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OVERSIGHT OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

HEARING

BEFORE THE

SUBCOMMITTEE ON INTELLECTUAL PROPERTY

OF THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

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OVERSIGHT OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

WEDNESDAY, JULY 26, 2023

UNITED STATES SENATE,
SUBCOMMITTEE ON INTELLECTUAL PROPERTY,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:30 p.m., in Room 226, Dirksen Senate Office Building, Hon. Christopher A. Coons, Chair of the Subcommittee, presiding.

Present: Senators Coons [presiding], Hirono, Padilla, Welch, and Tillis.

OPENING STATEMENT OF HON. CHRISTOPHER A. COONS, A U.S. SENATOR FROM THE STATE OF DELAWARE

Chair COONS. This hearing will come to order. We are here today to conduct oversight of the U.S. Patent and Trademark Office. I want to thank Director Kathi Vidal for participating today.

I also want to thank Ranking Member Thom Tillis and his staff for putting this hearing together on a consensus basis. This is our second hearing in 2 weeks, our third in 2 months. And Senator Tillis, you and your team continue to be great partners. There are, in fact, more to come.

Director Kathi Vidal leads one of the largest intellectual property offices in the world, with more than 13,000 public servants, an annual budget of roughly $4 billion. Last year, the USPTO received about 460,000 new patent applications, a 1.5 percent increase over the number filed in 2021.

The agency expects about 730,000 unexamined patent applications by the end of the year, an increase of roughly 40,000. Trademark application filings increased to over 940,000 in 2021 before dropping a little bit back to more normal levels around 800,000. The surge in 2021 caused an increase in application pendency, for which the agency has hired 92 trademark examiners to address.

The USPTO has set an adjusted patent and trademark phase six times under its important fee setting authority that the American Invents Act established in 2011. The agency is currently engaged in another round of adjustments to help it fulfill its mission of fostering innovation, competitiveness, and economic growth.

U.S. global leadership and competitiveness depend on our ability to foster and protect innovation and creativity at home and abroad. Ensuring the predictability and the reliability of our patent system incentivizes innovation, rewards ingenuity, and improves our global competitiveness.

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Over the last decade, however, changes to our patent laws have chipped away at that system, threatening long-term investments in research and diminishing our stature on the global stage. To take one example, consider the introduction of the Patent Trial and Appeal Board, or PTAB.

Created by Congress in 2011, the PTAB, under proceedings that are known as AIA reviews that determine patent validity, have made it far easier to challenge an issued patent at the USPTO than in district courts.

AIA reviews were intended to be a faster, cheaper alternative to district court patent litigation. But that is not exactly how it has worked out. Eighty-five percent of PTAB reviews are also the subject of parallel patent litigation in Federal court. This means patent owners have to defend their rights on two fronts at the same time.

Rather than making litigation more streamlined, the PTAB system in its current form has just made it duplicative. These AIA reviews in the PTAB aren't being filed by small or innovative companies. Typically, large and well-established companies have filed thousands of AIA reviews against patents they have been accused of infringing, hoping to strip those patents away from their holders.

Director Vidal, I support your recent efforts to use administrative rulemaking to address issues like these, to minimize inefficiencies, to provide additional protections to under-resourced inventors.

I hope that you turn around the proposed rule quickly. In my view, however, Congress also needs to step up to the plate and act. That is why I have introduced, along with Senator Tillis, and Senators Durbin and Hirono, the PREVAIL Act, a bill that would make some commonsense reforms at the PTAB to protect inventors from costly, unnecessary, and duplicative proceedings.

These commonsense reforms include establishing a standing requirement to file an AIA review, limiting the number of challenges that can be brought against the same patent, and barring challengers from pursuing parallel challenges at the PTAB and in Federal District Court. I also remain concerned about the scope of subject matter that is eligible to be patented.

Many witnesses appeared before this Subcommittee over the last few months and have highlighted the uncertainty in our patent eligibility laws. Why does this matter?

Critical technologies like medical diagnostics, software, and core AI are not eligible for patent protection here in the United States under our current law but do qualify for protection in Europe and China.

So, I was happy to join Senator Tillis in introducing the Patent Eligibility Restoration Act last month. That bill will turn eligibility—will return eligibility to important inventions, while resolving legitimate concerns over the patenting of ideas, discoveries of what already exists in nature, and social or cultural content that everyone agrees is beyond the scope of patent protection.

I look forward to working with my colleague Thom Tillis and others, and with stakeholders to move PREVAIL and PERA through Congress to restore predictability and reliability to the patent grant. We also, last topic, need to be concerned about counterfeit goods from abroad.

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In 2021, more than 80 percent of counterfeit goods entering the United States originated in China. Although we seized more than $3 billion of counterfeit goods at the border, that number amounts to only a fraction of the total value of counterfeits. These counterfeits can be unsafe and harm consumers.

They are more than just fake sports gear or fake watches. As Co-Chair of the Congressional Trademark Caucus, along with Senator Grassley, I know how dangerous counterfeit goods can be.

To give just one example, fake lithium batteries that have exploded or caught fire caused 70 deaths and more than 350,000 serious injuries just last year.

I applaud the PTO's efforts under Director Vidal's leadership to teach younger Americans about the differences between real and fake products and the potential harms of purchasing counterfeit goods—the importance of buying real with the so-called "Go for Real" trademark campaign.

The USPTO can't solve this problem alone, however, so I am planning to soon reintroduce, along with Senator Tillis, the SHOP SAFE Act to protect consumers from harmful counterfeit goods sold online.

I look forward to hearing from you, Director Vidal, to exploring your efforts to address these issues at the PTO and discussing the work we intend to do here in Congress to promote America's innovation economy. I will introduce you in a moment, but first, I want to turn it over to my Ranking Member and friend, Senator Thom Tillis.

OPENING STATEMENT OF HON. THOM TILLIS, A U.S. SENATOR FROM THE STATE OF NORTH CAROLINA

Senator TILLIS. Thank you, Mr. Chairman. It has been about 4 years, a little over, since we had a USPTO oversight hearing, so I welcome the opportunity to engage the USPTO. But I also have to say that you have already demonstrated a willingness to engage, hearings and oversight are important, but I want to directly thank you for your leadership in the USPTO, and your dedication to work in this agency and work with our offices.

We get consistently good reports from our staff. And we also appreciate, it is not lost on me that detailees from the USPTO are also a very important part of us getting to, I think, a good outcome in this Congress. We are back to the same thing, strong, reliable, predictable IP rights are paramount to incenting U.S. innovation.

This innovation, which fuels economic growth for our great country, and innovation is critical to our national security. We want to encourage future inventors, big and small, to come forward and embrace our patent system.

We also want to encourage interest in serving our patent system by encouraging the next generation of patent examiners and trademark examining attorneys.

We want to take a moment to thank them for all of their hard work. They are in the trenches, and they have got a lot stacked against them. But I think our faith in the patent system has to exist at all stages of the patent lifecycle, from examination to potential litigation.

That is why I introduced, along with Chairman Coons, the Patent Eligibility Restoration Act. I have a handout here suitable for framing. I will let you be the first recipient. So that we can start communicating this.

We pursued multiple avenues to encourage patent reform, but it is crystal clear that a legislative solution is necessary to provide an appropriate patent eligibility framework to ensure the future of American innovation and American leadership in the world is secure. U.S. patent eligibility law has become confused, constricted, and unclear, and has led to inconsistent case decisions, uncertainty in innovation and investments, and unpredictable business outcomes.

This bill, I believe, restores patent eligibility to important inventions across many fields, such as medical diagnostics, biotechnology, personalized medicine, artificial intelligence, 5G, and blockchain, to name a few. This will ensure that the U.S. remains the world's innovation leader in the years to come.

To help support U.S. innovation, I also joined Chairman Coons on the PREVAIL Act—we will get you one suitable for framing, too—which is also good, sound policy worked out on a bipartisan basis.

When properly constructed and administered, the PTAB can play a vital role in maintaining strong, reliable, and predictable IP rights. However, the PTAB has been subject to practices that have been abusive and open to gamesmanship. While a number of policies have been put into place to crack down on abuses of the PTAB, practices can be changed with each new USPTO director.

That is why I think legislation is necessary to codify some of these reforms to provide long-term stability and certainty at the PTAB, and to permanently end some of the abuses that we have seen in the past. So, Director Vidal, thank you for being here, and I look forward to your testimony and our continued partnership as we move forward. Thank you.

Chair COONS. Thank you, Ranking Member Tillis. I would like to turn to our witness. I will offer a brief introduction, if I might.

Today, we welcome the Honorable Katherine, Kathi, Vidal, Undersecretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. In addition to leading the PTO, Director Vidal serves as the Principal Advisor to the Secretary of Commerce on both domestic and international IP policy matters.

Prior to joining PTO, Director Vidal served as managing partner of Winston & Strawn's Silicon Valley office, where she represented clients ranging from large and well-established companies to small startups in patent litigation. Earlier in her career, she led Fish & Richardson's litigation group of 270 attorneys and 11 offices worldwide.

Previously, Director Vidal was an engineer for both Lockheed Martin and General Electric, working on aircraft and engine control systems before going on to pursue a career in IP law.

Director, after I swear you in, you are going to have 5 minutes for an opening statement, then we will proceed to questioning. Each Senator gets 5 minutes. We will likely do a second and even a third round just depending on attendance and timing.

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Director Vidal, could you please stand to be sworn in? Please raise your right hand after me: Do you swear or affirm that the testimony you are about to give to this Committee will be the truth, the whole truth, and nothing but the truth, so help you God?

Director VIDAL. I do.

Chair COONS. Thank you, Director Vidal. You may proceed with your opening statement.

STATEMENT OF HON. KATHERINE VIDAL, UNDERSECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, ALEXANDRIA, VIRGINIA

Director VIDAL. Thank you. Chairman Coons, Ranking Member Tillis, and Members of the Subcommittee, thank you for this opportunity to discuss the great work the United States Patent and Trademark Office, USPTO, is doing.

I must start by thanking you for your unwavering commitment and focus on our IP ecosystem. I am confident that together we can shape IP policy and practices to be an even greater catalyst for job creation and opportunity in each of your States and across our great Nation.

In addition to the transparent, data-driven, and surgical changes we have made and intend to make this Administration to better support our stakeholders and the issues they face, there are a few key areas of focus I would like to highlight.

First, the USPTO, like you, is focused on AI, including as related to patent protection and the copyrighted works that drive so much of our economy. I am working with the White House, the rest of Commerce, the Copyright Office, and across Government on AI policy and see it as one of our greatest challenges and opportunities.

Second, as you well know and have said, we need robust, reliable, and transparent IP rights, and efficient and effective enforcement, not just here but across the globe. The USPTO is working globally to strengthen the innovation, creativity, and entrepreneurship ecosystem, to hold competitors to their agreements, to curb abuses and unfair practices, and to directly assist stakeholders facing IP issues abroad.

At home, we are ensuring that the patents we issue continue to incentivize innovation, and the trademark register is accurate so that businesses can assess and rely on those protections of our trademark laws.

Third, we are working across Government on the intersection of IP and competition policy, including, as related to standards, to promote a strong IP ecosystem while maintaining the U.S. as an entrepreneurial Nation that promotes startups, small businesses, and small enterprises.

We are collaborating with the Food and Drug Administration and the United States Department of Agriculture to take into consideration the needs of small family farmers and the concerns of patient advocacy groups.

Fourth, the USPTO is committed to an all-of-Government approach to leveraging IP rights to catalyze U.S. economic competitiveness and national security. We are doing that inclusively, and forming the partnerships, relationships, and alliances that will

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help us reach every corner of our country, including our schools, our military, military spouses and veterans, as well as opening new outreach offices under the Unleashing American Innovators Act passed by Congress last year.

Mr. Chairman, I am honored and proud to be a part of the USPTO, an incredible agency with dedicated and knowledgeable public servants. As a steward of the agency, I must add, as a fifth and last point, that we are also working on reshaping the USPTO as a workplace centered around the values of purpose, opportunity, equity, inclusion, and wellness.

To better serve the American public and stakeholder community, we are innovating America's innovation agency. We cannot do all we are doing without your collaboration. The USPTO is grateful that Congress continues to provide it with fee setting authority, which enables the USPTO to continue to build, retain, and effectively manage its workforce. We look forward to working with this Committee to ensure USPTO maintains that authority.

In closing, we look forward to continuing to work with you and alongside you to use our intellectual property system to grow jobs in every community and to foster economic prosperity and innovations that will benefit all across our great country. Thank you, again, for the opportunity to testify today, and I look forward to your questions.

[The prepared statement of Director Vidal appears as a submission for the record.]

Chair COONS. Thank you, Director. I appreciate your update on the USPTO, its operations, and processes. I am going to start by exploring the importance of a reliable and effective patent system, as well as PTAB reform. And then, in a second or third round, we will talk about patent eligibility as well as counterfeit goods and other issues.

In January, the ITIF issued a report entitled, "Wake Up, America," that found China is likely to overtake the U.S. in innovation and advanced industry output.

What patent system reforms do you think should be part of a meaningful and effective strategy to ensure we maintain our competitive edge in global technology leadership?

Director VIDAL. There—so, first of all, thank you for that critically important issue. That is one of our main areas of focus. I will say there is a lot of work that the USPTO is doing right now in view of stakeholders' concerns in regard to China. Part of it relates to counterfeiting, which I know we will take up later.

Part of it relates to ensuring that U.S. companies have fair treatment in China, or, at least at a minimum, get the assistance from our IP attachés in our China group as they navigate China when it comes to intellectual property.

In addition to that, we at the USPTO have been engaged interagency with the rest of Government to deal with Chinese threats. We have also been engaged with the IP office and with government in China to hold them to the commitments that they have already made to the United States.

And regularly, we are involved with engaging them on new reforms that they may be proposing within China to make sure that our stakeholders' views are considered alongside that.

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Chair COONS. Let me mention one of the efforts that I have undertaken with Senators Tillis, and Hirono, and Durbin, the PREVAIL Act. It is a bill that includes measures to align the PTAB and its practices with Congressional intent, to have an alternative to litigation to decide validity of a patent.

Your ANPRM, your advanced notice of proposed rulemaking, includes several proposals that overlap with that bill positively. I was pleased to see that. But several of your Director Review decisions and guidance on how the PTAB ought to exercise discretion on institution, on beginning a patent validity review, have narrowed practices that previously helped curb multiple attacks on the same patent.

Some of the ANPRM proposals indicate similar direction toward policy reversals. Is the Office seriously considering rolling back these previous improvements?

Director VIDAL. The intent behind the ANPRM is to, number one, memorialize some of the efforts that are working productively, including on serial and parallel attacks.

We recently did a study on serial and parallel petitions which shows that the guidance that we have offered, the precedential decisions that we have offered is—they are working. And so, part of the ANPRM is to memorialize that. The rest of the ANPRM has proposals that came out of stakeholder feedback so that we can gather additional data in deciding what to move forward with and what, importantly, not to move forward with.

So those are not per se proposals from the USPTO in terms of what we believe are the best avenues for moving forward. It is more an attempt to gather additional data so that we can either move forward with some of the proposals or variations of the proposals.

Chair COONS. Would you just, as a matter of general principle, agree that if you have got a proceeding in the district court and the PTAB at the same time, covering the same topic, addressing a patent validity, that that doesn't really fulfill congressional intent for the PTAB to be an alternative and more efficient form for patent review.

Director VIDAL. We hear that very often from stakeholders, Senator.

Chair COONS. And can you share with me what your views are on that?

Director VIDAL. So, my views are going to be informed by the responses to the ANPRM. I do think that there are concerns with overlapping proceedings in the PTAB and with district court.

In terms of where the USPTO draws that line, whether we continue on with the Fintiv guidance, whether it is a—whether we evolve that in some way to better serve stakeholders and better serve the intent of the AIA, my views on that will be informed by the responses to the ANPRM.

Chair COONS. You got over 14,000 comments to the ANPRM, which speaks to the degree of awareness and engagement, and I think PTO regulations can address some of the concerns that I hear about PTAB.

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Do you have a sense of timeline for when you might issue a notice of proposed rulemaking and then be able to implement a final rule?

Director VIDAL. In terms of the timeline, we are working on the NPRM now. There may be two of them. We haven't decided whether to put everything in one package, or given the breadth of the ANPRM, whether we break it up into two NPRMs—one more procedurally focused and one more substantively focused.

So, we are still in the process of analyzing that and analyzing the comments. We realize that we need to move as fast as possible, while being very deliberate about what we are doing moving forward.

I do plan soon to announce some of the initiatives that we will likely not move forward with so that we can keep everybody's focus on the initiatives that we do plan to move forward with.

Chair COONS. One potential way to address some of the issues in PTAB that is in the PREVAIL Act, is a standing requirement for inter partes review. It is my concern, anyway, that there have been a significant number of companies formed specifically just to attack patents that have already received district court damages awards.

You have taken some steps to address this, which suggests you may share these concerns. How would implement—just broadly speaking, how would implementing a standing requirement help address some of the current abuses of PTAB?

Director VIDAL. So, in terms of a standing requirement, that is something that stakeholders have brought to our attention, that they believe that will help. That what we are seeing in terms of practice before the PTAB is when the parties do have what would be—might qualify as a standing requirement, their activities tend to align with their business purposes.

When parties don't have what might be a standing requirement, we have seen parties take advantage of the system. There have been recent instances of that where the parties are trying to monetize and otherwise use the PTAB process for personal gain as opposed to its original intent.

Chair COONS. Well, thank you for your testimony so far. I look forward to our second round of questioning, and I will defer to the Ranking Member, Senator Tillis.

Senator TILLIS. Thank you, Mr. Chair. I think the patent system works best when there are clear rules of the road to guide inventors and businesses when they are considering obtaining a patent and protecting the fruits of their labor in research and development.

Following a series of Supreme Court cases though, one critical requirement for obtaining a patent, whether a patent is eligible in the first place for patent protection under 101, has become the opposite of a model of clarity, in my opinion.

So, I know you stated during your confirmation hearing that you thought that more clarity around Section 101 would be helpful. Do you still think that is true?

Director VIDAL. I do, Senator Tillis. And you will see that view articulated in the Government brief in the *Tropp* and *Interactive Wearables* case, where we set that forth.

You will also see it in the 2022 report to Congress, where in both of those we articulated that we do need a very predictable, reliable system in order to encourage investment, in order to encourage the fruits of labor that result in innovation, and in order to bring products to market.

We need a system that the public can rely upon when they get an IP right.

Senator TILLIS. Can you cite any examples of work that you are in process of or work that you have done to try and help on this issue already within your authority?

Director VIDAL. So, one example is our engagement at the Supreme Court level with the Department of Justice. We work very closely with them on these issues. We are also trying to identify other mechanisms within the judicial system to bring more clarity when it comes to 101 law.

In addition to that, the guidance, the 2019 guidance and the additions that we have made under my tenure provides at least some certainty within the United States Patent and Trademark Office in terms of whether somebody is able to obtain a patent. We issued a request for comment on that guidance to receive feedback on whether we should modify that guidance.

We have not made a final decision on whether to modify that, but we continue to provide additional training based on cases that we are seeing. But as you may recognize, within our purview, there is only so much that we can do.

Senator TILLIS. What about the—I have a belief that Congress probably needs to do something, too. Do you have any opinion on that? I know you are not telling us how to implement policy, but what sort of enablers or things that we should be thinking about? Anything you may have heard that wouldn't be particularly helpful?

Director VIDAL. So, I want to commend the attention that you have placed on this area of law. To me, it is one of the critical areas that we need more clarity in to really have a more robust economy and to incentivize innovation. As you recognized, if Congress were to step in, you could really impart the clarity that is needed that would take perhaps much longer through other mechanisms.

Senator TILLIS. I know you haven't, and it may be a matter of policy, you haven't taken a position on any of the bills that we are proposing, but not necessarily expecting a response here, but I would be very interested in engaging with the Office, if there are any concerns with it, to get to a point to where you all are comfortable that what we are doing on the legislative front is matching with what you believe is an enabler that will help us get to where I think we both want to be.

I did—I am going to wait and ask a couple of other questions in a second round, Mr. Chairman, but I did want to reemphasize the counterfeit goods.

One of the hearings that just sticks in my mind—I ride mountain bikes, and it is like cars and everything else, everybody has their preferred products. I happen to use Specialized equipment, and I saw a very—relatively small person take about a one foot step in

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the air and absolutely crush a helmet on that floor. That was counterfeit.

I have broken—in my mountain biking, I am better than this may suggest, but I have broken two helmets mountain biking. And if it would have been one of those helmets, I probably wouldn't have made it.

And we need to really do a better job, I think, of America—of educating the American public that whether it is batteries, it is safety equipment, the Chinese are willfully allowing companies to counterfeit products, send them here, sell them at the price—same price point, and potentially creating life-ending consequences as a result.

So, I look forward, as we have future hearings, to shine light on that. I yield back, Mr. Chair.

Chair COONS. Thank you, Senator Tillis. Senator Hirono.

Senator HIRONO. Thank you very much, Mr. Chairman. Ms. Vidal, it is good to see you. A recent World Intellectual Property Organization study found that the U.S. lags behind China and much of the world in our efforts to fully mobilize the inventive talent of our Nation's women.

Recent reports by the National Bureau of Economic Research and Citigroup estimate that closing our racial and gender patent gaps would add $1 trillion—$1 trillion to our annual GDP. This is to say nothing of the growth that could be unleashed by expanding opportunities to underserved geographies and veterans.

Unleashing this potential is why we passed Senator Leahy's Unleashing American Innovators Act last year. Mr. Chairman, I ask unanimous consent to place a letter Senator Leahy sent to me about the importance of that legislation into the record.

Chair COONS. Without objection.

[The information appears as a submission for the record.]

Senator HIRONO. Unleashing our country's full potential is also why last Congress I worked with Senators Tillis, Coons, and other colleagues to introduce the IDEA Act, which directs the PTO to collect demographic information that patent applicants submit on a volunteer basis—voluntary basis, so that we have data to rely upon as we make certain decisions.

So, my staff is now working with you, with your staff, on some technical changes to the bill that I referred to, and I hope to reintroduce it soon. Can you speak about how important it is to unleash our country's full innovative potential, meaning women and minority persons?

Director VIDAL. Thank you for that question. That is a very key focus of mine through the work that I am doing for the Council for Inclusive Innovation, to the work that I am doing across the United States Patent and Trademark Office. I am focused on that for the very reasons that you note, that not only is it a matter of equity, it is a matter of—it is a national imperative that we do this.

It is going to unlock innovation. In terms of demographic information, I agree that collecting it would be extremely helpful to inform our policies, to inform our actions. That is why, in view of the Act that you introduced, I have been working separately at the USPTO to find ways to be able to satisfy the Paperwork Reduction

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Act requirements, while still being able to collect that data. So, we are working in parallel to try and make that happen.

Senator HIRONO. Do you have any specific kinds of programmatic changes or whatever you are pursuing to, for example, focusing on women to submit their patents?

Director VIDAL. I do, Senator. The Secretary of Commerce and I founded the Women's Entrepreneurship Initiative, and through that initiative, we are working to help women across the country learn about the innovation ecosystem, learn the value of intellectual property, and learn the resources that we have available.

That is everything from trainings that we offer, to pro bono help if they are under-resourced, to our pro se offerings, where if people are filing on their own, we provide additional assistance. So, we are trying to provide all of that information. In addition to that, we are trying to figure out where women might opt out of the process.

We have seen studies that suggest that when women receive a rejection letter as part of the patent process, they are more likely to opt out than men. So, we are creating additional language around that.

We are creating cover letters that welcome people, everyone, not just women, to the United States Patent and Trademark Office, that let them know of the available resources, and that encourage them on their way and really put some of these objection letters and final rejections into context so that they will persist in obtaining patent protection.

Senator HIRONO. We were told the story of Sara Blakely, the inventor of Spanx. She talked about how she had her invention, and she went to all these male attorneys to ask them for help and patent it, and they basically laughed in her face. And it was when she went to a female patent attorney that she was able to patent her product or her invention.

So, I think that the idea of expanding and diversifying, it runs across all gamuts, including lawyers, you know, to be able to know a product when they see it. But when it comes to diversifying the ecosystem for patents, we really have to be intentional about it.

And whatever you can do to get across to women in our country, girls in our country, that they can invent things and that they can be part of a huge economic—make a huge economic difference to our country. So, I would like to continue to hear what you are doing and be as supportive as I can be.

Director VIDAL. May I address that briefly?

Senator HIRONO. Yes.

Director VIDAL. So, I do want to let you know that in addition to the efforts that I explained, we are also broadening the bars to practice before the United States Patent and Trademark Office. We believe that will have an impact on diversity as well.

We are broadening the patent bar. We are in the process of setting up a design patent bar so that people who do not have electrical engineering degrees can still practice before us if they are practicing in the area of design patent protection. And we are also looking at broadening the PTAB bar.

Senator HIRONO. Thank you.

Director VIDAL. Thank you.

Chair COONS. Thank you, Senator Hirono. Senator Padilla.

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Senator PADILLA. Thank you, Mr. Chair. On April 21st, the Patent Office published an advance notice of proposed rulemaking that proposed substantial changes to the rules governing administrative review proceedings before the Patent Trial and Appeal Board. To say that this rulemaking is of intense interest to many of my constituents would be a dramatic understatement.

Ms. Vidal, you noted in your testimony there were over 14,000 public comments from stakeholders, which I understand to be an unusually large number. I know you referenced—you responded earlier to questions from the Chairman that spoke to not just a large number, but thoughts on how to address many of the concerns expressed in that public comment, pathways forward, and the timing of proposed rulemaking.

So, I won't be repetitive with those questions, but I do want to also acknowledge our former colleague, Senator Leahy, who recently wrote two op-eds critiquing the rulemaking as exceeding the Patent Office's statutory authority and conflicting with the America Invents Act.

And I will quote from Senator Leahy—he says, "I can say with absolute certainty that the proposed rules directly conflict with the legislation on a variety of matters, especially on provisions that limit access to the PTAB." And he points to the proposed standing requirements for PTAB proceedings and shortened the deadline for filing a petition for review from 1 year to 6 months.

So, just given that and more of the concerns I am sure you have heard, I wanted to afford you an opportunity to respond to those viewpoints.

Director VIDAL. Thank you, Senator. In terms of what was in the ANPRM, they all fall within the USPTO's authority, including those under 35 U.S.C. 2(b), 2(a), 314(a), 316(a)(2), (a)(4), (a)(6), (b), 317(b), 324(a), 326(a)(2), (a)(4), (a)(6), (b), and 325(d). That said, it is not clear that we are moving forward with all of those proposals. As I mentioned earlier, the proposals in the ANPRM serve two purposes.

Some of those proposals really codified our existing practices, which we have received positive feedback on, and which are actually becoming very effective. And they provided the option for stakeholders to suggest changes to those existing practices.

The other proposals in the ANPRM were ones that came from stakeholders. And instead of the USPTO making a decision without data, we decided to float all of those in the ANPRM so that we could receive data from stakeholders and determine what to move forward on.

So, in terms of where we are going from here, we do plan to—I plan to release something soon on what we have decided based on the comments we're not moving forward on, so that people can focus on the areas where we are planning to potentially make a difference, and then we will move forward with the NPRMs on those topics.

Senator PADILLA. Okay. That is helpful. Thank you for that.

Director VIDAL. Thank you.

Senator PADILLA. I also want to ask a follow-up question on something Senator Hirono raised, and that is the value of diversity in inventorship. She spoke to gender and ethnic diversity. Research

has also found that inventors are becoming increasingly geographically concentrated.

A National Science Board found that in 2020, 41.6 percent of U.S. counties had zero patents granted to people residing in that county. And as a representative of California, I know that the general Bay Area and the Central Coast appears to be very well represented in terms of patenting.

The Central Valley of California, and other regions in our State for that matter, are not. So could you speak about the importance of meeting potential inventors where they are, with research showing that inventors are increasingly concentrated, as I mentioned? What steps are being taking to extend participation in inventing and patenting in communities across the country?

Director VIDAL. I am very focused on that issue. I will just tell you some of the things we have done already. So, I brought together our regional offices in Colorado in July to talk about how we could better use the regional offices to have more reach within the regions.

Beyond that, as part of our Council for Inclusive Innovation, we are starting an IP ambassadors program so that we can use all of our great employees in every State. I know we have 385 employees in the State of California dispersed throughout the entire State. They could then work as ambassadors and work with communities to be there and support innovation.

In addition to that, we have Patent Trademark and Resource Centers in libraries around the country. I started sending individual letters to each of the libraries where we don't have a PTRC and asking them to join the PTRC program so that we can bring patent and trademark resources into communities.

I immediately got a response from Virginia Tech, who signed up immediately. They are a minority serving institution, and so I am looking forward to doing more and to making sure that I am reaching every university and—or every university that has a library, including community colleges and ones in remote areas so that we can bring those resources to them. That is just a little bit of a flavor for the work that we are doing, but we are very adamant that we need to get everywhere, including, I will note, onto military bases.

I am going to military bases across the country. And I am going to Delaware soon. I have been to North Carolina. I have been to a number of States. Not hit California yet, but I have been to Hawaii, and met with military bases, worked with the schools on innovation training, worked with the military service people, their spouses, veterans on how to be part of the innovation ecosystem.

Senator PADILLA. Well, you have an open invitation to come to California. Look forward to welcoming you there.

Director VIDAL. Yes. I get there once in a while.

Senator PADILLA. Thank you, Mr. Chair.

Chair COONS. Thank you, Senator Padilla. Senator Welch.

Senator WELCH. Thank you very much. There are no two stronger champions of the intellectual property rights of innovators and patent holders than the two leaders of this Committee, Senator Coons, Senator Tillis, and I support your efforts in that respect. I do have a different concern that I want to talk about.

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[Poster is displayed.]

Senator WELCH. It is really important, your responsibility, to have patents issued timely, appropriately, for innovators. It is your responsibility to help enforce those patents so that the innovators get the benefit of the intellectual property that they created. But what I have seen is, in particular in the drug industry, an abuse by patent holders of that period of exclusivity.

That is an extraordinary benefit that is provided to the innovator who comes up with a drug. They get a period of exclusivity, essentially monopoly, and it involves something that is absolutely essential and vital to the well-being of American citizens. But as you know, many of these patent holders then use devices to extend that period beyond the original grant of exclusivity.

And I just want to give an example of AbbVie and HUMIRA. That period of exclusivity was supposed to expire in 2016—in Europe it did. But by creating a patent thicket and using the term of art that AbbVie in its own documents used, a "patent estate," they were able to create litigation obstacles to biosimilars and competitors coming on the market, at the time that their period of exclusivity ended.

And what that meant—I am just showing this chart, 2016, this is what the price was of the HUMIRA—$1,870 bucks. They have extended the patent all the way through 2023—it is now almost $3,200. During that time, there was an extra cost to U.S. taxpayers and folks who are purchasing healthcare, $19 billion, $100 billion in additional revenue.

And where you have a patent system that can be abused by the patent holders, and they go beyond the period of exclusivity, it is brutal on the cost of healthcare for American employers who are providing healthcare through employment, to taxpayers through the Medicare and Medicaid program, into private payers.

HUMIRA, in the U.S., is $3,000. Right now, in Sweden it is $225, $10 bucks in Germany.

So, the question I have, and I am sure this is a concern to you, is: What is the ability and the commitment of the Patent Office to stop the extension of that period of exclusivity and monopoly power that has been so consistently abused by the drug companies to rip off American taxpayers, American employers, and American consumers?

Director VIDAL. Thank you, Senator, for shedding light on that critically important issue. As you know, President Biden has made lowering prescription drug prices in America a key——

[Technical problems experienced.]

Senator WELCH [continuing]. We all want the prices lower. I want to know what you see as the obligation of the Patent Office to not—on the one side, protect the patent rights of the intellectual property holders, I get that, but the abuse by the patent holders to extend beyond the period of exclusivity so they can rip off American consumers.

Director VIDAL. So, I can let you know what the USPTO is doing in that regard. You know, certainly patents cannot be extended themselves, the actual patent, unless there is a patent term adjustment.

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We are looking into those patent term adjustments. Indeed, our Office of Patent Quality Assurance is reviewing applications that have the highest risk for unwarranted extensions of the patent term.

In addition to this, we issued a request for comment for robust, reliable patents to get feedback on what more we can do, including with regard to obviousness-type double patenting—that is one of the reasons that U.S. patents can continue to issue where they don't in other countries.

Senator WELCH. Let me just ask this. I don't get it where you get a patent, let's say for 20 years and it goes on for 30 years or 35 years. I mean, 20 years is easy enough to figure out. That is when it should end. And there has got to be some capacity on the part of our system to deal with that extension abuse. So, I really welcome some concrete suggestions or legislative proposals you think may make sense to enable you to enforce that side of the patent exclusivity period. Thank you.

Director VIDAL. Thank you.

Senator WELCH. Yield back.

Chair COONS. Thank you, Senator Welch. I am going to yield to Senator Tillis for the first of a second round of questions because his schedule requires him to depart relatively soon. Senator Tillis.

Senator TILLIS. Yes. Thank you, Mr. Chair. I have got to go to a Veterans' Affairs Committee, but I want to thank Senator Welch—we have had several different discussions about how we go about attacking and creating a sustainable change in the trajectory of drug pricing in this country.

There is a markup, just got completed in Finance, which I think is critically important. It relates to the PBMs' contribution to the escalation of cost. So, I look forward to working with you.

My question, it wasn't prompted by Senator Welch's, but my final question, I want it for you: I sent two letters to the USPTO about the findings published by the Initiative for Medicines, Access, and Knowledge, I-MAK, on drug-related patents that appear to overstate the periods of exclusivity based on their analysis of relevant patent protection. I think one thing we've got to do here is just make sure that we are all talking from the same set of facts.

If, in fact, this is true—and there is data supporting the fact that maybe this is wrong—I just want a good independent assessment of data so that when people quote a source, we know it is a reliable source. I haven't—I don't think we've got feedback yet, but I was wondering if you could give me any update on the progress of our letter.

Director VIDAL. I appreciate that. That is one of the initiatives we are working on with the FDA. So that is a collaborative effort that we are working on with them.

Senator TILLIS. Good. Well, I think that will get our facts right. My final question is just a simple one. I think you are doing a good job. I have a variety of reasons why I am pleased with your work. I am glad to support your confirmation. But what more do we need to be doing—this has less to do with the policy discussions that we were talking about here.

But as you are looking ahead to the USPTO and you are looking support for Congress, something that is going to require either ap-

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propriations or authority, can you give me some insight, if any, into what you would like for us to consider other than what is moving through this Committee at this time?

Director VIDAL. Yes, certainly anything related to the USPTO's fee setting authority would be very helpful. We also have approximately $1.2—$1.3 billion locked up that we have not been able to get access to. Getting access to that money would let us move to updated IT systems, would help us enable our outreach.

There is much we could do with that money without having to impose the fees on consumers. So, I would say both of those are top of mind.

Senator TILLIS. Good. We will keep those in mind, but just make sure you communicate with mine and Senator Coons' office on other things that we should be doing, that just give you more tools to continue to improve. And I appreciate you being here today.

Director VIDAL. Thank you, Senator Tillis.

Chair COONS. Thank you, Senator. And I know you and Senator Welch and others have a markup you need to get to. Thank you for working so collaboratively on this hearing.

Director Vidal, I think we certainly agree that the current framework for determining which inventions are eligible for patent protection is just not working.

We see remarkable developments in artificial intelligence and medical diagnostics.

What changes, in your view, to the patentability framework would provide greater certainty to inventors around what can be eligible for patent protection?

Director VIDAL. In my view, and a lot of this was articulated in the *Tropp* and *Interactive Wearables* case, we need more certainty and clarity. Right now, the biggest issue is that beyond that, certainly there are categories of inventions like patent diagnostics, if those were singled out as areas that could be patentable, certainly, that would also provide additional clarity.

Chair COONS. I was struck the Federal Circuit held that the guidance that you offered was not binding on courts. I think an obvious implication of that is that Congress has to step in. Am I wrong? Can the USPTO take further steps to tackle patent eligibility that I'm missing?

Director VIDAL. Changing the guidance, I don't believe, would be of any help when it comes to tackling it at a higher level. Certainly, that would control the patents we issue, but what happens with them when they leave our doorstep is beyond our control.

So, beyond that, we are engaged with the court system to try and make positive change there. Be more than happy to work with you and Senator Tillis' office on the proposals that you have out there and provide technical assistance on that.

Chair COONS. Well, we invested a huge amount of time in trying to sort of square the circle of patent eligibility, and we intend to take another strong run at it and would be grateful for your close cooperation.

The areas that are currently outside the ambit of patent protection have become more and more critical to our country, our competitiveness, our economy, and I am afraid we are creating a critical vulnerability for our competitiveness.

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Let me talk about counterfeit goods for a moment, if I can.

What is the Patent and Trademark Office doing to address the rapid proliferation of counterfeit goods, especially those marketed online? And what do you think Congress could do to address the sale of counterfeit goods online?

Director VIDAL. Starting with the second question, anything that Congress could do to create laws and create rules that would cut down on counterfeiting would be much welcomed.

I am very concerned about the effect that counterfeit goods not only have on our economy, same thing with pirated goods have on our economy, but also, as you mentioned, on the health and safety of our people. In terms of what the USPTO is doing, you mentioned the "Go for Real" campaign, that has been a real successful campaign. We have also created online games that have been downloaded by 17,000 educators to educate them about counterfeit goods.

We teach children through our "Camp Invention"—280,000 children last year—about counterfeit goods and the dangers, and help teach them the reason why they want us to respect IP because they have great ideas that they want respected. Beyond that, we work both domestically and internationally on policy.

We just—and we are going above and beyond when it comes to counterfeit goods. I made that clear as soon as I came on board that that was something that I wanted to tackle. We just issued a "Federal Register" notice, trying to find out from our stakeholders future strategies when it comes to anti-counterfeiting and anti-piracy, and what more the USPTO and U.S. Government can do to help.

We work with law enforcement agencies. We work with other countries to help set up infrastructures and laws within their countries. Even as I sit here today, we have over 50 judges from the Indo-Pacific region over at the USPTO engaged in dialog with a judge on the Federal Circuit and other judges in the United States on issues like this so that we can have a common ethos when it comes to counterfeit goods and the importance of IP enforcement, as well as IP protection.

Chair COONS. I have to say, Director Vidal, I just, I am impressed with the range, the scope, the ambition of your outreach. Just because I am not asking a question about inclusion and outreach as Senators Hirono and Padilla and others have, doesn't mean I don't value it. It is a valuable part of the tireless work you are doing.

The SHOP SAFE legislation that Senator Tillis and I are seeking to move would actually hold online platforms liable for harmful counterfeits unless they adopt a set of best practices. I recognize that is a step the USPTO can't take, and I would welcome input or technical assistance on that.

Let me just reference PTO fee diversion, something I have been passionate about for a very long time, because the PTO is funded with fees, not tax dollars. At different points over the last 25 years, more than $1 billion in user fees have been diverted to other Government agencies from the PTO.

I think giving the PTO rate-setting authority is a key part of legislative engagement with the Congress. How important is it for you

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to be able to keep all of the fees that you collect? And have you given any thought to whether or not changing the fees for IPRs, for PTAB proceedings, so that they at least capture your actual costs—might also make sense as a way for you to—I mean, it seems odd to me for inventor application fees to be subsidizing, to some extent, challenges to those very patents.

Director VIDAL. Well, I appreciate the feedback on the IPR, and PTAB fees. We are going through fee setting right now, both on the patent side and the trademark side, so that is something that we are looking into when it comes to those fees.

In terms of how important it is for us to keep all our fees, we are not funded by U.S. taxes. So in order for us to operate, in order for us to bring down pendency, to be innovative and creative, and to stay agile, which is especially important now as we are seeing artificial intelligence in over half of our technology groups and patents and we are seeing new scams on the trademark side of the house, we really need the ability and flexibility to be able to allocate fees and allocate our workforce so that we can keep on top of the most pertinent issues at the time.

Chair COONS. I must say, I am struck by the reach of some of the trademark scams. My folks shared with me a scam in which a Chinese company filed 2,000 trademark applications under the name of a dead American lawyer.

You have certainly warned about scammers calling trademark holders, impersonating examiners, demanding payment not to cancel registrations. What more could we do together to identify fraud and make the trademark registry cleaner, better, more accessible, but also more protective for legitimate rights holders?

Director VIDAL. I am happy to take that back to my team and talk to you. I know that every time we see something, we make changes.

So, in view of the latest scam, which is, as you mentioned, is people impersonating the USPTO and watching when trademarks are filed and immediately reaching out and say, if you want to get your trademark, you have to pay us money, we are now putting a cover letter on trademarks as well.

I don't believe it has gone out yet, but we have crafted one that lets people know that we are not going to ever call them and ask for fees. And so, we are always—it is a little bit like whack-a-mole, but we are always trying to figure out what is the best response and how quickly can we put it into effect.

And then also, as you recognized, we communicate with our stakeholders directly and try and get the message out. But it is just really important that we inform our stakeholders, and then take any action we can.

We have taken a lot of actions with regard to sanctions, with regard to sending lawyers to our Office of Employment—Enrollment and Discipline, and we are doing everything we can at every stage, and we are investigating, you know, all of these types of activities to make sure we stay on top of it.

But to the extent that we might be able to work together on that, I would love to talk to the experts in my office and see what great ideas they may have.

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Chair COONS. Thank you. This is my last question. Our first Subcommittee hearing was on foreign competitive threats to innovation, and it highlighted China's abusive practices, with a particular focus on standard essential patents, or SEPs.

Given that ongoing challenge, or that abuse, I have been following, with genuine concern, recent proposed regulations by the European Union for what would essentially be an SEP rate court.

That regulation, I am concerned, validates China's practices that have also harmed U.S. patent holders, and I have shared those concerns with Secretary Raimondo during an Appropriations hearing, and she agreed the proposal is problematic.

What steps has the USPTO taken to communicate concern to our European colleagues, and what steps do you think the administration can and should take to guard against restrictions on SEP licensing in the EU and globally?

Director VIDAL. As I mentioned in my opening remarks, that is one of the things that I am keenly focused on, is standards, because I think it is critical to our economy. I will say that when we withdrew the 2019 policy statement around SEPs with NIST and DOJ, it was because we see standards as an international issue, that individual countries weighing in, in these ways, could be extremely problematic.

So, what we have done when it comes to the EU directorate is, I have met with the EUIPO in Geneva just a week and a half ago. I have also spoken to other stakeholders in Europe about this.

We also are issuing soon an FR notice, a "Federal Register" notice, to seek feedback from U.S. stakeholders on international SEP policy so that we can inform an all-of-Government approach. That is going to be not just the USPTO—I am doing that with NIST, our standards and technology group, and ITA, our international group within Commerce, so that we can get an all-of-Government approach to this that is data driven by feedback.

Chair COONS. Well, Director Vidal, I appreciate your participation today. Thank you for your perspective and the work that you are doing, and all the folks at the USPTO, to promote and protect innovation.

I am grateful to the Members who were able to attend, and in particular to Ranking Member Tillis for being a great partner. We will continue to hold hearings, as the year goes on, on some of the more thorny issues that we explored today—patent eligibility, PTAB reform, and others. We welcome your partnership and engagement as we move forward.

I think we do have a genuine opportunity for bipartisan progress in this Congress and we are going to work hard to achieve that with the legislation I referred to: PREVAIL, PERA, and others.

Just for the record, Members may submit questions for our witness. They are due at 5 p.m., 1 week from today, on August 2nd.

I want to thank you, again, for participating today, Director Vidal. I very much look forward to continuing to work with you.

And with that, this hearing is adjourned.

[Whereupon, at 3:28 p.m., the hearing was adjourned.]

[Additional material submitted for the record follows.]

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APPENDIX

Additional Material Submitted for the Record

Witness List
Hearing before the
Senate Committee on the Judiciary
Subcommittee on Intellectual Property

"Oversight of the United States Patent and Trademark Office"

Wednesday, July 26, 2023
Dirksen Senate Office Building, Room 226
2:30 p.m.

The Honorable Katherine Vidal
Undersecretary of Commerce for Intellectual Property and Director of
the U.S. Patent and Trademark Office
Alexandria, VA

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STATEMENT OF

KATHI VIDAL

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE

SUBCOMMITTEE ON INTELLECTUAL PROPERTY
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

"Oversight of the U.S. Patent and Trademark Office"

July 26, 2023

I. Introduction

Chairman Coons, Ranking Member Tillis, Chairman Durbin, Ranking Member Graham, and Members of the Subcommittee:

Thank you for this opportunity to discuss the operations, programs, and initiatives of the United States Patent and Trademark Office (USPTO).

The USPTO advises the President, through the Secretary of Commerce, on a full range of national and international intellectual property (IP) issues, including patents, trademarks, copyright, trade secrets, and enforcement. IP is a critical engine that powers our economy and one reason our Nation is a global leader in innovation and entrepreneurship. As we face humanitarian and environmental crises, and new technologies and globalization present evolving and challenging IP issues, we need to encourage the progress and growth that IP protection can provide. We need an IP ecosystem that will cultivate an innovation mindset and catalyze inclusive innovation and entrepreneurialism, economic prosperity, and U.S. competitiveness, and bring that innovation to positive impact.

To that end, the USPTO is working to ensure that it issues patents, registers trademarks, and upholds and protects clear and enforceable IP rights that incentivize innovation and commercial enterprises—whether large or small—and helps to bring that innovation to positive impact, including job growth, higher paying and more stable employment, national security, and solving world problems.

I am honored to be here with you today to provide the Committee with an overview of the USPTO's recent activities and accomplishments, and to share the advancements that the USPTO has implemented this past year in pursuit of this goal. Since my confirmation, I have received valuable feedback from nearly 100 external stakeholder meetings, in internal small-listening sessions with over 1,500 USPTO employees, in my 130+ fireside chats, and in all my

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interactions across the country and the globe with inventors, entrepreneurs, and everyone who cares about making our IP ecosystem work for all.

I am especially grateful for the thoughtful responses the USPTO has received to its recent requests for comments (RFCs). These comments are critical in the USPTO's process of engaging in data-driven decision-making and determining how to adjust processes and policies to provide a strong IP system for all. With valuable input from a variety of stakeholders, the USPTO is able to promote robust, reliable, and transparent IP rights and enforcement. The USPTO is making great strides in creating more clarity and certainty around examination, post-grant challenges, Director Review, and discretionary denials. The USPTO seeks to ensure our patent laws provide the certainty necessary to encourage innovation and investment in the same. The agency is committed to making change where it is needed, not only through changes to our own procedures and regulations but also through our work with Congress and other executive agencies, as well as upholding the strong IP system that has made America the innovation engine that it is.

None of the USPTO's work is possible without the dedication and hard work of the USPTO's highly educated and talented workforce. The USPTO continues to build, retain, and effectively manage the workforce it needs to serve the public and stakeholder community.

The USPTO is pleased that Congress continues to provide it with the authority to spend all anticipated fee collections. This provides us with resources to continue reducing the patent and trademark application backlog, shortening patent and trademark pendency, improving patent quality, protecting the integrity of the trademark register, expanding access to our patent and trademark system to underrepresented communities, engaging effectively internationally, and investing in our information technology (IT) infrastructure. This also enables the USPTO to continue to expand its nationwide workforce, including by providing necessary financial agility when responding to increased demand as we have seen in trademarks over the past few years.

Since the enactment of the Leahy-Smith America Invents Act (AIA), USPTO's fee setting authority has allowed the agency to more efficiently set user fees to recoup its operational costs. In 2018, Congress extended the USPTO's fee setting authority for eight additional years to 2026. We look forward to working with the Committee to ensure that the USPTO maintains this authority.

The agency is also pleased that Congress passed the Trademark Modernization Act, which has provided the USPTO with more tools to help maintain the trademark register, and the Unleashing American Innovators Act, which builds on the USPTO's outreach to America's underserved and underrepresented communities. Information on how the USPTO has implemented, and is taking steps to implement, these laws is set forth in more detail below.

The following provides an overview of some of our key programs and initiatives.

II. Patent Operations and Initiatives

Patent Quality

Providing high-quality, efficient examination of patent applications is key to the issuance of robust and reliable patent rights. The USPTO continually works to equip our examiners with the guidance, training, tools, advanced technology, and procedural resources they need to meet this

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challenge.

As part of quality improvement efforts, the USPTO has developed or implemented tools and programs to improve our examiners' ability to access the best prior art as early as possible in prosecution. The USPTO has developed Global Dossier, which enables examiners to view work done by examiners in other IP offices, including the prior art references cited in related patent applications. The USPTO has also released two capabilities to the examining corps, which allow for examiners to use AI functionality to automatically and securely retrieve potential prior art from US and translated foreign patent document collections: More Like This Document, released at the beginning of FY 2022, allows examiners to use AI to retrieve similar U.S. and foreign patent documents, and Similarity Search, released at the beginning of FY 2023, provides examiners with the ability to emphasize aspects within their applications to help further guide AI in retrieving prior art.

The USPTO has also instituted Post Grant Outcomes, a collaborative effort between the Patent Trial and Appeal Board (PTAB) and the Patents (examination) division to establish a learning loop, which leverages and readily introduces PTAB decisions into patent examination to improve patent prosecution. In addition, the USPTO has also launched a program, the Relevant Prior Art Initiative, that brings relevant prior art into a patent application under examination in a fully automated manner and has developed an electronic tool that will improve examiners' ability to review this prior art. Although this program is currently limited in scope, the USPTO is currently evaluating and reassessing approaches to expand the program.

The USPTO also continues to refine the patent application classification and routing systems to best leverage the technological expertise of the patent examination corps in assigning a patent application to the most appropriate patent examiner, especially when the patent application encompasses more than one technology. These refinements place a greater emphasis on matching the technologies described in the applications with the technology backgrounds and experience of the examiner. As a result, the USPTO is better able to assign applications that are better aligned to the patent examiners' expertise and experience.

Further, to ensure quality work product, the USPTO's Office of Patent Quality Assurance provides assessment and analysis of patent examination quality through random selection of product reviews. The quality review system is designed to not only provide individual feedback to examiners, but also to improve consistency through collecting minable data utilized for evaluating performance and trends and to project training needs. These data are also utilized by Patents managers to create action plans for their specific technology area. In order to solicit external feedback on the review process, its methodology and resulting data are available to the public.

Recognizing that patent quality is a joint effort between applicants and the USPTO, the agency continually engages with its stakeholders, including universities, non-profits, small businesses, corporations, and individual inventors, on issues related to patent quality via speaking engagements, conferences, roadshows, virtual chats, and surveys, as well as through various efforts of the Office of Patents Stakeholder Experience. Through collaboration with external stakeholders, the USPTO remains focused on continuing to improve the quality of patent products, processes, and services to address stakeholder concerns.

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Robust and Reliable Patents Initiatives

The USPTO issued an RFC on initiatives directed at bolstering the robustness and reliability of patents to incentivize and protect new and nonobvious innovation while also facilitating the broader dissemination of public knowledge to promote innovation and competition. The RFC sought input on a variety of topics, including prior art searching; support for claimed subject matter; request for continued examination practice; restriction, divisional, and rejoinder practice; and non-statutory double patenting practice. The USPTO is reviewing the comments and will use them to inform improvements to the agency's procedures and the patent system as a whole.

Examiner Training

Providing training and guidance to USPTO's employees is of utmost importance for supporting high-quality examination. The USPTO recognizes that quality begins with an extensive, structured entry-level training program for patent examiners that trains them to address all issues that may hinder patentability during prosecution and to identify all allowable subject matter. Examiners continue their education throughout their tenure at the USPTO with regular refresher training and master level training, as well as training on new case law. Training curricula are developed yearly with the addition of new modules.

To increase examiners' knowledge of a specific technology, experts from industries and academia volunteer to share their technical expertise with examiners. The USPTO's Patent Examiner Technical Training Program provides opportunities for technologists, scientists, engineers, and other experts from industry and academia to voluntarily provide technical training and expertise to patent examiners. The Site Experience Education (SEE) program provides an opportunity for commercial, industrial, and academic institutions within the continental United States to voluntarily host patent examiners for technical site visits. Organizations that participate in the SEE program contribute to improving the quality of patent examination by keeping patent examiners updated on the latest technologies and innovations in their field of examination. To strengthen the USPTO's workforce expertise, the agency also offers legal studies. In addition, the USPTO regularly organizes or participates in continuing legal education credit offerings across the country.

In furtherance of the President's July 2021 Executive Order on Promoting Competition in the American Economy, the USPTO is also working closely with other federal agencies in training examiners. For example, the USPTO and the Food and Drug Administration (FDA) have collaborated in training events to discuss how examiners can utilize publicly available information and resources from the FDA as prior art during patent application examinations. USPTO is also working with the U.S. Department of Agriculture to explore initiatives to improve the quality of the patent examination process for agriculture related innovations, including enhancing prior art search capabilities and providing additional training and guidance to patent examiners.

Patent Pendency and Inventory

The timely issuance of patents helps inventors and investors bring inventions to impact more quickly. The USPTO recognizes the importance of continually refining and defining optimal pendency to take into consideration the external environment affecting workload inputs, the commitment made to customers, and the need to ensure that there is a balance between workload

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and production capacity. Based on stakeholder feedback, including from individual inventors, the USPTO is looking into providing more flexibility around the speed of examination, including the option to slow the examination process to give applicants time to assess the viability of their inventions, and expanding the ability to expedite the examination process.

The USPTO received approximately 457,500 serialized patent applications (new patent filings) in FY 2022, which represents an increase of 1.6% over the number received in FY 2021. The inventory of unexamined patent applications is anticipated to be approximately 733,300 at the end of FY 2023, which is an increase of approximately 43,800 from FY 2022.

The USPTO remains committed to processing patent applications promptly and has established patent timeliness goals based on Patent Term Adjustment (PTA) timeframes. Reducing the number of patent term adjustments issued provides consistently shorter pendency for all applications and gives applicants greater certainty of the timeliness of their own cases. For FY 2022, the USPTO met its target of 80% of total PTA compliance for mailed actions (i.e., office actions the agency mailed to applicants), but did not meet the PTA compliance target of 87% for remaining inventory (i.e., cases awaiting action from the USPTO), which was 85%. The underperformance was due to the increase in applications awaiting a first office action. We are examining other ways to reduce pendency, including making changes to examiner hiring and retention policies. Our FY 2023 goal is to maintain the 80% total PTA compliance for mailed actions and increase the target to 86% for PTA compliance for remaining inventory.

Fee Setting Authority

The USPTO's fee setting authority, as established in 2011 by the AIA, permits the agency to set and adjust fees to ensure that aggregate revenue recovers the USPTO's aggregate costs to fulfill its mission and ensure long-term financial sustainability. To date, the USPTO has used its AIA fee-setting authority six times. The USPTO anticipates setting and adjusting both patent and trademark fees with a FY 2025 effective date to better align aggregate revenue and costs and refine certain fees for policy considerations. The USPTO has already started the process of adjusting patent fees by submitting a proposal to the Patent Public Advisory Committee (PPAC) and assisting PPAC in holding a public fee setting hearing on May 18, 2023. The USPTO is reviewing public comments and will consider these comments, as well as the written report from PPAC that provides advice and recommendations on the fee proposals, in preparing the Notice of Proposed Rulemaking on the new patent fees.

III. Trademark Operations & Initiatives

The USPTO registers marks (trademarks, service marks, certification marks, and collective membership marks) that meet the requirements of the Trademark Act. The USPTO creates and maintains the federal register of trademarks that now includes approximately 3,100,000 live registrations. Federal trademark registration provides important benefits to trademark owners that help them to enforce rights in their mark against unauthorized users and to enlist the help of U.S. Customs and Border Protection to exclude counterfeit goods from importation.

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The Accuracy of the Trademark Register and the Implementation of the Trademark Modernization Act

For the public and the USPTO to reliably determine whether a mark is available for registration, the trademark register must accurately reflect marks that are in use in the United States for the goods and services identified in the registrations. Over the past several years, there has been a rise in behaviors that undermine the accuracy and reliability of the trademark register that include a steady growth of abuses of the filing system, attempts to circumvent rules of practice, and outright fraud. Protecting the trademark register from these harmful actions and ensuring the accuracy and integrity of the trademarks the USPTO registers and maintains remains a top priority. The USPTO's Register Protection program includes tools that can be used internally as well as tools that external stakeholders can use to fight these harmful behaviors.

The Register Protection program's internal tools include the Administrative Sanctions Program, through which the USPTO reviews suspicious behavior and issues sanction orders for rule violators. Since mid-2021, USPTO has issued approximately 150 orders for sanctions that have terminated over 19,000 invalid applications and sanctioned 3,500 invalid registrations. Another tool is the Director-initiated expungement and reexamination nonuse cancellation proceedings created under the Trademark Modernization Act, through which marks that are no longer in use and registrations emanating from scammers are eliminated from the register. Since the proceedings were implemented, the USPTO has instituted approximately 147 Director-initiated proceedings against registrations that are not in use. Through the Post-registration Audit Program, the USPTO requests proof of use to establish that the mark is actually in use on the goods and service identified in the registration at the time of the maintenance filing and, if proof is not provided, the USPTO imposes a $250 penalty. The USPTO currently audits approximately 5,000 registrations a year. The USPTO also expends significant resources in educating customers to avoid scams such as impersonations of the USPTO, misleading solicitations, or engaging unauthorized practitioners. The USPTO also encourage customers to report when they have been a victim of a scam, which helps the agency gather information about evolving behaviors and combat fraud.

The USPTO also has tools available for third parties to protect the trademark register. The Trademark Modernization Act created the ability for third parties to file petitions to request institution of *ex parte* nonuse proceedings before the Director. Since implementation, the USPTO has received approximately 334 third-party petitions and instituted approximately 166 nonuse proceedings on the registrations identified in those petitions that resulted in the cancellation of a total of approximately 1100 goods or services. Third parties can also file a letter of protest to submit evidence that the specimens of use submitted in a pending application are fake or fraudulent. Since December 2021, the USPTO received approximately 122 Letters of Protest providing evidence of nonuse and, where the evidence was determined to be relevant and forwarded to the examining attorney for consideration, nearly one-third of those cases resulted in a refusal to register based on the evidence provided. Third parties may also file petitions to cancel a mark at the Trademark Trial and Appeal Board (TTAB) for fraud, abandonment, or nonuse, or that an application or registration is void *ab initio,* which may be based on findings made in orders issued through the Administrative Sanctions Program.

Consistent with the Trademark Modernization Act, the USPTO has implemented the shortened response periods during pre-registration in December 2022. Implementation of post-registration shortened response periods is planned for October 2023.

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Trademark Pendency

The USPTO's Trademark Organization is guided by the strategic goal to optimize trademark quality and timeliness. Trademark application filings unexpectedly surged in 2021 during the pandemic to over 940,000 applications because many individuals and small businesses formed businesses and began selling online at that time. While application filing levels returned to normal in 2022, the resulting unexamined inventory, along with new applications, increased overall pendency. First-action pendency —the time from filing to the initial examination — has increased from 3.5 months to 8.5 months. However, with the smaller growth in trademark filings in recent months and recent hiring, pendency has remained relatively flat and the USPTO has brought down the unexamined inventory by 5% since its highest level in 2022 and expects to make even more progress in the coming months.

The USPTO has taken proactive steps to lower the number of unexamined applications and reduce first-action pendency. The USPTO hired approximately 90 new trademark examining attorneys in FY 2022 and FY 2023, respectively. The USPTO has continued to improve initial trainings so that new examining attorneys can quickly start examining trademark applications. The USPTO is also conducting a business process optimization analysis of the entire trademark examination process and exploring possible efficiencies in existing practices, policies, and procedures. The USPTO will also continue to develop numerous automated processes to assist examination in areas such as suspension checks and checking addresses on commercial mail-receiving agencies. The USPTO will continue to explore other ways to address pendency and inventory.

Anti-Counterfeiting Initiatives

The USPTO is working to protect brands by working to change the narrative around purchasing counterfeit products and informing consumers about the dangers and consequences of purchasing counterfeit goods. The USPTO and the National Crime Prevention Council are working together to educate the public about safe buying behavior and the importance of decreasing the demand for counterfeit goods through a series of public service announcements (PSA), which have received an estimated 1.2 billion views. The USPTO's most recent radio ad reached an estimated audience of 10,000,000 through the end of February 2023. In January, the USPTO also released a new online game and educational toolkit that was distributed to educators through Young Minds Inspired, the nation's leading provider of free educational outreach programs and has been downloaded by nearly 17,000 educators.

Fee Setting Authority

As noted above, the USPTO anticipates setting and adjusting both patent and trademark fees with FY 2025 effective dates to ensure that aggregate revenue recovers costs and to refine certain fees for policy considerations. The USPTO has begun the process of adjusting its trademark fees by submitting a fee proposal to the Trademark Public Advisory Committee (TPAC) and assisting them in holding a public fee setting hearing on June 5, 2023. The USPTO is reviewing public comments and will consider these comments, as well as the written report from TPAC that provides advice and recommendations on the fee proposals, in preparing the Notice of Proposed Rulemaking on the new trademark fees.

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IV. Patent Trial and Appeal Board

AIA Trial Filings and Ex Parte Appeals

As established by the AIA, the PTAB is a neutral tribunal within the USPTO that, if requested, reviews final rejections in patent applications made by examiners during prosecution (*ex parte* appeals) and determines patentability questions of challenged claims in issued patents raised by third parties in AIA trial proceedings.

In FY 2022, the USPTO received approximately 1,350 AIA petition filings and issued approximately 1,100 decisions on institution and approximately 450 final written decisions within the AIA's statutory due dates. The inventory of *ex parte* appeals was approximately 4,600 appeals at the end of FY 2022, with an average pendency of 12.1 months, meeting our ultimate pendency goal for *ex parte* appeals of about 12 months.

Issuance of Procedural Improvements and Guidance

The USPTO has made several significant changes to AIA trial proceedings during the past year to provide even more enhanced transparency, fairness, certainty, and predictability.

In order to promote transparency and clear and consistent decision-making, the USPTO issued an RFC in July 2022to receive stakeholder feedback on its processes regarding Director Review, Precedential Opinion Panel review, and internal circulation and review of PTAB decisions. Until those rules are finalized though notice-and-comment rulemaking, I issued the "Interim process for PTAB decision circulation and internal PTAB review," which provides that the Director is not involved, pre-issuance, in directing or otherwise influencing panel decisions, and the PTAB panel has final authority and responsibility for the content of a decision. These steps, which were taken before the Government Accountability Office issued its report on "Increased Transparency Needed in Oversight of Judicial Decision Making" in December 2022, are consistent with, and incorporate, many of the recommendations in that report. We have reviewed the public comments to the RFC on these processes and intend to issue a Notice of Proposed Rulemaking (NPRM) soon that will set forth proposed rules governing pre-issuance internal circulation and review of decisions within the PTAB, as well as a separate NPRM as it relates to Director Review and related processes. In the meantime, the USPTO recently issued an updated standard operating procedure and easily accessible websites that provide detailed information regarding the USPTO's current interim practice in this area.

In addition, the USPTO is currently reviewing over 14,500 public comments on the Advanced Notice of Proposed Rulemaking (ANPRM) that we issued in April on the rules of practice for *inter partes* review (IPR) and post-grant review (PGR) proceedings. In the ANPRM, the USPTO solicited comments regarding the rules the Director and, by delegation the PTAB, will use in exercising discretion to institute IPRs and PGRs. The changes under consideration are intended to avoid abuses, minimize inefficiencies, and afford additional protections to under-resourced innovators while also ensuring that petitioners have an opportunity to raise meritorious challenges in AIA proceedings. The USPTO also solicited comments regarding proposals that would allow petitioners to pay additional fees for higher petition word-count limits, provide a separate briefing process for discretionary institution arguments, and require parties that settle prior to institution to file with the PTAB copies of any settlement agreements.

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V. Domestic and International Intellectual Property Policy

The USPTO plays a leading role in promoting strong and balanced protection and effective enforcement of IP at home and abroad. In particular, the USPTO "advise[s] the President, through the Secretary of Commerce, on national and certain international intellectual property policy issues," and advises "Federal departments and agencies on matters of intellectual property policy in the United States and intellectual property protection in other countries."

USPTO Initiatives to Promote Drug Accessibility

The USPTO is committed to ensuring that the United States' strong patent system continues to incentivize life-saving innovation in drugs without unnecessarily delaying accessibility to generic, biosimilar, and more affordable versions of those drugs. This work includes current and future initiatives taken by the USPTO and ongoing collaboration with the FDA.

The USPTO has undertaken several initiatives that seek to further this goal. As noted above, the USPTO published its RFC on robust and reliable patents. The USPTO also issued a Federal Register Notice clarifying the patent applicant's duty of disclosure and duty of reasonable inquiry, and hosted a panel discussion on these duties. The USPTO has also launched a new public webpage that provides a list of applications for patent term extension that have been filed within the past five years and a list of patents that have had terms extended.

In furtherance of the President's July 2021 Executive Order on Promoting Competition in the American Economy, the USPTO is working with the FDA to continue to incentivize innovation and reduce potential misuse of the patent system to improperly delay competition. As noted above, the USPTO and the FDA have held cross-training events where we discussed resources and information that are publicly available from the FDA that could be used by examiners as prior art during patent application examination. The USPTO and the FDA also hosted a joint public listening session to hear from representatives of patient advocacy groups, pharmaceutical and biologic industries, generic and biosimilar industries, and academia. The USPTO and FDA also jointly published a request for comments on USPTO-FDA collaboration initiatives, and the agencies are now reviewing the comments received to decide on next steps.

Artificial Intelligence and Emerging Technologies

The USPTO plays an important role in incentivizing and protecting innovation in critical technologies such as artificial intelligence (AI) and other emerging technologies (*e.g.*, quantum computing, synthetic biology, blockchain, precision medicine, and virtual reality), so these innovations can positively impact our country's competitiveness, economic prosperity, and national security. Last June, the USPTO launched a major new initiative called the AI and Emerging Technologies Partnership (the Partnership) that brings together diverse stakeholders including scientists, engineers, attorneys, academics, and entrepreneurs, to share perspectives, experiences, and insights on the intersection of IP, AI, and emerging technologies. The Partnership hosted several events that focused on a variety of topics, including an overview of the National AI Initiative and the USPTO's AI Patent Dataset, important patent policy issues, AI and biotechnology, and using AI technologies in the innovation process itself. In February 2023, USPTO published an RFC seeking stakeholder input on the current state of AI technologies and inventorship issues that may arise in view of the advancement of such technologies, especially as AI plays a greater role in the innovation process. The USPTO is digesting that input and plans to

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focus next on next steps.

Green Initiatives

In furtherance of promoting the USPTO's green initiatives, the USPTO launched a Trademarks for Humanity award, and this year's award recognizes brand owners who improve the environment through their products and services, a Patents for Humanity Green Energy category, and a joint work-sharing program with the National Oceanic and Atmospheric Administration. In May 2022, the USPTO launched its Climate Change Mitigation Pilot Program, which accelerates the examination of patent applications involving innovations to reduce greenhouse gas emissions. This program was recently expanded to encompass a more robust group of innovations in any economic sector that advance progress toward achieving net-zero greenhouse gas emissions. In July 2022, the USPTO formed a new partnership with the World Intellectual Property Organization (WIPO). WIPO GREEN is a global online platform that facilitates the dissemination and advancement of environmentally friendly technologies, provides opportunities for collaboration and partnership, and encourages widespread adoption. It provides opportunities for U.S. innovators to advance their innovation in green technologies and bring their ideas to market and to the world. In May 2023, the USPTO, the Federal Laboratory Consortium, and AUTM sponsored the Green Energy Innovation Expo that highlighted the impact of green energy in the fight against climate change. The event sought to facilitate partnerships between businesses and federal laboratories, universities, and private-sector innovators—including government-funded startups—offering a wide range of green energy technologies for licensing, including green hydrogen, energy storage, and wind energy. And, at the annual IP5 meeting in June 2023, the USPTO, along with its partners, discussed how to address climate change through an accessible and inclusive IP system and strategies to leverage their resources to further incentivize and promote sustainable innovations.

International Activities

Among other things, the USPTO advocates for global IP norms and understandings, and conducts technical assistance and capacity-building programs for foreign governments and U.S. stakeholders through its Global Intellectual Property Academy (GIPA). In FY 2022, the USPTO conducted 222 training programs through GIPA, including programs coproduced with the USPTO's regional offices, serving over 18,600 individuals. Approximately 62% were patent, trademark, and copyright officials, prosecutors, police, customs officials, and policy makers from the United States and 162 other countries, including intergovernmental organizations. Approximately 38% of all attendees were representatives of U.S. small and medium-sized enterprises, IP practitioners, and IP owners and users.

The USPTO continues to work toward global IP harmonization. In FY 2022, the USPTO established cooperative agreements designed to improve IP systems and enhance the enforcement of rights with the IP offices of Japan, the European Union, Saudi Arabia, Malaysia, France, and Peru, as well as the National Research Development Corporation of India and the WIPO. The USPTO, with the International Trade Administration, participates robustly in U.S. government-wide trade policy processes to improve international IP protections and enforcement practices available to U.S. rights holders. These include bilateral, regional, and multilateral negotiations and dialogues, as well as annual country review processes such as Special 301, which is a congressionally-mandated annual review of the state

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of IP rights protection and enforcement in U.S. trading partners around the world.

China-Related Activities

The USPTO's China Team in Alexandria, Virginia, along with IP attachés on the ground in China, bring extensive knowledge of, and experience with, China's IP system. In addition to the IP attachés, the USPTO Mission in China has 5 local Chinese attorneys on staff who specialize in Chinese IP law. Rights holders have expressed a range of concerns about the IP landscape in China, including bad faith misappropriation of trademarks, the theft of trade secrets, infringement of patents, excessive government involvement in intellectual property licensing transactions, and a lack of judicial and administrative transparency. The USPTO has responded by presenting a series of China IP Roadshows and webinars, which inform rights holders about the most effective ways of protecting and enforcing their IP in China. Since 2017, the China Team has taken their road shows to more than 30 cities, and has held 20 webinars. Since December 2022, the team visited a wide range of cities, including Greenville, South Carolina; Minneapolis, Minnesota; Omaha, Nebraska; and Dallas, Texas and plans an additional roadshow this year including in San Diego, California. The USPTO was pleased to have featured addresses from Members of Congress and municipal leaders at many of our China IP roadshows and looks forward to their continued involvement. The USPTO also supports broader U.S. government-wide efforts to address threats posed by China, by advising and coordinating with other U.S. government agencies on strategies to promote U.S. IP policy and encourage effective IP protection and enforcement in China.

IP Attaché Program

The IP Attaché Program is an important asset that supports the USPTO's efforts to promote strong and balanced protection and effective enforcement of IP rights abroad. The attachés' fundamental role is to provide technical expertise assisting embassy officials on IP issues; advocate for U.S. IP policy positions for the benefit of U.S. stakeholders with governments in the host region; educate foreign government officials on IP matters, including judges, prosecutors, patent and trademark examiners, customs officials, police, and policy makers; assist U.S. stakeholders with IP concerns in the host country or region; and build grass-roots support for U.S. policy objectives by conducting public awareness programs on IP with embassy teams. The USPTO currently has thirteen IP attachés serving in the U.S. and Foreign Commercial Service in Belgium, Brazil, China, India, Mexico, Peru, Thailand, Ukraine, the United Arab Emirates, the U.S. Mission to WIPO, and the WTO, where most of these attachés cover a broader region. The IP Attachés have proven to be effective advocates for U.S. IP in overseas markets and the USPTO will continue to work with its interagency partners to ensure that their contributions continue to serve and advance American interests abroad.

VI. USPTO Regional Offices

The USPTO is actively working to better serve the local innovation economies through its four regional offices in Detroit, Dallas, Denver, and San Jose. Among other things, these offices serve as hubs for IP outreach and education efforts and provide inventors, small businesses, and entrepreneurs easier access to USPTO personnel and resources, including walk-in services to obtain general IP information; work stations for searching patents and trademarks; a hearing room to host PTAB proceedings; and interview rooms to connect applicants to examiners across the country. In FY 2022, our regional offices met with over 600 stakeholders, including small

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and large companies, independent inventors, universities, and government entities, and held over 600 training events. Regional office outreach efforts have included broad-based and issue-specific IP seminars for startups, small business and independent inventors; tech-specific partnership meetings; participation in science, technology, engineering, and math (STEM) education events; and working relationships with regional stakeholders including business interests and federal, state, and local government officials.

Under the recently enacted Unleashing American Innovators Act, the USPTO is working to implement the provisions in that law, including those directing the USPTO to establish a new Southeast Regional Office and four community outreach offices. The USPTO issued a Request for Comments on these new offices and the comment period closed on July 17, 2023. The USPTO is reviewing these comments as it considers where to establish the Southeast Regional Office and the first of the community outreach offices, the Northern New England Community Outreach Office.

VII. Education and Access

At the highest level, the USPTO exists to promote American innovation through IP, across all geographic regions of the United States and across all demographics. The USPTO has established several new programs and expanded and/or improved existing programs to fulfill this mission.

Expanded Legal Services

The USPTO has expanded access to patent legal services. First, the USPTO has expanded its Patent Pro Bono Program, which provides free legal services for financially under-resourced independent inventors and small businesses by increasing annual funding by 42% to $1.2 million. The program has provided more than 95,000 hours of free legal services to independent inventors and small businesses since we started collecting data in 2015, and that assistance has resulted in more than 2,000 patent application filings. Our data show that pro bono applicants self-identify as 43% women, 35% African American or Black, 14% Hispanic American, 5.7% Asian American or Native Pacific Islander, and 1.5% Native American.

Second, the USPTO also launched its PTAB Pro Bono Program, which matches volunteer patent professionals with financially under-resourced inventors to provide free legal assistance in preparing *ex parte* appeals to the PTAB, and plans to expand the program to AIA trial proceedings later this year. Finally, the USPTO has expanded its participation in existing law school clinic programs to a record high of more than 60 law schools around the country, which provides critical free legal services to the public, including to inventors, entrepreneurs, and small businesses. The USPTO hopes to continue to add additional law schools to the program.

New Programs for First-time Applicants

The USPTO has also implemented new programs and initiatives for first-time applicants. First, the USPTO has implemented a new pilot program to provide first-time micro entity filers with expedited examination during the agency's initial review of a patent application at no additional

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charge. The pilot program also provides a collection of free training resources for applicants to help ensure their success. Second, the USPTO is developing a pilot pre-prosecution assessment program to support first-time applicants by assessing the strengths and weaknesses of their potential patent applications. Third, the USPTO launched its new IP Identifier tool, a virtual resource designed for those who are less familiar with IP that can help a small business understand if its idea or creation is IP and how patents, trademarks, and copyrights may help protect this IP as the business owners establish and/or grow their business. Fourth, the USPTO also launched AccessUSPTO, a pilot program that works with national organizations that do not specifically focus on IP, but whose members could benefit from learning how to protect their ideas, creations, and brands. Finally, the USPTO launched its Stakeholder Application Readiness Training, a virtual course that provides training, tailored to pro se applicants, such as individual inventors and small businesses, about the patent filing process and provides resources for submitting a nonprovisional patent application.

The USPTO continues to offer extensive free services and courses to educate members of the public, including those new to the IP ecosystem, on ways in which IP protection can help them bring their ideas to reality. These programs include the Patent Pro Se Assistance Program, which provides pro se applicants with additional assistance for obtaining a patent; patent and trademark "boot camps", which are eight-part series that cover the basics of filing for a patent and trademark; free educational events that inspire, educate, and empower underserved and under-resourced communities of innovators; inventor and entrepreneur resources that provide information to assist them at every stage of protecting their inventions and/or brands; and free programming offered every quarter, such as the Hispanic Innovation series, the Invention-Con series for independent inventors, the Proud Innovation program, the Veterans Innovation and Entrepreneurship event, and the new Together in Innovation program, which focuses on networking, teamwork, and mentorships.

Council for Inclusive Innovation

The USPTO has also expanded outreach to underrepresented communities. The USPTO plays a vital role in the government's Council for Inclusive Innovation (CI^2) by providing the primary support for CI^2. Under CI^2, the USPTO launched a new pilot program to expedite the first round of examination in qualifying patent applications from first-time micro-entity filers at no additional charge. The pilot program also connects applicants with free, vetted patent training resources to help ensure their success. Other CI^2 initiatives include an internship program that provides hands-on training to community college and university students, including learning about the USPTO's role in protecting IP, granting patents and trademarks, and fostering innovation. The first group of interns joined the USPTO in January 2023. CI^2 is also coordinating and amplifying the USPTO's nationwide community outreach campaign targeted at communities with historically low patent participation rates, including the development of "IP Champions," an initiative the USPTO plans to stand up later this summer, in which USPTO employees can volunteer to use their expertise to educate the public on the importance of IP. The USPTO will also work with the Minority Business Development Agency to better ensure that underserved entrepreneurs are not only aware of, but also take greater advantage of, their IP rights when starting or scaling their businesses.

Education and Outreach to Underrepresented Communities

Our outreach to underrepresented communities includes a range of entrepreneurship programs.

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Last fall, U.S. Secretary of Commerce Gina Raimondo and I co-founded our Women's Entrepreneurship (WE) initiative to inspire and empower more women leaders to jumpstart their journeys of innovation, advance the conversation around challenges and opportunities for women-owned businesses, and tap into women's potential through entrepreneurship. The WE initiative includes a new resource hub that provides key information about IP protections, as well as resources that help women connect with each other, identify sources for funding, and launch their own businesses. Similarly, the Black Innovation and Entrepreneurship Program was expanded to provide programming on a monthly (rather than annual) basis and offered a hybrid program for the first time this year.

The USPTO has created new educational programs for Minority Serving Institutions in collaboration with the National Society of Black Engineers, which include training on IP basics, best practices for patent and trademark filers, and information on local resources for independent inventors and small business owners. These programs were presented at Howard University in Fall 2022, the University of Puerto Rico in Spring 2021, and the University of Houston in Summer 2022.

The USPTO also held a series of monthly free webinars in collaboration with the U.S. Department of the Interior's Indian Arts and Crafts Board and the nonprofit Indian Dispute Resolution Services, founder of the Acorn Project for Native American small businesses. These webinars offered information and guidance to Native American visual artists from experienced entrepreneurs, e-commerce sellers, IP specialists, fellow artists and craftspeople, and others on how to navigate today's e-commerce environment.

The USPTO is also working to encourage and support more active-duty military, military family members, and veterans to bring their innovations to life, build successful businesses, and protect their creations with IP. This includes events at Fort Liberty, MacDill Air Force Base, and Joint Base Pearl Harbor, and the military innovation competition Dragon's Lair.

Fostering the Next Generation of Creators and Innovators

IP and invention education are critical to bringing more Americans into the innovation ecosystem. The USPTO is working to engage young students early and continue to provide training and opportunities for them to gain exposure to IP as they mature. Last year, the USPTO educated over 280,000 children through its partnership with the National Inventors Hall of Fame's Camp Invention summer camps; launched a new online resource EquIP HQ which features online games, interviews with inventors, and lesson plans for the classroom; hosted monthly webinars for K-12 educators to encourage and support the integration of IP activities into their STEM/STEAM curricula; and hosted the National Summer Teacher Institute, a multi-day professional development training opportunity designed to support elementary, middle, and high school teachers as they increase their knowledge of concepts of making, inventing, and IP creation and protection. The USPTO also developed and hosted its first-ever Master Teacher of Invention and IP Education Program to cultivate a national network of teacher-leaders who will empower fellow educators to foster invention and IP education in schools, districts, and communities.

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VIII. IT Modernization

The USPTO relies on technology for virtually all aspects of its business. In order to provide reliable, modernized systems to employees and the public, the USPTO is committed to improving the stability and delivery of its IT systems. The USPTO continues to invest in IT modernization and retire legacy systems. IT modernization efforts enable more secure, effective operations to support a national teleworking workforce.

The USPTO has stabilized and modernized critical systems for agency operations and IP examination. This includes moving to a new, modern data center, which is expected to be complete by July 2023. This move will enhance disaster recovery and improve the security, resiliency, and stability of systems in a new state-of-the-art facility. This data center will also provide the USPTO with the ability to launch new systems and move critical applications to the cloud that can improve the efficiency, speed, and resilience of IT systems.

Emerging technology using AI, Machine Learning, and robotic process automation all bring new, potential opportunities to the agency for its operations and workforce. These tools can serve as catalysts for operating efficiencies and enhancing the work of examiners, not replace them. In a human-first approach, the USPTO is deploying AI tools responsibly to assist patent examiners and the public with prior art searches.

IX. Conclusion

Chairman Coons, Ranking Member Tillis, Chairman Durbin, Ranking Member Graham, and all members of the Subcommittee, I appreciate your continued support of the goals, priorities, operations, and employees of the USPTO. We look forward to working with you to promote robust and reliable IP rights at home and abroad that incentivize innovation and bring that innovation to positive impact.

# # #

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Director Kathi Vidal –
Oversight of the United States Patent and Trademark Office
Questions for the Record
Submitted August 2, 2023

QUESTIONS FROM SENATOR COONS

1. In my view, if the Patent Trial and Appeal Board (PTAB) is meant to operate as an *alternative* to district court litigation, then the invalidity burden should be the same in both forums. The PREVAIL Act (S.2220), which I introduced earlier this year with Senators Tillis, Durbin, and Hirono, would change the burden of proof for invalidity at the PTAB to match the "clear and convincing" burden applied in district court. You appear to agree, as the "compelling evidence" standard for PTAB proceedings proposed in the U.S. Patent and Trademark Office's (USPTO) Advance Notice of Proposed Rulemaking (ANPRM) is essentially the same as the "clear and convincing" burden used in district courts. Should Congress simply make this change by statute?

2. In July 2023, you granted Director review of a PTAB decision issued in December 2021 that denied review of a challenged patent and still has a pending request for rehearing. How does your decision in this case—made more than eighteen months later—support the USPTO's strategic goal of promoting the efficient delivery of reliable intellectual property rights?

3. What is the average amount of time for the USPTO or the PTAB to decide Director review requests and rehearing requests in *inter partes* reviews and post grant reviews (collectively, AIA review(s))?

4. What is the average amount of time for the USPTO to issue a trial certificate in an AIA review once an AIA review is complete because the time for appeal has expired or any appeal has terminated?

5. What is the average amount of time for the Director or the PTAB to issue a decision on remand in an AIA review?

6. For each of the below sub-parts, please identify the number of AIA reviews and the corresponding AIA review numbers (e.g., IPR20XX-XXXXX).
    a. How many AIA reviews currently have Director review requests or rehearing requests that have been pending longer than 90 days?
    b. In the last three years, how many AIA reviews have had trial certificates issued more than 60 days after the AIA review was complete?
    c. How many AIA reviews currently have decisions on remand pending for more than 180 days?

7. The America Invents Act (AIA) provides that the USPTO is to recover its costs through charging user fees for its services. In cases before the U.S. Court of Appeals for the Federal

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Circuit, the USPTO has represented that the fees it charges for an AIA review are lower than the costs of an AIA review to the agency. *See Mobility WorkX, LLC v. Unified Patents, LLC*, No. 20-1441, Brief for Intervenor, ECF No. 54, at 31 (Nov. 9, 2020); *New Vision Gaming & Development, Inc. v. SG Gaming, Inc.*, No. 20-1400, Brief for Intervenor, ECF No. 42, at 9 (Nov. 16, 2022). The USPTO's recent fee-setting proceeding provides its costs and fees for AIA reviews. *See* USPTO, *Table of Patent Fees – Current, Proposed and Unit Cost*, http://www.uspto.gov/sites/default/files/documents/Patent-Fees-Current-Proposed-Unit-Cost-PH2023.xlsx (Apr. 2023) (setting forth USPTO's proposed fees). The table below, which was produced using the data in the USPTO's fee proposal document, illustrates that the USPTO proposes to continue to conduct AIA reviews at a loss to the agency.

Fee Code	Fee Category	Description	Current fee	Proposed fee	FY2020 Unit Cost	FY2021 Unit Cost	FY2022 Unit Cost
1406	PTAB fees	Inter partes review request fee – Up to 20 claims	$19,000	$23,750	$22,556	$23,052	$21,980
1414	PTAB fees	Inter partes review post-institution fee – Up to 20 claims	$22,500	$28,125	$39,531	$34,245	$37,563
1408	PTAB fees	Post-grant or covered business method review request fee – Up to 20 claims	$20,000	$25,000	$30,018	$34,287	$37,683
1416	PTAB fees	Post-grant or covered business method review post institution fee – Up to 20 claims	$27,500	$34,375	$42,414	$46,998	$49,198

a. Is the USPTO operating AIA reviews at a loss to the agency; that is, does the USPTO lose money when it conducts an AIA review?
b. Given that the fees the USPTO charges for an AIA review are lower than the costs to the agency, how is the USPTO making up those costs?
c. Are patent applicants being charged more fees to subsidize the costs of AIA reviews?
d. Why is the USPTO not charging petitioners for the full costs of AIA reviews?

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8. Hundreds or thousands of patents cover smart phones, but some have criticized pharmaceutical companies for seeking more than one patent related to a drug product. The USPTO's recent *Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights* (RFC) also appears to focus on pharmaceutical products.
    a. Does the USPTO treat patent applications from the pharmaceutical industry differently than patent applications from other industries?
    b. What objective evidence supports the changes to examination practice (e.g., restricting continuation practice, having the validity of patents "stand and fall" based on other patents) that the RFC contemplates?

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Questions from Senator Tillis
for Kathi Vidal
Witness for the Senate Committee on the Judiciary
Subcommittee on Intellectual Property Hearing
"Oversight of the
U.S. Patent and Trademark Office"

1. Following a series of Supreme Court cases, one critical requirement for obtaining a patent – whether a patent is eligible in the first place for patent protection under 35 U.S.C. § 101 – has become the opposite of a model of clarity.

   a. You stated during your confirmation hearing that you thought that more clarity around Section 101 was important. Do you still think that this is true?

   b. What has the USPTO done to provide greater clarity in this area?

   c. As innovation continues to rapidly develop in emerging technology areas such artificial intelligence, medical diagnostics and biotechnology, would greater certainty in what can be protected by patents further help fuel innovation?

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d. Would more clarity around what categories can be patented and those that cannot, such as natural laws and unmodified genes, help fuel innovation and help maintain American competitiveness?

e. Do you agree that the Patent Eligibility Restoration Act prohibits the literal patenting of the DNA in one's body?

f. Criticism has been raised regarding patents being obtained on frivolous or obvious ideas simply because they are tied to technology, such as a computer – something like the patenting of a method to propose marriage over the internet.

   Do you agree that the Patent Eligibility Restoration Act prohibits the patenting of something like a marriage proposal simply because a claim makes a passing reference to "doing it over the internet?"

g. Would you agree that the Patent Eligibility Restoration Act would go further than the current USPTO guidance can, under the current law, to

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provide better guidance to examiners, and by extension, to anyone seeking a patent?

2. What is the status of the USPTO "Deferred Subject Matter Eligibility Response Pilot Program?"

3. There are a wide range of proposals presented in the USPTO's April 2023 Advance Notice of Proposed Rulemaking. Several of which are in conflict with what is being considering in the PREVAIL Act.

   a. While Congress continues to explore legislative change, can you provide assurances that the USPTO is taking into consideration this proposed bipartisan bicameral legislation with regard to the steps that you are and will be taking?

   b. While it's vital that changes to PTAB be made, concerns have been raised about whether the USPTO has authority to make some of them without further Congressional authorization.

      Can you comment on the USPTO's position on the scope of the Director's regulatory authority versus when legislative action is required?

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4. Some court judges use the technique of putting both experts on the stand together and allow each to clarify where and why he disagrees with the counter-expert.

   Have the Administrative Patent Judges used this technique, and if so, why not?

5. Director review of PTAB decisions is required by the Supreme Court, though the review likely requires the assistance of subordinates who may not be Administrative Patent Judges.

   What policies and procedures do you follow to conduct Director review? How often are such decisions delegated to subordinates, and by what authority are you able to delegate such authority?

6. Cross-examination of experts is often crucial to determining credibility, sound basis of opinions, and therefore truth. Yet in IPR and PGR proceedings live testimony is rarely ordered.

   As many cases turn on the "battle of the experts," would it be reasonable to require live testimony by

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witnesses, at least for focused cross-examination? Would you support such a policy?

7. Last year, I sent two letters to the USPTO regarding findings published by the "Initiative for Medicines, Access & Knowledge" (I-MAK) on drug-related patents that appear to overstate the periods of exclusivity for many medicines based on their analysis of the relevant patent protection. The USPTO, in conjunction with the FDA, was asked to provide its own data on this topic.

   What is the current status of your investigation into this matter?

8. Concern has been raised regarding the European Union's recent proposal to create a new "competency center" that would attempt to set prices for standard-essential patents.

   Can you expand upon what you and the Administration have done, in particular, to push your European colleagues to reconsider this misguided proposal, and what you are planning to do going forward?

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9. In recent years, there has been growing concern about the involvement of foreign interests – and particularly of foreign sovereign wealth funds – in funding U.S. patent litigation. Currently, such parties are allowed to fund patent litigation with few restrictions, and there is no nationwide requirement that such funding be disclosed to the judge or opposing party.

   a. Do you agree that the involvement of foreign interests in funding domestic patent litigation raises significant concerns with respect to U.S. national and economic security?

   b. If so, do you think that U.S. law should require disclosure when foreign interests – and particularly foreign governments – are involved in funding patent infringement suits against U.S. companies?

10. Currently, there appears to be little negotiation occurring between the USPTO of the United States Trade Representative and its Chinese counterpart on IP. This makes the USPTO's role, including its China-based attachés, even more important.

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Can you please tell us what related activities the USPTO both has, and is, engaged in?

11. What is your reaction to China's recently released new IP "abuse" rules and a proposed new guideline on SEP litigation and antitrust?

12. Concern has been raised regarding proposals by the USPTO to restrict or apply greater scrutiny to well established U.S. continuation practice (e.g., terminal disclaimers, continuation applications, continuation-in-part applications, and divisional applications).

    What is the objective evidence that the USPTO is relying upon to make the determination that such changes are needed?

13. Prior art searching by a Patent Examiner is a vital component to patent examination and strong patents.

    Do you agree that an emphasis should be placed on performing complete and thorough searches at all stages of prosecution?

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14. A significant aspect to searching prior art, when performed by a Patent Examiners, is looking for non-patent literature (NPL).

    a. What is the USPTO's long-term plan for improving the non-patent literature (NPL) sources that are available to Patent Examiners for use during examination?

    b. Does the USPTO need anything from Congress to help with making NPL more accessible?

15. For decades there has not been a major change to the time afforded to Patent Examiners for the examination of patent application, yet the nature of the technology from which these patent applications are derived and the complexity of this technology have only increased. In addition, the proliferation of prior art which Patent Examiners must search for and review, in order to make patentability determinations, has only increased and it has done so at a rapid pace.

    Do you believe that additional time should be afforded to patent examiners to examine patents?

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16. Over the years internal goal posts for defining "quality" for patent examination can shift annually within the USPTO. There is concern that this can potentially lead to confusion on the part of the Patent Examiner, because rather than having all aspects of quality examination equally reinforced, a single particular area becomes the primary focus for a given year.

    a. Do you have similar concerns about the shifting focus of "quality?"

    b. How can a more holistic approach to quality be achieved to ensure thorough, consistent, and high quality of examination of patent applications?

17. A recent Bloomberg report cited a scam where a Chinese company filed 2,000 applications under the name of a dead American lawyer. Scammers are impersonating trademark examiners, misusing the USPTO seal, and demanding payment on the threat of canceling a trademark registration. The Trademark Modernization Act of 2020 granted resources to the USPTO Register Protection Office and that the office has been sanctioning bad actors.

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a. What is the USPTO doing under your leadership to make the Registry work better and support American IP?

b. Does the USPTO require any additional tools?

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USPTO Responses to Questions for the Record – Chairman Coons
U.S. Senate Committee on the Judiciary
Subcommittee on Intellectual Property

"Oversight of the U.S. Patent and Trademark Office"
July 26, 2023
Witness: The Honorable Kathi Vidal, Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office
Submitted: September 21, 2023

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1. In my view, if the Patent Trial and Appeal Board (PTAB) is meant to operate as an alternative to district court litigation, then the invalidity burden should be the same in both forums. The PREVAIL Act (S.2220), which I introduced earlier this year with Senators Tillis, Durbin, and Hirono, would change the burden of proof for invalidity at the PTAB to match the "clear and convincing" burden applied in district court. You appear to agree, as the "compelling evidence" standard for PTAB proceedings proposed in the U.S. Patent and Trademark Office's (USPTO) Advance Notice of Proposed Rulemaking (ANPRM) is essentially the same as the "clear and convincing" burden used in district courts. Should Congress simply make this change by statute?

Response: The ANPRM did not itself seek to raise the standard for institution for all proceedings, nor did it seek to modify what burden of proof would ultimately apply in patentability determinations made by the PTAB, but instead sought input the USPTO will use to determine whether a petition presenting compelling merits should be allowed to proceed even if that petition would otherwise be discretionarily denied (for example, on the basis of pending parallel litigation in district court). As noted by the Office of the Federal Register, the optional ANPRM step is used to solicit "comments aimed at developing and improving the draft proposal or by recommending against issuing a rule."[1]

Congress has the sole authority to change the burden of proof for invalidity at the PTAB. The USPTO is ready to provide technical assistance to Congress based on the USPTO's technical expertise in this area including its experiences exercising discretion to deny AIA proceedings in view of parallel district court litigation as well as the feedback it received in response to the ANPRM.

2. In July 2023, you granted Director review of a PTAB decision issued in December 2021 that denied review of a challenged patent and still has a pending request for rehearing. How does your decision in this case—made more than eighteen months later—support the USPTO's strategic goal of promoting the efficient delivery of reliable intellectual property rights?

[1] https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf (*How does the agency involve the public in developing a proposed rule?*)

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Response: As discussed in more detail below in response to Question 3, the median processing time for a Director Review request is 55 days. This period begins when a Director Review request email is received by the USPTO, and ends on the day that a decision on Director Review is issued. Occasionally, there are exceptional circumstances that cause a Director Review request to be a statistical outlier. As discussed in response to Question 6, such exceptional circumstances may include the complexity of the legal or technical issues presented in the case, such as issues of first impression. Accordingly, the Director may allow additional party briefing, permit amicus briefing, order discovery, conduct an oral hearing, and/or collaborate with other agencies when necessary. The USPTO makes every effort to ensure that Director Review requests are timely processed. The Director, and her advisory team, further ensure that each Director Review request is given thorough consideration and fair resolution – thereby promoting the reliability of the intellectual property rights involved.

3. What is the average amount of time for the USPTO or the PTAB to decide Director review requests and rehearing requests in inter partes reviews and post grant reviews (collectively, AIA review(s))?

Response: Director Review requests: In the twelve-month period from August 1, 2022 through July 31, 2023, the median amount of time for the USPTO to decide Director Review requests was 55 days and the mean was 67.5 days. This corresponds to the length of time from when a request for Director Review email is received until a decision on Director Review is issued. This does not include any *sua sponte* grants of Director Review, which do not have a corresponding pendency period because they are not requested by a party.

Rehearing Requests: In the twelve-month period from August 1, 2022 through July 31, 2023, USPTO has identified 181 rehearing requests filed. Of those, 130 have been decided as of August 2023, with a median pendency of 73 days and a mean of 87 days.

4. What is the average amount of time for the USPTO to issue a trial certificate in an AIA review once an AIA review is complete because the time for appeal has expired or any appeal has terminated?

Response: After a proceeding fulfills the requirements of 35 U.S.C. § 318(b) for issuance of a trial certificate, the approximate average amount of time to issue a trial certificate in FY2023 (October 1, 2022-August 8, 2023) was 41 days. After a recent significant migration from PTAB's old IT system to its current IT system (Patent Trial and Appeal Case Tracking System or P-TACTs), the USPTO has recently been able to more accurately track AIA review proceedings through the Federal Circuit appeals process and make improvements to management of its data into a more centralized system. The improved trial certificate functionality was fully deployed in June 2022. This has led to a quicker and more efficient process for issuing trial certificates since the IT system migration.

5. What is the average amount of time for the Director or the PTAB to issue a decision on remand in an AIA review?

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Response: A proceeding on remand from the Federal Circuit often involves additional briefing from the parties and may involve submission of additional evidence and an oral hearing before the Board. In some rare instances, a remand may require a complete redo of an AIA trial.

For the first 10 months of FY2023 (October 1, 2022—July 31, 2023), the median amount of time for the PTAB to issue a decision on remand from the Federal Circuit in an AIA review was 178 days from the Federal Circuit's mandate and the mean was 202 days.

For FY2022 (October 1, 2021–September 30, 2022), the median amount of time for the PTAB to issue a decision on remand from the Federal Circuit in an AIA review was 181 days from the Federal Circuit's mandate and the mean was 244 days.

During FY2022, a number of additional AIA reviews involved a Federal Circuit remand for the limited purpose of allowing appellant the opportunity to request Director review, pursuant to the Supreme Court's decision in *United States v. Arthrex*, No. 19-1434 (2021). In these cases, the median amount of time for the Director to issue a decision (or for the PTAB to issue a forfeiture order) was 87 days from the Federal Circuit's limited remand order and the mean was 94 days.

6. **For each of the below sub-parts, please identify the number of AIA reviews and the corresponding AIA review numbers (e.g., IPR20XX-XXXXX).**
   a. **How many AIA reviews currently have Director review requests or rehearing requests that have been pending longer than 90 days?**

Response: Director Review Requests: As discussed above in Response to Question #3, the pendency of a Director Review request is calculated from the time a Director Review request email is received until a decision on Director Review is issued. There are currently no pending Director Review requests that have been pending longer than 90 days.

While none are currently pending more than 90 days, cases on Director review may occasionally take longer. Director Review requests often present complex legal and/or technical issues, including issues of first impression. Accordingly, the Director may allow additional party briefing, permit amicus briefing, order discovery, conduct an oral hearing, and/or collaborate with other agencies when necessary.

Rehearing Requests: Although USPTO does not discuss specific pending matters, generally speaking, requests for rehearing may take longer than 90 days, for example, in view of holds due to parties' concurrent requests for Director Review or review by the USPTO's former Precedential Opinion Panel (POP), holds to ensure consistency with other decisions in related proceedings having different schedules, additional briefing by parties, and the requirement for panels to comply with statutory deadlines in other docketed cases.

Proceeding No.	Req._Rhg._Date	Status Notes
IPR2021-00799	16-Nov-22	Pending

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IPR2022-01127	02-Feb-23	Proceeding terminated as to one of two petitioners; pending
IPR2022-01223	28-Feb-23	Pending
IPR2021-01466	10-Apr-23	Pending

In addition, the following AIA proceedings have panel rehearing requests that previously were held pending determinations on concurrent requests for POP review:

Proceeding No.	Req._Rhg._Date	Date Returned to Panel	Status Notes
IPR2022-00279	29-Jul-22	5-Oct.-22	Additional briefing filed; pending
IPR2022-01356	17-Mar-23	18-Apr-23	Pending
IPR2022-01357	17-Mar-23	18-Apr-23	Pending
IPR2022-01358	17-Mar-23	18-Apr-23	Pending
IPR2022-01359	17-Mar-23	18-Apr-23	Pending
IPR2022-01523	17-Mar-23	8-May-23	Pending
IPR2022-01257	06-Mar-23	25-May-23	Pending
IPR2022-01258	06-Mar-23	25-May-23	Pending
IPR2023-00049	27-Apr-23	7-Jun-23	Pending
IPR2023-00050	27-Apr-23	7-Jun-23	Pending
IPR2022-01522	5-May-23	8-Jun-23	Pending
IPR2022-01497	25-Apr-23	27-Jun-23	Pending
IPR2022-01545	25-Apr-23	27-Jun-23	Pending
IPR2022-00449	31-Aug-22	24-Jul-23	Pending
IPR2022-00450	31-Aug-22	24-Jul-23	Pending

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IPR2022-00628	26-Oct-22	24-Jul-23	Pending
IPR2022-00629	26-Oct-22	24-Jul-23	Pending
IPR2022-00701	26-Oct-22	24-Jul-23	Pending
IPR2022-01236	21-Feb-23	24-Jul-23	Pending
IPR2022-01388	02-Mar-23	24-Jul-23	Pending

b. In the last three years, how many AIA reviews have had trial certificates issued more than 60 days after the AIA review was complete?

Response: In the last three years, there have been approximately 1,235 proceedings that have had trial certificates issued more than 60 days after the proceeding fulfilled the requirements of 35 U.S.C. § 318(b) for issuance of a trial certificate. The vast majority of these proceedings were prior to the deployment of P-TACTs (PTAB's new IT system).

As explained in the response to Question 3, P-TACTS provided significant enhancements over the prior system. Prior to the deployment of P-TACTS, PTAB did not have the ability to track a proceeding through the appeals process at the Federal Circuit. The trial certificate issuance process relied on manual tracking and multiple data repositories outside the IT system. With the deployment of P-TACTs, the USPTO has made significant improvements to the trial certificate issuance process. The USPTO will continue to refine and improve its processes to minimize the amount of time to issue a trial certificate.

c. How many AIA reviews currently have decisions on remand pending for more than 180 days?

Response: There are currently no AIA reviews that have decisions on remand from the Federal Circuit pending for more than 180 days since the Federal Circuit's mandate.

In one set of AIA reviews—IPR2018-00766, -00767—the Federal Circuit issued a limited remand order for the PTAB panel to consider an issue of first impression: the impact of an inventorship correction in an AIA proceeding made after the PTAB's final written decision. However, the Federal Circuit retains jurisdiction of the case since no mandate has been issued. Thus, a decision on remand for this case has been pending for more than 180 days since the Federal Circuit has not issued its mandate.

7. The America Invents Act (AIA) provides that the USPTO is to recover its costs through charging user fees for its services. In cases before the U.S. Court of Appeals for the Federal Circuit, the USPTO has represented that the fees it charges

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for an AIA review are lower than the costs of an AIA review to the agency. *See Mobility WorkX, LLC v. Unified Patents, LLC*, No. 20-1441, Brief for Intervenor, ECF No. 54, at 31 (Nov. 9, 2020); *New Vision Gaming & Development, Inc. v. SG Gaming, Inc.*, No. 20-1400, Brief for Intervenor, ECF No. 42, at 9 (Nov. 16, 2022). The USPTO's recent fee-setting proceeding provides its costs and fees for AIA reviews. *See* USPTO, *Table of Patent Fees – Current, Proposed and Unit Cost*, http://www.uspto.gov/sites/default/files/documents/Patent-Fees-Current-Proposed-Unit-Cost-PH2023.xlsx (Apr. 2023) (setting forth USPTO's proposed fees). The table below, which was produced using the data in the USPTO's fee proposal document, illustrates that the USPTO proposes to continue to conduct AIA reviews at a loss to the agency.

Fee Code	Fee Category	Description	Current fee	Proposed fee	FY2020 Unit Cost	FY2021 Unit Cost	FY2022 Unit Cost
1406	PTAB fees	Inter partes review request fee – Up to 20 claims	$19,000	$23,750	$22,556	$23,052	$21,980
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1416	PTAB fees	Post-grant or covered business method review post institution fee – Up to 20 claims	$27,500	$34,375	$42,414	$46,998	$49,198

a. Is the USPTO operating AIA reviews at a loss to the agency; that is, does the USPTO lose money when it conducts an AIA review?

Response: Yes, under the current fee structure, the unit costs for most AIA reviews exceed the fees paid for reviews with up to 20 claims.

b. Given that the fees the USPTO charges for an AIA review are lower than the costs to the agency, how is the USPTO making up those costs?

Response: Section 10 of the AIA requires patent fees to recover patent costs in the aggregate. The patent fee structure maintains cost recovery in the aggregate, instead of an individual fee level.

c. Are patent applicants being charged more fees to subsidize the costs of AIA reviews?

Response: The USPTO sets and collects patent fees in a manner to recover all patent related costs in the aggregate, rather than recover costs on a strict service-by-service basis. Accordingly, the cost of AIA reviews is recovered through aggregate patent fee collections. Patent maintenance fees, paid by patent holders that wish to maintain their intellectual property protection, currently comprise slightly more than half of all patent fees collected. Many USPTO services are partially subsidized by patent maintenance fee collections that do not have a unit recovery cost. Patent filing fees (i.e., applicant fees) only recover a portion of the unit cost for search and examinations performed and are also partially subsidized with maintenance fee collections. Therefore, patent applicants are not necessarily being charged more to subsidize AIA reviews.

d. Why is the USPTO not charging petitioners for the full costs of AIA reviews?

Response: As discussed above, the patent fee structure maintains cost recovery at the aggregate level. Additionally, per 35 U.S.C. § 311(a) and 35 U.S.C. § 321(a) the AIA, review fees should be set at reasonable amounts taking into account the costs of the review. "The Director shall establish, by regulation, fees to be paid by the person requesting the review, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the review." Changes to the review fees are being considered as part of the current rule-making process.

8. Hundreds or thousands of patents cover smart phones, but some have criticized pharmaceutical companies for seeking more than one patent related to a drug product. The USPTO's recent *Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights* (RFC) also appears to focus on pharmaceutical products.

a. Does the USPTO treat patent applications from the pharmaceutical industry differently than patent applications from other industries?

Response: No. The USPTO applies the same standards for patentability to all utility patent applications, regardless of technology area. All patent applications are examined for compliance with the requirements of eligibility, novelty, non-obviousness, adequacy of the specification under 35 U.S.C. § 112(a), clarity of claims under 35 U.S.C. § 112(b), and double patenting. Based on the complexity of the technology involved, examiners in different technology areas of the office are allotted different amounts of examination time. Additionally, examiners may be given more time for exceptionally complex cases on a case-by-case basis, e.g., to consider obviousness-type double patenting in large patent families.

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The Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (RFC) was issued as part of USPTO's response to President Biden's Executive Order 14036 to promote the interests of American workers, businesses, and consumers. The scope of the RFC was not limited to pharmaceutical patents but to improving the robustness and reliability of patents generally. The initiatives did not propose technology-specific changes to examination practice, and any initiatives that are implemented as a result of the RFC will be applied in a technology-neutral manner. The USPTO remains committed to treating all applications equally based on their merits.

b. What objective evidence supports the changes to examination practice (e.g., restricting continuation practice, having the validity of patents "stand and fall" based on other patents) that the RFC contemplates?

Response: The RFC sought input from the public on initiatives and topics directed at bolstering the robustness and reliability of patents while promoting innovation and competition, as well as to gather responses to inquiries from Congressional members.

For continuation practice generally, the USPTO's data show that continuation applications have tripled in the decade from 2011-2021 and, as of 2021, accounted for nearly a quarter of all serialized filings. The RFC seeks feedback on proposals such as whether the USPTO should revise the timing of filing a continuation or divisional application, or whether there should be greater scrutiny of continuation applications. At this time, the USPTO is not considering changing examination practice with respect to when a continuation or divisional application may be filed. That said the USPTO remains committed to issuing robust and reliable patents and will continue to refine internal quality review protocols and other practices to ensure continuation applications are appropriately examined.

With respect to having the validity of patents "stand and fall" together, the RFC asked whether a terminal disclaimer filed after an obviousness-type double patenting rejection should be an admission of obviousness; whether patents tied together by a terminal disclaimer should stand and fall together; and whether any changes need to be made to the patent system generally regarding obviousness-type double patenting. The USPTO continues to evaluate whether it can and should make changes, within its authority, to obviousness-type double patenting and terminal disclaimer practice in order to promote innovation and competition.

As acknowledged in the RFC, "multiple patents directed to obvious variants of an invention can pose a heavy burden on examiners because examiners are required to compare the claims in these multiple patents and pending applications to determine if the claims are patentably indistinct from one another such that a non-statutory double patenting rejection is proper." The USPTO is studying compliance rates for obviousness-type double patenting rejections in examination of patent applications in large patent families. The results of this study and the comments received in response to the RFC will be used to inform changes, if any, including potential rulemaking in this area.

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USPTO Responses to Questions for the Record – Ranking Member Tillis
U.S. Senate Committee on the Judiciary
Subcommittee on Intellectual Property

"Oversight of the U.S. Patent and Trademark Office"
July 26, 2023
Witness: The Honorable Kathi Vidal, Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office
Submitted: September 21, 2023

1. **Following a series of Supreme Court cases, one critical requirement for obtaining a patent – whether a patent is eligible in the first place for patent protection under 35 U.S.C. § 101 – has become the opposite of a model of clarity.**

   a. **You stated during your confirmation hearing that you thought that more clarity around Section 101 was important. Do you still think that this is true?**

Response: Yes. Providing greater clarity in the law, including around Section 101, will result in more efficiencies within our intellectual property and innovation ecosystem and will go a long way toward encouraging the investments in innovation the U.S. patent system was designed to incentivize and protect.

   b. **What has the USPTO done to provide greater clarity in this area?**

Response: The USPTO has developed and issued updated guidance on the examination of subject matter eligibility (SME) under § 101. In June 2020, the USPTO issued a revision to the ninth edition of the Manual of Patent Examination Procedure (MPEP), which consolidated and incorporated all prior guidance on subject matter eligibility and responded to public comments. The MPEP (particularly Sections 2103 through 2106.07(c)) is now the single source for the agency's patent eligibility guidance. The USPTO has also issued 46 examples providing eligibility analysis of various fact patterns to assist USPTO personnel and stakeholders in evaluating SME. The examples address a wide range of technologies, including artificial intelligence, biotechnology, business methods, computer-related inventions, diagnostic and treatment methods, pharmaceutical treatments, precision medicine, and software. The USPTO also conducted extensive training over several years to keep its patent examiners informed about SME issues and how to apply the USPTO's guidance when evaluating patent claims.

In June 2022, the USPTO published a report summarizing public views on how the current state of patent eligibility jurisprudence impacts investment and innovation in critical technologies. The following month, the "Director's Blog," entitled "Providing clear guidance on patent subject matter eligibility," summarized the work the USPTO has done on subject matter eligibility and invited the public to comment on the subject matter eligibility guidance. The USPTO extended the period to comment to the blog via a Federal Register Notice (FRN) on September 1, 2022.

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The USPTO received 33 comments in response to the FRN. The USPTO is evaluating the comments to determine next steps.

The AI-inventorship Federal Register Notice sought stakeholder input on the current state of AI technologies and inventorship issues under 35 U.S.C. §§ 101 and 115 that may arise in view of the advancement of such technologies, especially as AI plays a greater role in the innovation process. The USPTO received 69 written comments from a diverse group of stakeholders. The Office is in the process of considering the feedback and determining next steps.

The USPTO staff continues to engage with stakeholders to provide greater clarity in this area through participation in various public events.

In recent years, the USPTO has worked closely with the Department of Justice (DOJ) on multiple Calls for View of the Solicitor General (CVSG) briefs, in which the government asked the Supreme Court to either clarify how patent eligibility should be properly analyzed or to correct the Federal Circuit's misapplication of the Alice two-step framework. (*See e.g.*, *HP, Inc. v. Berkheimer*, No. 18-415; *Hikma Pharms. USA Inc. v. Vanda Pharms. Inc.*, No. 18-817; *Interactive Wearables, LLC v. Polar Electro Oy*, No. 21-1281; *Tropp v. Travel Sentry, Inc.*, No. 22-22.) The USPTO, in coordination with DOJ, continues to look for opportunities to participate as an intervenor or amicus in appropriate cases to assist in clarifying patent eligibility law.

c. **As innovation continues to rapidly develop in emerging technology areas such artificial intelligence, medical diagnostics and biotechnology, would greater certainty in what can be protected by patents further help fuel innovation?**

Response: Yes. The U.S. patent system can only play its role of incentivizing and protecting innovation, including in certain key technological areas, if it is clear that what technologies are protectable and if there is sufficient certainty in our laws to enable inventors and investors to rely on the patent grant.

d. **Would more clarity around what categories can be patented and those that cannot, such as natural laws and unmodified genes, help fuel innovation and help maintain American competitiveness?**

Response: Yes. The U.S. patent system can only play its role of incentivizing and protecting innovation, including in certain key technological areas, if it is clear that what technologies are protectable and if there is sufficient certainty in our laws to enable inventors and investors to rely on the patent grant.

e. **Do you agree that the Patent Eligibility Restoration Act prohibits the literal patenting of the DNA in one's body?**

Response: The Patent Eligibility Restoration Act of 2023, introduced in the Senate on June 22, 2023, states that "[a]n unmodified human gene, as that gene exists in the human body" is not eligible for patent protection. Thus, under this proposed language, an unmodified human gene as it exists in the human body would not be eligible for patent protection.

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f. **Criticism has been raised regarding patents being obtained on frivolous or obvious ideas simply because they are tied to technology, such as a computer – something like the patenting of a method to propose marriage over the internet.**

Do you agree that the Patent Eligibility Restoration Act prohibits the patenting of something like a marriage proposal simply because a claim makes a passing reference to "doing it over the internet?"

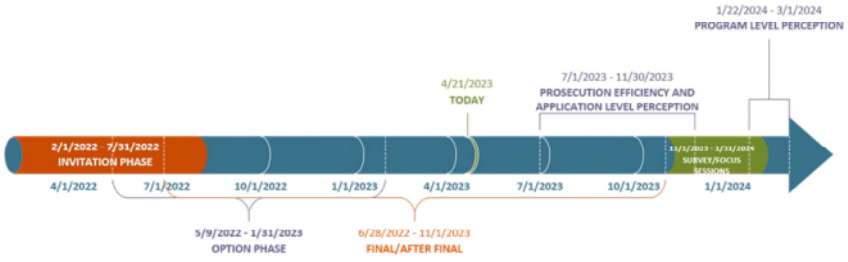
Response: The Patent Eligibility Restoration Act of 2023, introduced in the Senate on June 22, 2023, states that "a process that is substantially economic, financial, business, social, cultural, or artistic, even though not less than 1 step in the process refers to a machine or manufacture" would not be eligible for patent protection, unless "[t]he process described […] cannot practically be performed without the use of a machine or manufacture." Whether the scenario set forth in the question would be eligible for patenting under the proposed language set forth in the Patent Eligibility Restoration Act would depend on the specific claims of the patent application.

g. **Would you agree that the Patent Eligibility Restoration Act would go further than the current USPTO guidance can, under the current law, to provide better guidance to examiners, and by extension, to anyone seeking a patent?**

Response: The USPTO is required to follow current law, and the guidance set forth in the MPEP and the examples on SME follow the current law. The Patent Eligibility Restoration Act of 2023 seeks to change the current law by eliminating all existing judicial exceptions to patent eligibility and sets forth criteria for determining whether an invention is eligible for patenting.

2. **What is the status of the USPTO "Deferred Subject Matter Eligibility Response Pilot Program?"**

Response: A timeline for the pilot is set forth below. The USPTO is on course to complete the pilot by mid-year FY2024. Currently, around 85% of pilot applications have reached disposal. The USPTO is continuing to gather prosecution data and surveying examiners to assess impacts at the application level. The USPTO also plans to hold examiner focus sessions and develop an applicant survey to collect examiner and applicant feedback about the program. The USPTO currently expects to complete the focus sessions and the applicant survey by the end of the first quarter of FY2024 and to issue a final report by the second quarter of FY2024.



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3. **There are a wide range of proposals presented in the USPTO's April 2023 Advance Notice of Proposed Rulemaking. Several of which are in conflict with what is being considering in the PREVAIL Act.**

    a. **While Congress continues to explore legislative change, can you provide assurances that the USPTO is taking into consideration this proposed bipartisan bicameral legislation with regard to the steps that you are and will be taking?**

Response: The USPTO welcomes and will take into consideration the feedback it receives from all stakeholders, including Congress.

    b. **While it's vital that changes to PTAB be made, concerns have been raised about whether the USPTO has authority to make some of them without further Congressional authorization.**

    Can you comment on the USPTO's position on the scope of the Director's regulatory authority versus when legislative action is required?

Response: The Director's authority to prescribe regulations in general for USPTO is found in 35 U.S.C. § 2(b)(2), which provides that the Director may establish regulations, not inconsistent with law, which shall govern the conduct of proceedings before the USPTO. Other sections of the Patent Act authorize the Director to prescribe regulations concerning specific procedures, e.g., 35 U.S.C. § 135(b) provides that the Director shall prescribe regulations setting forth standards for the conduct of derivation proceedings. In the Leahy-Smith America Invents Act (AIA), Congress provided the Director with specific authority to prescribe regulations governing the conduct of AIA proceedings before PTAB, including regulations concerning inter partes review (35 U.S.C. § 316) and regulations concerning post grant review (35 U.S.C. § 326). When USPTO undertakes rulemaking in connection with PTAB proceedings, it relies upon the Director's authority provided for in Title 35 to prescribe such regulations.

As provided for in 35 U.S.C. § 2(b), the Director's authority to prescribe regulations extends to regulations that are not inconsistent with existing law. When USPTO undertakes rulemaking it does so within the bounds of this authority. The USPTO also welcomes the opportunity to provide technical assistance to Congress on any statutory language concerning proposed changes to PTAB procedures, or other Office proceedings.

4. **Some court judges use the technique of putting both experts on the stand together and allow each to clarify where and why he disagrees with the counter-expert.**

    Have the Administrative Patent Judges used this technique, and if so, why not?

Response: The PTAB receives relatively few requests from parties to present live testimony. The PTAB will hear live testimony at the oral hearing when it is helpful to the decision-making in that proceeding. For example, the PTAB has authorized live testimony on several occasions involving fact witnesses. A request for live testimony is more likely to be granted where the PTAB determines that the demeanor of a witness is critical to evaluating that witness's

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credibility, e.g., where an inventor is attempting to antedate a reference by establishing a prior reduction to practice. *See K-40 Electronics, LLC v. Escort, Inc.*, Case IPR2013-00203 (PTAB May 21, 2014) (Paper 34) (precedential).

Generally, the PTAB does not hear live expert testimony because the credibility of experts usually turns less on demeanor and more on the plausibility of their theories. The PTAB, which consists of technically trained and legally experienced judges, evaluates the expert's theories by considering the expert's declaration(s) and supporting evidence, any cited testimony of the expert elicited at deposition, and the underlying prior art references. Expert testimony that is conclusory and unsupported by evidence is typically entitled to little weight. *See Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 (PTAB Aug. 24, 2022) (precedential). This practice leverages the technical expertise of the judges and lowers costs to the parties.

While the PTAB has not yet employed the specific technique proposed, the PTAB would be open to using the proposed technique, if helpful in a particular case.

5. **Director review of PTAB decisions is required by the Supreme Court, though the review likely requires the assistance of subordinates who may not be Administrative Patent Judges.**

   What policies and procedures do you follow to conduct Director review? How often are such decisions delegated to subordinates, and by what authority are you able to delegate such authority?

Response: The USPTO has set forth its interim policies and procedures to conduct Director Review on the USPTO website at https://www.uspto.gov/patents/ptab/decisions/revised-interim-director-review-process. In July 2023, the USPTO updated the interim processes for Director Review stating that Director Review is available for decisions on institution and final written decisions of AIA post-grant proceedings. In general, a party may request Director Review of a decision on institution or a final written decision of an inter partes review or post-grant review by timely filing a request for rehearing of that decision and emailing the USPTO at Director_PTABDecision_Review@uspto.gov to request Director Review.

Although the USPTO has established an Advisory Committee, which includes representatives from different business units at the USPTO (and thus includes non-judge members), the determination of whether to grant or deny Director Review is exercised only by the USPTO Director. The Advisory Committee only serves to advise the Director, whereas all decision-making authority on Director Review resides with the USPTO Director.

The USPTO's July 2023 update provides that the Director may choose to delegate Director Review to a Delegated Review Panel (DRP). The DRP comprises of executive judges from the PTAB and operates as a panel independent of the Director. However, the Director retains the ability to review decisions *sua sponte* from the DRP. This update also established an Appeals Rehearing Panel (ARP). The ARP consists of the USPTO Director, Commissioner for Patents, and the PTAB Chief Judge. The Director, in her sole discretion, may convene the ARP to *sua sponte* review a decision in an *ex parte* appeal, reexamination appeal, or reissue appeal.

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6. **Cross-examination of experts is often crucial to determining credibility, sound basis of opinions, and therefore truth. Yet in IPR and PGR proceedings live testimony is rarely ordered.**

   As many cases turn on the "battle of the experts," would it be reasonable to require live testimony by witnesses, at least for focused cross-examination? Would you support such a policy?

Response: As discussed in the Response to Question 4, the PTAB generally does not have live expert testimony in IPR and PGR proceedings. The PTAB's rules permit seven hours of cross-examination of opposing experts as part of "routine discovery." Thus, the transcripts of the cross-examination provide substantial information to the PTAB panel in its decision-making.

As also discussed above in Response to Question 4, live testimony is permitted on a case-by-cases basis when helpful to the PTAB in decision-making. While the PTAB has not yet employed the specific technique described in your question, the PTAB would be open to using the proposed technique, if helpful in a particular case.

7. **Last year, I sent two letters to the USPTO regarding findings published by the "Initiative for Medicines, Access & Knowledge" (I-MAK) on drug-related patents that appear to overstate the periods of exclusivity for many medicines based on their analysis of the relevant patent protection. The USPTO, in conjunction with the FDA, was asked to provide its own data on this topic.**

   What is the current status of your investigation into this matter?

Response: Over the past year, the USPTO, in consultation with the FDA, has completed this study and has drafted a report summarizing the results. The study provides an assessment and analysis of patent, exclusivity, and drug approval data to help inform USPTO and FDA's shared goals of fostering affordable access to medicine while incentivizing innovation. Specifically, the USPTO conducted a transparent analysis of a representative sample of drugs listed in the FDA's Orange Book between 2005-2018 using available public data points (e.g., patent numbers and exclusivities listed in the Orange Book, patent filing and issue dates, and drug application approval dates). Mapping the scope and duration of exclusivity and patent protections associated with a particular FDA-approved drug product can be complex and may inform but not fully reflect the time it took (or can be expected to take) for a generic or biosimilar version of that product to come to market.

8. **Concern has been raised regarding the European Union's recent proposal to create a new "competency center" that would attempt to set prices for standard-essential patents.**

   Can you expand upon what you and the Administration have done, in particular, to push your European colleagues to reconsider this misguided proposal, and what you are planning to do going forward?

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Response: The USPTO, along with other in the Department of Commerce, are closely tracking the European Commission's SEP proposal. On April 26, Secretary Raimondo testified before the Senate Appropriations Committee, indicating she shared Congress' concerns about the EU SEP proposal and that her team in Brussels had met with the EU to discuss the proposal. She also informed Congress that when she attended the U.S.-EU Trade and Technology Council in May, she would broach the SEP proposal with her EU colleagues.

The USPTO and others in the Department of Commerce are closely working with colleagues across the U.S. Government to engage with the EU on its proposed initiative We are carefully considering the proposal and its ramifications in detail. Moreover, the proposed regulation still needs to be passed by the European Parliament and the Council of the European Union to enter into force. Additionally, as I indicated in my Senate Oversight hearing, I've met with our colleagues at the European Union Intellectual Property Office and other stakeholders in Europe to discuss this issue. The USPTO held a public listening session on September 20, alongside the International Trade Administration and the National Institute of Standards and Technology, that gathered stakeholder views on the proposal.

9. **In recent years, there has been growing concern about the involvement of foreign interests – and particularly of foreign sovereign wealth funds – in funding U.S. patent litigation. Currently, such parties are allowed to fund patent litigation with few restrictions, and there is no nationwide requirement that such funding be disclosed to the judge or opposing party.**

    a. **Do you agree that the involvement of foreign interests in funding domestic patent litigation raises significant concerns with respect to U.S. national and economic security?**

Response: Where patent litigation funding is provided by foreign third parties, especially sovereign funds owned or under the control of governments hostile to U.S. interests, the USPTO agrees that concerns could arise about U.S. national and economic security.

    b. **If so, do you think that U.S. law should require disclosure when foreign interests – and particularly foreign governments – are involved in funding patent infringement suits against U.S. companies?**

Response: The USPTO supports a robust, reliable and transparent patent system.

10. **Currently, there appears to be little negotiation occurring between the USPTO of the United States Trade Representative and its Chinese counterpart on IP. This makes the USPTO's role, including its China-based attachés, even more important.**

    Can you please tell us what related activities the USPTO both has, and is, engaged in?

Response: The USPTO is pursuing five main lines of effort to protect America's innovators, creators, and brand owners.

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First, through its team of experts based at USPTO headquarters and in three cities in the People's Republic of China (PRC), USPTO engages and educates U.S. rights holders on the importance of IP protection, including outreach to American IP right holders on challenges in protecting and enforcing intellectual property rights in the PRC. These efforts include providing free online written materials designed to be especially helpful to small- and medium-sized enterprises, free in-person seminars and webinars featuring government, business, and academic experts on U.S. and the PRC intellectual property systems, such as the USPTO's "China IP Roadshows," and engaging with American rights holders in two-way information exchanges to accurately assess rights holders' needs and in private one-on-one meetings as requested, including consultations with the USPTO's PRC-based personnel.

Second, the USPTO engages with its counterparts at both the national and local levels in the PRC Government to advance U.S. interests, press for legal reform, provide training, and share illustrative rights holder experiences. The USPTO will continue to press the PRC to level the playing field for American companies and rights holders and to encourage the PRC to comply with its international and bilateral treaty obligations involving IP, including full implementation of all intellectual property commitments of the Economic and Trade Agreement between the Government of the United States of America and the Government of the People's Republic of China (also known as the Phase One Trade Agreement).

Third, the USPTO focuses on capacity building for protection and enforcement of IP in key countries along international trade routes, improving IP systems in key transit points around the world to reduce the flow of counterfeit and piratical goods.

Fourth, the USPTO serves as a resource for the executive and legislative branches to advise on PRC-related IP issues including the preparation of reports on critical IP issues, such as the PRC's use of subsidies for patent and trademark applications, which have cluttered IP registries and harmed legitimate rights holders. The USPTO will continue to serve as a resource for technical evaluation of draft legislation upon request.

Fifth and finally, the USPTO supplements bilateral engagement by coordinating with like-minded foreign governments bilaterally and in multilateral forums to pursue initiatives that address PRC IP concerns.

11. **What is your reaction to China's recently released new IP "abuse" rules and a proposed new guideline on SEP litigation and antitrust?**

Response: On June 29, 2023, the PRC State Administration for Market Regulation issued final revised "Provisions on Prohibiting Intellectual Property Abuse to Preclude or Restrict Competition" and on the same day a draft measure entitled "Anti-Monopoly Guidelines for Standard Essential Patents." The USPTO's views are consistent with the 2023 Special 301 report issued by the Office of the United States Trade Representative, which indicates that "[r]ight holders have raised concerns about the application of [the PRC's] Anti-Monopoly Law (AML) to the licensing of patents in certain instances[,]" including that AML enforcement could be "misused for the purpose of depressing the value of foreign-owned IP in key technologies." The USPTO agrees with the report's conclusion that it is critical that AML enforcement be "fair,

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transparent, and non-discriminatory" and "afford due process to parties", and that the competition law "should not be used when there is no harm to competition or the competitive process to advance industrial policy or other non-competition goals." Furthermore, the USPTO has recently issued a request for comments seeking feedback from U.S. stakeholders on standard essential patents.

12. **Concern has been raised regarding proposals by the USPTO to restrict or apply greater scrutiny to well established U.S. continuation practice (e.g., terminal disclaimers, continuation applications, continuation-in-part applications, and divisional applications).**

    What is the objective evidence that the USPTO is relying upon to make the determination that such changes are needed?

Response: The Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (RFC) sought input from the public on initiatives and topics directed at bolstering the robustness and reliability of patents while promoting innovation and competition, as well as to gather responses to inquiries from Congressional members.

For continuation practice generally, the USPTO's data show that continuation applications have tripled in the decade from 2011-2021 and, as of 2021, accounted for nearly a quarter of all serialized filings. The RFC seeks feedback on proposals such as whether the USPTO should revise the timing of filing a continuation or divisional application, or whether there should be greater scrutiny of continuation applications. The USPTO is not, at this time, considering changing examination practice with respect to when a continuation or divisional application may be filed. That said, the USPTO remains committed to issuing robust and reliable patents and will continue to refine internal quality review protocols and other practices to ensure continuation applications are appropriately examined.

13. **Prior art searching by a Patent Examiner is a vital component to patent examination and strong patents.**

    Do you agree that an emphasis should be placed on performing complete and thorough searches at all stages of prosecution?

Response: MPEP sections 904 through 904.02(b) set out the appropriate process for conducting the patentability search for a patent application. The USPTO instructs examiners to, after having obtained a thorough understanding of the invention disclosed and claimed in the application, conduct a search of the prior art as disclosed in foreign and domestic patents and published applications, as well as other published documents (non-patent literature). The USPTO also indicates that an inventor name search should be made to identify other applications and/or patents which may be applicable for double patenting.

The initial search should cover the invention as described and claimed, including the inventive concepts toward which the claims appear to be directed. Following the first Office action, however,

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the examiner need not ordinarily make a second search of the prior art. An additional search may be necessitated by the applicant's amendments to the claims in response to the first Office action to determine whether any more pertinent reference has become available subsequent to the initial prior art search.

Planning and conducting searches are also major activities in the Patent Examiner Performance Appraisal Plan (PAP) Quality element. Examiners are expected to both plan (i.e., identify the most appropriate strategies, reference sources, and classification relevant to the technology) and conduct (i.e., find and cite the closest or best prior art to make rejections under 35 U.S.C. § 102 and 35 U.S.C. § 103) a complete and thorough search in every application as early in prosecution as possible. To this end, the PAP Quality element further identifies exemplary activities related to search, such as searching the applicant's inventive concept as defined at the time of the first action on the merits and citing prior art on the record pertinent to significant though unclaimed features of the defined invention.

14. **A significant aspect to searching prior art, when performed by a Patent Examiners, is looking for non-patent literature (NPL).**

    a. **What is the USPTO's long-term plan for improving the non-patent literature (NPL) sources that are available to Patent Examiners for use during examination?**

Response: The USPTO maintains an extensive collection of NPL resources. The vast majority of these are available electronically and are primarily categorized as books, journals, and databases. The USPTO electronic library includes over 600,000 books, over 72,000 journals and access to over 40 commercial databases. The link below lists our available resources as of October 2021. https://www.uspto.gov/learning-and-resources/support-centers/scientific-and-technical-information-center-stic/prior-art

In addition to maintaining curation of the electronic library, our future plans include continuing our examiner education and information dissemination programs, focusing our Scientific and Technical Information Center research staff on assisting patent examiners with non-patent literature searching, and integrating access to electronic NPL sources into the primary search tool used by patent examiners and working overtime to federate that search mechanic to allow a single query language to work in all databases and collections.

    b. **Does the USPTO need anything from Congress to help with making NPL more accessible?**

Response: The USPTO always stands ready to work with Congress on ways to ensure that it issues robust and reliable patents, including ensuring a robust prior art search.

15. **For decades there has not been a major change to the time afforded to Patent Examiners for the examination of patent application, yet the nature of the technology from which these patent applications are derived and the complexity of this technology**

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have only increased. In addition, the proliferation of prior art which Patent Examiners must search for and review, in order to make patentability determinations, has only increased and it has done so at a rapid pace.

Do you believe that additional time should be afforded to patent examiners to examine patents?

Response: Timely issuance of high-quality patents by our examiners is critical to providing the certainty that businesses and entrepreneurs need to invest in, develop, and roll out innovative new products and services. The USPTO's strategic plan to issue and maintain robust and reliable patents and improve patent application pendency recognizes this, and the USPTO is diligently working to equip our examiners with the guidance, training, tools, advanced technology, and procedural resources they need to address increasingly complex patent applications. Application pendency and examination quality do not separately exist in vacuums. For example, too expeditious of an examination could result in uncertainty of rights in the marketplace due to insufficient patent quality, while drawn out, improperly focused, and overly detailed examination could impede a business or innovator's ability to make timely and cost-effective decisions. Thus, a careful balance is necessary.

Therefore, the time patent examiners are allotted to examine applications is a critical link between patent application pendency and quality. In fiscal year (FY) 2021, the USPTO implemented a process that revised the time allotted for examining patent applications. This implementation was possible due to an initial phase that started in FY 2020 and offered an increase in the base or minimum time patent examiners are allotted to examine each application. Through this revision, additional time is allotted for applications that contain particular attributes above a specified threshold, including the overall number of claims, the length of the specification, and the number of pages in any filed Information Disclosure Statement. Examination time is now also based on an application's classification "picture," which represents the full scope of technology covered in an application and accounts for multidisciplinary inventions. The new method for allotting examination time is more transparent and flexible as adjustments can be made as the patent examination or prosecution conditions change. This flexibility allows for maintaining the necessary time to ensure stakeholder confidence in the certainty of resultant patent rights and enables optimal pendency, cost, and quality levels. The USPTO continues to study the impacts of these changes on patent examiners and stakeholders, collecting information and feedback to develop targeted solutions to continue improving the processes by which time is allotted for examining patent applications. We are also evaluating whether further adjustments to examination time—or new, creative measures to make examination more efficient—may benefit patent quality, recognizing at the same time that such adjustments may affect patent pendency. The USPTO implemented AI solutions into examiner-facing search tools last fiscal year to ensure examiners have the best search tools possible and to aid in efficiently considering ever-increasing volumes of prior art. The USPTO also uses AI to route patents to patent examiners with the appropriate technical background. In regard to pendency, though the use of AI may have some impact, there are numerous non-technology factors which may have a more significant impact on pendency.

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These include pre-examination processes, the number of examiners on staff, examination time, and filing trends from applicants.

16. **Over the years internal goal posts for defining "quality" for patent examination can shift annually within the USPTO. There is concern that this can potentially lead to confusion on the part of the Patent Examiner, because rather than having all aspects of quality examination equally reinforced, a single particular area becomes the primary focus for a given year.**

    a. **Do you have similar concerns about the shifting focus of "quality?"**
    b. **How can a more holistic approach to quality be achieved to ensure thorough, consistent, and high quality of examination of patent applications?**

Response to 16a and 16b: The USPTO seeks to ensure robust and reliable patents by monitoring patent quality using a variety of indicators including patent quality metrics, process measures, and perception surveys.

The patent quality metrics are determined from a random sample of Office actions reviewed by the Office of Patent Quality Assurance (OPQA) for statutory compliance. For fiscal year (FY) 2023, through the end of quarter 2, the percentage of Office actions reviewed that meet statutory compliance for each statute is:

- 35 USC 101: 98.3%
- 35 USC 102: 96.4%
- 35 USC 103: 92.1%
- 35 USC 112: 94.5%

The granularity of data obtained by reviewing all claims in an Office action for statutory compliance provides meaningful feedback to Technology Center (TC) management and quality assurance specialists and facilitates the identification of quality trends, training opportunities, as well as an evaluation of recent training at the examining corps level and below. In addition to the random reviews that underpin the statutory compliance metric, OPQA conducts numerous other reviews throughout each fiscal year, often in partnership with the TCs.

The USPTO also leverages process measures that assist the agency in tracking the efficiency and consistency of the examination processes. This includes evaluating certain types of transactions in the Patent Data Portal (PDP) as well as use of a standard review form to identify trends and examiner behaviors indicative of best practices, potential quality concerns and consistency of practice.

Since 2006, the USPTO has conducted both internal and external stakeholder perception surveys semi-annually. The internal quality survey administered to patent examiners focuses on internal and external factors impacting examiners' ability to provide high-quality patent examination. The external survey gathers perceptions about examiners' adherence to rules and procedures and satisfaction with search and prior art. The results of these surveys are a vital quality indicator and used to validate other USPTO quality related metrics assuring alignment with our stakeholders' perceptions. While the survey questions remain static to facilitate longitudinal analyses, a single open-ended question is incorporated during each enumeration to explore current topics of interest to the USPTO, such as specific effects of recent quality efforts or considerations for pending

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quality initiatives The key performance measure obtained from the external perception survey is a quality Net Promoter Score (NPS) that measures the net difference of customers rating overall examination quality as "good or excellent" and those reporting quality of work product as "poor or very poor". An NPS target of greater than 50 is sought by USPTO, which is a widely-adopted threshold to signify the healthy performance of an organization. The quality-related NPS for USPTO has remained strong over the past two years and is currently well above target at 57. Recent improvements in the score can be attributed to a focus on response to applicant's arguments, a statistically-derived key driver of customer perceptions. The monitoring of these indicators supports the investigation of specific quality issues relevant to our stakeholder community as well as to the specific needs of each TC providing insight into whether patent quality is improving as well as whether a particular patent quality initiative is successful.

In addition to measuring the success of our ongoing quality initiatives, the USPTO continues to implement new initiatives including the Post Grant Outcomes, a collaborative effort between the Patent Trial and Appeal Board (PTAB) and the Patents (examination) division to establish a learning loop, which leverages and readily introduces PTAB decisions into patent examination to improve patent prosecution. In April 2023, the USPTO launched a new Research and Development (R&D) Unit to drive transformative innovation and improvements in patent examination practices. Focused on sound problem solving principles and data-driven decision making, the R&D Unit comprises a group of examiners drawn from all utility patent technology areas. The unit explores potential solutions to challenges faced in a complex examination system and then tests initiatives for efficacy and impacts on a multitude of factors, including quality, pendency, and employee and customer experiences. Using standardized procedures to create, develop, and analyze clear measures of success for the initiative allows the unit to determine whether the initiative is successful in meeting its stated objectives before the agency decides to pursue it on a larger scale.

17. **A recent Bloomberg report cited a scam where a Chinese company filed 2,000 applications under the name of a dead American lawyer. Scammers are impersonating trademark examiners, misusing the USPTO seal, and demanding payment on the threat of canceling a trademark registration. The Trademark Modernization Act of 2020 granted resources to the USPTO Register Protection Office and that the office has been sanctioning bad actors.**

    a. **What is the USPTO doing under your leadership to make the Registry work better and support American IP?**

Response: Protecting the Trademark Register from these scams and ensuring the accuracy and integrity of the registrations the USPTO issues and maintains remains a top priority of mine and the USPTO. The USPTO's Register Protection program includes tools that we can use internally as well as tools that our external stakeholders can use to fight scams. We continue to grow our capacity and are in the process of formally establishing the Register Protection Office (RPO).

Since mid-2021, we have issued over 300 orders for sanctions that have terminated over 19,000 invalid applications and sanctioned 3,500 invalid registrations. This year, we added a staff attorney to lead the investigation and monitoring of USPTO.gov accounts. This attorney

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recommends the suspension and take down of offending accounts whenever warranted. During this period, we suspended more than 40 USPTO.GOV accounts. We have also referred more than 50 individuals to the Office of Enrollment and Discipline for investigation and possible discipline.

Another internal Register Protection tool is Director-initiated expungement and reexamination nonuse cancellation proceedings that was established under the Trademark Modernization Act for those registrations that are not in use and to eliminate registrations emanating from scammers. Since mid-2021, we have instituted more than 150 Director-initiated proceedings against registrations that are not in use, with 1,466 goods and services cancelled and removed from involved registrations. The USPTO is also collecting evidence for use in several hundred more of these cases, most of which are linked to so called "specimen farms," which are e-commerce websites designed solely to incubate fake specimens of use to satisfy USPTO requirements.

The Post-registration audit is yet another internal tool through which the USPTO requests proof of use to establish that the mark is actually in use on the goods and service identified in the registration at the time of the maintenance filing and, if proof is not provided, the USPTO imposes a $250 penalty. The USPTO currently audits 5,000 registrations a year.

The USPTO also spends significant resources trying to get the word out to our customers to avoid scams that include impersonations of the USPTO, misleading solicitations, or unauthorized practitioners, and to contact us if they get scammed so the USPTO can gather information about evolving scams. The USPTO recently started sending out official "Welcome Letters" to trademark applicants to help them more quickly and easily navigate the trademark application process and connect them with relevant resources, including directing them to the USPTO's website that helps them protect against trademark scams. Unfortunately, like some many other industries, the USPTO has seen exponential growth in the number of trademark scams being reported to the USPTO. In FY2021, we counted 190 emails from customers about scams, which increased to 357 in FY2022, and exploded to 965 through the third quarter of FY2023. Our staff reviews each email that we receive, and we provide tips to help customers avoid being scammed and what they should do if they have fallen victim to a scam. Since the USPTO does not have criminal or civil enforcement authority, we are limited as to what we can do to help customers scammed by private actors. However, we will continue to partner with federal agencies who do have this authority.

In addition to our internal Register Protection tools, the USPTO also has external register protection tools that stakeholders can use to join us in our efforts to protect the register and to fight scams. One such tool is the Trademark Trial and Appeal Board (TTAB), where parties may file petitions to cancel a mark at the TTAB for fraud, abandonment, nonuse, or that an application or registration is void *ab initio,* which may be based on findings made in orders issued through our Administrative Sanctions program. Another tool created by the Trademark Modernization Act is the ability for third parties to file petitions to request institution of *ex parte* nonuse proceedings before the Director. We have received 357 third party petitions since 2021 and have instituted nonuse proceedings on the registrations identified in 182 of those petitions.

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As a result, we have cancelled a total of 2,302 goods and services. Third parties can also file letters of protest wherein they can submit evidence that the specimens of use submitted in a pending application are fake or fraudulent to the USPTO for consideration.

Through the end of June 2023, we received 122 Letters of Protest providing evidence of nonuse. The evidence was relevant in 58 of those cases and forwarded to the examining attorney for consideration. In about 18 of those cases, the evidence was used in a refusal to register, 15 cases are awaiting examining attorney action, and 3 cases expressly abandoned before examining attorney action.

b. **Does the USPTO require any additional tools?**

Response: The USPTO is evaluating whether additional tools are needed and stands ready to work with Congress to address this issue.

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July 26, 2023

The Honorable Chris Coons
Chairman, Subcommittee on Intellectual Property
218 Russell Senate Office Building
Washington, DC 20510

The Honorable Thom Tillis
Ranking Member, Subcommittee on Intellectual Property
113 Dirksen Senate Office Building
Washington, DC 205

Dear Senators Coons and Tillis,

I am writing on behalf of Unified Patents to present to you a brief summary of the over 14,500 public comments submitted in response to the U.S. Patent and Trademark Office's (USPTO) Advance Notice of Proposed Rulemaking (ANPRM). We respectfully request this letter be entered into the record for today's hearing.

Unified is a subscription-based membership organization with 250+ member companies of all shapes and sizes, ranging from small companies (*e.g.*, CD Universe, CCTV Camera Pros, DoctorsPartner), open-source coders, and regional cable companies (e.g., through organizations such as Open Invention Network, the Linux Foundation, and CableLabs), to large multinational corporations (*e.g.*, Ford, Paramount, Mastercard, Philips, Infineon, Pinterest). Members span industries and collectively represent many of the largest—and smallest—patentholders in America. Unified's singular mission has been to improve patent quality and deter unsubstantiated, abusive patent assertions by non-practicing entities (NPEs) worldwide.[1]

The overwhelming public response to the ANPRM was unprecedented—it was the most commented-on administrative patent-related action in the USPTO's history. Over 95% of all public comments (13,235, or 96.11%, to date), and more than 75% of unique comments (2,287, or 81.01% of unique comments, to date), opposed the ANPRM's proposals.[2] The concerns expressed by the myriad stakeholders across industry, the public, and interest groups highlighted the detrimental impact of the proposals that would make it harder to challenge invalid patents or impose new *ultra vires* standing requirements for petitioners. A wide range of comments demonstrated the changes would hurt the economy, inhibit innovation, and be burdensome to the government and

[1] *See* https://www.unifiedpatents.com/faq.
[2] *See* https://www.unifiedpatents.com/insights/2023/7/23/anprm-public-comments.

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productive businesses, increasing costs and complexity and running counter to Congress' original intent.

Stakeholders repeatedly emphasized their desire for the PTAB to be an accessible and efficient alternative to litigation, consistent with the intent of the America Invents Act (AIA). The proposals set forth in the ANPRM were widely criticized as inevitably raising drug prices, empowering NPEs, and hindering the USPTO's ability to address its own past mistakes, all at a substantial cost to the US government itself in implementing and administering them. And many influential commenters and scholars noted they lack the authority to legislate the changes.

Several recurring themes emerged from the thousands of comments submitted in opposition to the proposed changes:

1. **Concerns over NPEs**: Thousands of comments—9,584 comments posted to date, or 71.82% of all comments—highlighted the need to protect productive businesses of all sizes from abusive patent litigation by NPEs or patent trolls. Proposals that add procedural hurdles were feared to make businesses more vulnerable to costly and bad-faith patent infringement assertions.

2. **Harm to Small- and Medium-sized Entities (SMEs)**: Thousands of stakeholders specifically objected to new standing requirements that would limit who can petition for PTAB review. These requirements would restrict access to PTAB review, particularly affecting third-party entities that deter abuse by challenging invalid patents and protect SMEs from exploitation.

3. **Impact on Open-source Software:** Hundreds of comments from individual stakeholders and companies in the open-source community expressed concern that the proposed changes to post-grant proceedings would harm open-source software development. Accessible PTAB review was viewed as crucial to promote new, accessible software innovation.

4. **Inevitability of Higher Drug Prices:** Organizations in the pharmaceutical and health sectors strongly opposed the ANPRM's proposals, stressing that weak patents often delay medical progress and competition, increasing costs for patients and reducing access to essential medicines and technologies. Some commenters detailed numerous drugs that have gone generic and would not have been able to

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be challenged under the proposed rules, directly resulting in higher drug prices for American consumers.

5. **Economic Implications:** The proposed changes were widely opposed by various civic, business, and labor groups, as well as patent policy experts, practitioners, and bar associations, who all emphasized the negative economic consequences and higher costs associated with restricting access to the PTAB.

Given the unprecedented public response against the ANPRM's proposals, it would be unwise for the USPTO or Congress to proceed with new restrictions on PTAB review. Such actions would prioritize special interests over overwhelming opposition and hinder the progress of innovation and economic growth that underpinned the bipartisan AIA.

We respectfully urge you to consider the views expressed by the stakeholders throughout this ANPRM comment period and safeguard the existing PTAB processes that serve as a tool to challenge questionable patents and to promote innovation. We look forward to working with you and your colleagues to ensure that changes to patent policy are guided by the public's concerns and the best interests of the American economy.

Sincerely,

Unified Patents

cc: The Honorable Members of the Senate Committee on the Judiciary Subcommittee on Intellectual Property

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U.S. Chamber of Commerce

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July 26, 2023

The Honorable Dick Durbin
Chair
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Lindsay Graham
Ranking Member
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Chris Coons
Chair
Subcommittee on Intellectual Property
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Thom Tillis
Ranking Member
Subcommittee on Intellectual Property
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Chairs Durbin and Coons and Ranking Members Graham and Tillis:

The U.S. Chamber of Commerce's ("Chamber") Global Innovation Policy Center ("GIPC") appreciates the opportunity to share its thoughts regarding today's hearing entitled *"Oversight of the U.S. Patent and Trademark Office."*

While the Chamber supports and applauds many of the recent efforts undertaken by the United States Patent and Trademark Office ("USPTO"), especially Director Kathi Vidal's efforts to promote inclusive innovation, we are concerned about the impact of some of the agency's recent contemplated actions involving changes to proceedings before the Patent Trial and Appeal Board ("PTAB") and patent examination practices. We are especially concerned with the impact of potential changes to patent examination practices on the life-sciences innovation ecosystem. The Chamber's comments and concerns regarding recent USPTO actions can be summarized in the following six points:

1. USPTO's and Director Vidal's relentless focus on promoting inclusive innovation is necessary because more people must be engaged with the patent system to unleash American innovation. Congress should take all the necessary steps required to support the agency's efforts;
2. Congress should support USPTO's efforts to improve patent quality through enhanced examination processes, more technology, resources, and personnel by ending fee diversion and reappropriating previously diverted fees to the USPTO—but it should be highly skeptical of those efforts labeled as "quality" initiatives that, in reality, are veiled attempts to restrict the ability of innovators to secure legitimate patent rights. Many of the Office's initiatives outlined in its "Robustness and Reliability" and "PTO-FDA Collaboration" dockets unfortunately fall into this category

3. USPTO's contemplated changes to the PTAB, as envisioned in its advanced notice of proposed rulemaking (ANPRM), may make litigation before the PTAB operationally difficult and even less predictable, thereby potentially undermining the legal certainty needed by innovators and technology adopters, alike;
4. USPTO must renounce any measure that undermines the life-sciences innovation ecosystem, including contemplated changes to continuation practices, examination guidance, and so-called "collaboration" efforts with the Food and Drug Administration ("FDA");
5. USPTO must stick to its area of expertise and its critical jurisdictional mandate of granting patents that satisfy patentability, and refrain from participating in partisan agendas that seek to impose price controls on innovative products; and
6. USPTO must continue to be the United States government's champion for IP rights, taking an active role in advancing IP protections both domestically and globally.

Our concerns and suggestions are outlined in more detail below.

I. Inclusive Innovation Unleashes Economic Potential, Makes America Stronger, and Ensures America's Continued Global Leadership.

The Chamber applauds USPTO's focus on inclusive innovation. While USPTO has emphasized inclusive innovation in previous years, Director Vidal's dedicated focus on this issue should be commended. Since her confirmation as Director, she has relentlessly championed efforts to enhance and promote inclusive innovation, ensuring that all Americans, regardless of personal background, social, or economic status, are empowered to do what Americans do best: create the next best innovation that will change the world.

Unfortunately, far too many Americans are underrepresented in our patent system and face barriers to innovation and entrepreneurship. This is especially true for women and people of color. Research shows that, as recently as 2016, the "woman inventor rate" was only 12%, even though women account for more than half of the U.S. population.[1] For people of color, the patent gap is even more pronounced, with some studies suggesting that people of color only hold six patents per million people and patent less than half as many inventions as their Caucasian counterparts.[2] And due to the lack of sufficient data, it is difficult to quantify the patent gap for LGBTQ+ individuals, veterans, and those who face geographic and economic challenges.

These Americans face difficulty accessing the patent system for several reasons. Some lack a strong network of mentors to help them learn about inventing, patenting, and

[1] Robin Rasor, Testimony Before the Senate Judiciary Committee Subcommittee on Intellectual Property, *TRAILBLAZERS AND LOST EINSTEINS: WOMEN INVENTORS AND THE FUTURE OF AMERICAN INNOVATION, April 3, 2019* ("The number of patents with at least one-woman inventor increased from about 7% in the 1980s to 21% by 2016. Despite this increase, the percentage of all patent inventors that are women, or the annual "women inventor rate," reached only 12% in 2016, even though women represent close to 30% of the total science and engineering workforce.").

[2] Holly Fechner and Matthew S. Shapanka, *CLOSING DIVERSITY GAPS IN INNOVATION: GENDER, RACE, AND INCOME DISPARITIES IN PATENTING AND COMMERCIALIZATION OF INVENTIONS*, Technology and Innovation, Vol. 19, 2018.

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entrepreneurship.[3] Others, especially those lacking institutional support, resources, or legal backgrounds, face difficulties navigating the complex and confusing patent system. Many others lack the economic resources to hire attorneys and proceed through the costly patent prosecution process, especially since they will face additional costs to defend against patent infringements or the post-grant invalidation processes.

Promoting inclusive innovation and reducing the patent gap is a moral imperative and critical to America's economic and national security. Inclusive innovation could add trillions of dollars to our economy, creating tens of thousands of new businesses and hundreds of thousands of new jobs.[4] Like all jobs in IP-intensive industries, these jobs pay solid middle-class wages, provide stability, and allow their recipients to achieve the American dream.

USPTO and Congress should use every option on the table—including improving industry collaboration, strengthening the USPTO pro bono program, providing financial resources and educational materials, and establishing early mentorship networks—to achieve this goal. A whole-of-government and society approach is needed. The Chamber and its innovative members stand ready and willing to work with Members of Congress and USPTO to achieve this goal, and we hope you will take advantage of our diverse membership's expertise, experiences, and resources to promote inclusive innovation.

II. Efforts to Improve Patent Quality by Investing in More Technology, Resources, and Personnel is Warranted, and Congress Should Support Such Efforts by Ending Fee Diversion and Reappropriating Previously Diverted Fees Back to USPTO.

The Chamber praises USPTO's focus on improving patent quality[5] by investing in technology, resources, and personnel. As the Chamber noted in multiple recent submissions to the agency, many of our innovative and diverse companies have legitimate concerns around patent examination quality in their art areas. Investing in these critical topics will improve the patent examination process, lead to higher patent quality and stronger patent rights, and reduce excessive—and excessively costly—litigation.

Without repeating the Chamber's submission to the USPTO in full, we appreciate that so much of the agency's action is dedicated to the very common-sense, low-hanging fruit the Chamber previously identified: hiring more examiners, increasing coordination between art units,

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[3] Dr. Barbara Gault, Testimony Before the Senate Judiciary Committee Subcommittee on Intellectual Property, TRAILBLAZERS AND LOST EINSTEINS: WOMEN INVENTORS AND THE FUTURE OF AMERICAN INNOVATION, April 3, 2019.

[4] Lisa D. Cook, *Policies to Broaden Participation in the Innovation Process*, Policy Proposal 2020-11 (Washington, DC: The Hamilton Project, August 2020); Jennifer Hunt et al., *Why Don't Women Patent?*, National Bureau of Economic Research Working Paper 17888 (Cambridge, MA: National Bureau of Economic Research, March 2012).

[5] However, the Chamber does not support misguided attempts to restrict patents which are framed under the guise of improving patent quality. For example, as noted later in this submission, the entire "Robustness and Reliability" initiative is simply a veiled attempt to restrict biopharma innovators from being able to patent legitimate inventions in the guise of "quality."

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enhancing training, and providing new and updated prior art search software.[6] The Chamber fully supports and is intrigued by the USPTO's embrace of enhanced AI capabilities to ensure a more robust examination process. While so much of the policy conversation surrounding AI and patent examination focuses purely on improving prior art searches, the prospect of integrating AI applications into the *entire* examination process presents a unique opportunity to improve efficiencies, reduce examination time, and enhance patent quality and technological innovation.

While supportive of all these patent quality improvement measures, the Chamber reiterates its previous comment that such actions will take significant financial investments and resources which may be beyond the USPTO's current budgetary capabilities. To fully implement these measures and invest in the success of USPTO, the Chamber believes that USPTO needs access to all previously diverted fees. These fees, totaling almost $1.2 billion, have unfairly been withheld by Congress and must be appropriated to and invested in USPTO. The Chamber and its member companies stand ready and willing to work with you to secure these appropriations so that you may invest in the necessary tools needed to improve patent examination and patent quality processes.

The Chamber also encourages this Committee to engage in robust oversight of USPTO's implementation of the *Unleashing American Innovators Act*. As the Chamber noted in its comments on the USPTO's Draft 2022-2026 Strategic Plan, USPTO should quickly study its fee structure as mandated by that act. In doing so, the Chamber recommended that USPTO review whether the fees for examination match the actual cost. Additionally, the Chamber urged USPTO to explore what incentives are created by using maintenance fees to cover examination costs. To support this objective, the Chamber suggested that USPTO study the data related to the amount and timing of examination costs, examination fees, and maintenance fees. The Chamber also strongly urges this Committee to utilize its oversight responsibilities to ensure that USPTO appropriately and adequately implements the provisions of the *Unleashing American Innovators Act*.

III. The broad changes contemplated by the PTAB ANPRM, if effectuated as a final rule, may make litigation before the PTAB operationally difficult and even less predictable, thereby potentially undermining the legal certainty needed by innovators and technology adopters, alike.

As the Chamber noted in its comments submitted to the USPTO[7], we are concerned that proposals envisioned by the PTAB ANPRM may undermine predictability if effectuated in a final rule. These concerns are two-fold.

[6] *See* GIPC comments to USPTO on robust and reliable patent rights, February 2, 2023; *See also* GIPC comments to USPTO on 2022-2026 Draft Strategic Plan, February 17, 2023.
[7] *See* Chamber of Commerce to USPTO on Advance Notice of Proposed Rulemaking, RIN No. 0651-AD47 (PTAB), June 20, 2023.

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First, many of the concepts, terms, and standards contemplated by the ANPRM appear vague, overbroad, or subject to ongoing change. For example, throughout the ANPRM, the agency indicates that it will use a "compelling merits" standard in several scenarios to determine whether to institute a PTAB proceeding. While the ANPRM does define what constitutes compelling merit, it does so by referencing a single precedential PTAB decision and a Director's memorandum, rather than a statute. Precedential decisions and memoranda can and do change, meaning the definition of "compelling merit" and how that definition is applied in the various institution scenarios envisioned by the ANPRM may change. In addition, at several points throughout the ANPRM, the USPTO asks stakeholders to define specific terms and concepts that will be utilized in making institutional decisions, further muddying the anticipated effect of the proposals.

Second, the Chamber believes that many of the concepts embodied in the ANPRM could prove to be operationally unworkable. Some proposed changes attempt to articulate what appears to be a clear rule on when an institution may or may not occur. This is the type of certainty—independent of any policy consideration—businesses need to make decisions. However, these same rules then contain multiple contemplated exceptions to their application based on various contextual factors, including potential litigation and the entity's size and financial status. Alleged bright-line rules containing numerous exceptions do not allow businesses to know if an institution against them will occur. If anything, the multitude of contemplated regulations on the institutions, each with its various exceptions, seems more likely to benefit litigators than inventors and end-users.

The Chamber strongly supports the goal of the ANPRM to add predictability, certainty, and reliability in PTAB proceedings to encourage investments in long-term, high-risk, capital-intensive innovation. However, given the wide-ranging and broad scale of the potential proposals in the ANPRM, it is not clear at this point that any future proposed rule would achieve this goal. If the USPTO proceeds with rulemaking, we urge scaling back the breadth of the recommendations and carefully reviewing whether proposals are consistent with the balance sought by Congress in the America Invents Act. This Committee must continue to exercise proper oversight over the USPTO as it engages in this rulemaking to ensure Congress's statutory intent is effectuated.

IV. USPTO must renounce misguided efforts that undermine America's life-sciences innovation ecosystem, including contemplated changes to patent examination practices and alleged "collaboration" efforts with other agencies.

As the Chamber indicated in its comments to USPTO earlier this year[8], we are alarmed by several contemplated agency actions. Specifically, the Chamber is concerned about proposals that would change life-sciences patent examination and continuation practices and to require so-called "collaboration" with non-expert agencies. While we appreciate and share the USPTO's goal of improving overall patent quality, we believe these efforts do not relate to quality, and are unwarranted, unsupported by evidence, and should be abandoned.

[8] *Id.*

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A. Contemplated Changes to Life-Sciences Patent Examination Practices.

As the Chamber noted in its February comments to USPTO, we do not believe that the agency's contemplated changes to life-sciences patent examination practices are in any way supported by independent, objective facts. All federal policymaking should be evidence-based and premised on the best available data. Effective and empirical research is the best metric for deciding if any policy should be undertaken. In contrast, the USPTO's contemplated proposals come in response to political hyperbole driven by activists that equate the mere existence of a duly issued patent with a barrier to market access.

In their request for comments, USPTO did not once reference any objective study or data point supporting the necessity for taking the scope of systemic regulatory actions contemplated. While advocates for weakened patent rights for life-saving treatments routinely cite studies that parrot false narratives regarding so-called "patent thickets" and "evergreening,"[9] these studies have been rightly criticized for their inaccurate use of underlying data, lack of transparency, and flawed methodology.[10]

The Chamber rejects the false and misleading narrative that so-called "patent thickets,"[11] a label that unfairly and inaccurately stigmatizes the necessity of filing additional patent claims (collectively, a "family") covering improvements to existing medicines, are responsible for high drug prices and do not represent true innovation. Scholars have demonstrated that biopharmaceutical "patent thickets" are mostly a myth.[12] If anything, both practice and reality suggest that more patents in a family strongly support innovation and economic growth, patient choice, and the public good. Innovation is not a one-off, siloed process. Often, when a life-sciences innovator files an initial patent claim, they do so in the early stages of research and development, years before an intended product reaches the market and all aspects of its applications and treatments have been clinically tested. Extensive clinical trials and investments in further research and development are required to discover subsequent health conditions that the initial product may treat, as well as a host of other innovations with direct patient benefit. From more effective delivery devices and improved and patient compliance, to alternate dosages and extended release formulations, mitigation of side effects, and even entirely new treatments, continuing innovations deliver invaluable benefits to patients and consumers. [13]

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[9] *See Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices,* The Initiative for Medicines, Access & Knowledge; *See also* Evergreen Drug Patent Search Database, University of California College of Law.

[10] Mossoff, Adam, *Unreliable Data Have Infected the Policy Debates Over Drug Patents*, Hudson Institute, January 2022.

[11] Individuals and organizations variously define a patent thicket in this context as the process of a branded company obtaining purportedly obvious variants of the same patent with the sole purpose of delaying the entry of a generic competitor. *See* Kristen Osenga, *Are "patent thickets" to blame for high drug prices, Richmond-Times Dispatch, Nov. 30, 2022.*

[12] *Id; see also* Mossoff, *supra* note 10.

[13] *Osenga,* supra note 11 ("It's no secret that drug manufacturers regularly continue to innovate drugs long after they're originally proven safe and effective. There are countless legitimate reasons to do so. Sometimes, post-market research suggests that a particular dosage or delivery method could be superior to the original.").

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Each stage of innovation requires new investment and risk, made possible by incentives like the potential for patent protection. For the life-sciences industry, this typically means decades of investment and risk for a single medicine. According to one study, the median cost of getting a new life-sciences innovation to market was $985 million, with an average overall cost of $1.3 billion.[14] Other studies estimate the cost, based on the amount of research and clinical trials required, could be as high as $2.56 billion.[15] The reality is that cutting-edge medical treatment, and the hope it gives patients with previously uncurable diseases and illnesses, is costly. To justify these substantial costs and investments, many of which never materialize or become profitable, innovators must have access to potential patent protection for innovation that arises throughout the product's development lifecycle. Simply put, given the significant costs associated with bringing any iteration of a product to market, without continuations to facilitate claiming of previously disclosed embodiments, or without the ability to secure full scope of protection through the use of terminal disclaimers and additional protections for follow on innovations, life-sciences companies cannot invest in new or improved versions of their medicines.

For the Chamber, the life-sciences innovation ecosystem, and the patent system that supports it, are working. Continued innovation, and the patent practices which facilitate it, provide innumerable benefits to patients, giving them better, more effective medicines and allowing public access to more data, which can and will spur future innovations. Moreover, current continuation practice and related practice concerning terminal disclaimers are crucial to the flourishing of this innovation – and are a foundational element of the US system that has promoted American innovation and continues to be a draw for investment in the pharmaceutical sector even when compared to other advanced economies. Continuations provide the flexibility to pursue protection for different inventions described in the initial patent description without fear that deserving inventions would lose protection solely due to earlier decisions to pursue a different embodiment. This not only promotes innovation but also facilitates efficient and higher-quality patent examination by dividing claim sets into more manageable pieces and, perhaps more importantly, provides incentives to accelerate disclosure of information to the public as inventors will have no fear that they would lose protection if an invention were disclosed in an application but not initially claimed. A restrictive approach to these applications or limits on terminal disclaimer practice would be counter to these policy goals.

The Chamber also notes that while proposals aimed at changing patent examination practices are targeted toward the life-sciences industry, such changes will, and must, apply to all sectors, consistent with the technologically neutral nature of the patent system. It is unwise for the agency to consider changes to examination practices, which will, under well-established US and international law, apply to all art units and technology sectors, simply to address a ***perceived and disproven*** problem in life science patent examinations.

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[14] *See generally* Wouters OJ, McKee M, Luyten J, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market*, 2009-2018, JAMA, March 3, 2020

[15] DiMasi JA, Grabowski HG, Hansen RW., Innovation in the pharmaceutical industry: New estimates of R&D costs, J Health Econ. 2016;47:20-33.

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Given this, the Chamber believes that it is wholly misguided for USPTO to proceed with its contemplated amendments to life-sciences patent application processes, which would needlessly put patient benefits, economic growth and consumer choice at risk. The Chamber urges the Members of this Committee to resist efforts by USPTO to make these harmful changes, exercise appropriate oversight, and hold the agency accountable if it attempts to do so.

B. Proposed Interagency Collaboration Efforts.

In general, the Chamber believes that inter-agency coordination is good governance. However, the current FDA collaboration initiative under consideration by USPTO fails to identify a problem[16] that needs to be solved, and is not so aimed. Rather, it appears to parrot anti-intellectual property activist language, and appears aimed at harmfully politicizing two agencies whose expertise and mandates have nothing to do with drug pricing. In our opinion, these initiatives are based on a false narrative that there are "too many patents on innovative medicines." This simplistic conflation of a single patent with a single medicine is technologically inaccurate and spectacularly counter-productive from a policy perspective and distracts USPTO and FDA from their core work and missions of granting patents that advance innovation, and evaluating and approving safe and effective innovative medicines that enhance human health and improve Americans' lives.

The USPTO's proposed collaboration also ignores the failures that have occurred from similar partnerships in other countries. As Members of this Committee may know, in 2021, the United States "welcome[d] limits on the role of Brazil's National Sanitary Regulatory Agency (ANVISA) on issues relating to the patentability of new pharmaceutical inventions but continues to monitor the situation in light of long-standing concerns about duplicative reviews by ANVISA of pharmaceutical applications."[17] The United States found that ANVISA's disastrous intrusion into patent matters in Brazil, and the lingering concerns about duplicative reviews, was damaging and undermining life-saving innovations.

The agency's current collaboration proposal shares similarities with many failed restrictions and measures the United States successfully, and rightfully, opposed in Brazil. It is perplexing that ideas long criticized by U.S. Administrations of both parties, such as involving drug regulatory agencies in patent examination, are now gaining currency in the United States.[18] Members of this Committee should encourage the agency to abandon its current misguided collaboration efforts and reject legislative efforts to require such collaboration.

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[16] *See* Emily Morris, Mark Schultz, and Joshua Kresh, *Response to Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (PTO-P-2022-0025)*, February 1, 2023; *See also* Erika Lietzan & Kristina Acri, *Distorted Drug Patents*, Washington Law Review v. 95, October 1, 2020.

[17] 2021 Special 301 Report, available at https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20(final).pdf

[18] See generally, comments to joint FDA-PTO listening session Jan. 19, 2023, available at https://www.regulations.gov/document/PTO-P-2022-0037-0001/comment

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V. Implementation of harmful price controls will limit the ability of American patients to access new, life-saving medications. As the expert agency, USPTO must advocate against the imposition of these policies.

In March, the Chamber released its *2023 Patient Access Report (Phase One)* ("The Report"). As the Chamber recently explained in a letter to Department of Health and Human Services ("HHS") Secretary Xavier Becerra, the Report confirms what proponents of the free market system already know: marketplace competition and effective intellectual property protections give patients greater access to the latest life-saving medicines.[19] In contrast, the Chamber's research shows that market-restrictive policies-like artificial price controls-deter future innovation, inhibit patient access, and ultimately limit patient choice.

Reducing barriers to access has long been a health policy priority and focus for Congress and the business community. The Chamber supports appropriate, practical efforts to help mitigate and overcome obstacles to accessing life-saving medicines. However, government price setting will create additional access challenges for Americans.

Unfortunately, many have accepted the flawed premise that government intervention and price setting is the most effective way to provide patients with life-saving innovations. This approach is embodied within the drug pricing provisions of the *Inflation Reduction Act* ("IRA"). While the IRA claims to promote access by controlling prices through so-called "negotiation," the reality is that innovators are forced to comply with the government's arbitrary and coercive price control scheme or face crippling penalties. At the same time, incentives to develop generic and biosimilar medications, one of the critical components in the innovative ecosystem in today's biopharmaceutical market, are virtually destroyed – embedding price controls in the U.S. market in a way that would be virtually irreversible for future generations of medicines.

The Chamber's Report cautions that the IRA's drug pricing penalties will harm patients by causing them to forfeit early and extensive access to the best life-saving medications. The Report's methodology shows that in other OECD countries which have implemented price controls, patients see fewer overall biopharmaceutical product launches, including biologics and oncology products, and have delayed access to medicines.[20] For example, before enacting the IRA's price controls, out of 104 new oncology products released globally, 80% were launched in the U.S., while only 58% were launched in Europe. Similarly, in several benchmark countries, patients can often wait up to several hundred days to receive access to life-saving treatments, waiting an average of 133 days in Germany and up to 500 days in Spain.[21]

The IRA's anticipated harms have revealed themselves through the numerous life-sciences innovators who have officially ended product research and development programs, explicitly citing

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[19] Ltr from David Hirschmann, President and CEO, Global Innovation Policy Center, to Secretary Xavier Becerra, March 22, 2023.

[20] The report found that fewer biopharmaceutical products overall launched in Canada, Japan, South Korea, Australia, and European Union member states than in the United States over the past 20 years.

[21] *Patient Access Report: Phase One*, Global Innovation Policy Center, March 21, 2023.

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the new price controls. In addition, research by The Pharmaceutical Research and Manufacturers of America ("PhRMA") shows that the IRA's pricing provisions may put the development of more than 400 medicines in the pipeline for leading chronic diseases affecting older Americans at risk.[22] This research indicates that these potential medicines under development target some of the most common yet seriously chronic diseases affecting America's seniors, including Alzheimer's, diabetes, and congestive heart failure.[23] Unfortunately, this report also demonstrates that the IRA's ill-conceived price controls are already having a "chilling effect" on research and development. According to the report, life-sciences innovators believe the IRA's current framework will undermine advances critical to patient well-being.[24] When asked, some 82% "or more of companies with pipeline projects in cardiovascular, mental health, neurology and cancers expect substantial impacts on R&D decisions...."[25]

These are just a few of the most prominent examples of innovative, life-saving products whose realization, availability, and access are ironically threatened by the IRA's price controls, which purportedly aim to improve access. As more information comes to light, it is likely to become clear that the most vulnerable patients – including older Americans, those diagnosed with rare diseases, and underserved populations– will pay the price for innovation lost to the IRA.

Unfortunately, instead of recognizing this growing body of evidence and changing course, the Biden Administration is doubling down and calling for even more restrictive price controls. Under the President's proposals, the number of life-saving medications subject to disastrous price controls could be quadrupled to as much as 40 products. In addition, the President's proposals would decrease the time such products could sell at fair market prices before arbitrary price controls kick in. Finally, the President's proposal would extend price controls to the private sector market.

To describe these additional price control policies as disastrous for American innovation would be an understatement. First, these proposals signal to America's life-sciences companies that there is no support for developing further inventions and cures. According to Nick Shipley, Chief Advocacy Officer for the Biotechnology Innovation Organization, the President's proposals would "further destabilize Medicare, slow critical investment in future research and development, stall drug innovation, and ultimately harm patients." This would, in sum, represent another blow to the millions of patients with debilitating diseases who depend on America's private sector to innovate new cures and treatments.

Government intervention in the market, especially establishing prices, undermines the innovation ecosystem that enabled the U.S. to become one of the most inventive countries in the world. As a practical matter, price controls nullify one of the critical rights associated with

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[22] Medicines in Development 2023 Report: The Leading Chronic Diseases Impacting Older Americans. Pharmaceutical Research and Manufacturers Association of America. Available at; https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/MID-Reports/MID-Chronic-Illness-Older-Americans-2023.pdf.
[23] *Id.*
[24] *Id.*
[25] *Id.*

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intellectual – or any other form of – property, putting biopharmaceutical innovation effectively on a non-market footing. As the expert agency tasked with advising the President and Congress on IP matters, USPTO must consider the implications of price controls for patients and engage with CMS before it proceeds further with implementing the IRA's framework, which would jeopardize U.S. leadership on biopharmaceutical innovation and access to treatments. In addition, USPTO must assert itself and resist calls to use the patent system as a form of price controls from this Administration and Congress.

The Members of this Committee should work with USPTO to rectify the harmful anti-innovation policies promoted by the IRA. The ability of American patients to access life-saving innovations in a timely manner depends on it. Indeed, the outcome of the IRA and further price controls—namely, less innovative medicines and longer wait times—isn't what any Member of this Committee or the USPTO wants to see.

VI. USPTO must continue to be the government's champion for IP rights, reassert its influence, and take a more active role in advancing IP protections both domestically and globally.

The Chamber appreciates USPTO's focus on global IP enforcement and collaborative stakeholder engagement. These are worthy and laudable efforts and are critical to USPTO's central mission as America's leading innovation agency. The Chamber particularly appreciates the USPTO's focus on global engagement through the Global IP Academy.

However, the Chamber also suggests that USPTO should take a more assertive, forward-leaning role on domestic and global IP issues, consistent with its role as the primary advisor to the President and the Administration on IP-related matters. The USPTO must take account of this reality and boldly assert that it, as opposed to another agency, should be leading the inter-agency process affecting IP policy decisions for the Executive Branch.

There are continuing challenges worldwide that deny adequate and effective intellectual property with a negative impact on crucial American industries that run the gamut from motion pictures to innovative pharmaceuticals. From global IP frameworks and protections to domestic policy, the expert agency must reassert its leadership and ensure that focus is not limited solely to particular enforcement goals. The agency should address global challenges for innovative American industry, including support for robust intellectual property at multilateral organizations. The Chamber believes that multilateral organizations can expand participation in the global innovation ecosystem for all countries by creating an effective rules-based framework to protect IP rights. Ongoing attempts to waive IP rights in the name of enhancing access are misguided, contrary to this goal, and will dismantle the global framework for innovation that will be critical to delivering the next generation of solutions for emerging challenges, be it future pandemics, access to health, or climate change.

Additionally, the Chamber is concerned with the proposed text before the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property

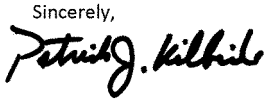
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and Genetic Resources, Traditional Knowledge and Folklore (IGC) which would establish new disclosure requirements in patent law for innovations based on genetic resources and associated traditional knowledge. The Chamber believes that the additional disclosure requirements will inject uncertainty into the international patent ecosystem and discourage investment in innovations that utilize genetic resources. Ahead of the diplomatic conference in 2024, the Chamber believes that USPTO can play a critical role in maintaining the current framework for patent disclosure requirements. The Chamber encourages Congress and Members of this Committee to provide USPTO with the resources, statutory authority, and support it needs to reassert itself as the principal agency on all aspects of global IP issues, including those under consideration within the multilateral organizations.

VII. Conclusion

The Chamber appreciates the opportunity to submit these comments for the record for this hearing. We stand ready and willing to work with this Committee to find ways to ensure the USPTO maintains patent quality, promotes inclusive innovation, and does not engage in practices that harm America's creative ecosystem, including those in the life-sciences.

Sincerely,



Patrick Kilbride
Senior Vice President
Global Innovation Policy Center
U.S. Chamber of Commerce

cc: Members of the Committee on the Judiciary

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PATRICK LEAHY
VERMONT

COMMITTEES:
AGRICULTURE, NUTRITION, AND FORESTRY
APPROPRIATIONS
JUDICIARY

United States Senate
WASHINGTON, DC 20510–4502

December 21, 2022

Dear Senator Hirono,

Thank you very much for your hard work with me and Senator Tillis recently to unanimously pass out of the Judiciary Committee the Unleashing American Innovators Act, S.2773. Your support meant a lot to me; it allowed the Judiciary Committee to unanimously pass our bill out of Committee; it allowed the Senate to pass the bill by unanimous consent as well; and it gave us the opportunity to include the text in this year's upcoming omnibus appropriations bill. I am excited to send this bill, alongside the rest of this year's omnibus, to President Biden's desk.

As I have said before, in Committee and on the Senate Floor, innovation is the lifeblood of the American economy. Going back centuries, our Founders had the foresight to enshrine the American spirit of rewarding innovation into our Constitution, pushing the United States to be the longstanding global leader in innovation. Unfortunately, like too many other aspects of our society, the benefits of our innovation ecosystem have not been felt equally by Americans from all backgrounds. The bipartisan Unleashing American Innovators Act will make the patent system more accessible to Americans from all backgrounds and ensure that we do more to harness our country's untapped potential.

This bill builds on the success of the 2011 Leahy-Smith America Invents Act, which built a network of U.S. Patent and Trademark Office (PTO) satellite offices around the country, bringing the PTO closer to where Americans actually innovate. This bill adds a satellite office and a network of smaller community outreach offices to boost participation from across the country, including from rural areas like Vermont. It further reduces patent application fees for small businesses, improves access to the patent pro bono program, and establishes a pre-prosecution assessment pilot program to give first-time prospective patent applicants a chance to make an informed decision about whether it is worth spending the time and money on a patent application.

All of these steps are designed to boost access to the patent system for underrepresented groups. A recent PTO study found that only twenty-two percent of U.S. patents list a woman as an inventor, even though women make up at least fifty percent of our population. Other studies have found that African Americans apply for patents at about half the rate of white Americans, controlling for factors like education. This bill represents Congress doing more to ensure that these and other underrepresented groups have the opportunity to participate in the system.

In Committee, you spoke so eloquently about this bill's purpose of unleashing the full power of all of the creativity in our country. That includes, particularly, as you said, unleashing the creativity of "women and minorities, who can be very much supported in the patent system, which is a very complicated system." As you fittingly stated, "whatever we can do to foster the ability of all of these groups and individuals to participate in our system will be a good thing.

And it certainly will be helpful to our economy." I fully agree, and our bill fosters that outreach to women and minorities.

During the Judiciary Committee's consideration of the Unleashing American Innovators Act, some members pointed out to me that it did not make sense to choose the locations of new satellite offices and community outreach offices based on the locations of women, people of color, or other demographic categories, as those demographics may change over time, and regardless, many of those demographic groups, like women, are dispersed throughout the country. In this Committee's great tradition of compromise, you, Senator Tillis, and I agreed to take out explicit references to women, people of color, and other demographic categories in determining where to locate new satellite offices and community outreach offices. That textual change does not mean, however, that the PTO is limited in the outreach it does, especially after a satellite office or community outreach office has been established. The PTO currently undertakes, and under this new legislation should increase its activities in outreach to women, people of color, and other underrepresented demographic groups.

By building on the structures we put in place in the Leahy-Smith Act ten years ago, we can ensure that the next generation of innovators in America reflects the full potential of our greatest natural resource—the genius of the American people. I am proud to have gotten this far, alongside you and Senator Tillis and the rest of the Judiciary Committee, on this important piece of legislation. Expanding access to the patent system is not a partisan issue; it is an issue of maintaining American competitiveness and extending opportunity to all Americans, no matter their background, demographics, economic status, or location. Thank you for your hard work on this issue.

Sincerely,



Senator Patrick Leahy

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