA-required processes or protocols should not be eligible for patents. Currently drug companies are able to patent protocols such as the risk evaluation and medication strategy or REM, a drug safety program that the FDA requires for certain medications. Drug companies' ability to patent the mandatory REMs protocols enables them to use that patent to block competitors.

Granting this type of patent does not advance innovation. REM's programs are not inventive and they're easy to replicate. For this reason we urge the USPTO to cease issuing these types of patents. We also urge the FDA to de-

list this type of patent in the Orange Book so they cannot be used to delay competitors.

On behalf of our community of patients, thank you for inviting input on your joint efforts. Nobody benefits more from true clinical innovation than the patients in our community who depend on prescription drugs to live and thrive.

Again, opponents of reform to your agencies will argue today, and have already argued, that the status quo is acceptable. This collaboration was born out of an acknowledgment by both of your agencies and this administration that the correct balance between innovation and competition is not being struck currently, and often it results in harm to patients. Increase in ongoing collaboration between your agencies will help ensure we strike the better balance that can result in improved public health through increased competition and lower drug prices.

Thank you.

DIRECTOR VIDAL: Thank you, Mrs. Bourland. Do we have questions from our panel?

No questions? All right. Thank you very much.

Our next speaker is Mr. Corey Salsberg from Novartis.

MR. SALSBERG: Hi, guys, good afternoon. On behalf of Novartis thank you very much for the opportunity to participate in today's listening session.

We are a science-based healthcare company whose purpose is to reimagine medicine to improve and extend peoples' lives. I invite you to learn more about our company in the background section of my written statement.

Let me start by saying that we strongly share your agencies' goal of ensuring that our innovation system strikes the appropriate balance between encouraging meaningful innovation while supporting a competitive marketplace that can promote greater access to medicines for American families.

We are concerned however, that the pursuit of this goal has been unduly influenced by misleading statements, inaccurate data, and false

narratives about the patent system, and our industry's alleged misuse of it that has dominated media headlines and permeated political debates over the last few years.

To help keep your work on this goal on mission we'd like to suggest two things. First, your agencies should ensure that you carefully distinguish between actual misuses of the patent system and legitimate uses that critics simply call misuse because they don't understand or don't like how the system works.

Second, efforts should be made to ensure that any data and evidence considered or incorporated into your work are accurate, reliable, and relevant.

On the first objective, far too often critics allege misuse simply by employing inflammatory terms like ever-greening and thicketing that have no accepted meaning. We implore your agencies to reject these unhelpful labels and to instead adopt the thoughtful mandate that is set forth in the executive order that

initiated this dialogue. That mandate asks your agencies to work together to ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law.

This mandating encompasses two very important principles. One, there's nothing remarkable or wrong about seeking, obtaining, or enforcing patents on pharmaceutical inventions in ways that comply with our nation's patent law. And two, there's nothing remarkable or wrong about the appropriate use of those patents to protect the innovations they cover, which may postpone entry of generic and biosimilars during the patent term. The patent system, of course, was designed to allow just that, which is what creates the economic incentive and makes it work. It's only when delays are unjustified that they should raise any potential concerns.

Now these principles provide important context for this discussion because in the vast

majority of cases activities are vilified as ever-greening and thicketing are not only lawful but they're critical innovation, and they're exactly the types of uses that the patent system was designed to, and should, incentivize.

For instance the claim that it is misuse to obtain multiple patents per product misunderstands both patent law and the innovation process. Patents are not issued for commercial products, they're issued for inventions, which the law has defined since 1793 to include among other things, machines, manufactures, processes, compositions of matter, and any improvements to any of those.

In today's advanced society commercial products in almost every single field are comprised of many different patented inventions. A Smartphone may have as many as 250,000 patented components, and as you've already heard, a golf ball may contain as many as 70. With an average 10 to 15 year timeline to develop a single medicine and an almost 88 percent failure rate, it

should not come as a surprise that a technology as complex as a medicine also typically features many different inventions by the time of launch.

Those inventions, which may include novel formulations, indications, routes of administration, and manufacturing methods are a direct result of our innovation process and they reflect the many challenges we have to overcome and the problems that we have to solve to develop a compound into a single safe and effective medicine.

And because compound patents are typically filed a decade or more before we reach that point and only last for 20 years, patents on further innovations play an important practical role in helping us realize enough effective patent term to sustainably finance our work.

The related claim that non-compound patents are undeserving of patents is also wrong. Sorry, non-compound inventions. The very first patent issued in America was not for a device or for a novel ingredient, but for a method of

manufacturing potash. In our field, consider the impact of PCR on DNA sequencing and the lives saved by Prontosil, the first synthetic antibiotic that won the 1939 Nobel Prize for medicine. Both the subject of process or formulation patents, not compounds.

Patents beyond compounds are also at the heart of the emerging technologies that are defining our future, such as personalized cell and gene therapies, gene editing, and RNA based medicine. Patenting these inventions is not thicketing, it's an appropriate use of the systems that reflects the realities of pharmaceutical science and enables the development of treatments and cures.

As to the frequent claim that post-launch inventions are undeserving of patent protection, our patent laws have specifically incentivized improvements since 1790 precisely because our founders understood that all scientific progress builds on what comes before and that innovation is a process that does not end

with the first-generation product. After we launch a new medicine we continue to look for ways to make it safer, more effective, useful for a different disease, or otherwise more beneficial for patients.

Some of our own examples include converting our Alzheimer's medicine Exelon from oral form into a transdermal patch to improve patient compliance and eliminate a gastric side effect. Inventing our now standard of care heart failure drug, Entresto, through an innovative combination of one previously approved and one never-before approved ingredient, and further developing our breast cancer drug, Piqray, into a new drug, Vijoice, the first treatment ever to address the root cause of rare disease PROS.

Examples like these which require substantial additional investment in R&D after the original medicine was launched are not ever-greening, they're legitimate uses of the system to advance and enable further innovation that benefits patients.

Let me end by briefly addressing the issue of inaccurate data. As you've heard from others today, study after study has concluded that the actual time that new medicines spend on market before facing generic competition averages between 12.2 and 14.6 years, not decades as commonly alleged. This is well below the standard 20-year patent term that you're supposed to get, and right in line with a minimum 14 years that our patent term extension systems aims to provide to medicines.

Despite this, commonly cited sources continue to publish inaccurate data or misleadingly add up consecutive terms on separate patents without regard for whether those patents have any real-world impact on generic entry. Because many have written and already spoken about these concerns I'll just end with a very quick example. A 2017 report from I-MAK claims that our cancer drug, Gleevec, had a patient duration of 35 years and would only face generic competition in 2029. When in fact generics launched in 2016,

almost two years before I-MAK even published its report. The actual time Gleevec spent on the U.S. Market without generic competition was less than 15 years. The same report claims that Gleevec was covered by a total of 73 patents, when the real number was five, with another one to four possibly covering the way we make it if you actually opt to use that particular manufacturing method.

So examples like this show why, in our view, it is imperative that your agencies work to ensure that you proceed on an accurate, reliable, and relevant evidence base.

Thanks again for the opportunity, and I look forward to your questions.

JUDGE HORNER: Thank you, Mr. Salsberg. Do we have questions from the panelists? Mustafa.

MR. UNLU: Hi. Yes, so you've said that patent thickets, ever-greening, product hopping, are terms that don't have any accepted meaning. Do they have any meaning at all according to you, or are they part of the inaccurate data that you were talking about?

MR. SALSBERG: Well the way that they are most frequently used is to look at the numbers of patents on a drug and conclude that that's a patent thicket. What we would say is the question of whether something is a thicket is whether or not it's preventing generics from getting on the market. And as the data systemically time and again shows, looking at every single FDA approved drug, you can count on one hand the number of drugs that gets more than 20 years of effective patent terms. The average is below what the system is supposed to give. So that is our response to thickets.

On ever-greening, again, I mean, you know, this term is used often interchangeably with the idea of follow on innovation. And the most that is written about ever-greening looks at whether or not a patent was filed after a drug was first launched in the market and says that anything beyond that is ever-greening. And this is the way that these terms are often used.

Number one, there is no accepted

definition or consensus on it. And number two, again, what ought to be looked at from a policy perspective is how much effective patent term are innovative drugs getting on the market and when are generics actually entering. That to us is the key question.

MR. UNLU: Thanks. And that segues into my second question. You said it's only a problem when generic competition is unduly delayed.

MR. SALSBERG: Uh-huh.

MR. UNLU: How would we figure out if generics are being unduly delayed?

MR. SALSBERG: Well I mean I think I'll start by saying that's of course up to you to decide what you think is undue. But, you know, legally speaking I go again primarily back to patent term. Our patent system globally and in the United States, is supposed to give 20 years, and that of course is a generic term that applies to all fields of technology. In our field it takes us 10 to 15 years on average before we can even get our product on the market. So when you

look at how much term is right you ought to be looking at the time from when the product is able to be launched. Because, rightly of course, the FDA requires us to do safety and efficacy studies before we can get there.

I would also note that the term even going back to 1790, the original patent term in this country was 14 years, which is about what we get now. Today it's 20, we're not getting that in almost any case. Sure, there are a handful of examples of drugs that have gotten more than 20, but they're very, very rare. So I would say that, you know, if delays are occurring well below the 20 years that's supposed to happen, that is one factor to consider. The second factor of course is to see whether what is being done is compliant with law. You know, the fact that a patent, a valid patent that has been granted by the patent office and has a presumption of validity and has not been invalidated, is stopping a generic from infringing that patent and copying the same thing doesn't mean that that's an undue delay. That's a

legitimate delay. That is the whole purpose of the patent system. And the reason why it's the purpose of the patent system is because we need to be able to have that time on the market without competition in order to fund the average, well over a billion dollars all the way up to two and a half, depending on which study you look at, that it costs to invent each drug.

MR. UNLU: Thank you.

MR. RITTERBECK: You mentioned a couple of times that in your view there's a lot of inaccurate data being presented out there. And I think the one example you gave was there was a report that said a drug was covered by a total of 73 patents when in reality it was either somewhere five to nine.

MR. SALSBERG: Yep.

MR. RITTERBECK: Do you have any thoughts on like why or how those discrepancies are so large and it's not even close?

MR. SALSBERG: It's our actual drug so we can speak directly to it. So that particular

case in this I-MAK report. Among the 73 patents, total patents that were listed, 44 of them were abandoned patent applications. So not only did these never issue as patents but of course provide no exclusivity, but in many cases any subject matter that is the subject of those abandoned patent applications would be dedicated to the public when it's not claimed. So in a way it's the anti-patent, it's the opposite of a patent, abandoned patent applications. As for the rest, one of them was a pending application that I believe never granted.

The rest we don't really know because I-MAK did not at that time disclose what patents they were counting. But our best guess is that these are patents filed by third parties, possibly some patents that might read on some other version or aspect of the drug that's not part of the product. Not the drug, of the ingredient. Maybe a use that's never been tested. It's not part of our product so if a generic copies us they are not going to run anywhere near those patents.

But I think the key figure here is that 44 out of 73, they called them patents and I'll just remark, you know, unfortunately, this figure was picked up in the Staff Majority House Oversight Report that was just previously referenced by the previous speaker, as a fact. 73 patents is the fact that's quoted, and you can see that unfortunately this data that originates in unchecked third-party sources is now being picked up by official sources as well without any further checking as to its accuracy.

And that's why, you know, we share Senator Tillis' concern in the letter he wrote to your agencies last year that before you start relying on this data it's very important that you look at its accuracy. And if it's accurate, then by all means you should use it, but let's make sure that we're actually checking the legitimacy, the reliability, and the reasoning and the logic before we start citing it in official reports.

JUDGE HORNER: All right. No further questions. Thank you, Mr. Salsberg. And our

final speaker for Session 4, Mrs. Azeen James of Fresenius Kabi.

MRS. JAMES: Hello, my name is Azeen James, I'm Vice President and Chief ID Counsel for biosimilars at Fresenius Kabi. Fresenius Kabi is a healthcare company specializing in bringing low cost medicine to patients, including sterile injectable generics and biosimilars. Thank you for including me in the listening session today.

At the outset I just wanted to second the comments that were made by Professor Tu regarding the misuse of obviousness type double patenting in terminal disclaimers. As Professor Tu highlighted, there is peer review data that clearly shows that patent thickets are delaying market entry for generics and biosimilars.

And the fact that these terminally disclaimed patents expire on the same date doesn't solve the problem. Basically it's a numbers game. And as Ms. Bourland noted, it's the mass number of patents that is a barrier for market entry. Biosimilars especially do not enter the market

when you have this large number of patents.

Now turning to the topic of the USPTO/FDA coordination, I'm going to focus on a specific tactic that's commonly being used by branded drug companies, and I think this is an actual example of a misuse that you can see happening in the patent system.

So the practice involves two steps. The first one is the branded drug company files a patent to cover the backbone of the drug, the structure of it, the amino acid sequence, peptide sequence. And that's what we primarily call the product patents.

But then an ancillary patent is filed years later that is directed to claiming technical features of that molecule. This is not something that's an improvement, it's not innovative, it's actually technical features that are present on the drug that was patented earlier. And examples of these technical features are glycan profiles, charge profiles, variants, impurity levels, etcetera.

Now the difference between the filing dates of the principle product patent and the ancillary product patent and the subsequent expiry dates basically allows a patent owner to put an early stick in the sand covering the product, and then improperly prolonging that monopoly on the actual product patent beyond the expiry of the primary product patent.

Now when pursuing this strategy it's necessarily a branded drug company withholds information from the USPTO. This is not the same thing as providing inconsistent statements to the FDA and PTO because to get the approval they actually have to provide these technical details to the FDA. This is more of a selective information sharing. And it's, you know, the case, the Hospira case that Mr. Korn mentioned doesn't really apply here because we're not talking about inequitable conduct or misrepresentation, this is what they select to disclose to the FDA.

And unfortunately because what they've

disclosed to the FDA is confidential, a patent examiner who is examining the ancillary product patent doesn't have access to that information to determine whether it's prior art or not to this kind of ancillary product patent with these technical features.

And this is a tactic that as a biosimilar company we're seeing more and more often used by branded drug companies. In our written submissions we gave several examples of molecules where we have seen that, but just to highlight a couple. For example the product Herceptin, which is trastuzumab. The actual peptide sequence was covered by an application filed in 1991, but then in 1999 in a separate application, claims were filed to cover the acidic profile of the same molecule.

For Actemra, Tocilizumab, the claims of the peptide were covered in an application filed in 1992, and almost two decades later a new application was filed in which they claimed the glycosylation profile. So basically these aren't

improvement patents, these are product patents that are just going after a specific technical feature on the molecule.

Now we believe that there are two simple ways that the agencies can address this gamesmanship and to stop it. One, we think that the USPTO could encourage patent examiners to source prior art material regarding that primary principle product patent. That way the examiners have access to information to determine whether the primary product patent is relevant prior art to the ancillary technical feature patent.

These sources could be lists of applicants, published patent term extension response for the drug, drug bank databases, commercial databases that talk about product approvals, and especially FDA guidance documents that show whether for regulatory approval such technical data was required to be disclosed. Because that will show that the branded company had that information and that is nothing novel or new or improved.

Second, examiners should be able to talk to someone at the FDA with questions regarding the technical features that the second patent is being sought. This information can help the examiners determine whether that primary patent is prior art and whether the ancillary claims are either anticipated and/or obvious over the first one. The FDA could answer questions regarding the specific technical information, they could provide documents showing the guidance which could serve as prior art against the ancillary patents, and they could provide relevant extracts related to that specific technical feature that's being sought.

Now as we all know, FDA dossiers are hundreds of thousands of pages long, but to ease the burden on examiners we could have the selected few pages that relate to that specific technical feature be provided to them.

And to ease the burden on the FDA, we think that this kind of collaboration could be limited to approved products. And that way you

limit, substantially reduce the number of patents that are at issue and the number of patents for which an examiner may need support on.

Finally, we think the onus shouldn't just be on the agencies, we think that patent applicants should provide statements to the USPTO that the information they provided them is consistent and the same that they've provided to the FDA. And that kind of puts more of inequitable conduct pressure on them as well to ensure that the examiners have the right information for the analysis.

Again, thank you very much for inviting me to this, and I'm happy to answer any questions.

JUDGE HORNER: Thank you, Mrs. James, for your comments. Do we have any questions from the panel? Mustafa.

MR. UNLU: Yeah. So, thank you, that's fascinating information. So if I understand correctly, the first patent is filed for an amino acid sequence and then there are some years that pass and then there's a patent for glycosylation

patents?

MRS. JAMES: Right.

MR. UNLU: Does it take that long to get that information, or is that obtained normally when you first create the molecule? I'm trying to understand what part of improvement --

MRS. JAMES: That information is available when that first product patent is disclosed. So our position is that the patent applicant should apply for the claims for those technical features at that same time too. But by them withholding that glycosylation information and filing it a decade later, it actually prolongs the product patent by another decade. So it's information that's inherently in the molecule and is disclosed to the FDA in order for the drug to get approval.

MR. UNLU: Yeah, so this is going to demonstrate my ignorance of patent law. But how is that patentable if it's already known?

MRS. JAMES: Because the examiner doesn't know that it is known. So the examiner

gets this application and basically talks about let's say Manos 5 glycan at a certain percentage on a certain amino acid. And the patentee says that this is, you know, newly discovered information that helps the activity of this drug. However, that information was available a decade before when the actual amino acid sequence was filed. Because in order to meet the activity, that amino acid sequence inherently had that Manos 5 glycan profile.

MR. UNLU: And that information is provided to FDA as well. And your suggestion is they should be shared -- you also heard concerns about confidential information being shared because as you know, information in FDA is confidential and we can't disclose it, and apparently it's not as it comes to the PTO.

MRS. JAMES: Yes, and that's a very valid concern. I know that there is statutes, you know, that allows the USPTO to keep it confidential. But I do know that one of the speakers this morning mentioned a valuable thing

in that some other people need to have access to that information to be able to know why the patent was invalid.

So I do think there needs to be more thought put into how that information is kept confidential with the PTO, but it's definitely prior art that's out there that a biosimilar company or the patent examiner doesn't have access to. And it's a gamesmanship that's being played often with biosimilars products, with biologic products.

MR. UNLU: Okay. Thank you.

MRS. JAMES: Thank you.

MS. EVANS: Thank you for your comments. You mentioned that because the patent applications or patents expire on the same date does not help the problem, it's the number of patents that stops the biosimilars. Can you speak a little more to that, please?

MRS. JAMES: Sure. So as a biosimilar manufacturer, when you start to pick the products that you're going to develop one of the first

things you do is you do a patent landscape, right? Because you want to make sure that you don't infringe any patents and you want to abide by the law.

So when you come across a biologic that let's say has 100 patents surrounding it, my job is to go to my senior management and say, look, here are these 100 patents. In order for us to get on the market on X date we have to either design around certain patents or we have to invalidate all these patents.

So then it becomes a numbers game because in order to file IPRs we have to file IPRs against every patent and every claim. And that's about a million dollars per patent. So if I have to challenge 50 patents that's $50 million I don't have. And as you know, there's certain arguments that we can't even use in an IPR. And then there's the issue of standing of whether we can appeal it or not.

So then when my senior management looks at that number of patents, even if the expiry

date's the same, they say, you know what, let's put this biologic to the back of the line and we'll develop it later.

And so instead of us coming on the market, let's say in 2024, we may not come on the market until 2029 because we're not going to invest the resources to develop this if we have to spend hundreds of millions of dollars fighting these patents.

So that's where the number thing discourages you to come to market. Because biosimilars won't even put it in the line of developing. And the earlier we can develop the earlier patients can have access to a lower cost medicine.

JUDGE HORNER: Go ahead, Dan.

MR. RITTERBECK: Thanks for your comments. Just a quick I guess comment or question. In your comments you mention that there's peer reviewed data that shows that patent thickets are delaying generic and in biosimilar competition, and forgive me if I missed it, but I

didn't see a citation to that peer review data, so --

MRS. JAMES: I actually believe in our written submissions there's a footnote, I hope I put it in there. There's a recent paper that was just published by Denver University Law Professor Dr. Chao, and Rachel Goode, that looks at biosimilars on the market and looks at the number of patents and the timing of when they came on the market, I think that analyzes it. And I believe that Professor Tu also has some papers that address those issues.

MR. RITTERBECK: Perfect. Thank you.

JUDGE HORNER: I think we have one more question.

MS. FERRITER: Thank you very much. And I apologize for just asking you this question but I'm about to leave here, and a number of others have made the same point about the situation where there's obviousness type double patenting and statements where there's a terminal disclaimer if the first patent is invalidated, everything else

should. As you know, a patent would have multiple claims of the obviousness type double patenting rejection. Usually it's over just one or more claims but not all of the claims in the patent. Can you help me understand why the whole network of patents should stand or fall even though the claims could be quite different?

MRS. JAMES: So, you know, when a patent continuation is granted over an obviousness type double patenting rejections, terminal disclaimers filed, the whole patent gets the terminal disclaimer over the patent.

And as a biosimilar, we basically, let's say there's five patents in the first one and there's 10 patents in the second one, we have to invalidate every relevant patent that goes under there. And so again, it becomes a numbers game for us because the more, you know, so for a branded company it's an actual economic benefit. You just give them money and you get multiple patents and then we have to bring it down. They are basically the same, the reason they got the

non-obviousness double patenting rejection was because they were claiming the same specific thing.

So it is really a patent claim-by-claim analysis but I think that's how the terminal disclaimer function works within the patent system.

JUDGE HORNER: Yes, I think Karin's point was that if there's one claim in a patent that's deemed to be an obvious variation of another claim in a different patent, but there are 19 other claims in that patent that are not obvious, they did not get the double patenting rejection. And if we tie all of those patents together then claims may fall that wouldn't have otherwise been subject to that rejection.

MRS. JAMES: Yes, and as a biosimiliar really our concern is that claim in which we either are being asserted that we infringe or we're invalidating. So I understand what you're saying. And I think, you know, that's just like a claim-by-claim kind of --

JUDGE HORNER: I'll just take this opportunity to highlight for those listening and here today that our technology center that examines pharmaceutical applications has been doing recent training for examiners, both refresher training and enhanced training on obviousness type double patenting so that they're able to identify those instances where that is happening and can certainly raise rejections when they're proper to be raised.

We're going to take a break. I know we're running a little bit long so it's 3:28. We'll come back and start the next session at 3:38. So we'll take about a 10 minute break.

(Recess)

JUDGE HORNER: We're going to go ahead and get started. So if everyone can take their seats. This microphone is --

JUDGE HORNER: Yes. Okay. Thank you. We are ready for our last session of the day. And before we get started, I'll go ahead and ask our panel members to introduce themselves one more

time.

MR. UNLU: Good afternoon. I'm Mustafa Unlu. I'm at the Office of Therapeutic Biologics and Biosimilars at the Center for Drug Evaluation and Research in the Food and Drug Administration.

MS. DAVIS: Hi, I'm Kristin Davis. Director of the Office of Generic Drug Policy in the Office of Generic Drugs at CDER at FDA.

MR. RITTERBECK: Good afternoon, everyone. My name is Dan Ritterbeck. I'm a regulatory counsel in CDER's Office of Regulatory Policy at FDA.

MS. TERROT: I'm Marianne Terrot. I'm an Associate Chief Counsel in the FDA's Office of the Chief Counsel.

JUDGE HORNER: I'm Linda Horner, administrative patent judge on the Patent Trial and Appeal Board for the USPTO.

MS. TILL: Mary Till in the Office of Patent Legal Administration at the USPTO.

MR. SALIMI: Hi. Ali Salimi, from Office of Legal Administration. I work with Mary

Till.

JUDGE HORNER: Okay. Thank you. So, our session five the primary topic is patent term extension and patent use codes. And our first speaker is Mr. Victor Van de Wiele? Van de Wiele from Harvard Medical School.

MR. VAN DE WIELE: Thank you very much. So, I'm representing today the program and regulation of therapeutics in law at Harvard Medical School, and especially our work on patent term extensions from the past and present as well. Essentially what I'll be saying is quite short, but what we did is we replicated the methodology of one of our existing papers back in 2017, and we looked at all the drug approvals between 2018, that is type one and type two drug approvals. So, the new molecular entity and the new active ingredient, and we paired that with the USPTO's website on patent term extensions from looking at potential correlations between these data.

We made a couple of interesting findings, and I think presenting these here today

might incite debate on the current status quo based off of the data. So first of all, we found that half of all drugs examined were associated with PTE. So that means out of 600 plus drugs, there's a grand total, 319 patents received or related or received patent term extension. Now the median exclusivity, so that is the point of drug approval of a drug until, and this is something we came up with, until the expiry date of the patent that received the patent term extension was 12.92 years. So that is for both small molecules and biologic drugs. This is the median of that cohort. The patents that we looked at were generally, not generally, one third of those patents were secondary patents. That means that contrary to mainstream beliefs not all patents that receive PTE are primary patents. There was also one third that were secondary patents.

Third, 20 per cent of those patents, so there's 319 patents, were BLA related. So those were related to a biologic drug. Why is that

important? Because we know that biologics already received 12 years of regulatory exclusivity. And what we found is that on average, the market exclusivity this term, again for biologics was 13.5 years. So that means beyond those 12 years regulatory exclusivity already, biologics received 1.5 years extra to enforce a patent that received, sort of, key patent in court to extend their market exclusivity beyond that regulatory exclusivity. Then we also found finally that 45 percent of these patents were litigated, but only a fraction ended up being invalidated. So that means that these are generally strong patents, which makes sense because two thirds of these patents that we looked at were primary patents which were associated with the active ingredient, but then also means that the other half wasn't litigated at all or wasn't tried to be enforced or maybe it was, but it didn't. Or maybe manufacturers looked at it and said, actually, there's no way we'll be able to invalidate this.

So, what are what are these findings

telling us? So first, I think that patent term extension maintains high health care spending. Yes, it was part of this larger bargain with Hatch-Waxman Act that in exchange for it, is abbreviated new pathway for generics and the ANDA litigation process. Originators receive these patent term extensions. But nevertheless, if we're looking at the numbers, this means that beyond the five years of market regulatory exclusivity that small molecule drugs already get, there is an extended period of up to seven, eight, nine years for a drug during which patents can be enforced. And third, 20 percent of these patents were by biologic related patents. Again, biologics already received 12 years of regulatory exclusivity. So, we have to be careful and think as to whether these patents should receive the extension to first, whether these drugs should receive the extension in the first place, and whether what are the timelines therefore makes sense.

So finally, little litigation and little

grants or little even pursuit of applications for these drugs indicate that we should rethink the relevance of patent term extensions in the 21st century. They were relevant in 1984 when the Hatch-Waxman Act was enacted. But maybe now, with the advent of patent thickets, maybe enforcing your key patent is no longer the way to get as much exclusivity out of your out of your innovative product as possible. And therefore, I think it's important that this discussion is being held and that the USPTO and FDA think about ways in which patent term extensions are still relevant and whether there should be caps on whether they are granted or not. So, thank you for the opportunity.

JUDGE HORNER: Thank you for your comments and for sharing with us your research. Do we have any questions from the panel?

MR. SALIMI: I have a quick question. In reading the materials submitted, maybe I misunderstood, but you said only 48 per cent of the BLAs get ask for patent term extension. Is

that true?

MR. VAN DE WIELE: No. So, we only looked at the amount of BLAs that actually -- so the BLA is with patent term extension and within that cohort. So, 75 percent were associated with secondary patents. That's the main finding for BLA, for BLAs. Yeah.

MR. SALIMI: I see. In examining or reviewing our process for patent term extension, did you come across anything that we have done wrong in processing these applications? Have we neglected any statutory consideration for patent term extension? Have we given extra patent term for any wasn't warranted.

MR. VAN DE WIELE: No. I think the process is working just as it was intended to work. The only thing that we have to rethink whether larger molecules, the BPCIA introduced biosimilars and covered biologics, but it was a different act. In the Hatch-Waxman Act, there were different compromises that were made. And I just think generally what we focused on is that

these biologic drugs are applying for it, but maybe they shouldn't be receiving it in the first place. But I think the system works exactly as it's done, and the terminal disclaimer is always present, and I think the USPTO did well in that sense. Yeah.

MS. TILL: Yeah, I just had one question that you were talking about, the data exclusivity that protects something different than what patents protect. So, you're I think -- is your opinion that because 12 years of data exclusivity is granted for biologics, that they don't need to have the extension under 156, even though it's a different type of protection?

MR. VAN DE WIELE: Well, you have to think, right, is that regulatory exclusivity really still relevant if, you know, for most biologics or biosimilars that try to enter the market litigation precedes it. And the litigation is actually the way to measure how long or when biosimilars can enter. So, I think the patent term extension aids the problem of patent thickets

or whatever you want to call them and by extending the time during which litigation needs to take place. And that litigation is exactly what causes the delays in biosimilar entry.

MR. UNLU: Hi. Thank you for your presentation. I have a quick -- couple questions. When you said mean exclusivity, this is from approval to the date of entry of follow on product, and it includes a patent term extension. So everything you looked at had a patent term extension or not everything?

MR. VAN DE WIELE: No. So, the median exclusivity is from a drug approval date to the expiry date of that extended patent. So that doesn't mean that by the time that first that patent expires, biosimilars enter, it's just the measure, that this is how much time we truly think the mean -- that if there is one patent that will be litigated that's that extended patent and that's kind of truly the market exclusivity of a drug, not just the regulatory exclusivity, because the fact that main patent is present means that it

is still up for litigation, that it's a strong patent because that is a conception that patents within the patent term extension are strong patents and are difficult to litigate. Yeah.

MR. UNLU: So, you didn't look at actual entry date you just looked at how long that was left on the patent after extension.

MR. VAN DE WIELE: That's correct. Yeah.

MR. UNLU: And what -- is there a standard deviation on these numbers?

MR. VAN DE WIELE: Yes. Did I not provide them in my comments?

MR. UNLU: I will look.

MR. VAN DE WIELE: Okay. Sure. Sorry.

MR. UNLU: Thanks.

JUDGE HORNER: Any other questions. Okay. Thank you.

MR. VAN DE WIELE: Thank you.

JUDGE HORNER: We'll move to our next speaker, Ms. Emmabella Rudd with T-1 International.

MS. RUDD: Good afternoon. My name is

Emmabella Rudd. And since the age of five, my life has depended on insulin. Currently, I reside in Washington, D.C., where I'm pursuing my Masters in Health Policy at Georgetown University. For many years, my work has encompassed advocacy for insulin prices as well as diabetes research at both state and federal levels. At the age of five, I was suddenly struck with symptoms of Type-1 diabetes, frequent urination, extreme thirst and significant weight loss with no family history of the disease. I was almost misdiagnosed, and if I would have been diagnosed the next day, I would have lost my life.

Now, 16 years later, and my chronic disease continues to be profited off the system due to exploitation of the patent system. Today I am testifying to say that the PTO and FDA should carefully scrutinize patent applications to ensure that pharma companies do not receive longer patent monopolies than they are entitled to under the law. Drug makers often argue that additional patent applications filed prior to regulatory

approval incentivize companies to invest in the development of a new drug and should not be characterized as ever-greening. However, the drug makers' intentions are not as transparent as they seem. By doing this, they stifle generic competition. Are these patents justifiable when the drug's improvements are not groundbreaking to those that use it?

We as patients want to see novel and groundbreaking technologies that will improve our lives as diabetics. Since the age of five, I've seen incredible breakthroughs. However, we just continue to see patents on technologies that have not changed for an extended period of time. Very excitingly, just in November of 2022, TZIELD was passed by the FDA. A drug that will delay the onset of Type-1 diabetes by two years. Currently, the cost of this treatment is $193,000 for the 14-day treatment. If I had the choice to delay the onset of my diagnosis when I was diagnosed at the age of five, I would take it without hesitation.

But would I be able to afford it? The

price tag for TZIELD is out of reach for many, and if the manufacturer applies for and receives more patents, whose terms extend after its original patent expires, which is likely to do, given the current policy to yield will continue to be inaccessible for Americans. The high and inaccessible price of this will ultimately increase US health care spending and not improve the reality of Type-1 diabetes patients. Already we see limited lifespans. We will be at risk for worse health outcomes, not having the access to this drug. If the intent of TZIELD's manufacturers is to work towards a world with option to delay the onset of type one diabetes, patent ever-greening should not be an option in this case. The option to profit more due to endless market exclusivity should not be an option. Generics should be launched as quickly as possible to improve public health in the United States. I think that TZIELD is a novel and innovative new medicine right now in a successive lifetime of a lifetime and an innovation. And I'm

extremely excited for that.

However, many insulins are not. We should overall raise the incentive standard required for patients or for patents. This would make manufacturing and biosimilars and interchangeable insulins and other diabetes technologies and cures a more worthwhile investment for new manufacturers and competitors. With this said, PTO should carefully scrutinize every aspect of pharma companies' extension applications, including applicants' compliance with the PTO's duty of disclosure. Lastly, PTO should invite third party participation in the extension process, including participation by patient groups. As patients we're the experts. We should be included in every step of the way as we are utilizing these drugs to stay alive. I can't go without just a couple of hours of insulin. And neither does any other Type-1 diabetic.

We should be included in every step of the way as we are utilizing them to stay alive.

That is, at the end of the day, the most important. Now, this could look like or operate as a disease specific patient coalition or working groups to review patents and/or to provide training to the PTO and FDA. And what this looks like in our day to day lives. How do these drugs impact us and do the new patent applications really affect us? Patients, like I said, need to be at the table as our lives are at stake. Pharmaceutical companies have been invited to the table for years, yet we as patients have been left out and are not being recognized as experts we are. The PTO and FDA at its foundation is existing to serve the health and wellbeing of the American people and not to prioritize the market and its manufacturers for profit. In order for this system to work, patients need to be included in the conversation always. Thank you.

JUDGE HORNER: Thank you, Ms. Rudd. Thank you for being here today and for sharing your perspective as a patient and your advocacy for the system and for the patient population with

Type-1 diabetes. I'm intrigued by what I've heard today from you and from a few of the other speakers about getting patients more involved. Particularly, I know there's some patient advocacy and patient advisory groups at FDA. We don't really have anything like that currently at PTO, but certainly that's something we're going to explore. So, I appreciate your input and recommendations here on that point specifically, and I'll open it up for the other panel members if anyone has any questions. No other question. Okay. Thank you very much.

MS. RUDD: Thank you.

MR. SALIMI: I have a question.

JUDGE HORNER: Oh, go ahead.

MR. SALIMI: Yes. Thanks for being here. You advocate that we should ask from FDA, to get engaged with the FDA more so. The question is third parties can petition the FDA to determine when it comes to their regulatory review period. But under what statutory authorization do we have to request for that? Do you have any ideas

whether we have the statutory authorization to request FDA for the PTO redetermination?

MS. RUDD: Currently, I don't have the answer to that, but I can get back to you in the written comments. But as far as overall, just the inclusion, I think at this time, you know, it's like you had said that there are groups, working groups that stand. I think it's important that we look into that and try to bring that to the table for now. But as far as the statutes, I am not familiar, but I can provide that in the comments.

MR. SALIMI: Yeah, but you know, you can take an active, more active participation when the FDA publishes these, their regulatory review period in the Federal Register. And if you guys and your group have any question regarding the time, that's when you can act and file a petition, us in the USPTO, we really don't have any authorization to question what the FDA gives us. So that's just something to keep in mind.

MS. RUDD: Okay. Thanks.

JUDGE HORNER: And I'll also note here

that we've recently, the PTO has recently enhanced the information on our Web page so that when PTE applications are filed, there's an easy way to identify those through our Web page so that if third parties do want to challenge in a petition to the FDA, they are aware of those PTE applications when they're filed. So, we're trying to increase the transparency there on that issue.

MS. TILL: I had one question. You were mentioning this newly approved product called TZIELD, that is a biologic for delaying the onset of Type-1 diabetes. I guess the question I have is, that's a biologic product, so it would be subject to the data protection exclusivities of the BPCIA, and that's a 12-year data exclusivity. Do you, in your opinion, do you believe that that's something that is then a barrier to bringing biosimilars, or is that just you anticipate that at that, the time that that exclusivity is lapsed, that a biosimilar would potentially be available?

MS. RUDD: Absolutely. So, we've heard

from other speakers today talk about how after these 12, 14-year, you know, patent market exclusivity, they're limited to just that one and the price will most likely stay high. But after that, 14 years, and that's how it's always operated. And yes, it limits who can access it because it limits, okay are private insurance companies going to cover this. Definitely depends on the patient and what health care they receive. Right. However, after the 14 years, they could take advantage of perhaps filing for another patent and that could limit more access to patients later.

So that could keep the price high, that could keep market exclusivity very streamlined. And so, what I am saying here is that I don't want the drug manufacturers to take advantage of that. I believe that at this foundation that they want this to be accessible to patients and to put off the two-year mark of Type-1, you know, living with Type-1 diabetes is very difficult. And year after year if you're, you know, despite how well you

take care of yourself, it's going to hurt your health. And so, if they have that two year, it's going to make a huge difference. Right.

And so, what I -- myself and I can speak on behalf of other Type-1, we want to see that accessible and we don't want it to see it being taken advantage of. We want to see more innovation. We want to see that two-year become four years and eventually, hopefully a cure. However, we want it to see it be accessible. We don't want patents to be part of that limitation. So --

JUDGE HORNER: Thank you very much. We'll move to our next speaker, Ms. Patricia Kelmar from the US Public Interest Research Group.

MS. KELMAR: Thank you. Yes, I'm Patricia Kelmar. Thank you for having me today and thanks for sticking it out. I know we're getting to end of a long day, but I'm the Senior Director for Health Care Campaigns for US PIRG, which is the Public Interest Research Group. We are a nonprofit, nonpartisan consumer advocacy

organization with grassroots members in our 24 states. Working to address high health care prices, we support improved access to generic and biosimilar drugs because we know that a competitive health care market helps to keep prices in check.

The FDA's own data shows that with even just one generic alternative, you can bring prices for that drug down by as much as 40 per cent. That's a lot of savings. We applaud your agency's joint commitment to collaborating to improve access to generic and biosimilar drugs. And thank you so much for the opportunity to speak today. I think all of us here is patient and consumer advocates are seeing this as one of those opportunities to play a role, an active role without having to figure out how to formally submit comments and go through portals and keep track of regulatory notices and the things that people with a bigger staff might be able to do. So we thank you for this more informal but important opportunity to speak.

Drug prices, as you all know, drive up the cost of health care for patients, for insured families, and our state and federal health programs. Two thirds of US adults rely on prescription drugs, and yet one in four people struggle to pay for them. When people can't fit drugs in their monthly budgets, they make decisions that negatively impact their health, such as not filling prescriptions at all or skipping doses. And those high prices impact beyond the patient community, all insured people, because drug expenses make up about 20 per cent of our insurance premiums. And when drug prices go up, so do our premiums.

But we can change that by doing more to allow generic competitors to come to market. Savings from new generic approvals are dramatic, as the FDA's own study shows $10 to $20 billion every year over the last couple of years. And that's the power of a competitive marketplace. Unfortunately, recent use of misuse of patents by pharmaceutical companies is undermining the price

competition. Patents are meant to spur innovation, but the monopoly pricing granted by a patent isn't meant to last forever. These days, drug makers spend significant time and money obtaining new patents for medications already on our pharmacy shelves.

They're blocking our access to generics and biosimilars. And although a wrongly granted patent or a weak patent can be challenged in federal courts, these challenges take years and come with an average median cost of three and a half million dollars per case. So, it's no wonder that we don't see, you know, more challenges to some of the patents that have been granted. We'll offer just a few of the recommendations to support access to lower cost generics and biosimilars, and you'll find more details in the written comments that you have before me. But in the interest of time, I'll try to summarize more quickly. Less emphasis on -- so our first recommendation is less emphasis on swift review and more emphasis on quality review.

Part of the PTO's own mission is to provide high quality and timely examination of patent applications. With only 8000 patent examiners reviewing 600,000 patent applications every year, patent examiners are under great pressure to work quickly to serve the clients, the patent applicants. A 2016 PTO presentation shows, in fact that 55 per cent of a patent examiner's performance appraisal is based on productivity and docket management. And the result is that examiners spend an average of just 19 hours per application. This emphasis on swift reviews works against the PTO's mission to also provide high quality patent examinations. And the tension is clear. We understand that you may increase, you may be considering increasing patent examiner time, and we applaud that change.

It's time to shift away from the overemphasis on speed and urge a return to your mission's directive to serve the public, taking the time to conduct high quality examinations which could benefit by having less over patenting

fewer patent thickets and a rejection of overly broad patents. Our second recommendation is to urge more stringent review of patent applications for prescriptions already on the market. And this is where you might be wanting to spend some of that extra time. Patent applicants should clearly disclose when a new application, including a continuation application claims aspects of a drug already on the market.

Those applications should be assigned to more experienced examiners who should get that additional time. Examiners need access to a wider array of information for prior art searches, including the scientific information provided to the FDA by drug companies. I've understood that there's some confidentiality issues that might be -- might arise in that situation, but I'm sure there's a lot of smart people in this room that can help puzzle that out. I'm not that person, but I encourage you to pursue that. FDA experts knowledgeable with that prior approved drug should assist patent examiners in their review.

These changes should expose patents filed simply to prevent or postpone generic competition. Third, better identification of conflicting statements by pharmaceutical applicants. You've already heard a lot about that. We think that this kind of double speak is probably hard for you to uncover. So, our recommendation is flagging applications which correspond to substantially similar drugs, sharing information given to both agencies, especially regarding clinical tests and spending more quality time reviewing to unearth those conflicting claims that might either signal an attempt to game the system or might simply just be mistakes.

Fourth, clearly there's been a lot of finger pointing in this room about what data is true and what data isn't true. So, we need better database for the public and academic researchers to be able to utilize so that we can get to the source of some of these problems. If we have better information, regulators, researchers can do the work of looking at what the trends are and

understanding more about the patent system and identifying solutions to bring generics and biosimilars to market sooner. Fifth collaborative auditing and regulatory enforcement. We haven't really talked too much about enforcement today, but it seems like it would be great to collaborate between the two agencies on your different enforcement powers to share ideas and understand how you can support one another in the work that you're doing to oversee regulatory and statutory compliance.

Hopefully that's already happening, but if it isn't, that's a recommendation as well. And then we did spend a lot of time talking today about patient engagement. I'd like to underscore that too often policy solutions are proposed, analyzed and decided with hardly any consumer input. And when policymakers lose touch with the end user and in this case, I would say it's not the patent applicant or the FDA new drug applicant, but the public. Sometimes those consumer interests are put last.

As a public interest advocate, I often walk into policy meetings with less technical knowledge than most, but I offer the valuable insight, as you've heard from others today, on the impact of your decisions by speaking from the perspective of an insured individual paying for health care or of a patient speaking about using health product services. So those are the values that you get from talking and involving consumers. I understand that there are more formal ways to engage consumers, but I think we all have in the room here some ideas on ways to better engage patients. Personally, I've worked with the National Quality Forum on a patient advisory council to better involve patients and consumers in their issues.

The National Quality Forum does a lot of very highly technical quality measurement for hospitals and deciding which measures to use in the CMS star rating. And I'd be happy to share more learnings from that, but I think there's more room obviously to encourage patient involvement,

maybe in a less formal way. Thank you for your consideration of these ideas. We look forward to further collaboration with your collaboration. Thanks for this opportunity today to really talk about this and explore some meaningful recommendations.

JUDGE HORNER: Great. Thank you for your comments and for being here today. I'll turn it to the panel if we have questions. FDA questions? Ms. Till? Ali?

MS. TILL: You spoke about the patent misuse. Do you have examples of what that is -- how you envision or what you believe that to be?

MS. KELMAR: So, I use that as a broad term to include what some here have said are, you know, misnomers or inflammatory language or something like that. But consumers and patients need a way to talk about these issues in more plain language. Right. We're not going to read long academic journals. So, things like patent thickets, that's something we can understand. It's many, many patents that are trying to block

competition that make it really hard to bring litigation to challenge patents. So, patent thickets, product hopping, these are some of the things that we've identified as consumers looking at the reasons that it's getting harder and harder to get generic drugs to market. And we're waiting longer and longer. Does that answer your question? Thank you.

MR. SALIMI: Hi. You spoke about the resources that we need to provide more resources to our examiners beside what we have already. What they are capable of in, what they are capable -- what they have as of now. What other resources do you know that we can provide to the examiners that they don't -- that they lack now, today?

MS. KELMAR: Well, I'm not the person in the room, so you all would be the better experts for that. I mean, I think it would be great to understand I don't know how much internal thought processes or gathering back of information, but it seems like doing these prior art searches are pretty difficult. And the complexities of working

with another agency that has a lot of the information that you might need is a difficult thing to do. So, if there's more time, I understand you're doing more training. Probably that is all helping.

But I would go to the examiners themselves and see how they can get help. And then there are other experts in this room who are closer to that, that, you know, a brainstorming session with them might be a great opportunity. I think it's just really hard for us to engage with the PTO, which has traditionally just been a much more buttoned down. There's three doors to enter and you have to fit in that door to be able to participate. So, a little more informal conversation might be a way to get the ball rolling.

MR. SALIMI: Just for the record, you might want to know that our examiners have access to the most sophisticated databases that exists, and they can find any article that gets published anywhere in the world, something that perhaps a

lot of people don't know. But we have a lot of tools available to the examiners. Now, I'm not saying that they're going to find exact order each and every time but given the time and everything else that they have, they have the most sophisticated databases available to them, perhaps absent Homeland Security or some of these other folks. And the Office spends a lot of money to maintain those, you know, to license those databases. Just for --

MS. KELMAR: I'm glad to hear that, thank you. And I -- it's an unenviable job, I'm sure, for patent examiners, especially when you're facing 600,000 applications a year. That's a lot.

JUDGE HORNER: Well, thank you again for being here. We're going to move on to our final speaker. We saved the best for last. Professor John Thomas from -- Jay Thomas from Georgetown University Law Center. You may begin when you're ready.

PROF. THOMAS: Thank you very much for having me here today. I observed that amongst the

seven government panelists, I have two former students, one at FDA and one at USPTO. So, I'm expecting some tough questions. It is my birthday today, so I ask for your forbearance. The whole of government approach affords the USPTO and FDA a long-delayed opportunity to revisit neglected opportunities to fulfill the goals of the Hatch-Waxman Act and encouraging pharmaceutical innovation while also promoting access to medicines. With these brief remarks, I focus upon the FDA publication known as the Orange Book. I've also provided more extensive written remarks with additional views.

Orange Book patent listings hold extraordinary consequences for public health. They allow brand name drug companies to sue generic firms for patent infringement, even though the generics have done nothing more than file an entirely accurate petition to the government asking for marketing approval. In such cases, FDA ordinarily may not approve the ANDA for 30 months. This 30-month stay effectively acts as a

preliminary injunction against the generic firm without requiring the patent proprietor to address the usual equitable factors or to post a bond. These incentives strongly encourage brand name drug companies to identify as many patents to the FDA as possible.

Numerous patents that fail to meet the statutory criteria have made their way into the Orange Book. Despite all of that, FDA has no oversight over the Orange Book. FDA simply lists in the Orange Book all identified patents without review. If a private party disputes the listing of a patent in the Orange Book, FDA merely informs the brand name drug company. Unless the brand name drug company withdraws or amends the patent information, FDA will not change the information in the Orange Book. FDA could do a much better job and at least take a rough initial look or perhaps a more substantive look to assess the propriety of Orange Book patent listings.

The agency should also provide for a more robust Orange Book listing challenges. FDA

plays no substantive role in current Orange Book listing challenges. The agency merely allows any interested person to provide it with a statement of dispute unless the brand name drug company withdraws or immense its patent information in response to that dispute, FDA will not change the information in the Orange Book. A USPTO stands in a position to fill this gap. Administrative proceedings for the propriety of Orange Book listings could be conducted by the PTAB. But that's a determination that is well within the capability of APJs, as it's a paper-to-paper comparison between a patent and an ANDA. Those proceedings would comport with increased emphasis on administrative dispute resolution in the patent system, harness the considerable expertise of APJs in adjudicating adversarial proceedings and in view of the rapidly declining number of ex parte appeals to the PTAB, make use of available USPTO capacity.

Let me address my sort of final comments to the FDA's anomalous non statutory use code

practice. FDA does not assess the right to exclude afforded by a method of use patent in terms of the claim that the USPTO grants. Rather, FDA relies upon patent proprietors to paraphrase the scope of their claims, using 250 characters or less. FDA apparently did not establish the 250-character limit following consultation with USPTO academics, jurists, anyone, as far as I can tell. Rather, FDA decided this highly condensed summary of complex legal texts granted by a peer agency was appropriate due to the size of a database fields and FDA's antiquated computer system. FDA has elevated use codes to the status of proprietary rights to which generic drug companies are accountable. If the use code indicates that the patent claims a method of use for which approval is sought, then the generic must submit an ANDA with either a paragraph three or paragraph four certification.

Otherwise, the generic applicant may submit a Section 8 statement. At the outset, FDA does not verify any of the submitted use code

information provided by brand name drug companies. It merely lists the use code and its accompanying narrative in the Orange Book. FDA's dispute resolution process with respect to use codes is also severely constrained. The relevant FDA regulation limits statements of disputes regarding use codes to 250 words directed to "the person's interpretation of the scope of the patent". FDA then forwards this information to the brand name drug company. Unless the brand name drug company withdraws or amends its patent information in response to this dispute. Then nothing happens to the use code. This anomalous non statutory use code practice for paraphrasing patents is so reductionist as to be absurd.

It results in broader intellectual property protection from brand name drug companies than Congress has allowed. It should be terminated immediately. FDA should read the claims of issued patents as the USPTO granted them, not in a summary and potentially self-serving form that may inaccurately portray

the scope of exclusivity they provide. If FDA remains unwilling to acquire sufficient experience or expertise to construe the legal text to which all members of the public are accountable and which were granted by a pure agency, then FDA ought to avail itself of USPTO resources as soon as possible. Thank you for the opportunity to submit these remarks.

JUDGE HORNER: Thank you, Professor Thomas. Open it up to the panel for a questions. Yes, go ahead.

MS. DAVIS: Thank you very much for your comments. Could you talk about if the FDA were to depart from its ministerial role and substantively weigh in on these patent disputes, how do you see it playing out then, if, say, the FDA decided one way or the other and then a company, whether it's the new drug applicant, the generic drug applicant, wanted to further challenge that, because I think normally these things play out in the courts and for example, as a counterclaim in patent litigation. So how would you see the

process playing out or how would you suggest it be structured if the FDA would --

PROF. THOMAS: Well, how the structure currently works is that FDA foists responsibility for policing the Orange Book upon the Federal Trade Commission or private antitrust enforcers. So that's where we are right now. If you looked at it, my sense is there would just be less abuse of the Orange Book because individuals wouldn't want to test that. But I think where you're going and it's true, you would be subject to litigation in the District Court for the District of Columbia.

JUDGE HORNER: That was kind of -- Oh, I'm sorry. Go ahead.

MS. DAVIS: Just to clarify so that then the recourse would be to the courts. Is that how you would see it playing out?

PROF. THOMAS: If an entity disagreed with -- if a brand name drug company disagreed with your decision not to list a patent in the Orange Book, then that they would have the

opportunity to sue you essentially, yes.

MS. TILL: Okay. So, my question kind of leans into that as well, because your other alternative was to have APJs make these determinations as to whether a patent was properly listed or not. But the listing is not under a patent statute. So, if APJs were to do that procedure, what if the brand company disagreed? What would be the remedy?

PROF. THOMAS: Okay, so let's be quite clear about this. The Orange Book has been littered with patents on tablets, shapes and scoring, containers. There's a litigation going on right now with a REMS computer system listed in the Orange Book. So don't think that these -- the FDA's task may be simpler than you seem to be letting on. It's not always a very complex determination, but right now it's just these patents go into the into the Orange Book and there's just no oversight. And they block generic competition by the automatic action of a statute.

So, again, APJ's could be detailed to

FDA. There's a lot of trust between your agencies in terms of different and there could be more. Or alternatively, the FDA could simply hire a patent attorneys. FDA currently has patent attorneys on its staff. It used to write the use codes itself, and then for some reason you stopped and left it to the responsibility of self-interested brand name drug companies. So, but yes, so those are the opportunities the FDA could revert to its former practice of writing the use codes or FDA could supervise use codes that are submitted by Orange Book patent listers.

JUDGE HORNER: Thank you. I think in the interest of --

MS. TILL: Can I ask one more question?

JUDGE HORNER: Oh, one more question.

MS. TILL: Sorry. So, if the use code practice was --

PROF. THOMAS: She's one of the former students, you know, that's --

MS. TILL: -- completely eliminated.

PROF. THOMAS: The tables are turned.

I'm sorry, Mary.

MS. TILL: If the use codes were completely eliminated, what would be a sort of alternative practice to informing the public and/or any potential and a filer of the particular claims in a patent that relate to a method of use?

PROF. THOMAS: Well, shockingly enough, the warning would be the patent claims as the agency actually issues them. I probably couldn't get fired from Georgetown University for doing almost anything, but I certainly wouldn't -- I don't tell my students that they should be reading 250-character abstracts of what, more than 100 claims in a patent. Again, it would be more rational for FDA to look at the abstract of a patent than a use code.

No patent attorney would ever tell you that the abstract of a patent sets forth its exclusive rights, but at least the abstract was read by USPTO. It often parrots claim one of the patent, and it's got like 150 to 250 words. That's the standard on the MPEP. That's at least

better than that of 250-character use code, which again is it's non statutory. This practice really needs to stop as soon as possible. It's absurd.

JUDGE HORNER: Thank you. Go ahead.

MS. TERROT: I did have one question. Are you proposing new statutory provisions to provide a basis for FDA to construe the claims, assess the scope of the patents to verify listings, or do you believe that authority exists in current law?

PROF. THOMAS: Every member of the public and the government is responsible for each claim in every issued patent that this agency puts out. And that includes the FDA. You don't need any statutory authorization. You should read the patents as your peer agency grants them and not wholly disregard them. There is no statutory provision needed one way or the other. You're the ones who have come up with this non statutory practice, which is just not the way anyone else in the universe reads patents and it's prone to abuse.

JUDGE HORNER: Okay. Thank you for your comments, for being here, and for your input. This concludes Session five. But before we wrap up, I'm going to invite Deputy Director Derrick Brent to make his way to the podium at the front of the room for some closing remarks. And while he does that, I'm going to give him a brief introduction. Derrick Brent is the Deputy Undersecretary of Commerce for Intellectual Property and the Deputy Director of the United States Patent and Trademark Office.

His responsibilities include working with Director Vidal to lead the agency advance IP policy for the benefit of the country and expand the USPTO outreach efforts to incentivize and support more innovation and entrepreneurship nationwide and execute the agency's policies, priorities and programs. Director Brent's career includes vast public service and private sector work, including significant experience in IP law and work to assist startups, as well as those who are underrepresented.

He served for six years as chief counsel for Senator Barbara Boxer. He also clerked for the Honorable Algenon L. Marbley, Chief Judge of the United States District Court for the Southern District of Ohio. After litigating at the law firm of Vorys, Saters, Seymour and Pease in Ohio, he served six years as a senior trial attorney at the U.S. Department of Justice Civil Rights Division, where he received a special achievement award for his trial work. Deputy Director Brent has also served in the private sector as vice President and Associate General Counsel for the multinational medical technology company, Masimo. I invite you to deliver some closing thoughts.

DEPUTY DIRECTOR BRENT: Turned -- it turned on. I was so used to all day looking at the microphones around and seeing the red light on, telling me that they worked. Then when I looked down and saw the red light that I actually thought this was a hot mic. So, and I've been trained for my days in the Senate to be careful around hot mics and had to dive across the senator

a few times to hit the mic button. I want to start off by thanking Linda. I want to thank all of the PTO staff, all of the FDA staff for their hard work and putting on an excellent listening session discussion.

It was a great conversation that was had here, and that's why I don't call it testimony or anything. It was really conversation because it was a truly an exchange. And I'm looking forward to as we go forward and hopefully this is the, I'm not going to say hopefully, I know it is the first of other sessions that we will conduct in order to better reach more understanding and to help find ways to make progress and work together. I also want to thank the patient advocates and the other speakers who came out today. Your time, your dedication combined with the hard work of the staff, putting this on help to make this a success.

And again, it's only one step and we have more to do. You know, I was -- a few years ago, I was interviewed by a former intern of mine

who was in law school. And she asked me an interesting question. She said, what was the life lesson that is served you well throughout your, you know, throughout your career? And I had to think thought about all my various sports coaches and my various teachers who yelled at me for different things because that's how lessons are learned. Right. But more importantly, I remembered something that was said, and I responded to her and I said, only through dialogue can we reach understanding.

And it's a comment that Director Vidal has repeated a few times to me. She really liked it. And by the way, I'd be remiss if I didn't thank if I didn't thank Director Vidal, as well as the FDA Commissioner Califf, for their leadership in getting this not only the working group together, but also providing the resources to make this conversation and these exchanges happen, and also the work that still will be -- that is still to be done, but only through dialogue can we reach understanding.

That's where we talk and we listen. And today was an example of that type of work, and it's the work we have to do. The other thing that this event showed today was that the work of the PTO and the FDA goes well beyond approval, denial and registration, simple administrative tasks. It reaches into the marketplace, but more importantly, it reaches into it reaches into the lives of people, the very people that we are sworn to serve. So, in conclusion, I say let's keep the conversation going. Let's keep the work going. There's more to do and there's better to do. Thank you for your time.

JUDGE HORNER: Thank you. This concludes our Listening Session. I would just like to thank our logistics team behind the scenes who put this whole event together. Starr Baker, Lorrie Jenkins, Rhonda Corbin, Alan Cogswell, Cheryl DaSilva and LaShawn Fortune. They put a lot of hard work in to make this run as smoothly as it did today, and we appreciate their efforts. Thank you, everyone.

(Whereupon, at 4:20 p.m., the PROCEEDINGS were adjourned.)

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CERTIFICATE OF NOTARY PUBLIC

COMMONWEALTH OF VIRGINIA

I, Mark Mahoney, notary public in and for the Commonwealth of Virginia, do hereby certify that the forgoing PROCEEDING was duly recorded and thereafter reduced to print under my direction; that the witnesses were sworn to tell the truth under penalty of perjury; that said transcript is a true record of the testimony given by witnesses; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this proceeding was called; and, furthermore, that I am not 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.

(Signature and Seal on File)

Notary Public, in and for the Commonwealth of Virginia

My Commission Expires: August 31, 2025

Notary Public Number 122985