UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT PUBLIC ADVISORY COMMITTEE MEETING

Alexandria, Virginia

Tuesday, September 27, 2022

PARTICIPANTS:

Opening Remarks:

KATHI VIDAL, Under Secretary of Commerce for Intellectual Property and Director of the USPTO

Patent Public Advisory Committee (PPAC) Members:

STEVEN CALTRIDER, Chair

TRACY-GENE G. DURKIN, Vice Chair

JUDGE SUSAN G. BRADEN (RET.)

DAN BROWN

JEREMIAH CHAN

CHARLES DUAN

SUZANNE HARRISON

HEIDI NEBEL

JEFFREY M. SEARS

Union Representatives:

CATHERINE FAINT, NTU 254

KATHLEEN DUDA, POPA representative

United States Patent and Trademark Office (USPTO):

JAY HOFFMAN, Chief Financial Officer,

CHRISTIAN HANNON, Patent Attorney, Office of Policy and International Affairs

LINDA HORNER, Acting Senior Lead Administrative Patent Judge, Patent Trial and Appeal Board

PARTICIPANTS (CONT'D):

DERRICK BRENT, Deputy Director of the USPTO

ANDREW FAILE, Acting Commissioner for Patents

ROBIN EVANS, Deputy Commissioner for Patents

BOB BAHR, Deputy Commissioner for Patents

VALENCIA MARIN-WALLACE, Deputy Commissioner for Patents

RICK SEIDEL, Deputy Commissioner for Patents

ROBIN EVANS, Deputy Commissioner for Patents

ROBERT BAHR, Deputy Commissioner for Patents

JACKIE BONILLA, Deputy Chief Administrative Patent Judge PTAB

SCOTT BOALICK, Chief Administrative Patent Judge PTAB

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P R O C E E D I N G S

(2:00 p.m.)

CHAIRMAN CALTRIDER: Good afternoon. I'd like to welcome everyone to the September 2022 PPAC meeting. Before we start, I want to raise just a couple of housekeeping matters. Our November meeting will be an in-person half day meeting under our old format. This is the last of our shorter but deeper dive discussions. We replaced the second quarter and the third quarter half day meetings with the shorter meetings. As we plan our meetings next year, please share your feedback on the mix, whether the short format or the quarterly longer format is better, more effective. I would really like to hear your input on how we plan our meetings next year. From my vantage point, I love the shorter format, deeper dive discussions with a relatively shorter agenda that we have more robust discussions, and the longer agendas where we just pack everything in. But I really want your perspective on that. The second piece of housekeeping is we do monitor the

chat, as well as the ppac@uspto.gov email during the meeting. We aren't always able to answer all the questions during the meeting, but rest assured we will follow up if we don't get to a question that's submitted during the meeting as a live feed. Let's begin today's meeting with introductions from PPAC members. Tracy, do you want to kick us off?

MS. DURKIN: Sure. I'd be happy to. Tracy Durkin, Vice Chair of PPAC.

MR. SEARS: Hi, I'm Jeff Sears, PPAC, Chair of the Finance subcommittee.

MR. CHAN: Jeremiah Chan, PPAC, Chair of the Legislative and Policy subcommittee.

MS. BRADEN: Judge Susan Braden. I'm chair this year of the Artificial Intelligence and IT subcommittee.

MR. BROWN: Hi, I'm Dan Brown. I'm the independent inventor rep and chair on the PPAC innovation expansion subcommittee.

MR DUAN: Hi, this is Charles Duan. I'm on the PPAC and I'm the Vice Chair of the people

PQUIP (phonetic) subcommittee.

MS. HARRISON: I am Suzanne Harrison and I'm Vice Chair of the Innovation Expansion committee.

MS. NEBEL: Hi, I am Heidi Nebel. I am a first year PPAC committee member.

MS. DUDA: Hi, I'm Kathy Duda, and I'm the POPA member of PPAC.

MS. FAINT: Cathy Faint. I'm Vice President of NTEU 245 and a member of PPAC.

CHAIRMAN CALTRIDER: Thank you. And when we get to our Director Vidal, I'll allow her to introduce her team as we get into that agenda. As I shared early in this year, our priorities for PPAC were reliability and the durability to patent rights, expanding the base of innovation and being good stewards. Last month, we did a deep dive on expanding the base of innovation through the Council of Inclusive Innovation. Today's agenda, we're going to touch on the reliability and durability of patent rights, as well as a check in on being good stewards. We have an update from

finance on the discussion of the FDA USPTO collaboration, as well as the SEP policies. But before we get into the meat of the agenda, I'd like to invite Director Vidal with any opening comments.

MS. VIDAL: Thank you, Steve, very much. Appreciate it. If we wanted to do introductions first, Andy, can you do an introduction to our team?

MR. FAILE: Sure can. I'll start and pass it to the next person. If that person would pass it to the next one, then we'll hit everyone. I'm Andy Faile, Deputy Commissioner for patents, currently acting commissioner for patents, and I will pass it to Valencia Martin-Wallace.

MS. MARTIN-WALLACE: Thanks, Andy. Hi, I'm Valencia Martin-Wallace, Deputy Commissioner for patents, and I'll pass it on to Rick Seidel.

MR. SEIDEL: Thanks Valencia. Rick Seidel, Deputy Commissioner for patents. I'll pass it to Robin.

MS. EVANS: Thanks, Rick. I'm Robin

Evans, Deputy Commissioner for patents. And I think I'll pass it to Bob.

MR. BAHR: Thanks. I'm Bob Bahr, Deputy Commissioner for patents, and I will pass it to Linda Horner.

MS. HORNER: Hi, I'm Linda Horner. I am an Acting Senior Lead Administrative Patent Judge. And I will pass it to Jackie Bonilla.

MS. BONILLA: Hi, I'm Jackie Bonilla. I'm Deputy Chief Administrative Patent Judge at PTAB, but also on detail as Senior Legal Advisor working with Kathi and the team on the 10th floor. And I will pass it along to Scott Boalick.

MR. BOALICK: Hi, Scott Boalick, Chief Judge of PTAB and I will pass over to Jay Hoffman.

MR. HOFFMAN: Thank goodness, I think we're out of passing after me. My name is Jay Hoffman. I'm the Chief Financial Officer. I honestly don't think there's anyone else left to pass to, but if there is I apologize.

CHAIRMAN CALTRIDER: Let's not forget Chris Hannon.

MR. HOFFMAN: Chris, I didn't see you up there.

MR. HANNON: No worries, thanks. Chris Hannon, Patent Attorney in the USPTO Office of Policy and International Affairs.

CHAIRMAN CALTRIDER: We have Derrick Brent right below me. Derrick are you still there?

MR. BRENT: Yeah. Derrick Brent, Deputy Director of USPTO.

MS. VIDAL: And Dede and Cherie. Okay, so, then we got most people. I think -- I know there are a few more on, so if anybody else wants to introduce themselves, that's great.

I just wanted to say a few words at the top of the hour. Very much looking forward to the good discussion today. I do want to thank everybody for all the engagement over the past five months. It's really helped us to shape the work that we do. We certainly -- and you can take down the slide. There's not really any interesting information on that. So, thank you

for all the engagement.

As you all know, I engage in a lot of stakeholder meetings, both within the USPTO, as well as outside the USPTO. So, I could come up to speed on all the issues that people see, all the opportunities that people see. The internal sessions I did with the unions, they were fantastic. It just reinforced that everybody here wants to do a great job. We want to issue robust and reliable patent rights. We want to improve the system as much as we can. And then externally, it's been great to hear everybody's ideas on how they want to work with us and contribute in that regard. So, I want to thank everybody for all of that.

In terms of the external listening sessions, I've been able to hear from both larger corporations, big organizations, as well as independent small inventors. So, it's been a really good mix. We've worked really hard to make sure that we're reaching out to a broad group of people, a broad group of stakeholders so that we

can hear more. We also have established even more ways that you can connect with us, including creating a directors' -- not only the Directors' blog, but there's an engage with the Director's page. So, if there's a topic you want to interact with us on, please either go to the page -- there's often an email where you can connect with us directly on a particular subject matter. Or if you can't find a place and you want to submit information, or ideas, go to the Directors' blog. We take all the comments we received very seriously. We're excited to get them. As I said, we use them to help shape with it what we do.

In addition to that, obviously, we've done a number of requests for comments. We want to engage with you directly on everything we do. We have more to come. Just a few of the ones that are either closing soon or have closed, we have a request for comment out on patent better eligibility. And looking forward to receiving more comments on that. I actually don't know if that's a request for comment or -- an official one

or if it's just an informal one. But we received a lot of feedback. Obviously, that's a very important issue. We actually had a request to extend it and that's why it's been extended to 10/15 because some of the organizations wanted even more time to make sure that they're gathering the feedback from everybody within their organizations. Director review and the Presidential Opinion Panel. That one is going to close on 10/19, so please if you have thoughts on that, provide them. There's other ones like the expansion of the Cancer Immunotherapy Pilot Program, which has already closed.

In addition to that we've got more RSCs and more engagement to come. We are working on RSCs related to robust and reliable patent rights. We have one of those that I'm hoping will issue within the next month. It's in the review process right now. We work very closely with PPAC and with stakeholders on that, and also addresses a letter that I sent to Commissioner Califf with the FDA on ways that we could have more robust and

reliable IP rights -- not specific to pharmaceuticals, but obviously impacting pharmaceuticals, as well as every other technology area.

In addition to that, we're working on the ANPRM related to discretionary denial of PTAB decisions. So, the AIA trials. So, hope to have that out for those take a little bit longer when it comes to actual rulemaking. But we're here working hard and moving everything forward. One thing I did want to highlight is I did a recent Directors' blog on training opportunities. So, I'd like to encourage everyone to take a look when you have a chance many of you've been involved in training before where you've either come into the office and work to help train our great Examiner's or you've invited them out to your facilities. And those are really amazing opportunities for the Examiners to really connect up and connect into the work that they do. A really great opportunity for you to describe the types of technologies you're seeing. And I know with COVID, we didn't

have as many opportunities as we did before. So, really would love to open that up and just open the floodgates, so that all of those missing opportunities come back sooner rather than later, so that the Examiners can engage with you on that. So, that's pretty much what I wanted to highlight in terms of the work that we're doing. It's -- I didn't go through all of it, but just want to highlight a few points. I think you also know we're working on guidance when it comes to 112, 103, when it comes to interviews, and final office allowances and the reasons for allowance. So, just looking at every part of the system to figure out how we can do even better. Serve the public more and create rights that are more certain that stakeholders can rely upon. So, thank you for joining us in those efforts. And with that, I will see if there are any questions before we delve into the content.

MS. HARRISON: Hi Director, it's Suzanne Harrison. And I just wanted to actually dive a little deeper into something that you said before.

And it relates to all of the stakeholder meetings that you had and informing some of your decisions. And I wondered if you could share a little bit about how those meetings have impacted or shaped your DNI perspective. And if there's anything you want to share with us about that.

MS. VIDAL: So, thanks, Suzanne, for that. I will say that a couple things. One, the broad feedback that I'm getting by meeting with various stakeholders -- I know Dan Brown has played a role with some of the independent inventors. I know you've played a role with some of the engagement with organizations and the great work that they're doing. It really has helped me think about how we can make more progress sooner rather than later through collaborations and through working across government. So, one of the things that it did -- and we just announced this today -- was I thought about not just having me as the Vice Chair of our Council for Inclusive Innovation but having Co-Chairs -- Co- Vice Chairs across government. So, today we announced that

the National Science Foundation, the Copyright Office, Shira Perlmutter, EDA, NIST, MBDA was one with Aaron Cradence (phonetic) -- we're all now going to be involved in pushing that initiative forward. And I know with your help, and with the help of others on the PPAC. So, we are excited about that. And thinking about this more in terms of thinking about the stakeholder holistically, especially those from underrepresented under resourced communities because they don't -- from what I understand from all my meetings, they're not connecting in with us by saying, hey, I need to get a patent. They're saying I've got this idea, or I want to move in this direction. And they need guidance all the way through. And some of that guidance may come from the USPTO. Some of that may come from the copyright office. Some of it may come from other areas of government. So, just really trying to think about our stakeholders -- and by stakeholders, I mean, the ones we want to have as stakeholders more holistically so that we can better serve them. And then also listening

to where those who have participated in the innovation ecosystem, where they had stumbling blocks and what their advice is on how we can help people more. So, one of the comments that I got was when you receive that rejection letter when you're applying for a patent, it's a letter that for a lot of people, is that is a big red stop sign. And just thinking about how we can better communicate that this is an opportunity to engage with the Examiners that are here working with you, alongside you to find subject matter that is allowable. We just want to make sure that at the end of the day, you have a strong IP right. That you work around any prior art, etc. So, I know the Examiners feel that way. Everyone I spoke to, they do not look at themselves in an adversarial position. They look at themselves as trying to solve for the same problem to make sure that when we issue patent rights, they're very strong. So, a lot of the work that we're doing on DEIA outside the organization -- there's a whole lot we're doing inside as well, which I know is off the

subject of your question. And I know we've got a lot of content today. But the work that we're doing outside was informed by that. And I will say it also informs policy decisions in terms of everything from the PTAB to other work that we do when we think about how do we shape policy within the USPTO so that we're supporting all Americans and moving the country forward.

MS. HARRISON: Thank you.

MS. VIDAL: Thank you, Suzanne.

CHAIRMAN CALTRIDER: Director Vidal, I don't have a question, but I will make your comment as we transition to the next item in the agenda. That is thank you, thank you, thank you. Your outreach, your external listening sessions and your stakeholder meetings have really been outstanding. And if those in the public have not engaged, either in one of those live meetings or virtual meetings, or on the Directors; blog, and the website, where you can contact the director directly, please do so. Because I can say that its sincerity in which the office is approaching

these outreach sessions to really listen and understand and really get to the core issues that these communities are experiencing has really just been outstanding. And I think there's going to be -- I'm excited about the improvements that are on the way. I'm excited about the energy and the focus that you're giving these problems. And I just would encourage -- whether it's PPAC members or members of the public -- to engage and take you up on those opportunities to attend the listening sessions, participate in Zoom meetings, to work through the website with the Directors' blog, and the submissions. It's just really been outstanding. Thank you.

MS. VIDAL: Thank you, Steve. Thank you for your leadership too.

CHAIRMAN CALTRIDER: Let's now go to Jeff for an update from the finance committee.

MR. HOFFMAN: Thanks very much. We're going to have a short update today on the current financial status, including a review of our spend and our revenue. I'm going to turn it over to the

office's CFO, Jay Hoffman. Jay, over to you.

MR. HOFFMAN: Great. Thank you very much, Jeff. And I believe we have some slides. If we could please bring those up. Great. I've already introduced myself. Let's go to the next slide. Okay, so first, is a review of the patent fee revenue collections. Bottom line is the fee revenue collections are tracking slightly above the appropriated expectation. The way you read this slide is that the X axis is in time going back to October of the start of a lot of this fiscal year, the Y axis is in millions of dollars. The purple horizontal line you see going across the top communicates that our current plan is to collect about $3.65 billion in patent fee collections. The green line is what we reported in the President's budget and what we were appropriated with, which was 3.608 billion. You can see here, from our 25-day moving average, we are right at expectation.

We're currently tracking about $12 million below the planning level, which is not

really a material difference. That $30 million above the appropriated level -- if these numbers hold through the end of September, and I suspect that they will -- we'll see a small deposit into the patent and trademark fee reserve fund that we'll need to request reprogramming for. Next slide please.

This slide looks at our cumulative spending and patents relative to our cumulative revenues. A very similar view here with the X axis in time dating back to the start of the fiscal year in October, the Y axis again in millions of dollars. You see a green horizontal line tracking across the graph here. That's the planned spending level for FY 2022. In patents, we had budgeted $3.46 billion in spending. As you're looking at these bars that go across, the sort of greenish colored bars are the spending levels, the red bars are the revenue. You can see here that we're tracking right at plan for our spending. So, we expect there to be very little difference between our budget and our actual

spending, and patents coming in at about $3.46 billion. Revenues will exceed our spending, so that's a good news story, meaning that in the aggregate for the year, we'll have a deposit into the operating reserve that of course we can use to finance future operations. So, let's take a look at the operating reserve. Next slide.

These are our operating reserve balances. The area that you see here is a 25-day moving average. The again -- the X axis is in time; the Y axis is in millions of dollars. We try to maintain a minimum patents operating reserve balance of $325 million, which roughly equates to about one month of operations. Our optimal patents operating reserve balance is just under $900 million -- 888 million. And that equates to about three months of operations. As you can see here, we're well above the minimum. The 25-day moving average as of August 31st, showed a patent operating reserve of $736 million. So, very near the all-time high. And it certainly puts us in a strong position to start FY 2023,

which begins on October 1st, so just a few days from now. And we should be able to navigate any economic uncertainty as a result of the upcoming. Next slide, please.

Finally, even though we are fee funded, we do require an appropriation from Congress in order to essentially have the authorization that we need to spend those fees. An appropriation for fiscal year 2023 for the federal government has not been enacted yet. There's a consequence of that -- it's highly likely and I'm sure you've seen this in the news reports -- that a continuing resolution will probably be enacted. That'll likely run through mid-December. And the only operational consequence of that is it does artificially cap the USPTO's access to the fees that we collect. We can only spend the fees that we collect starting October 1st at a rate consistent with the prior year appropriation. Not to worry. We have full access to the nearly $800 million in operating reserve balances I described on the prior slide. And if necessary, we can use

those funds to maintain operations until all of our fees are made available.

Both the House and the Senate have marked up the USPTO's appropriation request. And good news, they have recommended a level of $4.253 billion for the agency that is consistent with the fee estimate that we put forward. So, if that level is enacted, we should have full access to all the fees that we collect in FY 2023. Jeff, that concludes my brief remarks on the agency finances.

MR. SEARS: Thanks very much, Jay. It sounds like it is a -- or it has been a fairly uneventful year on the finance side. Would you say that as well?

MR. HOFFMAN: Those are our favorite kind. Yes, I would say that as well.

MR. SEARS: Excellent. Excellent. Very good. So, Steve, I'll turn it back to you for questions.

CHAIRMAN CALTRIDER: Any questions for Jeff or Jay? Jay, I'll lead us off with one. And

that is -- I think all of us were wondering or anticipating what the impact of COVID would be on patent filings. And I think we've discussed last month that the trademark side, you see a little more immediate impact. But on the patent side, it tends to be a little bit of a lagging impact. Do we think that a dip is yet to come on the number of filings? Or do you think we've traversed that with the relatively modest impact?

MR. HOFFMAN: You know, Andy and Rick are on. I can let them speak to application demand. But I'll just say from a revenue perspective, none of the projections I'm looking at show any sort of an additional lag reduction in patent revenues. But you're asking it from an applications perspective. So, I might let Andy or Rick speak directly to that.

MR. FAILE: Yeah, sure. So, we're right at plan. I believe we're about -- projecting about a 2 percent growth this year. I don't have the numbers in front of me, Steve, but we're right at that. We saw a little -- at the beginning of

the pandemic -- we saw a little dip. We were roughly flat -- actually just a touch under growth -- and then we've steadily come back up. So, we have not seen the volatility that for instance, a trademark side is seen. We've been a little bit flat now. We're coming back up somewhere around that 2 percent mark this year.

CHAIRMAN CALTRIDER: Thank you. Other questions?

MS. HARRISON: Hi Jay, it's Suzanne. I wondered if you could share with everyone how the USPTO is preparing for potential inflation. We've had a number of conversations about that. I thought that might actually be useful for you to share that.

MR. HOFFMAN: Yes. So, inflation has certainly been a big part of our budget formulation this past cycle. We are anticipating a fairly sizable pay increase for the workforce -- not just the USPTO, but for the entire federal government. I think the pay raises is 4.6 percent for this coming year. We've also seen larger than

expected inflationary increases in a lot of our non-personnel costs. Things like information technology, other contract work that we do -- those costs have gone up. And not surprisingly. They're expected to continue to go up. So, your question has been sort of well, how have you been planning around that? How have you been dealing with that? So, we've been -- we've done a couple of things that I can speak to here, that will be apparent in our upcoming budget submission. You know, one is we're really evaluating our need for physical space. You can see from this forum here, a lot of us are calling in from locations other than the USPTO main offices. And we've already announced plans to release two of the main campus buildings, and that'll result in some pretty significant savings. Prior to the release of those two buildings, we've released two satellite facilities in the Northern Virginia area. Another thing that we've done is we've set some cost containment targets on our Information Technology spend. Even though we spend a lot of money on

information technology, we're trying to make that investment as efficient as possible. And inflation has made that difficult, but that has not -- we've not given up. So, what we've done is we've set inflation adjusted cost containment targets in IT. And then the last thing is at some point, there's only so much belt tightening one can do at 5 percent pay raise levels if those happen year after year. Obviously, we have to have a fee structure that recovers our aggregate costs. As things stand today, our fee structure does recover our aggregate costs. However, in the next few years, if inflation drives it to a point where we in fact have to consider a fee increase, you know, that is something that we'll have to take a look at.

MS. HARRISON: Thanks, Jay.

CHAIRMAN CALTRIDER: Good question, good discussion. Any other question? Let's move on. Jeremiah.

MR. CHAN: Thanks, Steve. So, we thought we provide an update on what's been

happening on the legislative and policy side. And with that, I'll turn that over to some of our PTO colleagues.

MR. HANNNON: I believe I'm the investigator first, so I will take the floor. Again, Chris Hannon, in the Office of Policy and International Affairs, and today I'll just walk us through some updates in the SEP realm. So, if I can have the slide change, please. So, the first item that I think is of note here is that back in the general assemblies in WIPO, Kathi actually joined USPTO with WIPO on a memorandum of understanding that will cover some engagement between the agency and WIPO, as it pertains to sort of socializing U.S. Stakeholders with the availability of a service that WIPO offers through its arbitration and mediation center. So, this is particularly important for smaller enterprises that may not have the resources to engage in local litigation and may seek out mediation as maybe a preferred first step when there is a dispute that arises in set context.

And so, our first event is actually going to be coming up this October 6th. I hope some that follow this space would have seen our reactions in the events here on the uspto.gov page. And we have some information there about this event. But basically, the topics will include use of ADR for SEP disputes and how the WIPO Arbitration and Mediation Center actually has some experience in the space.

They've actually received a number of requests from firms in both Europe and Asia in terms of how to utilize their services. And so, I think it's going to be a good event to sort of socialize the availability of their services to date to a wider U.S. North American audience. And so, you can register for that event. It's a webinar that will take place this October 6th. And you can join that virtually.

And then, the other event that you see here is actually sort of in the very first stages. We have to get word out here. So, keep your eyes tuned to the Directors' blog after today.

Something possibly as soon as this week on this particular event. But the idea here is really to continue to engage with the stakeholders, or the SEP policy context and have an in person meeting soon coming -- pending some outstanding hurdles that we're working through here to sort of get that event stood up.

But a couple of things that I also mentioned here that aren't actually referenced on the slide, because you know, this is all developing very quickly. But it's coming October the 11th, we're actually going to organize through our regional offices in Detroit, an automotive listening session. So, we'll have a number of stakeholders come and be able to have an opportunity to sort of relay any issues or concerns that they may have to directly resolve so that we can actually have some feedback in that particular space. Because as the technology evolves, and standards become more important to the automotive industry -- and I mean, that in the sense of sort of merging the cellular industry

with the automotive industry -- I think it's important to sort of hear the unique challenges that that presents, and so we will have an opportunity like this coming October 11th in Detroit.

And last but not least, there will also be a global (inaudible) SEP symposium. Where Director Vidal will provide some remarks out on the 21st out in California. So, stay tuned for those events. But I will keep my remarks to that and pass the baton on. Thank you.

CHAIRMAN CALTRIDER: Thank you, Christian. Appreciate it. I think next, we have an update on an RFC that recently went out on reliable and robust patents. I'll hand it over to Raul (phonetic) and Linda Horner.

MR. BAHR: Actually, Mr. Chairman, this is Bob Bahr. I'm going to take the talking stick. Would you -- could you please advance the slide? Thanks. I'm going to mention too -- I noticed that we published -- or I noticed that we're about to publish -- the first is a request for comments

concerning subject matter eligibility guidance.

So, over the summer, there was a blog post that requested comments on the PTO subject matter eligibility guidance, which is now in MPE PE (phonetic) 2106. And then later, due to a lot of requests that we extend to comment period, we published the Federal Register notice -- we published it on September 1st -- but this federal register notice extended the due date for comments to October 15th of 2022. And also, this notice requested that, please send your comments, if you have them, on subject matter eligibility guidance to the federal e- rulemaking portal. It's mentioned in the Federal Register Notice. So, please use that portal when submitting comments on subject matter eligibility guidance.

Next is a Cancer Immunotherapy Pilot Program. This has an asterisk by it that says that notice has not yet published, but it's actually going to publish tomorrow. And it's currently available in the reading room -- so, the Federal Register Reading Room. So, in essence,

this notice extends that pilot program under the same parameters until January 31st of 2023.

And also indicates that between now and this time period, we're going to evaluate the program to see if we should expand the scope of the program during this period. So, that's with the RFCs and other notices, and I will pass it to Jackie Bonilla and asked that the slide be advanced.

JUDGE BONILLA: Hi everybody. There's just a few immediate updates coming from PTAB. The first one is, as you may know, we have a request for comment outstanding. It's directed to the Director Review Process, the Presidential Opinion Panel -- what we call the POP review process, and also an internal circulation review of PTAB decisions. So, we have the description of all three processes and a request for comment with some questions out and that now closes October 19th. We did a month extension on comments for that.

The other two are extension of pilot

programs. The Federal Register Notice hasn't gone out yet, but it's going out soon. The first one relates to the PTAB Motion to Men pilot. Just a reminder, this is if patentors want to file a motion to amend in an AIA trial, they have two new options relating to receiving preliminary guidance from the board. Or if they wish, calling for revised motion to amend after they receive an opposition from the petitioner or the preliminary guidance from the panel. So, we have an extension of that pilot.

We have an extension of another pilot which is our Fast Track appeals pilot. This is a pilot that allows applicants who have ex parte appeals at the board to pay a small fee and their appeals can go out of term. Right now, they are decided within six months but on average so far, they have been decided within two to three months after being docketed to PTAB. So, both of those pilots are being extended while we consider rulemaking in both of those areas. And with that, I will pass the baton to the next person.

MR. CHAN: Questions for the next segment?

CHAIRMAN CALTRIDER: Yes, yes. Jeremiah, I wasn't sure if you're taking questions at the end or agreeing to take him as we go. It's more of a comment than a question. But I think the motion to amend pilots -- I think perhaps in a future feedback meeting, it would be good just to have a review and a readout on how the pilots gone. You know, how many people are using the pilot program versus the other method -- the non-pilot process? And just what's the experience been on the pilot. So, it'd be great to get a readout at a future meeting.

MS. BONILLA: Absolutely. And we have a Motion to Amend pilot study that we've done over the years, and we have an update that's getting ready to come out. We're also planning on issuing a request for comments in the Motion to Amend pilot area to see what people think and if there are ways to improve it and things like that. But we can definitely do a presentation to PPAC on

what we have so far. Whenever you like.

CHAIRMAN CALTRIDER: Great, thank you.

MR. CHAN: Great, thanks. Great question, Steve. Any other questions? If not, I think we can probably move on with a couple minutes to spare.

CHAIRMAN CALTRIDER: Fantastic. You put us back on schedule. Linda, I think it comes over to you now.

MS. HORNER: It does. Thank you. So, I introduced myself earlier. I'm Linda Horner. If we can just go to the next slide. So, I'm here to talk about the USPTO FDA collaboration efforts. And just by way of background, just to remind everyone what sort of kicked off this effort. On July 9th of last year, President Biden issued an Executive Order (EO) on promoting competition in the American economy. This EO set forth President Biden's goals of promoting access to prescription medicines for American families and increasing competition in the marketplace. The EO required the Secretary of Health and Human Services through

the Commissioner of the Food and Drug Administration to write a letter to the USPTO Director, describing any concerns with misuse of the patent system to ensure that the patent system well incentivizing innovation does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law. Next slide.

So, in response to the EO, the FDA sent a letter to the USPTO. The FDA's letter recognized that patents are critical to fostering innovation. FDA noted that in light of attention being placed on certain patenting practices, FDA was actively evaluating the impact of pharmaceutical patents on access to drug products approved under their abbreviated pathways. The FDA invited collaborative engagement with USPTO to advance competition and access to medicines in its letter. Next slide.

So, on July 6th of this year, Director Vidal sent a responsive letter to the FDA. It discussed specific initiatives that the USPTO is

exploring to further promote robust and reliable patent rights across all technology areas. These initiatives include enhancing collaboration with the FDA, improving internal USPTO procedures for obtaining a patent to ensure robust and reliable patents are granted, improving the process for challenging issued patents before the PTAB, improving public participation in the patent system, and then considering any other new proposals to incentivize and protect innovation while minimizing unnecessary delays in bringing affordable medicines to market. Next slide.

So, one thing we've done is we began to act on many of the initiatives outlined in the July 6th letter. We've created a webpage to house all the updates on our current efforts. This can be easily found and navigated to from the uspto.gov landing page. So, if you go to the main uspto.gov page, there's an initiatives drop down menu near the top of the screen. You just click on that and select USPTO FDA collaboration initiatives, and it will take you to this page

shown here. This landing page includes background information about the collaboration initiatives -- many of the initiatives I just discussed. It will have copies of the letters I mentioned there. It will also contain links to notices, blogs, news, and reports related to our efforts on this initiative. And it will also have information about upcoming and past USPTO engagements with FDA and with the public.

And if you go to the next slide, if you were to click on the news and reports link, you'd pull up the page shown here. This is a subpage where you can find public Federal Register Notices, agency blog posts, and other news. You can see here, a link to our recent Federal Register Notice and duties of disclosure and reasonable inquiry, links to two blog posts by Director Vidal, and a link to a new public web page that contains information about patent term extension applications which are available for pharmaceutical patents.

So, if we were to click on the bottom

link, you'd be redirected to a page that provides Excel files that contain information on PTE applications filed during the last five years, and also information on all patent terms extended under the statute.

Previously, the USPTO posted only patent term extension grants. We've updated this list of PTE grants on the new webpage, and it's now current and will be updated monthly. But more importantly for members of the public who want to track patent term extension applications that are filed, the Excel file on this linked webpage includes the application and patent number information, the PTE application filing date, the trade name of the product for which the patent term extension is sought, and a link to the file -- the actual application file in the patent center -- where the actual PTE application can be retrieved and reviewed. So, we've enhanced some accessibility there to some information relevant to drug patents. Next slide, please.

In terms of engagement with the FDA,

we're happy to report that the PTO recently hosted the FDA for a half day inter agency cross training event. The PTO presented. We covered topics including patent examination and searching -- specifically discussing what qualifies as prior art and which databases Examiners in technology center 1600 use for their searching and what information they use to do their searches.

The training also covered PTAB proceedings, specifically focusing on proceedings where petitions relied on FDA documents as prior art. And the goal is that the FDA will use this information to develop content for their follow up training. They're going to present some training to the USPTO on FDA's publicly available resources. Next slide.

And this is my last slide. So, critical to our efforts is also engagement with the public on all of these initiatives. As Director Vidal mentioned in her comments, the USPTO is working on requests for comments to solicit public input on initiatives that were outlined in the July 6th

letter. We're also planning a joint USPTO FDA public listening session where members from both agencies will be present to hear input from the public on how the agencies can collaborate. We're still working out all the details and timing on that. So, check back on the collaboration webpage for more updates and information as it becomes available. In the meantime, we've created an email box, the USPTO-FDAcollaboration@uspto.gov. And the public can use that to direct to us any general inquiries or input they have. I think the next slide is the end slide. So, I'm happy to answer any questions.

CHAIRMAN CALTRIDER: Thank you. Thank you. Questions?

MR. DUAN: Steve, do you mind if I ask a question?

CHAIRMAN CALTRIDER: Sure.

MR. DUAN: So, first of all, thanks for this presentation. This is super helpful and like, really exciting. I just had a quick question on the timing. So, you mentioned that

there was going to be a follow up FDA training for USPTO on EOs and the prior art resources. And then there would also be this public listening session. I'm wondering, kind of, what the timing is of those two relative to each other and particularly, it would seem useful if the FDA training went before the public listening session. That would provide an opportunity during the listening session for people to talk about, kind of, what prior art resources had been identified and were available. I think that would be a useful topic of discussion. But have you given thought to that, sort of, to the timing of those?

MS. HORNER: Yeah. Thank you for the question. That's a great question. And something to think about. Right now, we're targeting the public -- joint public listening session for late fall, early winter, so kind of mid-November, although that date could change. But that's our target right now. It's really up to the FDA in terms of when they're going to be providing us with their training. We just had the training

that we -- that PTO provided to FDA. And so, they're now, kind of, digesting all of that and coming up with their content to provide to us. And so, I'm not sure if we know for certain when they're going to be presenting that to us. It sort of depends on their schedule, and when they can put their materials together. But certainly, we welcome input from the public on any publicly available FDA resources that members of the public think would be useful for Examiners to be using. And help inform further training by FDA on those resources. And I can provide updates on timing, as we hear more from FDA on that.

MR. DUAN: I appreciate it.

MR. BROWN: I have a comment if we have time.

CHAIRMAN CALTRIDER: Yeah. Go ahead, Dan.

MR. BROWN: Thanks, Linda. That was a very, very good explanation. I just have a comment from an independent inventor perspective. I know this is a big Pharma thing. And, you know,

the administration, and the office are looking at dealing with that -- keep in mind empathy for the small inventor, that we don't have any unintended consequences that may flow out of this. Even things that may seem appropriate, not difficult for patent holder in big Pharma to do, they put a lot of burden on a small inventor, even from, you know, practicing and trying to enforce their rights. And so, these changes, you know, focus based on, you know, obviously, the need, but any kind of consequences, like we suffered in the past on some things is really tough. So, I'm sure inventors need to look at this and comment appropriately. But this is my comment.

MS. HORNER: Dan, thank you for the comment. Yeah, I welcome input from the independent inventor groups to RFCs that will be coming out soon. I think we're exploring a lot of different topics here. And certainly, we want to hear from all viewpoints. And we'll be trying to spread the word and publicize the RFC and the public listening session as widely as we can, but

to the extent that you and others can help get the word out to those inventor groups as well. That would be really helpful so that we can make sure that their perspective is taken into account as well and that their comments are solicited.

MR. BROWN: Thank you. I will do that, Judge.

CHAIRMAN CALTRIDER: I have a question that goes to the September 16th training, but it probably carries through to the upcoming training that you anticipate as well. What's the attendance been like at those sessions? And, you know, what are you doing to kind of keep it to stick? Because it's good to have an hour or two hour -- I'm not sure how long they are - session, but undoubtedly, you have some people that are unable to attend for whatever reason, and how do you, kind of, get more ingrained into practice?

MS. HORNER: Yeah, that's a great question. So, we were really pleased with the turnout for this first event. We did hold it as a hybrid event. We had about 20 people on campus.

But we had 80 total FDA participants for that training session, both virtual and in person. It was a great turnout. We were very pleased with that number. And they came from organizations within FDA from across the whole agency. So, it was really helpful to have all the different perspectives from within their agency. And we had some pretty robust discussions about things as we posed questions to them about, yeah, what kind of resources do you have? And we just started talking through a lot of the issues of how things qualify as prior art and when they become publicly available documents. It was a really helpful first discussion, and the event was about three hours. And so, it was a large enough block of time to really feel like we had time to dive into the topics, but not a full day. So, we did get a pretty -- I think, because we held it virtually as a hybrid, and we limited the duration to something, kind of, manageable, I think that helped with the attendance. And I imagine that FDA will probably follow a similar model when they

provide us with their training.

CHAIRMAN CALTRIDER: Are their respective IT staffs from FDA and USPTO part of that? Because it strikes me that there's a tremendous wealth of information at the FDA that is publicly available, and should be accessed as prior art, but the navigating and finding it is a little bit of a needle in the haystack. Particularly if it's not part of our database and search. So, how do -- are the two IT groups also talking about how to perhaps collaborate in that space as well?

MS. HORNER: Well, we had representatives from our STIC (phonetic) service, so our science, technology -- I'm going to get it wrong -- but the service that helps Examiners with research and finding information for searching. We had representatives from our STIC (phonetic) service there as part of that discussion. And the FDA did talk about coordinating with their tech folks -- their IT folks -- to think through some of these issues and maybe adopt some best

practices going forward to make it clear when documents become publicly available. So, we're certainly proceeding with all those discussions.

CHAIRMAN CALTRIDER: Well, I appreciate this is only the first of many, many meetings to come. So, not trying to get ahead of you too much.

MS. HORNER: But that's a great suggestion to make sure that to the extent there are IT solutions to some of this. That we can make sure we're looking at those as well.

CHAIRMAN CALTRIDER: Other questions? Well, I was looking at our agenda, and I have to admit that I was quite nervous that we would be struggling to stay on time. And we started off a little bit behind schedule, but we've made the ground up. If there are no further questions, I will just ask if there's any new business anyone wants to raise? If not, we could yield back by my clock, about six minutes.

MS. DURKIN: I have one quick question since we have time that I want to ask that's been

on my mind.

CHAIRMAN CALTRIDER: Yes, go ahead, Tracy.

MS. DURKIN: And since we have some folks here who probably can answer the question. I know there's a big push to get DOCX used by more and more applicants. And as a practitioner, we're working hard at that. One of the things that I've been a little frustrated by is the fact that we can't file design patent applications with DOCX. And while there's not a big spec in a design patent application, it would be nice to, you know, just sort of test the waters with some simple filings like that. And so, I wondered if there are any plans to move design patent applications into DOCX.

MR. SEIDEL: So, I can take that. Obviously, that's a great suggestion. We're not quite there yet. We're still addressing our launch of January 1st, trying to get feedback on just the cases where the surcharge will apply. Primarily the 111 cases. On that patch, we don't

have 371. We don't have PCT, and we don't have design, but they're all on the radar in the future. So great suggestion. We'll get there as soon as we can. But we're not quite there yet.

MS. DURKIN: Thank you.

CHAIRMAN CALTRIDER: Any other questions, comments, or new business we need to tend to?

MS. VIDAL: Tracy, this is Kathi. I just want to thank you for raising that. Because obviously once we get people moved over to DOCX that will allow us much more flexibility and give us much more capabilities to do a lot of work before the application gets to examination. So, that should speed things up, improve processes, etc. So, thanks for raising that.

CHAIRMAN CALTRIDER: DOCX is a really important part of the quality improvement initiatives that are in the works at the office. It's somewhat foundational. And certainly, you have the PPAC support to make this transition and we encourage those in the public that haven't

tried DOCX to attend the training, to use the USPTO resources, and make that shift because it really is important to improve the quality of examination and the application going into this system. Very, very important. Any other questions or comments? Again, our next meeting is in November. It's a live meeting. I look forward to seeing everybody and participating. The agenda will be coming in its usual time -- sometime in late October. Thank you, and I appreciate everybody's time today.

(Whereupon, at 2:56 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