Patent Public Advisory Committee
2023 ANNUAL REPORT

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PATENT PUBLIC ADVISORY COMMITTEE OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

November 1, 2023

The President of the United States
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Re: The Patent Public Advisory Committee's Fiscal Year 2023 Annual Report

Dear Mr. President:

It is my honor and privilege to present you with the 2023 Annual Report of the Patent Public Advisory Committee (PPAC) of the United States Patent and Trademark Office (USPTO). Fiscal year 2023 marked the first full year of Director Vidal's tenure at the USPTO, and she has made an enduring and positive mark on the agency. While her work and progress are still ongoing, below are a few highlights from this year:

1. Linking patents and invention to increasing gross domestic product (GDP) and helping to ensure a robust U.S. economy.
2. Expanding the number and diversity of people who engage with the U.S. patent system, both geographically and demographically.
3. Continuing to be good financial stewards to ensure the patent system is both affordable and accessible to all participants.
4. Working collaboratively with other government agencies to ensure the USPTO has all the relevant data and information it needs to ensure it issues robust and reliable patent rights.
5. Increasing stakeholder engagement with numerous Request for Comments and Rule Making interactions. In fact, an Advance Notice of Proposed Rulemaking (ANPRM) relating to discretionary

institution practices in proceedings under the America Invents Act received a record number of stakeholder comments – over 14,000.

Yet there is still more work to be done. Since the early 2000s, the patent ecosystem has experienced a tremendous amount of environmental change and risk. In particular:

1. Judicial risk - the Supreme Court eBay[1], KSR[2], Alice[3], and Mayo[4] decisions fundamentally altered previous court precedent around the ability of a patent to exclude others, obviousness, 101 and patent eligibility.

2. Legislative risk – the America Invents Act (AIA) legislation changed the U.S. patent system from a first to invent, to a first to file system and significantly lowered the obstacles to challenge a granted patent, including the burden of proof, and the validity of the patent in post-grant proceedings before the Patent Trial & Appeal Board (PTAB).

3. Regulatory risk – the Federal Trade Commission has held several different views on whether and how patents are anti-competitive.

These collective changes to the patent ecosystem have led to IP stakeholder perceptions of increased ambiguity and uncertainty in the patent system. This year, the PPAC hosted a fee setting meeting to hear public comments on newly proposed user fees. What we heard in both oral and written comments, was:

- Overwhelmingly stakeholders were supportive of USPTO efforts to increase the reliability and predictability of patent rights. Many stakeholders would even be willing to pay more for obtaining a patent right, if it helped the agency improve the reliability of the right.
- Stakeholders are questioning why the USPTO needs to increase fees, when Congress could appropriate the $950 million dollars of user fees that have already been collected but not appropriated.
- User frustration over the increased perception of uncertainty within the patent ecosystem encompassing the USPTO, judiciary, regulatory agencies, and Congress.

Today, patents are sources of both value and risk for patent owners and political and geopolitical tools for nation states. This plurality of roles means that patent stakeholders including individual inventors, companies, universities, agencies, Congress and the courts are still learning about these new uses of

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1 ***eBay Inc. v. MercExchange, L.L.C.***, 547 U.S. 388 (2006), which drastically limited relief available to patent holders to stop further infringing activity (holding that in patent infringement cases a permanent injunction should not be automatically issued when a patent has been violated, absent exceptional circumstances but instead, a federal court must still weigh the four factor test traditionally used to determine if an injunction should be issued)

2 ***KSR Int'l Co. v. Teleflex Inc.***, 550 U.S. 398 (2007) (where the Supreme Court rejected the Federal Circuit's test for obviousness as it relates to patent validity as a too-rigid, too-narrow manner and makes obviousness easier to prove when asserting invalidity of a patent)

3 **Alice Corp. v. CLS Bank International**, 573 U.S. 208 (2014), Under Section 101 precedence and instruction to apply an abstract idea using a generic computer is not enough to transform that abstract idea into a patent-eligible invention. Petitioner's system and media claims are patent-ineligible, too, because they add nothing of substance to the underlying idea.

4 **Mayo v. Prometheus**, 566 U.S. 66 (2012), The patent claims say nothing significantly more than apply the law, i.e., apply the natural laws that they describe and that simple additional instruction, by itself, is insufficient to transform an otherwise unpatentable claim into a patentable one.

patents and how they affect the system today and in the future.

PPAC is proud to partner with the USPTO and Director Vidal to help prepare the USPTO for the upcoming challenges facing the agency over the coming years:

- The impact of artificial intelligence (AI) on both patent examination and validity and on inventorship, person of ordinary skill in the art (POSITA), and prior art.
- Examining USPTO patent and PTAB data since the implementation of the America Invents Act (AIA) legislated in 2011 to determine if the AIA implementation has led to the desired outcomes or if corrections and changes are needed.
- Collaborating with other government agencies to ensure the USPTO has all the relevant data necessary to ensure reliable and accurate patent examination.
- Working with the White House, Congress, the Department of Commerce and the Department of Defense to ensure that patents can help increase our national competitiveness (comprised of economic and technological competitiveness and national security).

This year PPAC created seven project teams to work with the USPTO on providing both the voice of the patent owner and our own collective insights and experience to USPTO operations: 1). Finance/Fee Setting; 2). FDA Collaboration; 3). USDA Collaboration; 4). AI and Search; 5). AI and Inventorship; 6). PTAB 7). Robust and Reliable Patents and 8). Expanding American Innovation

PPAC recommendations and highlights for improving the reliability and durability of the patent right are laid out in the attached report, however the following are particularly noteworthy;

1. **The USPTO's long-term fiscal stability is vital.** Ensuring that the USPTO is financially positioned with adequate resources for patent examination and other operations is of nationwide importance as explained above. In particular, the PPAC recommends Congress:

    a. promptly enact appropriations to avoid shutdowns or continuing resolutions that force the USPTO to deplete its operating reserve,

    b. extend or make permanent the agency's fee setting authority beyond 2026,

    c. appropriate or otherwise find a way forward on the approximately $950M in unavailable collected patent fees, and,

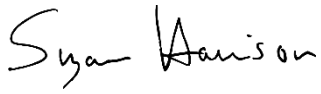
    d. provide the USPTO with greater flexibility in fee setting. Such an authority would help the USPTO maintain the sustainability of its fee funding model.

2. **The USPTO should continue to study AIA IPR outcomes and share such studies with the public.** These data are critical to understand why the PTAB and examination reach the same or different result and to enable continuous improvement of processes, as needed.

3. **The USPTO should continue to invest in search and examination capabilities and training.**

Thank you for your consideration of this report. We welcome any questions from you or your staff.

Respectfully,



Suzanne Harrison
Chairperson
Patent Public Advisory Committee
U.S. Patent and Trademark Office

Enclosure: Patent Public Advisory Committee Fiscal Year 2023 Annual Report

Cc: The Honorable Richard Durbin, Chairman, Senate Judiciary Committee
The Honorable Lindsey Graham, Ranking Member, Senate Judiciary Committee
The Honorable Chris Coons, Chairman, Subcommittee on Intellectual Property
The Honorable Thom Tillis, Ranking Member, Subcommittee on Intellectual Property
The Honorable Jim Jordan, Chairman, House Judiciary Committee
The Honorable Jerrold Nadler, Ranking Member, House Judiciary Committee
The Honorable Darrell Issa, Chairman, Subcommittee on Courts, Intellectual Property and the Internet
The Honorable Hank Johnson, Ranking Member, Subcommittee on Courts, Intellectual Property, and the Internet
The Honorable Gina Raimondo, U.S. Secretary of Commerce
The Honorable Kathi Vidal, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

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I. INTRODUCTION

A. EVALUATING THE AMERICAN INNOVATION DILEMMA

"U.S. Industrial competitiveness at home and abroad has become increasingly dependent on technological innovation. In all the dimensions of comparative advantage – price, quality, service, and innovativeness – U.S. producers are facing strong challenges by developed and developing countries alike. Because the United States has a strong research and development (R&D) capability, innovation is usually the most important edge that the United States has in meeting those challenges.

Innovation contributes to U.S. competitiveness both in high-technology and in basic manufacturing industries Aggressive R&D in product and process technologies will increase our ability to produce high quality goods at competitive prices.

Because innovation is the most important key to U.S. industrial competitiveness, the United States must maintain a domestic climate that is conducive to innovation and provides enough well-trained scientists and engineers. The United States must not overburden the innovative process with unnecessary regulatory requirements. It must promote the value of technology, knowledge and the innovative process, and, most important, it must nurture and cultivate the fruits of innovation – the intangible new ideas, theories, and advances in knowledge that underlie our industrial competitiveness." [5]

While the words and sentiments above ring true today, they are in fact from a 1985 Presidential Report on Industrial Competitiveness. In the late 1970's and early 1980's the United States technology supremacy was under challenge from Japanese Research & Development (R&D) and manufacturing prowess. Additionally, U.S. companies and investors were increasingly less willing to invest in technology development given the uncertain ability of patents to exclude others or provide tangible competitive advantage. Additionally, there was a strong call for action regarding new forms of protection for emerging technologies to ensure they were able to provide a competitive advantage for their nascent industries.

Many of these issues were first identified and analyzed under the Carter Administration and ultimately implemented under the Reagan Administration. This strategic change in the relationship between patents and competitiveness led to the creation of the Federal Circuit to reduce inconsistencies of Circuit court interpretations of patent law, thus strengthening the value of the patent right. Additionally, a Presidential panel was convened to create a report on Industrial Competitiveness which outlined over 30 recommendations over a variety of related topics to help better align government agencies, create tax incentives for companies and investors, and consider and address new forms of intellectual property (IP) protection for critical

5 Global Competition the New Reality, The Report of the President's Commission of Industrial Competitiveness, January 1985 Volume II, pg. 304

and emerging technologies.

United States history is littered with stories of how the courts' changing views on patents rights have affected patent owners. Some years Courts have strongly supported patent owners' rights and in other years, they have viewed patents as anti-competitive and/or monopolistic. What is interesting about the early 1980s efforts discussed above, was that two Administrations and Congress took a more holistic and strategic view of how patents related to national competitiveness.

Individual inventors, companies and investors utilize patents in a variety of ways to increase value to their business. But as with all business assets, while there is value, there is also associated risk and patents are no different. There are three main types of patent-related risk:

1. Intrinsic patent risk – the risks associated with the patent itself:
    a. Validity risk – will previously unknown prior art surface that anticipates the patented invention or renders it obvious or unenforceable?
    b. Enforceability risk – will a prosecution issue result in an inability to enforce the patent?
    c. Scope risk – Will a court construe the patent claims narrowly or broadly?'
    d. Design-around risk – Will competitors find a way to create commercial substitutes that avoid the patented claims?

2. Innovation risk – the uncertainty associated with the introduction of a new product, process or service. Examples of some elements of innovation risk are:
    a. Technology risk – will the technology ultimately perform as well as expected?
    b. Adoption risk – will it be accepted into the marketplace?
    c. Execution risk – will the company be able to commercialize the technology?
    d. Market risk – will a market evolve for this new technology or product?
    e. Infringement risk – will the technology be covered by one or more third party patents?

3. Environmental patent risk – the risk that an external entity will change the rules of the system in a manner that negatively impact patents. Such environmental risks include:
    a. Judicial risk – will a new court decision affect patent rights?
    b. Legislative risk – will a new law affect patent rights?
    c. Regulatory risk – will a new regulation affect patent rights?[6]

6 Harrison & Sullivan, "Edison in the Boardroom Revisited", John Wiley & Sons, 2013 pp.131-132

Since the early 2000s, the patent ecosystem has experienced a tremendous amount of environmental patent risk. In particular:

4. Judicial risk - the Supreme Court eBay[7] and KSR[8] decisions fundamentally altered previous court precedent around the ability of a patent to exclude others.

5. Legislative risk – the America Invents Act (AIA) legislation changed the U.S. patent system from a first to invent to a first to file system and significantly lowered the obstacles to challenging, including the burden of proof, the validity of the patent in post-grant proceedings before the Patent Trial & Appeal Board (PTAB).

6. Regulatory risk – the Federal Trade Commission has held several different views on whether and how patents are anti-competitive.

These collective changes to the patent ecosystem have led to IP stakeholder perceptions of increased ambiguity and uncertainty in the patent system. This year, the PPAC hosted a fee setting meeting to hear public comments on newly proposed user fees. What we heard in both oral and written comments, was user frustration over the increased perception of uncertainty within the patent ecosystem encompassing the USPTO, judiciary, regulatory agencies, and Congress. We understand our job at PPAC is to provide advice and perspectives from the public to the Director of the USPTO, but we would be remiss if we didn't highlight that many users are asking if it isn't time to think more holistically about the relationship between patents and national competitiveness?

7 ***eBay Inc. v. MercExchange, L.L.C.***, 547 U.S. 388 (2006), which drastically limited relief available to patent holders to stop further infringing activity (holding that in patent infringement cases a permanent injunction should not be automatically issued when a patent has been violated, absent exceptional circumstances but instead, a federal court must still weigh the four factors test traditionally used to determine if an injunction should be issued)

8 ***KSR Int'l Co. v. Teleflex Inc.***, 550 U.S. 398 (2007) (where the Supreme Court rejected the Federal Circuit's test for obviousness as it relates to patent validity as a too-rigid, too-narrow manner and makes obviousness easier to prove when asserting invalidity of a patent)

II. NATIONAL COMPETITVENESS

Both the Biden and Trump Administrations have made it abundantly clear that economic security is now national security. In the latest National Security Strategy, The Biden Administration stated, "*Technology is central to today's geopolitical competition and to the future of our national security, economy, and democracy. U.S. and allied leadership in technology and innovation has long underpinned our economic prosperity and military strength. In the next decade, critical and emerging technologies are poised to retool economies, transform militaries, and reshape the world.*"

Today, patents are sources of both value and risk for companies, and are both political and geopolitical tools for nation states. This plurality of roles means that patent stakeholders including individual inventors, companies, universities, federal agencies, Congress and the courts are still learning about these new uses of patents and how they affect the system today and in the future.

During her tenure, Director Vidal, has been working to tighten the link between economic and technological competitiveness and invention, specifically patents. PPAC is also committed to ensuring that the link between IP and national competitiveness (comprised of economic and technological competitiveness and national security) is explicit. In the 2022 PPAC annual report to Congress, we highlighted the rise of China as an innovation nation and the decreasing role the U.S. plays regarding global R&D.

The 2022 PPAC Report also observed that the world is embroiled in a global innovation race. One way our country can compete in such a race is to broaden our base of innovators and encourage more Americans to participate in the invention of new and more diverse and disruptive technologies. Fundamental to this goal is the assurance to individual inventors, universities, companies and investors that their efforts and investments will be sustainable through a robust and reliable patent ecosystem.

The USPTO has a substantial resource to assess progress, i.e., patent data. Patent data combined with demographic data can help us visualize who is and isn't participating in the innovation ecosystem. It can also help focus efforts on how to reach, attract and incentivize both new and underutilized inventors into the innovation ecosystem. We can enhance our economic and technological competitiveness by focusing on ensuring inclusion in innovation and invention processes for all future innovators*, with the confidence that they can protect and commercialize their patent rights*. Professor Lisa Cook, a former Edison Fellow for the USPTO and current member of The Board of Governors for the Federal Reserve, has observed that:

"If we quadruple the number of inventors, we could increase the overall level of U.S. GDP by up to 4.4 percent. For some reference, 4.4% percent of the $23 Trillion U.S. GDP in 2021 represents about $1 trillion in potential annual growth to the U.S. economy."[9]

Invention is directly tied to increasing our national Gross Domestic Product (GDP). Maintaining and growing GDP is the job of Congress and the White House. That growth is under threat from adversarial nations. Even without the advent of foreign competition,

9 2022 PPAC annual report: https://www.uspto.gov/about-us/organizational-offices/public-advisory-committees/patent-public-advisory-committee-ppac

strategies that would engage more Americans to participate more fully in our economic system is, in and of itself, a positive action. Given the legitimate threat from foreign innovators will persist in a fair and open market, a focus on creating a counter strategy to negate the domestic piracy of U.S. patents has become truly critical for both the U.S. and the USPTO. The PPAC encourages Congress and the USPTO to focus on each of the three components of national competitiveness (economic and technological competitiveness and national security) and understand how Congress and the USPTO can work collectively to strengthen each area from a patent perspective.

America's long standing economic prosperity and global leadership in innovation depends on first ensuring a level playing field for all inventors to create and protect their inventions. As a nation we also need every demographic to innovate, to seek and utilize patents where appropriate, to secure protection for their inventions as they move from inventions to technology development and ultimately to creating products and services to sell in the marketplace, reaping the ultimate reward from those efforts.

In summary, patents are now important building blocks for nation states and should be viewed as important elements of growing individual wealth, corporate wealth, state and national GDP and keeping our nation safe from our adversaries.

The first step is the granting of the patent right, which begins at the USPTO.

III. THE USPTO'S WORK

Against this backdrop, the USPTO – with advice of the PPAC – has been working over the past year on the following changes, initiatives and programs which are detailed below:

Work related to economic competitiveness:

- The USPTO has been working on the public perception of the USPTO and the patent system as one that is fair and impartial and worthwhile participating in by closing the loop between the PTAB and examiners, promoting guidelines used by both, advancing guidance and now promulgating rules around PTAB judicial independence and Director review, formalizing procedures relating to the PTAB, advancing guidance related to the PTAB to create more certainty and transparency, etc.
- The USPTO has been increasing and supporting more pro bono patenting efforts.
- The USPTO has been developing a national reciprocity relationship with our international trading partners that both incentivize the mutual respect for intellectual property rights, and has the teeth to disincentivize the piracy and counterfeiting of the trading partners intellectual property.

Work related to technological competitiveness:

- The USPTO has been prioritizing work on standard essential patents and critical & emerging technologies and collaborating with other relevant government agencies.
- The USPTO has worked to impart more certainty in patent eligible subject matter – continually adding examples to its Manual of Patent Examining Procedure (MPEP); and partnering with Congress to provide technical advice and expertise when needed.
- Ensuring U.S. positions in critical & emerging technologies such as artificial intelligence (AI), and climate change.
- The USPTO has been working through its AI/ET Partnership started under Director Vidal's leadership to advance AI and its use in patent examination as well as its effect on inventorship.

Work on national security:

- The protection of data.
- Ensuring continued integrity and transparency of patent data.
- Focus on increasing and diversifying STEM education pathways to ultimately increase the number of STEM students.
- Focus on diversifying IP practitioner pathways to ensure the IP ecosystem has a robust field of patent practitioners to meet our needs in the future.

IV. THE PURPOSE OF THE PATENT PUBLIC ADVISORY COMMITTEE (PPAC)

The American Inventors Protection Act of 1999[10], established a Patent Public Advisory Committee ("PPAC") to review the policies, goals, performance, budget, and user fees of the United States Patent and Trademark Office ("USPTO") in order to advise the Director of the USPTO on the same. Thereunder, the Secretary of Commerce ("the Secretary") is authorized to appoint nine individuals with a "substantial background and achievement in intellectual property, finance, management, labor relations, science, technology, and office automation" to serve on the PPAC for a three-year term. No voting member, however, may serve more than two consecutive terms. Importantly, at least one of the nine voting members must be an "independent inventor" and at least 25% of the PPAC members must represent "small entity patent applicants."

Statutorily, the PPAC must convene two public meetings a year, but the Chair can call additional meetings, in consultation with the Director. All PPAC meetings are open to the public, except where personnel, privileged or confidential information will be discussed. The Chair, in consultation with the Director, will post notice of all meetings, including an agenda or agenda description, on the USPTO's Web site (www.uspto.gov) five days in advance, so that members of the public may file written statements or questions prior to the meeting. Members of the public may make oral presentations only with prior approval of the Chair. Three non-voting members from Local Chapters 243 and 245 of the National Treasury Employees Union and the Patent Office Professional Association are also authorized to attend all PPAC meetings. All public meetings will be transcribed and posted on the USPTO's Web site for review.

Consistent with its statutory responsibility to advise the Director, PPAC members are authorized by 35 U.S.C. § 5(f) to request "records and information" from the Director, except for personnel, privileged, or information concerning patent applications required to be kept in confidence by 35 U.S.C. § 122. The work of the PPAC is reflected in a published Annual Report, due within 60 days after the end of the USPTO's fiscal year, which is transmitted to the President of the United States, the Secretary, the Director, and the members of the House and Senate Judiciary Committees.

The year 2023 marks PPAC's 24th year, and each Director of the USPTO has utilized PPAC in a different manner. Director Vidal utilizes the PPAC primarily to solicit opinions and advice on a variety of pre-decisional matters. Additionally, USPTO staff often seek PPAC input on a variety of different topics of interest. And finally, PPAC can solicit input from relevant stakeholders on topics of interest to the USPTO. This year we convened a meeting with select corporations and law firms on how they were using AI tools and the impact seen in their R&D groups, and the IP issues they view as relevant today and in the future.

Finally, it should be noted that PPAC members are allowed to work no more than 60 days each fiscal year.

10 Public Law 106-113, as amended by the Intellectual Property and High Technology Technical Amendments Act of 2002, Public Law 107-273

V. BEING GOOD STEWARDS: FINANCE

By statute, the responsibilities of the PPAC on finance include reviewing and advising the Director on the policies, goals, performance, budget, and user fees of the USPTO with respect to patents, holding a public hearing on the USPTO's patent fee proposals, and submitting a written report setting forth the committee's comments, advice, and recommendations following the public hearing.[11] This section reviews the financial nature of the USPTO's patents operations, discusses key initiatives and challenges that the USPTO has discussed with the PPAC, and provides recommendations PPAC has provided to the Director based on the PPAC's review of the USPTO 2023 Annual Financial Report and 2024 President's Budget Request.

A. BACKGROUND: HOW USPTO FUNDING WORKS

The USPTO's funding structure is unique among federal agencies, so for those unfamiliar with it, this section briefly provides background on the USPTO's operations and funding model.

1. Patent Examination

The primary driver of the USPTO's fiscal needs is the examination of patent applications by the about 8,500 patent examiners of the Patent Examining Corps. In FY 2023, the USPTO received over 515,000 new patent applications and granted approximately 340,000 patents. This core competency of patent examination is central to the USPTO's mission of driving U.S. innovation, inclusive capitalism, and global competitiveness for the benefit of all Americans. Timely and effective examination of patent applications protects innovators and the public, and ensures that issued patents are reliable, trustworthy, high-quality foundations for investment and progress. Examination is also skilled work, demanding technical knowledge, application of legal doctrines, and interpersonal relations with patent applicants to achieve positive outcomes.

HOW TO ASSESS THE EVER-INCREASING RATE OF TECHNOLOGY DEVELOPMENT
To help understand the ever-increasing rate of technological change, the first U.S. patent was granted in 1790. The millionth U.S. patent was granted in 1911, one hundred and twenty-one years later. In 1991, 80 years later, the 5 millionth U.S. patent was granted. In 2018, the 10 millionth U.S. patent was granted. In 2021 the 11 millionth U.S. patent was granted. In 2023, the USPTO granted 340,000 patents, which means that if the USPTO continues granting patents at the same rate as it did in 2023, it will take approximately 35 months to grant the next million U.S. patents. As AI becomes more ubiquitous, it is possible this time period could be significantly shortened in the future.

Direct costs of the USPTO's Patents program accounted for 71% of FY 2023 expenses ($2.9 out of $4.0B), of which 78% ($2.2B) went to personnel costs. The USPTO further expends resources on facilities, contracted services, and in-house technology that supports the Patent organization's mission.

11 35 U.S.C. § 5(d)(1) (general responsibilities); AIA § 10(d) (responsibilities related to fee setting).

2. The Fee Funding Model

Taxpayer dollars do not fund this important work of patent examination. Instead, USPTO patent costs are entirely offset by the fees that it charges patent applicants, patentees, and other users of the agency's patent-related services. In FY 2023, the USPTO reported fee collections of $3.6B from its Patents program, accounting for almost 89% of the agency's total fee collections.

Because of this model, the USPTO is often described as "fee funded," but the fee funding arrangement is subject to at least two important caveats. First, the USPTO does not have authority to spend its fees at will. Instead, collected fees are available to the agency only "[t]o the extent and in the amounts provided in advance in appropriations Acts,"[12] meaning that Congress must legislatively appropriate the USPTO's fee collections first. While Congress has recently appropriated the entirety of collected fees, it did not do so in the past, leaving about $950M of patent fees "temporarily unavailable" for use by the USPTO.

Second, being a government agency responsive to the public interest, the USPTO does not simply set its fees to recover costs on a service-by-service basis. In the interest of ensuring that the patent system is inclusive and widely accessible, the USPTO has set many fees below cost for patent examination and makes up the shortfalls created by these below-cost fees elsewhere among aggregate fee collections.

This policy manifests itself in at least two key aspects of the USPTO's fee structure. First, in accordance with statute, the agency provides a 60% discount on most patent-related fees for applicants and patent owners who qualify as "small entities."[13] Indeed, small entities who meet additional requirements may qualify as "micro entities" entitled to an 80% discount.[14]

Additionally, the USPTO has set its entry fees (that is, its fees for filing, search, and examination of patent applications) below the USPTO cost to perform these activities. The setting of entry fees below cost encourages entry into the patent system by all applicants, including small businesses and independent inventors. The cost of examination is subsidized by the payment of issue fees and post-issue maintenance fees paid after a utility patent is granted, both of which are set above the USPTO cost to perform these activities. Indeed, for an undiscounted utility application, the USPTO does not recover its costs for examining an application and issuing a patent until remittance of the second maintenance fee approximately seven and a half years after issuance. For this fee funding model to be sustainable, it is crucial that users continue to pay issue fees and maintenance fees.

The PPAC has reviewed the fee funding model and endorses it wholeheartedly. In the view of the PPAC, reducing the fee barrier to entry into the patent system promotes diversity, equity, and inclusion in innovation, thereby making the patent system accessible for all.

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12 35 U.S.C. § 42(c)(1).

13 35 U.S.C. § 41(h)(1).

14 AIA § 10(b), as amended by UAIA sec. 107. See the micro entity section of the USPTO website at www.uspto.gov/patents/laws/micro-entity-status for a detailed explanation of the qualifications for micro entity status.

B. FISCAL INITIATIVES

1. Operating Reserves

The USPTO maintains a patent operating reserve that is funded by unobligated carry-over balances from prior years and is available for the USPTO to spend without need for further appropriations. The operating reserve is a critical resource for weathering fluctuations in patenting activity, smoothing out irregularities in fee receipts, and mitigating delays in appropriations. Currently, the USPTO aims for an optimal level of operating reserves at about 3 month's expenses and a minimum level at about 1 month's expenses; the $942M in funds available at the end of FY 2023 is above the optimal level. The PPAC agrees with the USPTO's assessment of these operating reserves levels.

While the state of the patent operating reserves indicates the current financial health of the Patents program, the USPTO's forecasts show its patent operating reserve balance declining below optimal levels but staying above the minimum level by FY 2028.[15] According to the USPTO's analysis, there are at least two primary drivers of this anticipated decrease in the patent operating reserves. First, in the Unleashing American Innovators Act of 2022, Congress increased the fee discounts for small and micro entities to 60% and 80% respectively.[16] PPAC supports this effort that lowers barriers to the patent system and enhances inclusive innovation, but the law will also reduce USPTO fee collections by between $74 million and $110 million per fiscal year through FY 2028 according to USPTO estimates.[17] Second, pay raises and inflationary adjustments are expected to increase spending for the Patents program by about $173 million.[18] The USPTO has informed the PPAC that investment in recruiting, training, and promoting top-notch patent examiners is an agency priority, which the PPAC supports.[19]

The operating reserves are distinct from the Patent and Trademark Fee Reserve Fund (PTFRF). The PTFRF fund retains collected fees in excess of the annual appropriation, and those fees require additional Congressional approval in order to be available for the USPTO to use, as Congress has done for every year since the PTFRF was established.

2. Fee Setting Process

Since enactment of the America Invents Act in 2011, the USPTO has had authority under AIA Section 10 to "set or adjust by rule any fee" it charges for services, in order to recover aggregate estimated costs.[20] In order to adjust fees under this authority, the USPTO must first notify the PPAC of its proposed fees, require the PPAC to hold a public hearing and issue a public written report on the proposed fees, publish a proposed rule in the Federal Register, notify Congress, provide an opportunity for public comment, and issue a final rule setting the new fee levels.[21]

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15 Budget Request at 135 fig.1(d).

16 In Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. W, sec. 107(a), 136 Stat. 5518, 5521 (2022).

17 Budget Request at 159.

18 Budget Request at 140.

19 Budget Request at 25–26.

20 AIA § 10(a)(1)–(2). The USPTO also has authority to set fees for patent services to recover the estimated average cost of providing the service under 35 U.S.C. 41 § (d)(2), and authority to increase fees to reflect changes in the Consumer Price Index under 35 U.S.C. § 41(f).

21 AIA § 10(d)–(e).

This authority is currently set to sunset in 2026.[22]

A fee-setting proposal under this AIA fee process is currently underway. On May 18, 2023, the PPAC held a hearing on proposed fee adjustments. The PPAC published a report (attached here as an appendix) on the proceedings of that hearing and on the PPAC's views on the proposed fees, on August 14, 2023. As discussed in the report, the public commenters and the PPAC were supportive of many of the proposed fee increases, to the extent that those fees would bolster the USPTO's mission of quality patent examination by giving the Patent Examining Corps more examining time, training, and other resources.[23]

The USPTO has informed the PPAC that the agency anticipates the fee setting process to offset future costs and resolve the anticipated decline in the patent operating reserves.[24] The PPAC supports the USPTO's efforts to use its fee setting authority to recover aggregate costs and ensure the continued robustness of patent examination.

3. Other Cost Savings

Further in line with the agency's commitment to fiscal responsibility, the USPTO has informed the PPAC about several cost-saving measures it has taken recently. First, the USPTO plans not to renew leases on several buildings at its Alexandria, VA campus, by the end of 2024.[25] This and related changes are consistent with longstanding teleworking practices at the USPTO, and are expected to save between $27 million and $50 million per year.[26] Second, the USPTO continues to invest in technology to make its patent operations more efficient, potentially representing millions of dollars in cost savings per year.[27]

C. RECOMMENDATIONS

Based on the above information and on conversations with USPTO leadership, the PPAC is confident that the agency is financially moving in the right direction. The PPAC has also reviewed the USPTO FY 2024 budget and endorses it without reservation. The PPAC provides the following recommendations.

The USPTO's long-term fiscal stability is vital. Ensuring that the USPTO is financially positioned with adequate resources for patent examination and other operations is of nationwide importance as explained above. In particular, the PPAC recommends Congress:

1. promptly enact appropriations to avoid shutdowns or continuing resolutions that force the USPTO to dip into its operating reserve,
2. extend or make permanent the agency's fee setting authority beyond 2026,

22 AIA § 10(i)(2), as amended by the SUCCESS Act § 4.

23 PPAC fee report at 3–5.

24 PPAC fee setting letter at 1.

25 Budget Request at 10.

26 Budget Request at 82.

27 USPTO FY2022 AFR at 4.

3. appropriate or otherwise find a way forward on the approximately $950M in unavailable collected patent fees, and,
4. provide the USPTO with greater flexibility in fee setting. Such an authority would help the USPTO maintain the sustainability of its fee funding model.

KEY TAKEAWAYS
• The USPTO is in good shape financially and is a good fiscal steward. • Recovering the agency's aggregate costs and maintaining a sufficient operating reserve is crucial to the long-term ability of the USPTO to examine patent applications and accomplish its mission. Furthermore, as noted in the PPAC's fee setting report, the USPTO should ensure that some portion of revenues from fee increases go to providing patent examiners with greater time and resources for examination

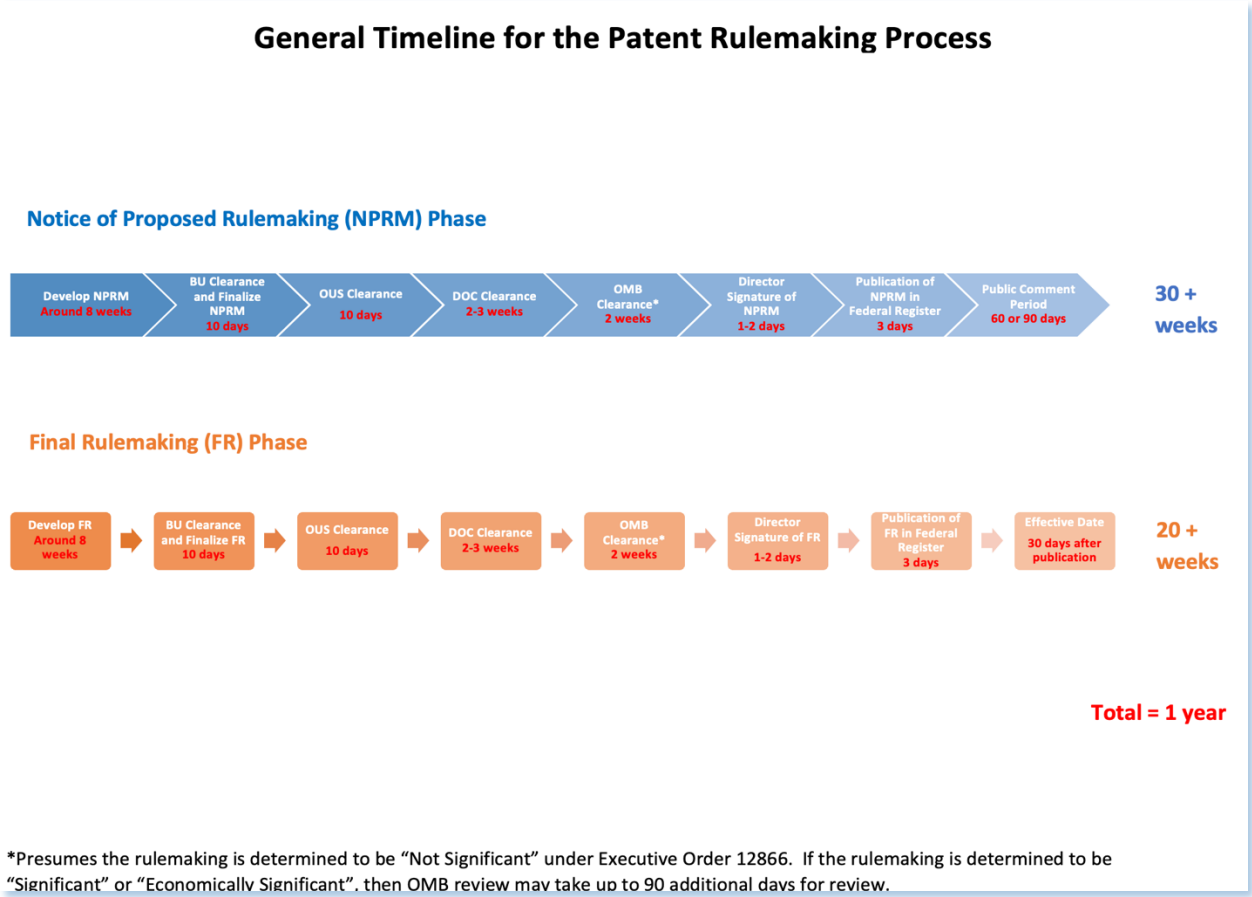
VI. KEY USPTO INITIATIVES IN FY 2023

A. RULEMAKING ACTIVITIES

Director Vidal, in her first full fiscal year of FY 2023, has undertaken a campaign of Listening Sessions with IP stakeholders to better understand what they feel is and is not working well with the USPTO and the IP ecosystem at large. She has also initiated a number of rulemaking processes based upon what she heard from stakeholders. The USPTO utilizes various methods to invite comment from the public on matters of interest, before implementing significant policies, changes, and rules. In particular, rulemaking is an extensive year long process comprised of distinct phases:

1. Advance Notice of Proposed Rulemaking (ANPRM): Optional notice published in the Federal Register for obtaining public input in the formulation of a regulatory change before the agency has made a decision on any particular proposal. In this phase, the USPTO has not committed to subsequent rulemaking, but is testing public reaction to different ideas. The USPTO typically does not use ANPRMs.
2. Notice of Proposed Rulemaking (NPRM): This notice is published in the Federal Register to inform the public of a regulatory change proposed by the agency. The USPTO chooses to issue patent NPRMs because it benefits from public input to shape final rulemaking. When publishing an NPRM, all written comments received in response must be considered.
3. Final Rulemaking: Required notice published in the Federal Register that promulgates the regulatory changes. In this notice, the agency also addresses the comments received in response to the NPRM.

Written comments are solicited, reviewed, and considered in the rulemaking process. Furthermore, public meetings, listening sessions, and public hearings are often held at the USPTO's discretion to engage in further dialogue for significant topics, including potential rulemaking.



Volume of USPTO Notices in the Federal Register and Written Comments Received in FY 2023

Type of Notice	FY 2023	Number of Comments
Final Rule	17	N/A
NPRM	2	20
ANPRM (optional)	1	14,530
Request for Comments (optional)[28]	32	700
Total	**52**	**15,250**

In FY 2023, the USPTO issued 52 rule-related notices in the Federal Register, sometimes taking into consideration up to hundreds or thousands of written comments per rule. This includes Request for Comments (RFC), which the USPTO uses to seek feedback on planned programs, projects, guidance, and other initiatives, often accompanied by a public engagement event for

28 Only counting RFCs with a comment period or announcing a public engagement event. Does not count administrative announcements without a response or engagement invitation.

live comments. Of notable interest is the ANPRM on Changes Under Consideration to Discretionary Institution Practices, Petition Word-count Limits, and Settlement Practices for America Invents Act Trial Proceedings Before the Patent Trial and Appeal Board (PTAB ANPRM) which received a record 14,530 comments. After reviewing the unprecedented number of comments to the ANPRM, the USPTO is now proceeding with the next phase, which will involve an NPRM that offers specific proposed rules, as well as another round of comments from the public thereafter.

The USPTO seriously and carefully considers the impact of all actions it takes and works with the public to balance all interests and determine the best solution. This clarity should help the public better understand an NPRM with specific rulemaking proposals that will trigger another opportunity for comments from the public as the Office proceeds with rulemaking. The USPTO commits to thorough and qualified decision-making in the journey of continuous improvement.

Making patents more robust and reliable is of great importance. There is no doubt that the USPTO has demonstrated significant effort, especially in FY 2023, to improving the patent system. Prioritizing and continuing such efforts is key.

B. ARTIFICIAL INTELLIGENCE AND HOW IT WILL IMPACT BOTH THE USPTO AND PATENTS

Artificial Intelligence (AI) is a transformative technology which combines computer science with robust datasets to enable rapid problem solving. AI is likely to have a transformative effect on both the USPTO and on patent law itself, however, we would like to focus our discussion on how AI impacts USPTO patent search and how AI affects inventorship determinations for patents.

AI and Patent Searching at the USPTO

The USPTO's use of AI tools in the future will likely affect patent examination in two areas, patent quality and classification. The USPTO already uses AI in limited ways to process patent applications. For example, when the USPTO receives a new patent application filing, it assigns the application with C* indicators, which identify which of the assigned Cooperative Patent Classification (CPC) symbols are relevant to the claims, from among the set of CPC symbols. Previously, this task was performed manually, but with the advent of AI, a machine learning tool has been developed that provides the C*s for the application filings. This has resulted in significant dollar savings for the USPTO.

Expansion to a fully AI-enabled classification process that will also assign the appropriate CPC symbols to an application filing is under development. PPAC cautions stakeholders that this process will not have any effect on examiner time but will further improve assignment of an application to the appropriate examiner.

The USPTO provides AI-based search capabilities in an examiner patent search tool which has been assisting examiners in finding potential prior art early in the examination process. The USPTO continues to evaluate other pathways for AI to assist in the patent search and examination process, including further enhancements to prior art search for examiners and the public.

The Future of AI Search from a POSITA Perspective

While AI's future promise in refining patent search is undeniable, it should be viewed as an auxiliary tool, complementing, not supplanting, the human intellect. Challenges such as understanding the Person having Ordinary Skill in the Art (POSITA) context, navigating complex situations, and managing inherent biases in AI underline the indispensable nature of human oversight.

While AI will augment search as a tool in the near future, it has not yet achieved the POSITA level of insight that a human examiner brings to the process.

A crucial distinction exists between a POSITA and someone inexperienced in the domain. A POSITA, equipped with technical expertise, employs refined search strategies, exhibits adeptness at interpreting patent documents, and conducts thorough prior art analyses. This is in stark contrast to someone without this background, emphasizing the intricate nuances and depth required in patent research.

Generative AI models, despite their allure, come with their own set of challenges. Their potential in automating tasks like data analysis must be weighed against their deficiencies in critical thinking, deep understanding of the POSITA context, and handling ethical intricacies. Their prowess, although remarkable as a search and analysis tool, does not diminish the need for human judgment when navigating the complexity of obviousness and novelty from the point of view of a POSITA and case law precedent.

The PPAC acknowledges and supports the USPTO investment in future tools to enhance search capability with AI assisted search but cautions against becoming overly reliant on reducing examination time for search. At least in the foreseeable future, the examiner is in the best and necessary position to provide the perspective of the POSITA to search. The PPAC encourages the USPTO to adopt AI as a supplementary tool, enhancing the existing patent examination process. Its integration should be well-thought-out, cognizant of the potential pitfalls and unintended consequences that can arise when changing a system that has historically been so reliant on human (POSITA) critical thinking. Finally, we encourage the USPTO to consider that any AI implementation be run in parallel with the existing examiner search. (Possibly duplicative for a while) until it can be ascertained that the AI is an enhanced form of the current searching and not introducing any unintended consequences, created by the use of the AI in place of human critical thinking, in the existing search process.

In conclusion, the future of patent search, while promisingly illuminated by AI's advancements, necessitates a harmonized approach. It is the confluence of AI's strengths with the unparalleled depth of human understanding and critical thinking of the examiners in light of ever evolving case law and judicial precedent, that will chart the way forward in patent search.

Inventorship issues and AI

The current state of the law is that both patent, including design patents, and copyright laws

require human inventors and creators for rights to attach.[29] Recognizing the importance of AI as an innovation tool, Senators Thom Tillis and Chris Coons, in a letter dated October 27, 2022, asked the USPTO and the U.S. Copyright Office to study any necessary changes to existing law to incentivize future AI-related innovations and creations. Prior to receiving the Tillis and Coons letter, the USPTO had already begun studying the impact of AI on inventorship. On February 14, 2023, the USPTO published a Federal Register Notice ("FRN") announcing a Request for Comments (RFC) on the AI inventorship issue. The FRN set a deadline of May 15, 2023, for responses and included 11 questions. However, the question most related to inventorship was:

> If an AI system can contribute to an invention at the same level as a human…, is the invention patentable under current laws?

In addition to the FRN RFC, the USPTO held two listening sessions directed to the questions raised in the RFC, one at the USPTO office on April 25, 2023, and the other at Stanford University on May 8, 2023. By the May 15, 2023, deadline, the USPTO had received 69 written comments from a diverse group of stakeholders, 19 comments from organizations, 10 from companies, and 40 from individuals. Remarks from the FRN RFC and the listening sessions are summarized below:

- Many commenters agreed that AI systems cannot and should not be listed as joint inventors of a patent application. Under *Thaler v. Vidal,* only natural persons may be listed as inventors.
- Many commenters also agreed that inventions with significant contributions from AI systems are patentable.
- However, there were a few commenters who believed that inventions created with significant AI contributions are not patentable.

Since there are diverging stakeholder perspectives on this issue, the USPTO has sought stakeholder input and continues to work toward clarifying AI's impact on innovation. While current case law is clear that an AI system alone does not qualify as an inventor on a US patent because it is not a natural person, engagement among patent offices worldwide should continue on this subject as this area evolves.

There is no doubt that AI will continue to transform the world, especially in the area of innovation. As protectors of innovation, the USPTO has an opportunity to be valued as a leading voice in the proactive and responsible engagement in this field. While at the same time, act as the guardian of the patent system with a focus on risk mitigation and the avoidance of unintended consequences of changes implemented without appropriate evidence supporting improvements.

29 Although the following remarks address the AI patent inventorship issue, there should be a common understanding between copyright law and patent law since both derive authority from the same provision of the U.S. Constitution, Article I, Section 8, Cl. 8.

KEY TAKEAWAYS
• As protectors of innovation, the USPTO has an opportunity to be a leading voice in providing thoughtful engagement and direction in this field. AI is poised to fundamentally affect how the IP ecosystem views patent search and examination, inventorship, what constitutes prior art and the POSITA. The USPTO is working toward thoughtfully created positions to address these issues, while ensuring a focus on risk mitigation and the strict avoidance of unintended consequences of changes without appropriate evidence of improvements. • AI has the potential to improve USPTO search and examination and to and leverage Examiner time more effectively, however stakeholders should expect it will take years for significant improvement to manifest.

C. INTERAGENCY COOPERATION

1. Proposals for Expanded USPTO-FDA Collaboration

In July 2021, the President's Executive Order 14036 instructed FDA to write a letter to USPTO "enumerating and describing any relevant concerns of the Food and Drug Administration (FDA)" to help ensure that "the patent system, while incentivizing innovation, does not also unjustifiably delay generic and biosimilar competition beyond that reasonably contemplated by applicable law."[30] Thereafter, a September 2021 letter from the Acting Commissioner of FDA called more generally for "[e]ngagement between FDA and USPTO" including to address use of the continuation process to create "patent thickets," "product hopping," and "evergreening."[31] A responsive letter from USPTO similarly called for interagency collaboration to, among other things, "[p]rovide examiners with training, in collaboration with the FDA, on publicly available FDA resources . . . and on the state of the art," "[e]xplore consistency in representations made to the USPTO and FDA," and "[w]ork with the FDA to understand how else the agencies' authorities and responsibility overlap."[32]

FDA product review and USPTO examination serve two unrelated and distinct purposes. FDA review determines a product's safety and effectiveness (e.g., new drugs, human biological products and medical devices), whereas USPTO examination of a patent application determines whether a claimed invention meets the statutory requirements for patentability. Over the past year, there has been a constructive dialogue between the agencies to determine whether increased coordination and collaboration would improve the quality of patent examination. This dialogue has focused mainly on identifying potential sources of publicly available FDA information that could be relevant to patent examination and exploring other areas where the agencies' authorities and responsibilities overlap. The agencies also jointly published a request for comments seeking input on the proposed initiatives set forth in USPTO's letter, including the initiative to explore consistency in representations made to the USPTO and the FDA.

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30 Exec. Order No. 14,036, 86 Fed. Reg. 36,987, 36,997 (July 9, 2021).

31 Letter from Dr. Janet Woodcock, Acting Commissioner of Food and Drug to Mr. Andrew Hirshfeld, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, at 4–5 (Sept. 10, 2021).

32 Letter from Kathi Vidal, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office to Dr. Robert Califf, Commissioner of Food and Drugs, at 3 (July 6, 2022).

To date, PPAC has not been presented with any data or cases that suggest that potential inconsistency of representations to the agencies is a practice warranting significant changes in either FDA review or USPTO examination. PPAC is aligned with and supports USPTO ongoing efforts to review whether any information sharing between USPTO and FDA would improve patent quality, so long as this information sharing does not publicly disclose confidential or trade secret information, provides meaningful improvements in patent quality, and does not impede USPTO patent examination or FDA review.

The recent proposals for increased collaboration between USPTO and FDA as to pharmaceutical patents must be considered against the backdrop of the governing laws, as well as the proposals' history and underlying evidentiary support. To encourage the development of groundbreaking medicines and promote patient access to medicines, Congress strategically calibrated its commitment to two core principles: to provide robust incentives for biopharmaceutical innovation in the form of patent and exclusivity protections while also promoting competition from generic and biosimilar products, through the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA).[33] The Hatch-Waxman Act has enabled considerable generic access, with generics currently comprising up to 92% of all drug prescriptions dispensed, up from 75% in 2009.[34] Innovator drugs with sales greater than $250 million in a 2017-2019 cohort have been found to have an average market exclusivity period from launch of the innovator drug to the launch of the first generic of 13 years in contrast to the statutory period of 20 years from filing of patent protection for other innovations.[35] Biosimilar products are also on the rise[36] with the recent approvals of interchangeable biosimilar products[37] and projections that such growth is expected to continue.[38] These trends demonstrate the robust competition that both laws have facilitated while also maintaining strong incentives to innovate. Given the success of the governing laws in driving biopharmaceutical innovation while ensuring access, considerable care should be given to any proposals to change FDA review or USPTO examination without supporting evidence.

In September 2021, Senator Thom Tillis, Ranking Member of the Senate Judiciary Intellectual Property Subcommittee, and Senator Patrick Leahy, then Chairman of the Senate Judiciary Intellectual Property Subcommittee, sent a letter to USPTO stating: "Unfortunately, it has come to our attention that some patent applicants may, in certain circumstances, make significantly different statements in submissions to other federal agencies that conflict directly with those made at the [PTO]."[39] The letter requested that USPTO "take steps to reduce patent applicants' making inappropriate conflicting statements in submissions to the PTO and other federal agencies[,]" including by creating a "smooth, predictable, and regular channel of information

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33 See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585; Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 804.

34 *See* IQVIA Institute for Human Data Science, *The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026,* at 39 (Apr. 2022); IQVIA Institute for Human Data Science, *Medicines Use and Spending in the U.S. A Review of 2018 and Outlook to 2023,* at 5 (May 2019).

35 Henry Grabowski et al., *Continuing trends in U.S. brand-name and generic drug competition*, 24 J. MED. ECON. 908, 911 (2021).

36 *See* FDA, Biosimilar Product Information (Aug. 24, 2023), https://www.fda.gov/drugs/biosimilars/biosimilar-product-information.

37 *See, e.g.*, The Center for Biosimilars, *FDA Approves Coherus' Cimerli as Interchangeable Biosimilar to Ranibizumab* (Aug. 3, 2022), https://www.centerforbiosimilars.com/view/fda-approves-coherus-cimerli-as-interchangeable-biosimilar-to-ranibizumab.

38 *See Global Biosimilars Market Growing to Exhibit a Noteworthy CAGR of 22.9% by 2033, Key Drivers, Growth and Opportunity Analysis - Research Nester,* GLOBENEWSWIRE (Oct. 12, 2022); *The Global Biologics Market Is Projected to Grow at a CAGR of 8.82% By 2032: Visiongain Reports Ltd,* GLOBENEWSWIRE (Oct. 12, 2022).

39 Letter from Sen. Thom Tillis and Sen. Patrick Leahy to Mr. Andrew Hirshfeld, at 1 (Sep. 9, 2021).

from other federal agencies to the Patent Office."[40] Additional Senate letters and academic papers reiterated the same themes. [41] However, there is little evidence indicating that conflicting statements to the agencies is a significant issue, and in the two examples cited in one academic paper, the system worked and courts found the patents unenforceable.[42]

Over time, questions have emerged regarding published criticisms of biopharmaceutical patenting practices, the reliability of the supportive evidence, and the suitability of these criticisms in driving policy reform. Senator Tillis underscored this point in letters to the FDA and the USPTO regarding concerns with underlying data in certain published reports. Senator Tillis's letters note that "several of the main sources driving the narrative that patents are to blame for high drug prices do not appear to meet [the] fundamental criteria" of being "based on accurate facts and data from reliable, unbiased sources" and that "[b]oth drug pricing, and matters of patent law and policy that impact the development of innovative medicines, are too important to rely on sources whose accuracy and reliability are in question."[43] In particular, Senator Tillis highlighted an analysis of Initiative for Medicines, Access & Knowledge (I-MAK) data that showed that I-MAK may have counted patents protecting a sponsor's drug to include abandoned patent applications, patents held by third parties, patents that expired after actual generic launches, and patents that do not cover the approved product or the approved method of using it.[44]

Based on concerns about the underlying data, Senator Tillis requested that USPTO and FDA conduct an independent assessment to study data from several data sources about patenting practices in the pharmaceutical industry. In her testimony during the recent Senate Oversight Hearing on July 26, 2023, Director Vidal reported that the agencies are working together on this request. PPAC supports USPTO and FDA efforts to complete this report, and hopes that it be made public, as the generation of relevant patent and exclusivity data, and accurate market exclusivity information, will assist policymakers in making informed decisions on patent-related policies in the biopharmaceutical technologies.

In addition to working on this study, USPTO and FDA have worked diligently to explore biopharmaceutical patenting with each other and key stakeholders, including whether information sharing can improve patent quality, and if so, the best way to collaborate. This work has included:

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40 *Id.* at 1–2.

41 Letter from Sen. Margaret Hassan and Sen. Bill Cassidy to Kathi Vidal and Dr. Robert Califf, at 1 (May 25, 2022) ; Arti K. Rai & W. Nicholson Price II, *An administrative fix for manufacturing process patent thickets*, 39 NATURE BIOTECH 20 (2021).;

42 *See* S. Sean Tu, *FDA Reexamination: Increased Communication Between the FDA and USPTO to Improve Patent Quality*, 60 HOUS. L. REV. 403, 407 n. 7 (2022). For example, this paper cited *Belcher Pharmaceuticals, LLC v. Hospira, Inc.*, 11 F.4th 1345, 1352-54 (Fed. Cir. 2021), a case between two generic companies, as evidence of a problem of inconsistent statements (Belcher filed a "literature-based" NDA, and "did not perform any clinical or non-clinical studies" to support its regulatory application in contrast to innovative pharmaceutical products resulting from new drug discovery and extensive pre-clinical testing and clinical trials). In *Belcher,* the Federal Circuit affirmed a finding of material, inconsistent statements made to FDA and USPTO that would otherwise bar patentability and found the patent unenforceable—a substantial penalty. This paper also cites *Merck v. Danbury*, a case from 1989 in which a medical device patent was also held unenforceable, but the paper notably does not cite any cases from the past 30+ years involving inconsistent statements from innovator pharmaceutical companies.

43 Letter from Sen. Thom Tillis to Dr. Janet Woodcock and Mr. Andrew Hirshfeld, at 1 (Jan. 31, 2022); *See also* Letter from Sen. Thom Tillis to Dr. Robert Califf and Mr. Andrew Hirshfeld, at 1 (Apr. 1, 2022) ("[S]ources are based on opaque methodologies, and appear to contain inaccurate or incomplete information that may be misleading policymakers").

44 *See* Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents*, HUDSON INST. (Jan. 2022).

- **Letter from FDA to USPTO** (September 10, 2021) & **Letter from USPTO to FDA** accompanied by a **joint USPTO-FDA blog** (July 6, 2022) outlining collaboration initiatives to execute on the President's agenda that aim to strengthen the agencies' relationship, expand the publicly available resources for assessing patentability, and examine agency policies to ensure the robustness and reliability of patents.
- **USPTO-FDA Cross-Training** sessions providing each agency with a deeper understanding of the policies and processes of the other that has led to the identification of changes to internal processes to improve accessibility and identifiability of public prior art.
- **Joint USPTO-FDA Notice of Public Listening Session and Request for Comments on Joint USPTO-FDA Collaboration Initiatives** (November 7, 2022) – This request sought public comments on proposed initiatives for collaboration between the agencies to advance President Biden's Executive Order on "Promoting Competition in the American Economy" and to promote greater access to medicines for American families. The agencies are continuing to discuss the public comments and assessing areas of potential further collaboration.
- **Joint USPTO-FDA Public Listening Session** (January 19, 2023) – The agencies held a full-day joint listening session to hear public comments on proposed areas of collaboration between the agencies. Topics included patient perspectives, patent examiner training, patenting practices in the pharmaceutical sector, applicant statements made to USPTO and FDA, and patent term extension and patent use codes. Speakers included representatives from a wide range of stakeholders, and included testimony from witnesses and panel of agency experts that questioned the witnesses. The discussion at the listening session aired all viewpoints and perspectives in a single forum with the policymakers from both USPTO and FDA present, and the agencies are continuing to discuss the public comments and assessing areas of potential further collaboration.
- **Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights** (October 4, 2022) – This request sought public comments on proposed initiatives directed at bolstering the robustness and reliability of patents to incentivize and protect new and nonobvious inventions while facilitating the broader dissemination of public knowledge to promote innovation and competition. The public comments provided the USPTO with valuable input and the Office is now considering the comments and assessing next steps for proposed rulemaking and fee setting.
- **Federal Register Notice on Duty and Disclosure and Duty of Reasonable Inquiry** (July 29, 2022) – This notice clarified the duties of disclosure and reasonable inquiry, including as to materials, or statements material to patentability, or statements made to the USPTO that are inconsistent with statements submitted to the FDA and other governmental agencies. This notice fostered a helpful dialogue between the agency and practitioners to clarify these duties.
- **New public webpage to enhance accessibility to patent term extension information** (September 1, 2022) – This new webpage improves the public's access to information about applications to extend patent term due to FDA regulatory review periods.

Information on patent term extension applications can be used by the public to identify and track PTE applications for filing a third-party due diligence petition to challenge FDA's determination of a regulatory review period.

Initial feedback from the constructive FDA/USPTO collaboration suggests that USPTO systems and search tools currently include access to publicly available information at FDA, but that confirmation of important dates of publication on these public sites would support USPTO efforts.

2. USPTO Collaboration with the USDA

Seeds Are the New Semiconductors

i) Strong IP around Seeds and Plant Varieties is an Issue of National Security.

Agriculture in the United States contributes over $1.2 trillion to U.S. GDP and provides for more than 10% of U.S. employment.[45] It is essential that agricultural technology continue progress as population increases in the wake of less farmland availability have led to a potential world crisis. It is a well-accepted statistic that by 2050, the global population is expected to reach 8.9 billion, which will require a 70 percent increase in agricultural productivity.

According to the World Intellectual Property Organization among others, climate change and dwindling land available for crop production, indicate that 90% of the required increase will need to come from technological advances in farming practices and higher yields.[46]

Thus, food security has become an issue of National Security. Nation states have also recognized this fact, with a strong push to achieve self-sufficiency that has incentivized them to purchase, and even to steal, agricultural assets from other countries. This presents significant

45 https://www.agri-pulse.com/articles/19906-opinion-proposed-patent-office-rules-threaten-rural-america

46 "Food Security, Climate Change and IP Rights" https://www.wipo.int/wipo_magazine/en/2011/03/article_0001.html

risks to the economic and national security of the United States.[47] A recent post from the Center on Global Food and Agriculture Chicago Council on Global Affairs, indicates that some nation states lag in seed breeding technologies and commercialization and are the weak link in their ability to balance grain supply and demand for food security.

Several high-profile prosecutions in the US of theft or "economic espionage" by foreign nationals of plant breeding materials and technologies have raised awareness that espionage and outright IP theft in the agricultural industry is on a much larger scale than previously understood. According to FBI, American agriculture, is one of the softest targets for IP theft, whether through access to privileged company research, the transfer of information out of university or government research facilities, or by simply digging up seeds in a field.[48]

Our adversaries have long worked to undermine American agriculture and to dominate the global food supply – whether by stealing valuable seeds directly from the ground, quietly buying up US farmland, or through deceptive trade practices.

ii) Strong IP Gives Americans Weapons to Help Fight Germplasm Theft and Spurs Investment in Plant Breeding.

The United States has the strongest IP regime for protecting plants and plant varieties in the world. With the decision of *Ex Parte* Hibberd in 1985,[49] and later with the US Supreme Court case of JEM in 2001,[50] patent protection for plant varieties is confirmed as a Congressionally intended part of our Intellectual Property System. *Ex Parte* Hibberd offers a unique opportunity to investigate the value of utility patents for plant varieties as opposed to other forms of protection that were previously in place. Prior to Hibberd it was thought that a plant variety developed through years of breeding and selection could not meet the patentability requirements of enablement and written description. This concern was remedied and then endorsed by the Patent Trial and Appeal Board, with deposit of seed at a recognized facility. Indeed, after *Ex Parte* Hibberd, private company investment in plant breeding skyrocketed, as did the introduction of new plant varieties.[51] This investment ensures US farmers will continue to reap the benefits of improved production and profitability. According to conservative estimates, the introduction of patent protection increased the total value of US agricultural land in 2002 by 7.5%, or roughly $80 billion ($117 billion in 2020 USD).[52] This increase occurred despite the presence of Plant Patents and/or Plant Variety Protection Certificate protections that were available, indicating the perceived value of utility patents.[53] The essential nature of the agriculture industry to the United States must be taken into account when considering policies that could have unintended consequences that will weaken economic incentives for plant breeding research.

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47 May 26, 2022, USCC.gov/research/China's-Interests-in-U.S.-Agriculture:-Augmenting-Food-Security-through-Investment-Abroad

48 August 25, 2021, blog post https://globalaffairs.org/commentary-and-analysis/blogs/china-seeds-are-new-semiconductors

49 *Ex parte Hibberd*, 227 USPQ 443 (Bd. App. & Int., 1985),

50 J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124 (2001)

51 Flowers of Invention: Patent Protection and Productivity Growth in US Agriculture Jacob Mosconay November 4, 2022, https://scholar.harvard.edu/moscona

52 Id.

53 Id.

A. Executive Order Promoting Competition in the American Economy[54]

Pursuant to President Biden's Executive order of July 9, 2021, which directs a "whole-of-government effort to promote competition in the American economy" the USPTO has been actively engaging and collaborating with the FDA, the USDA and other agencies which touch upon US Patent Policy. In furtherance of this objective, the USPTO has committed to explore joint USPTO-USDA opportunities for collecting broader stakeholder input from researchers, plant breeders, farmers, and others in the seed and agricultural input markets; to explore initiatives to enhance the quality of the patent examination process for innovations related to agricultural products and processes, including opportunities for enhancing prior art search capabilities and providing additional training and guidance to patent examiners; collaborate on initiatives that enhance the transparency of IP information for agriculture-related innovations and assess availability and viability of patented and off-patented germplasm; and to consider and evaluate new proposals for incentivizing and protecting innovation in the seed and agricultural-related space, including the broader adoption of research or plant breeders' exemptions when U.S. utility patents cover seeds.[55]

USDA-AMS had previously issued a report with findings and recommendations after a request for public comments and information about competition and market power, intellectual property, and other business practices in the seed industry that might affect the American farmer's ability to participate in a fair and competitive market. The USPTO created an Interagency Working Group on Competition and Intellectual Property in Seeds and Other Agricultural Inputs and, on March 23, 2023, Director Vidal hosted a meeting of the Group. Participants discussed potential interagency synergies that may be leveraged to address issues noted in the USDA report. The group has continued to work together, and much has been done to secure strong IP rights while also promoting healthy competition in the Agriculture Sector.

i) USPTO and PVPO meetings and to promote robust IP rights

On April 19, 2023, USPTO hosted staff from the USDA Plant Variety Protection Office (PVPO) to cross-train USDA and USPTO personnel. USPTO managers presented (a) an overview of plant and utility patents; (b) an overview of search databases regularly used by USPTO plant and utility examiners; and (c) search tips for the USPTO Patent Public Search tool. USDA PVPO managers presented (a) an overview of PVP examination and (b) how to submit a PVP application.

ii) Access to off-patent innovations for the progress and development of technology

On July 12, 2023, the USPTO-USDA interagency working group met with American Type Culture Collection (ATCC)'s IP and license enforcement management to help promote access to

54 Executive Order Number 14036, "Promoting Competition in America's Economy," at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promotingcompetition-in-the-american-economy/.

55 https://www.uspto.gov/blog/director/entry/increasing-transparency-boosting-competition-and

off-patent inventions.[56] ATCC management answered questions posed by USDA cooperators regarding seed accession, distribution, and storage.

iii) Outreach to farmers to educate about the role of IP in the agriculture industry

On July 19, 2023, USDA launched the Farmer Seed Liaison website. Through this website, USDA stakeholders can access USPTO Patent Public Search and the USPTO's 3rd party prior art submission page. The website also provides instructions on accessing patented seed and plant material from an International Depositary Authority.

PPAC Supports the USDA/USPTO goals as espoused in the USPTO Director Blog (adapted with PPAC comment)

1. **Ensure robust and reliable IP rights that enhance innovation and promote competition.**
   - Investigate and implement access to better searching through coordination of prior art through USDA PVP examines and USPTO patent examiners.
   - Gain shareholder input to understand the impact of breeder's exemptions and the likely negative impact on private research investment.
   - Ensure that federally sponsored research continues to be protected by technology transfer institutions through a system of contracts, patents and PVPs.
   - Continue to provide outreach and education to stakeholders about IP and how it functions in the seed industry so that purchasers of seed can understand their obligations.
2. **Ensure that IP owners exercise their rights within the scope of fair competition provided by law.**

   Help to ensure that seed deposits made for patents are readily available and accessible once patents have expired.
3. **Rebuild critical national infrastructure for variety development and the provision of seed and other planting stock to create resilient seed supply chains.**

   Ensure that patents and IP associated with plant varieties remain strong to secure financial investment in plant breeding and to offer utility patent remedies to dissuade international theft of IP.

[56] Seeds of plant varieties are deposited with International Depositary Authorities (37 CFR 1.803) to satisfy the enablement requirement, under 35 U.S.C. Section 112 of the Patent Statute. In the U.S., ATCC and the National Center for Marine Algae and Microbiota (NCMA) are the two recognized depositaries that accept seed and plant tissue deposits for patent purposes.

KEY TAKEAWAYS ON FDA/USDA AGENCY COLLABORATIONS
• The USPTO has access to data that can help to answer Congressional questions on patents for pharmaceutical and agricultural products and plant breeding and continues to be a source stakeholder regarding the same. • The collaborations with USDA, FDA as well as other agencies are ongoing and are valuable to increasing transparency of information that affects markets and maintaining robust patents with the sharing of art and other relevant information between agencies. • The USPTO's primary mission of issuing valid patents, must remain inviolate in the wake of potentially distracting outside influence and larger policy issues better left to Congress and the courts. • The USPTO-USDA collaboration promotes robust and reliable IP rights that enhance innovation and promote competition in agriculture.

VII. PTAB

As prescribed by the U.S. Constitution, art. I, section 8, the USPTO issues patents to promote innovation. The patent system fosters innovation by encouraging the public disclosure of ideas in exchange for the grant of exclusive rights for a limited time. Simply stated, the prospect of securing these exclusive rights provide a basis for investment. Inventors and investors contribute their time and money for research and development, ultimately to bring the results of such research to market. The patent system is, therefore, a driver for both jobs and prosperity. To do so, however, both inventors and investors must have confidence in the patent right. The system works effectively when the USPTO issues and maintains robust and reliable patents.

The Leahy–Smith America Invents Act (AIA) was passed by Congress and was signed into law on September 16, 2011. The intent of the AIA was to make the patent system more transparent, objective, reliable and efficient. Notably, the AIA created the Patent Trial and Appeal Board (PTAB), which is responsible for two types of post-issuance proceedings under the AIA:

> (1) *Inter-partes* review (IPR) which reviews challenged claims of a patent on the grounds that the invention lacks novelty or is obviousness over prior art in the form of patents and printed publications; and
>
> (2) *Post-grant* review (PGR), which reviews challenged claims of a patent on any ground of patentability. PGR must be brought within nine months of the patent's issuance.[57]

These proceedings are intended "to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs." H.R. Rep. No. 112-98, part 1, at 40 (2011), 2011 U.S.C.C.A.N. 67, 69; see S. Rep. No. 110-259, at 20 (2008).

The USPTO recognized this and noted in the recent Advanced Notice for Proposed Rulemaking (ANPRM):

> Congress designed the AIA to improve and ensure patent quality by providing "quick and cost-effective alternatives to litigation" for challenging issued patents. H.R. Rep. No. 112-98, part 1, at 48 (2011), 2011 U.S.C.C.A.N. 67, 69; see S. Rep. No. 110-259, at 20 (2008) (explaining that the "post-grant review system . . . will give third parties a quick, inexpensive, and reliable alternative to district court litigation to resolve questions of patent validity").[58]

The USPTO also recognized that "the changes made by [the AIA] are not to be used as tools for harassment or a means to prevent market entry through repeated litigation and administrative attacks on the validity of a patent," as "[d]oing so would frustrate the purpose of the section as

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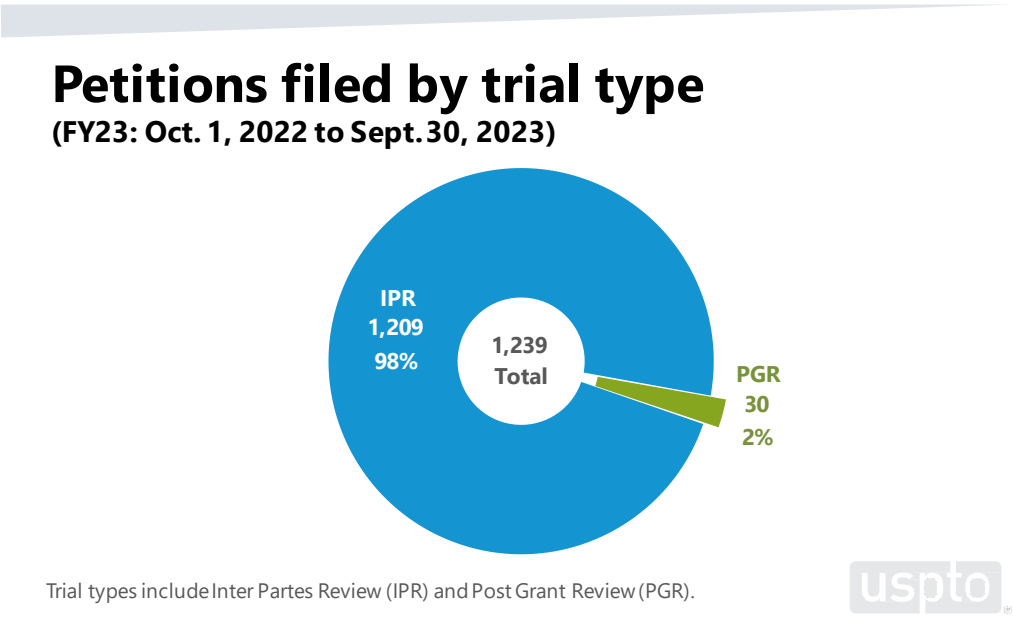
[57] The AIA also implemented a transitional program for review of covered business method patents (CBMs), which sunset on September 16, 2020.

[58] *Changes Under Consideration to Discretionary Institution Practices, Petition Word-Count Limits, and Settlement Practices for America Invents Act Trial Proceedings Before the Patent Trial and Appeal Board*, 88 FR 24503, 24503-2451 (April 21, 2023).

providing quick and cost-effective alternatives to litigation." H.R. Rep. No. 112-98, at 48 (2011).[59]

It is worth reflecting on data in relation to AIA proceedings, now that they have been in effect for nearly 12 years.

1. Current Data Indicates That IPR Remains the Most Prevalent AIA Proceeding with 98% of Petitions Being Filed.



The proportion of IPR petitions to PGR is particularly noteworthy for two reasons. First, IPR petitions may be more prevalent because they can be filed at any time during the patent term following the PGR nine-month window and often are filed later in the patent term because they are triggered by a challenger being sued for infringement. The PPAC has received feedback from stakeholders that this causes IPRs to be more disruptive to the expectations of investors and inventors, particularly for the independent or small inventor. Second, more than 80% of IPR proceedings have parallel litigation in Federal district court; although, it is worth noting that of patents asserted in district court patent infringement litigation, only about 20-30% are challenged in AIA proceedings.[60] IPR proceedings were designed by Congress to be a less expensive alternative to district courts. In practice, some stakeholders have reported to PPAC that parallel proceedings in both district court and before the PTAB have increased the costs and burden of patent litigation. Current jurisprudence and USPTO guidance, as well as stays and estoppel in district court, are positive steps to help ensure that the AIA proceedings function as intended.

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59 *Id.*

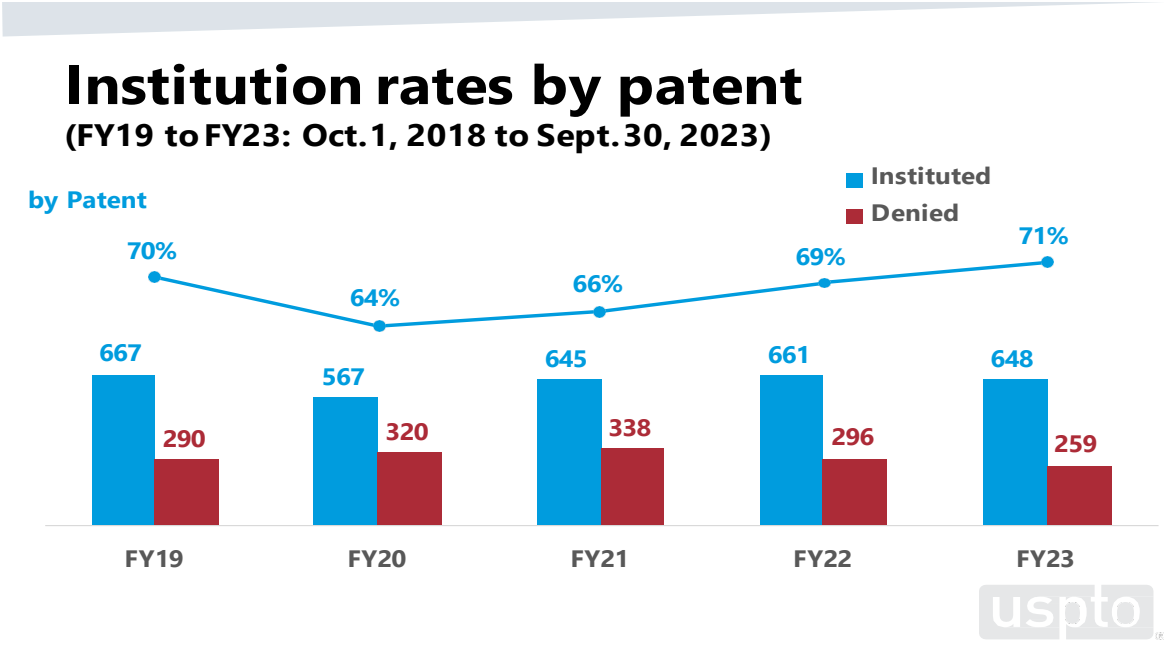
60 *See, e.g.*, RPX report at https://www.rpxcorp.com/data-byte/the-overlap-between-patents-asserted-in-district-court-and-challenged-at-the-ptab/ (June 1, 2023) (stating that "district court litigation has remained a key driver of PTAB proceedings, as 79% of the patents challenged in IPR petitions were first asserted in district court" and also "[o]f the roughly 25,010 patents that have been the subject of complaints filed in district court from September 16, 2011 through May 26, 2022, just under 7,020 of those patents, or 28%, have been hit with subsequent petitions for IPR.•

That said, the USPTO should always stay on top of ways to improve practices before the Office, including in AIA proceedings, as needed.

The PPAC applauds the USPTO for initiating the PTAB ANPRM and encourages the USPTO to continue to study IPR proceedings to meet the objectives of Congress.

2. Institution Rates and Results in Final Written Decisions.

Institution rate "by patent" for FY 2023, is 71%, which is about the same rate as that in FY 2019.[61] In interim years (FY20-FY22), the reduction and then increase in institution rate to approximately the same percentage may be random variability or a reflection that practitioners have adapted to changes in PTAB practice (e.g., as occurred in *General Plastic* (relating to serial petitions), *Advanced Bionics* (relating to practice under 35 U.S.C. § 325(d)), *Fintiv*, and Director's Memorandum on Interim procedure for discretionary denials in AIA post-grant proceeding with parallel district court litigation memorandum (June 21, 2022)). Institution rates for FY2023 reflect the third consecutive fiscal year increase and should continue to be monitored and studied.

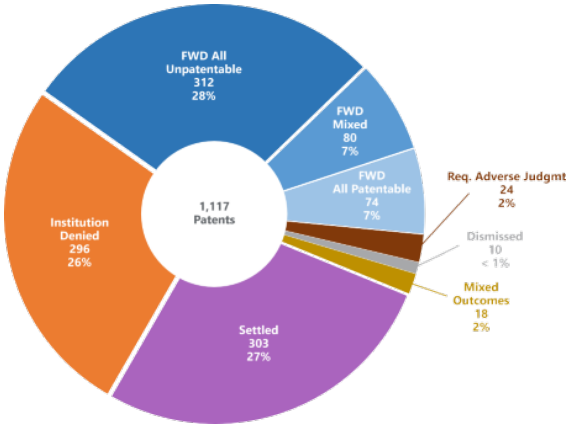


In relation to all outcomes in AIA proceedings, as seen below, about 42% of patents with AIA challenges ending in FY 2023 resulted in a final written decision (FWD). Beyond those, about 26% of patents challenged resulted in denials of institution, about 27% settled before reaching an FWD, and about 5% terminated or were dismissed for other reasons. When looking at FWDs "by patent," of the 42% of the patents reaching FWD (466), about 67% of those resulted in all challenged claims being found unpatentable, approximately 17% resulted in mixed results (some claims patentable and some unpatentable), and approximately 16% resulted in all claims upheld.

[61] *See* PTAB Trial Statistics FY23 End of Year Outcome Roundup IPR, PGR, slide 7.

Outcomes by patent

(FY23: Oct. 1, 2022 to Sept. 30, 2023)



FWD patentability or unpatentability reported with respect to the claims at issue.
"Mixed Outcome" is shown for patents receiving more than one type of outcome from the list of: denied, settled, dismissed, and/or req. adverse judgement only.
A patent is listed in a FWD category if it ever received a FWD, regardless of other outcomes.

The most consistent topic of feedback from the public and/or stakeholders to the PPAC has been the reliability and the durability of the patent right. While patent examination will never be perfect and some patents will inevitably issue that should not have issued, patent owners, as well as investors and other stakeholders, are understandably frustrated when an issued patent is later determined to be unpatentable. The USPTO considers every PTAB decision as an opportunity to learn and now has sufficient data to identify meaningful trends and opportunities to improve examination.[62]

Successful challenges having at least one independent claim in FWD issued in calendar year 2021 were sampled. Ninety-three percent (93%) of these challenges finding unpatentability of at least one independent claim were based on prior art not cited in prosecution; seventy-four percent (74%) on a mix of new prior art; and nineteen percent (19%) on art previously cited during prosecution. The prior art not previously cited during prosecution was a mix of U.S. or foreign patent documents and non-patent literature – in other words, art that is findable. Notably, there is an inherent lag in the data. The prosecution of the patents sampled generally occurred five or more years before the AIA proceeding. USPTO has adopted improved search capabilities over this period. Nevertheless, understanding why this prior art was neither cited by applicants or identified during prosecution may be informative to the public and applicants. It also supports USPTO on-going investment in searching capabilities, both IT investment and investment in additional training.

Seven (7%) of the challenges finding at least one independent claim unpatentable are based on prior art cited during examination of the patent. The vast majority of these cases (82%) had more than 100 references cited by the applicant in an information disclosure statement (IDS).

62 In past reports, we have referred to this data exchange as "closing the loop." See for example, PPAC annual reports – 2022, 2021]

While the USPTO does not have sufficient data to prove causation, the inference from the data is that over-citation of art during examination is counterproductive to a quality examination and issuing a reliable and durable patent right.

PPAC applauds the USPTO for this study and supports further study whether the doctrine of inequitable conduct (IC) is underlying both these findings. Inequitable conduct doctrine is a judicial, non-statutory, defense to an allegation of patent infringement. While the doctrine has somewhat mitigated under recent case law, the doctrine remains a severe remedy of unenforceability.[63] Inequitable conduct may act as a barrier to procuring reliable and durable patents. Applicants are fearful of being second guessed and are therefore over-disclosing information and prior art. The USPTO data are at least consistent with a breakdown in examination when examiners are overwhelmed by prior art. Because IC can also be found for a failure to cite references known to the applicant, the judicially created doctrine also contributes to the other extreme of applicants not searching the prior art prior to filing.[64] By not searching and remaining ignorant of the prior art, an applicant is less likely to be the target of an allegation of IC. PPAC encourages the USPTO to consider this possibility and its potential implications to patent examination.

63 Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011)

64 For some applicants the cost of searching also plays a factor in whether a search is undertaken prior to filing

RECOMMENDATIONS:

1. The USPTO should continue to study AIA IPR outcomes and share such studies with the public. These data are critical to understand why the PTAB and examination reach the same or different result and to enable continuous improvement.

2. The USPTO should continue to invest in search and examination capabilities and training.

KEY TAKEAWAYS
• The USPTO and Congress should examine patent and litigation data since 2011 to ascertain if the AIA legislation achieved its desired goals, and also determine if there were any unintended consequences in the implementation of the legislation that have arisen. • In the calendar year 2021 study sample, ninety-three percent (93%) of FWDs finding unpatentability of at least one independent claim were based only on prior art not cited in prosecution. The USPTO should not bear sole responsibility for prior art searching and should discuss with stakeholders' ways to encourage applicants to provide more prior art references. • One goal of the AIA legislation was to create a more efficient and cost-effective way to adjudicate patent validity challenges. However, more than 80% of IPR proceedings have parallel litigation in Federal district court. This is concerning as it appears that PTAB litigation is being added on top of existing litigation rather than in lieu of.

VIII. PATENT ELIGIBLE SUBJECT MATTER

Judicial decisions relating to patent subject matter eligibility have created uncertainty and unpredictability regarding the availability of patent protection. With the pace of technology creation in key arts, this is a threat to American competitiveness. While the USPTO Section 101 guidance has brought about needed consistency to the application of the law to examination, such guidance is not a long-term solution, as the courts do not operate under the guidance. Accordingly, the PPAC supports the USPTO continuing to raise this issue with stakeholders, policymakers, and via cases brought in the courts. Doing so, will hopefully spur long-term solutions.

IX. IMPACTING GDP: USPTO AND PRIVATE SECTOR EFFORTS

Innovation Expansion through Outreach, Education, and Inclusion

The USPTO under Director Vidal's leadership is working to link patents and invention more explicitly to national competitiveness, through both increasing invention activity and making patent protection available to more inventors around the U.S. It is widely known that innovation is a key driver of competitiveness and long-term economic growth. It is also known that patents are important measures of innovation.[65] Recent studies show that significant increases in U.S. innovation are achievable by encouraging inclusive innovation, which involves bringing under-represented individuals and communities into the innovation ecosystem. For example, one study finds that "if women, minorities, and low-income children were to invent patented technology at the same rate as white men from high-income households, the rate of innovation in American would quadruple,"[66] which represents about $1 Trillion in potential growth to the United States economy. Unfortunately, research has also revealed that inclusive innovation does not happen organically but must be encouraged, as substantial disparities in opportunities to innovate exist within various communities. For example:

- African American and Hispanic inventors seek patent protection at lower rates than other major racial and ethnic groups. A study of 3.9 million patent applications revealed the likely race of patent applicants as follows for domestic inventors: white (64.77%), black (.06%), Asian (12.45%), and Hispanic (.96%).[67]
- Patent grants for African American inventors lag far behind those of other communities. African Americans, make up 13% of the U.S.'s native-born population but less than 1% of the U.S. born innovators.[68]
- From 1976 to 2008, African American inventors were awarded six patents per one million people, compared to 235 patents per 1 million for all U.S. inventors.[69]

65 See Emily G. Blevins, *Patents and Innovation Policy*, CRS Report R47267 (November 30, 2022), available online at https://crsreports.congress.gov/product/pdf/R/R47267/3; see also *The Competitiveness and Innovative Capacity of the United States*, prepared by the U.S. Department of Commerce in consultation with the National Economic Council (January 2012), available online at https://www.commerce.gov/sites/default/files/migrated/reports/thecompetitivenessandinnovativecapacityoftheunitedstates.pdf.

66 Office of the Chief Economist, U.S. Patent & Trademark Office, *Progress and Potential: A Profile of Women Inventors on U.S. Patents* (2019), https://www.uspto.gov/sites/default/files/documents/Progress-and-Potential.pdf.

67 W. Michael Schuster et al., An Empirical Study of Patent Grant Rates as a Function of Race and Gender, American Business Law Journal Volume 57, Issue 2, 281, 285 (Summer 2020).

68 See For Black Inventors, Road to Owning Patents Paved with Barriers (Bloomberg Law 2020) (citing Information Technology and Innovation Foundation Survey).

69 See Lisa D. Cook, The Idea Gap in Pink and Black (Working Paper 16331), National Bureau of Economic Research (September 2010).

Sugimoto et al. found less than eight percent of all inventorships on U.S. patents were women between 1976 and 2013.[70] https://www.uspto.gov/sites/default/files/documents/OCE-DH-Progress-Potential-2020.pdf. Furthermore, while diversity among the practitioner community has improved, more work needs to be done. ADAPT, an industry initiative between law firms and corporations aimed at increasing diversity in the patent profession, recently released some very telling data. First, patent practitioners over the past decade have been declining.[71] This is at odds with the USPTO efforts to increase the amount of invention in the U.S., as there will be no one to assist with the increasing amount of patent applications. While we do not yet know the reason for the decline in practitioners, there are two things to note: 1) 2008 was the last big recession and law firm numbers overall have not returned to their pre-2008 levels since; 2) 2008 marked a significant increase in the negative patent narrative, which may potentially be driving people away from the profession. One more important thing to note about patent attorneys, is that they must have both a technical background and a law degree. This year, the USPTO reevaluated and updated qualifications to sit for the exam to qualify as a patent prosecution practitioner at the USPTO, which will now encompass a wider range of well-qualified patent agents and attorneys. The USPTO is also in the midst of potentially defining custom qualifications for practitioners of design patent prosecution and before the PTAB, thus removing unnecessary barriers to entry of qualified practitioners for the respective purpose. In a recent article, the Department of Defense cited the increasing lack of STEM educated students as a national security risk.

> *"The advances in technology that are going to drive where the world goes in the next 50 years are going to come from other countries, because they have the intellectual capital and we don't," said Jim Stigler, a psychology professor at the University of California, Los Angeles, who studies the process of teaching and learning subjects including math.*
>
> *The Defense Department has called for a major initiative to support education in science, technology, education and math, or STEM. It says there are eight times as many college graduates in these disciplines in China and four times as many engineers in Russia as in the United States.*
>
> *One result: Students from other countries are preparing to lead these fields. Only one in five graduate students in math-intensive subjects including computer science and electrical engineering at U.S. universities are American, the National Foundation for American Policy reports. The rest come from abroad. Most will leave the U.S. when they finish their programs.*[72]

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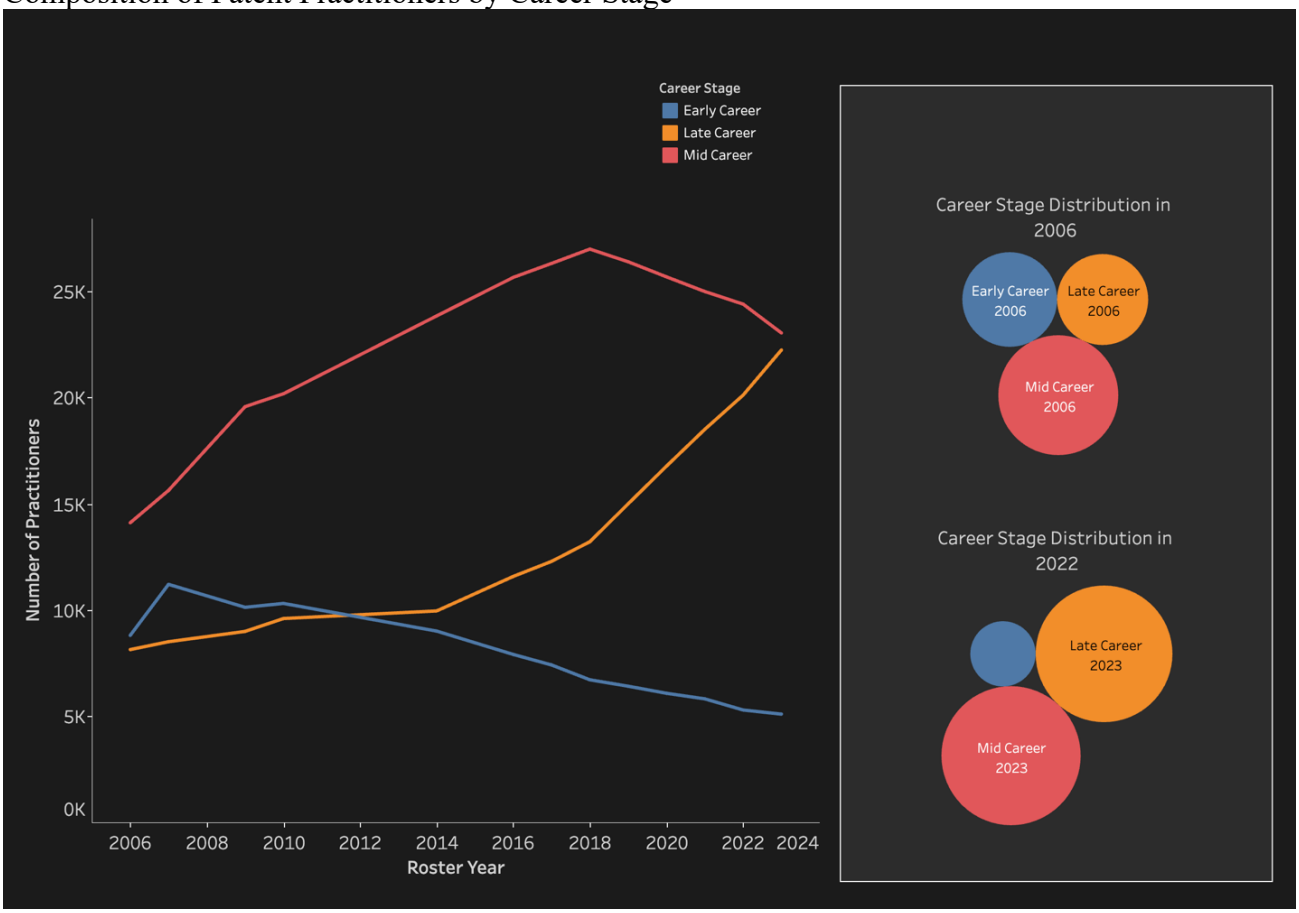
70 See W. Michael Schuster et al., An Empirical Study of Patent Grant Rates as a Function of Race and Gender, American Business Law Journal Volume 57, Issue 2, 281, 285 (Summer 2020) (citing Cassidy R. Sugimoto et al., The Academic Advantage: Gender Disparities in Patenting, 10 PLOS ONE 1, 5 (2015). However, with the help of programs directed to encouraging women inventors, the "Women Inventor Rate" (WIR) – the share of U.S. inventors receiving patents who are women – increased from 12.1% in 2016 to 12.8% in 2019. USPTO Progress and Potential: 2020 update on U.S. women inventor-patentees, available online at https://www.uspto.gov/sites/default/files/documents/OCE-DH-Progress-Potential-2020.pdf. The share of women among new inventors on issued patents also increased from 16.6% in 2016 to 17.3% by 2019. Id.

71 ADAPT Data 2023, Number of New Patent Practitioners Entering into the Profession by Registration Year.

72 "Defense Department calls for major STEM initiative as American math skills pose threat to national security", Associated Press, Published Sep. 26, 2023.

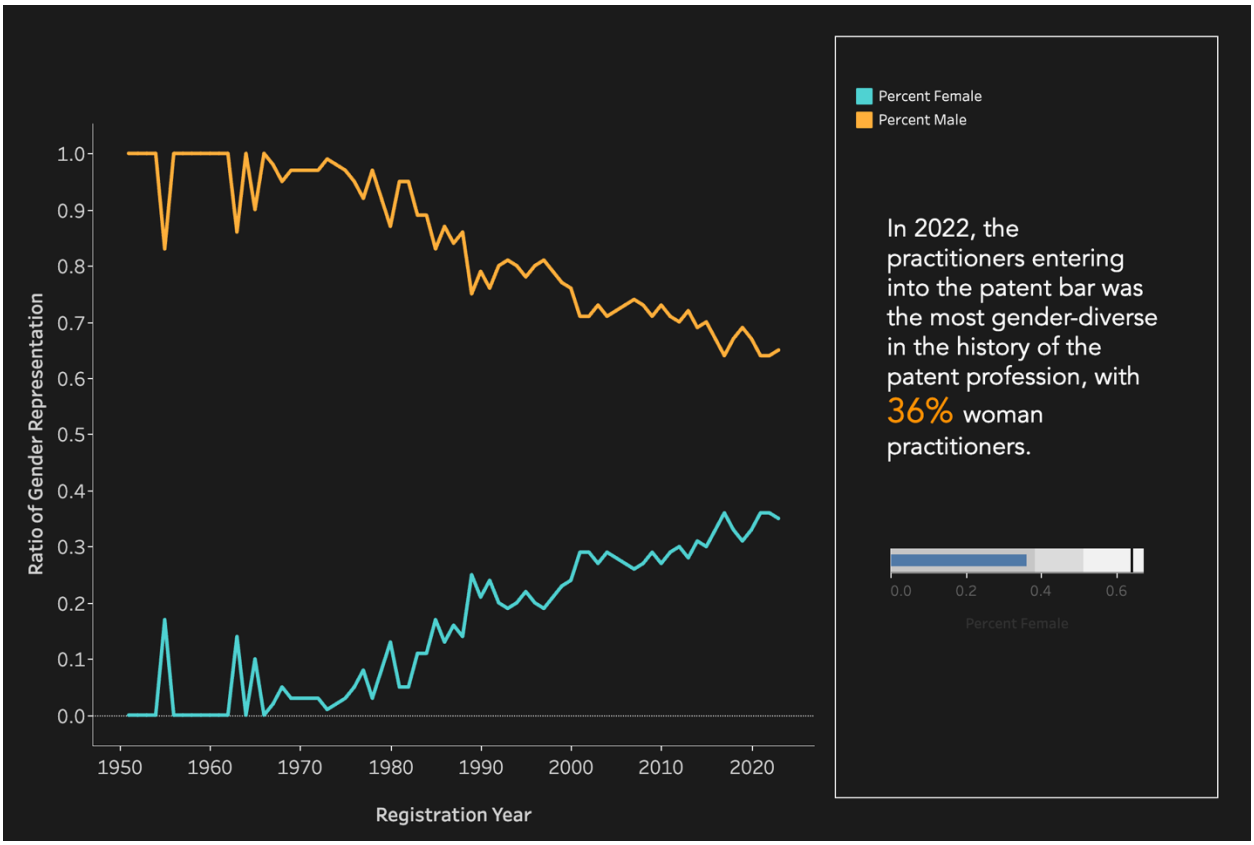
Composition of Patent Practitioners by Career Stage[73]



From reported practitioner demographics of gender, there has been progress towards more balanced representation over the years for new practitioners entering the patent profession. Currently, 26% of patent practitioners in total are women.[74]

73 ADAPT Data 2023, A Profession in Decline.

74 ADAPT Data 2023, *Closing the Gender Gap.*



Increasing the diversity of patent practitioners is key to both increasing the amount of invention, and also encouraging and serving a diverse innovator community.

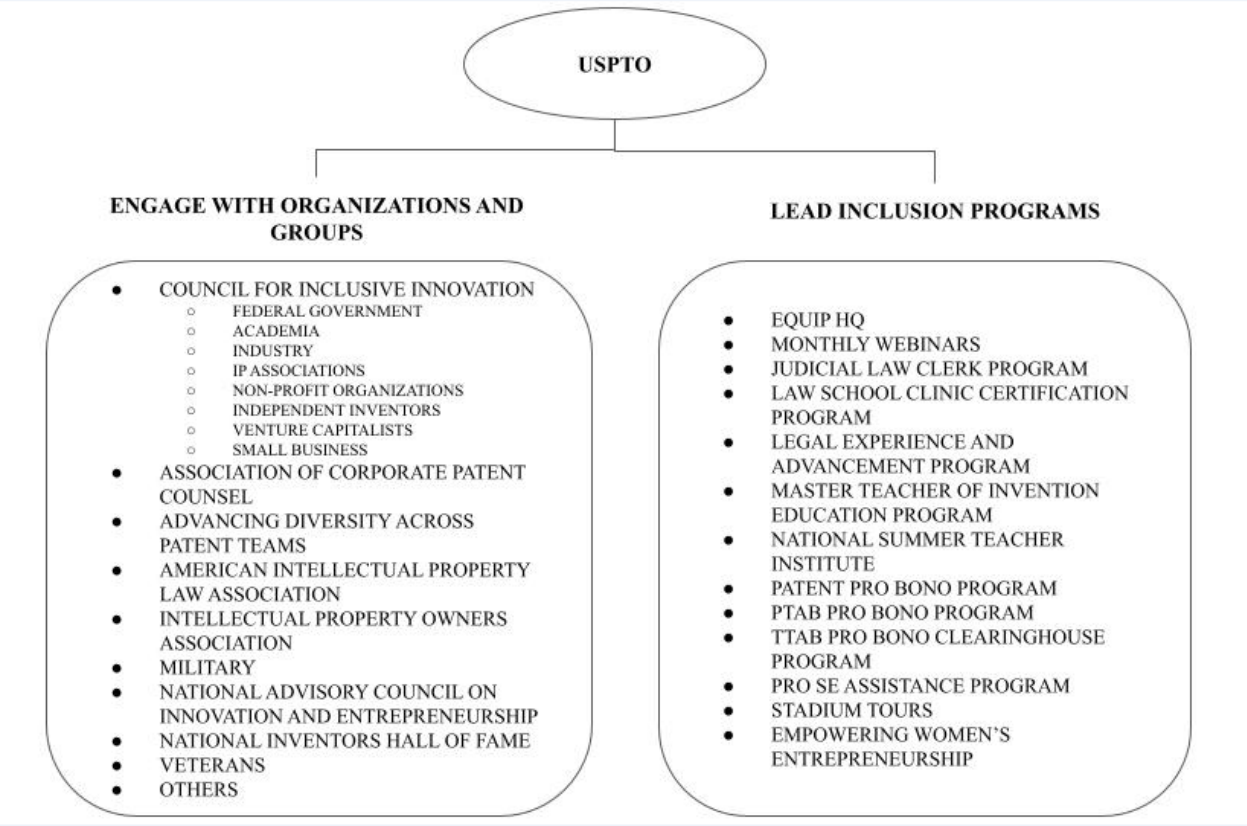
With respect to inclusive innovation, studies show an economic benefit to increasing the diversity of innovators and innovator teams:

- Companies in the top quartile of gender diversity on executive teams were 25% more likely to experience above-average profitability than peer companies in the fourth quartile. This is up from 21% in 2017 and 15% in 2014.[75]
- Companies with above-average diversity produced a greater proportion of revenue from innovation (45% of total) than from companies with below average diversity (26%). This 19% innovation-related advantage translated into overall better financial performance.[76]
- Increasing the number of [B]lack American inventors will … increase America's GDP by as much as 3.3 %.

75 Sundiatu Dixon-Fyle, *Diversity Wins: How Inclusion Matters* (McKinsey & Company Study, May 2020), available online at https://www.mckinsey.com/featured-insights/diversity-and-inclusion/diversity-wins-how-inclusion-matters#/.

76 Boston Consulting Group, *How Diverse Leadership Teams Boost Innovation*, available online at https://www.bcg.com/publications/2018/how-diverse-leadership-teams-boost-innovation

- Children at the top of their 3rd grade math class from high-income families are much more likely to become inventors, while high-scoring children from low-income or minority families are unlikely to become inventors.
- African American Engineers account for less than 1% of all engineers, but demographically represent about 14% of the U.S. population. Increasing the number of African American engineers would add approximately $1 Trillion to the GDP.



The USPTO prioritizes utilizing IP to increase national competitiveness by working with numerous organizations, both public and private and spearheading a variety of programs. While Director Vidal is especially passionate about this imperative, so too is the Secretary of Commerce, Gina Raimondo, who is participating in a number of these initiatives alongside Director Vidal such as the Council for Inclusive Innovation (CI^2) and Federal Co-Chair of the National Advisory Council on Innovation and Entrepreneurship (NACIE). CI^2 is focused on strategizing new ways to expand American innovation by tapping into the strength of our nation's diversity and increasing the opportunities for all Americans to participate in innovation and NACIE is focused on developing a strategy that strengthens America's ability to compete and win as the world's leading startup nation and as the world's leading innovator in critical emerging technologies.

The USPTO operates a multitude of outreach programs to offer support for innovators, e.g., Inventor Hour Webinars, Patent Pro Bono Program, as well as PTAB and Trademark Trial and Appeal Board (TTAB) Pro Bono Programs, Pro Se Assistance Program, and Empowering Women's Entrepreneurship (WE), some foster students and educators, e.g., EquIP HQ, Law

School Clinic Certification Program, National Summer Teacher Institute, and Master Teacher of Invention Education Program, and some provide opportunities or information to patent practitioners, e.g., Judicial Law Clerk Program, Legal Experience and Advancement Program, and PTAB Stadium Tours. It is especially notable that the Patent Pro Bono Program is gaining significantly increased interest and traction—a 45% year-over-year increase in applicants in Q1 2023.[77] Thus, the USPTO nearly doubled its budget to $1,200,000 in FY 2022 to support such demand. The USPTO continues to maintain that higher budget into FY 2024. Using the aforementioned approaches and tools, American innovation can reach untapped potential in under-represented student, educator, innovator, and practitioner communities. With this realized, the nation has a significant opportunity to expand GDP.

KEY TAKEAWAYS

- The USPTO has been successful in creating a more explicit link between patents and invention and national competitiveness, through both increasing invention activity and making patent protection available to more inventors around the U.S.
- The USPTO has successfully increased its outreach, education, and pro bono efforts to more effectively reach students, practitioners, and communities in underrepresented geographies and demographics.
- The Patent Pro Bono Program is gaining significantly increased interest and traction—a 45% year-over-year increase in applicants in Q1 2023.
- The USPTO has been very successful in partnering with both the private and non-profit sectors to provide more education, awareness, tools and assistance to students, practitioners, entrepreneurs, in underrepresented geographies and demographics.

77 Patent Pro Bono Report at pg. 30

GLOSSARY OF ABBREVIATED TERMS

ABBREVIATION	DEFINITION
ADAPT	Advancing Diversity Across Patent Teams
AI	Artificial Intelligence
AIA	Leahy-Smith America Invents Act
ANPRM	Advance Notice of Proposed Rule Making
ATCC	American Type Culture Collection
BPCIA	Biologics Price Competition and Innovation Act
CI²	Council for Inclusive Innovation
CPC	Cooperative Patent Classification
EOT	Extension of Time
FDA	U.S. Food and Drug Administration
FRN	Federal Register Notice
FWD	Final Written Decision
GDP	Gross Domestic Product
IC	Inequitable Conduct
IDS	Information Disclosure Statement
I-MAK	Initiative for Medicines, Access & Knowledge
IP	Intellectual Property
IPO	Intellectual Property Owners Association
IPR	*Inter Partes* Review
MPEP	Manual of Patent Examining Procedure
NACIE	National Advisory Council on Innovation and Entrepreneurship
NPRM	Notice of Proposed Rulemaking
PGR	Post-Grant Review
POSITA	Person Having Ordinary Skill in the Art
PPAC	Patent Public Advisory Committee
PTAB	Patent Trial and Appeal Board
PTFRF	Patent and Trademark Fee Reserve Fund
PVPO	Plant Variety Protection Office
RFC	Request for Comments
R&D	Research and Development
WE	Women Entrepreneurship
WIR	Women Inventor Rate

SUZANNE HARRISON, CHAIR

Ms. Harrison is the Founder of Percipience LLC, a board-level advisory firm focused on managing and developing IP strategy, quantifying and mitigating IP risk, and increasing IP value capture. Ms. Harrison was previously a Director with Inflexion Point Strategy, an IP investment bank providing IP transaction assistance, and was the CEO and Founder of Gathering2.0, the first online community to increase information transparency and efficiency in the patent transaction market. She is also the co-author of three published books, each of which takes an in-depth look at the concepts of intellectual asset management and highlights the winning strategies used by large companies to maximize the value of their IP. Ms. Harrison is serving her first term and second year as a PPAC member.

HEIDI NEBEL, VICE CHAIR

Ms. Nebel serves as the Managing Partner and Chair of the Biotechnology & Chemical Practice Group of McKee, Voorhees & Sease, PLC. Ms. Nebel has over 29 years of experience obtaining patents and designing IP strategy in the areas of biotechnology, chemicals, and pharmaceuticals. She serves as an advocate for her clients and believes that the best results come from working in close association with USPTO examiners. Her clients include over 40 universities and research institutions, as well as fortune 500 companies around the world. She is also an active member of ChIPs®, a nonprofit organization that advances and connects women in technology, law, and policy. Ms. Nebel is serving her first term and second year as a PPAC member.

STEVEN CALTRIDER

Mr. Caltrider is Vice President and Chief IP Counsel of the Dana Farber Cancer Institute (DFCI) and retired Vice President and General Patent Counsel for Eli Lilly and Company. His passion is creating and enforcing IP to enable life-saving innovation to reach patients. He has extensive litigation experience in the leading intellectual property (IP) forums (more than 30 countries), including U.S. Federal District Court, the U.S. Courts of Appeals for the Federal Circuit; courts in Canada, the United Kingdom, Germany, Japan and the Netherlands; as well as the USPTO, EPO, and JPO. Mr. Caltrider is experienced in managing global teams of attorneys and staff on a wide range of IP matters, from patent procurement to technology acquisitions and data security. Mr. Caltrider is also Chair of the American Bar Association Section of Intellectual Property. Mr. Caltrider received a bachelor's degree in chemical engineering from Purdue University and a law degree, summa cum laude, from the Indiana University Robert H. McKinney School of Law. Mr. Caltrider is serving his second term and fifth year as a PPAC member.

JUDGE SUSAN G. BRADEN (RET.)

Judge Braden began her career as a Senior Trial Attorney in the Department of Justice's Antitrust Division. She later became Counsel to two Federal Trade Commission Chairmen and was a federal trial and appellate litigator in private practice. In 2003, she became a Judge on the U.S. Court of Federal Claims; in 2017, she was designated Chief. After retiring in April 2019, Judge Braden was appointed to the U.S. Administrative Conference as a Public Member, and the Legal Advisory Board of the Washington Legal Foundation. She also serves as Jurist-In-Residence at the Center for Intellectual Property and Policy (CIP2), Antonin Scalia School of Law, George Mason University and on the Board of Directors, United Inventors Association. In July 2020, she was appointed by the Office of the United States Trade Representative as one of 10 individuals who will represent the nation in disputes arising under the United States-Canada-Mexico Trade Agreement. She also serves on the boards of two companies that create and sell software and artificial intelligence and a major construction company. Judge Braden received a bachelor's degree and law degree from Case Western Reserve University. She also received a Business Administration Certificate from Georgetown University and attended Harvard Law School's Program on Negotiation. Judge Braden serves as an Arbitrator, Mediator, and Special Master for the American Arbitration Association and FedArb. Judge Braden is serving her first term and third year as a PPAC member.

DANIEL BROWN

Dr. Brown is an award-winning designer, inventor, entrepreneur, and full-time professor at the Segal Design Institute of Northwestern University. He is a native of Chicago, where he attended St. Xavier University, earning a bachelor's degree in biology with a minor in chemistry. Additionally, Dr. Brown earned his master's degree from the McCormick School of Engineering at Northwestern University, and a Ph.D. in design from Coventry University in the United Kingdom. He has received over 100 U.S. and international utility patents for his novel product solutions in industry and has taken many of his inventions to market himself as a founder of two startups. Dr. Brown has seen both sides of the American Dream, enjoying the market success of his bionic wrench invention, while at the same time fighting counterfeit versions that almost destroyed his business. Dr. Brown believes that the best social system for our nation provides good jobs, but job creation and the economic benefits of innovation fundamentally depend on the ability of inventor-entrepreneurs to protect their investments through their intellectual property. He continues to work in support of an equitable, protectable, and sustainable intellectual property system for all inventors. Dr. Brown is serving his first term and third year as a PPAC member.

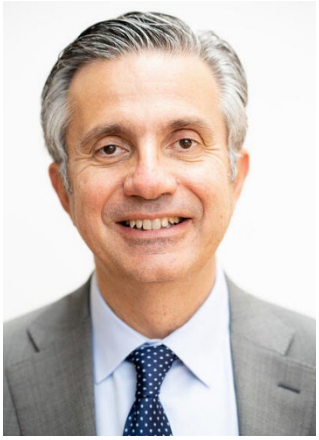
CHARLES DUAN

Mr. Duan is Assistant Professor of Law at American University Washington College of Law. He was also Director, Technology and Innovation Policy, at the R Street Institute, a nonprofit, public policy research organization in Washington, D.C. Prior to his current positions, Mr. Duan was Director, Patent Reform Project, at Public Knowledge, a nonprofit public interest organization, and he was a Research Fellow for Professor Paul Ohm at the Colorado Law School, a position funded by the National Science Foundation. He worked as a patent litigation and prosecution attorney at Knobbe Martens Olson & Bear LLP, as well. Mr. Duan is serving his first term and second year as a PPAC member.

LOLETTA (LOLITA) DARDEN

Ms. Darden is the Visiting Associate Clinical Professor and Director of the IP and Technology Clinic at The George Washington University Law School, where she has been since August 2022. Previously, Ms. Darden was an Associate Clinical Professor (with tenure) and Director of the IP Clinic at Suffolk University Law School for six years. Before joining Suffolk University, Ms. Darden worked for Sachnoff & Weaver, where she was a Partner and Patent Prosecution Department Chairperson. Prior to joining Sachnoff & Weaver, Ms. Darden was Chief IP Counsel for a small consumer products company, where she managed the company's IP prosecution and litigation portfolios and pioneered a strategy for strategically using and creating IP assets to enhance the company's competitive strength. As a law professor, Ms. Darden has taught IP survey, trademark law and practice, and patent law and practice. Ms. Darden is also a C-IP² Scholar at the George Mason University Center for Intellectual Property x

Innovation Policy, where her scholarship focuses on the protection and preservation of IP rights for creators and inventors. She is also a member of the Giles S. Rich American Inn of Court. Ms. Darden is serving her first term as a PPAC member.



HENRY HADAD

Mr. Hadad is Senior Vice President & Deputy General Counsel, Innovation Law, at Bristol Myers Squibb, where he is Chief Intellectual Property (IP) Counsel, leading a team supporting the company's efforts to discover, develop and deliver groundbreaking treatments for patients with serious unmet medical need. He was previously Chief IP Counsel at Schering-Plough Corporation and held roles at Johnson & Johnson and in private practice. During his legal career, Mr. Hadad has represented the innovative biopharmaceutical, generic, medical device and consumer goods industries, with a focus on IP procurement, litigation, transactions and policy in the United States and internationally, and is an active member of numerous IP educational, policy and advocacy organizations. Mr. Hadad is a passionate advocate for a strong and predictable IP system that drives innovation across all technologies, and in developing a diverse and inclusive pipeline of future leaders in the IP profession and the innovation ecosystem. He is a board member of the Intellectual Property Owners (IPO) Association, served as its President (2018-2019), and is currently chair of its Amicus Committee. Mr. Hadad holds a B.S. in Biology from Haverford College and a J.D., *cum laude*, from the American University, Washington College of Law. Ms. Hadad is serving his first term as a PPAC member.

OLIVIA TSAI

Ms. Tsai is Assistant General Counsel and Head of IP at Cruise, a leading autonomous vehicle company. At Cruise, she leads the team responsible for IP protection and strategy. She founded Cruise's Asian and Pacific Islander Employee Resource Group. Prior to Cruise, Ms. Tsai counseled in cutting edge technology areas at Cisco, Sandia National Laboratories, and in private practice. She has a BS in Electrical Engineering from the Massachusetts Institute of Technology and a JD from Case Western Reserve University. Ms. Tsai serves as Co-Founder and Corporate Secretary of Allied Transportation Association to bring together collaborative IP opportunities in the transportation industry. Ms. Tsai also serves as Founding Member of Advancing Diversity Across Patent Teams ("ADAPT") to promote the advancement of diversity, equity, and inclusion among patent professionals. Ms. Tsai is serving her first term as a PPAC member.

UNITED STATES
PATENT AND
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PATENT PUBLIC ADVISORY COMMITTEE
FEE SETTING REPORT

August 14, 2023

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Background

The USPTO is entirely funded by fees collected from its users and does not rely on the federal government's tax revenues. In the Leahy-Smith America Invents Act of 2011 (AIA), the USPTO was granted the authority to set its own fees, but only after following a structured process of collecting and considering public input. Following a biennial fee review conducted within the agency, the USPTO sent a fee adjustment proposal to the PPAC on April 20, 2023. As provided by the statute, the PPAC held a public hearing on May 18, 2023, at the USPTO in Alexandria, Virginia and collected public input both at the hearing and in the form of written submissions. This PPAC/USPTO Fee Setting Report reflects the PPAC's views after considering the written submissions and hearing testimony. After considering this Report, the USPTO will issue a Notice of Proposed Rule Making (NPRM) including a fee proposal incorporating any revisions made to reflect the PPAC's input. After collecting and considering further public reaction to the NPRM, the USPTO will issue a Final Rule specifying adjusted fees. It is currently expected that the new fees will go into effect in 2025.

The fee adjustment includes targeted adjustments to assignments, continuing applications, design patents, PTAB fees, significant increases to accelerated design patent examination fees, and surcharges for request for continuation, excess claims, patent term adjustment, terminal disclaimer and unintentional delay petitions. There is also a 5% across the board inflation adjustment. And finally, there is a request for another 5% across the board increase.

Criteria for Analyzing the Fee Adjustment Proposal

In preparing its recommendation on the USPTO's fee adjustment proposal, the PPAC has considered the appropriateness of both the aggregate proposed fee increase and the individual fee increases.[1] Assessing the aggregate proposed fee increases involves considering the USPTO's overall needs to fulfill its mission of supporting the country's innovation system, including the need to maintain a robust operating reserve. At the last fee setting hearing, which occurred in 2018, there was much discussion of improving the USPTO IT infrastructure to both assure its operational reliability and help examiners improve patent quality. That same need exists today, as the cloud migration program is only about 20% complete. Fulfilling both the public and the Director's interest and commitment to increase reliability and certainty in the patent system will require continued improvements to both the examination and PTAB processes. And finally, the PPAC reviewed the current context the USPTO finds itself in. First, the Unleashing American Innovators Act (UAIA) of 2022, signed into law December 29, 2022, reduced barriers to entry into the patent system by increasing small and micro entity discounts. As a consequence of new, higher discounts, the USPTO will collect significantly less fee revenue going forward relative to baseline estimates. In the fiscal year 2024 budget it is estimated to amount to a $600 million fee reduction. Second, the USPTO was required to provide a 4.8% pay raise starting in 2023. Additionally, in the FY 2024 budget, an additional 5.2% pay raise was included as part of an all of government requirement. Thus, the USPTO finds itself depleting its required reserve balances due to both Congress and required government raises.

[1] It should be noted that there were a number of both written and oral comments challenging the USPTO's authority under the statute to conduct the fee setting process. The PPAC has neither the ability nor the standing to make a legal determination as part of our role in the fee setting process. We have turned over all documentation regarding these challenges to USPTO legal.

Whether the aggregate fee increase makes sense depends upon whether, whether USPTO is prioritizing the right expenditures to fulfill its mission, and whether it is operating efficiently. It is also appropriate to consider the life cycle costs of getting and maintaining a patent and evaluating the incentive effect on applicants. The impact of costs on applicants, particularly small inventors, is an important factor in the assessment. It is important to both PPAC and the USPTO that price does not significantly inhibit an inventor's willingness to seek patent protection. Increases proposed for individual fees as well as newly introduced fees can be judged based on fairness, their effect on applicant behavior, and whether they are in fact likely to raise expected revenue.

Overall Public Sentiment

Overwhelmingly in both oral and written comments, the public wanted more a more reliable and durable patent right emanating from examination. Many mentioned they would be supportive of a fee increase if it was used by the USPTO to provide that increased reliability and certainty. In general, many commenters were supportive of an inflationary adjustment. In the oral comments, there were a number of references to patient advocates requesting that patents be weakened or eliminated in favor of reduced drug pricing. While the healthcare challenges and unmet medical needs of patients are both heartbreaking and compelling, this is both a misguided and ill-informed understanding of the relationship between patents and drug pricing. The availability of reliable and durable patents is the necessary foundation to billions of dollars of research investment into tomorrow's cures. Patents are vital part of the solution to today's unmet medical needs, not the problem. Furthermore, there are a number of other more relevant considerations, which are out of scope of this report, that affect drug pricing.

Aggregate Fee Increase

The PPAC supports this fee increase. The current fee proposal contained two separates, across the board fee increase. The first was a 5% inflation adjustment. As mentioned above, the USPTO has already included a 4.8% pay increase in 2023 and is looking at another 5.2% pay increase in 2024.

The PPAC does not support this fee increase. The second across the board fee increase of 5% was designed to front load fees in order to reduce the reliance on maintenance fee renewals. The PPAC does not support this fee as we believe it places an undue burden on individual inventors and small businesses.

After Final Consideration Pilot (AFCP-a 2.0)

The PPAC views this fee as problematic as it requires paying the fee without any guarantee of an interview. We suggest that the USPTO consider either of the following proposals:

a. Don't require a fee unless you can guarantee the applicant will get an interview
b. Alternatively, don't pay the fee until the applicant does get an interview

If either case were to be enacted, then PPAC would support the fee increase.

Assignments

Previous assignment recordation fees were eliminated by the USPTO in 2014, however since then, there has been an increase in frivolous recordation submissions. This fee increase was viewed as one potential way to reduce such submissions. **The PPAC is against this fee** as ensuring transparency of

ownership is key to patent data integrity, and we do not recommend USPTO to impose a fee that would provide an impediment to keeping assignment data up to date.

Continuing Applications

Continuing applications provide a high value mechanism for companies and inventors to keep a potential patent application in process over a longer period of time. **The PPAC supports this fee with the following modifications:** Drop the year three provision and only make applicable for year 7 or after. Three years is too short of a period, as there may not yet be an office action, particularly if the case was filed via the PCT or in art areas with significant backlog, or other information from which to evaluate the need to file one or more continuations.

Design Patents

The PPAC does not agree with this fee. PPAC believes that the USPTO should prioritize pendency issues before applying fees here, as many design patent users are already paying expedited fees given the long pendency backlog issues currently happening. Perhaps these issues could be addressed by a law change to implement maintenance fees.

Excess Claims

The PPAC is supportive of this fee increase with the following caveat: It is clear that the public wants more certainty that an increased fee will be spent on examination and/or giving the Examiners additional time to evaluate such cases.

Extension of Time (EOT) for Provisional Applications

The PPAC is supportive of decreasing EOT fees for provisional applications.

Information Disclosure Statement (IDS)

The PPAC is supportive of this fee increase, however we note that if Congress would reform inequitable conduct rules, this by itself may largely affect applicant behavior. With current inequitable conduct case law, there is undue pressure on practitioners to cite every possible reference or risk the practitioners right to practice or the enforceability of the case. The PPAC recommends a legislative proposal to change this pressure. Also, if additional fees are paid, we suggest the additional money should go towards allowing Examiner's more time to consider the additional references.

Patent Term Adjustment

This fee is proposed to cover the USPTO cost of a patentee requesting the adjustment of the patent term of their patent. **The PPAC is generally supportive of this fee with the following caveat:** If the USPTO made the adjustment mistake, then the applicant shouldn't have to pay, if not, then applicant should pay the fee.

Patent Term Extension

This fee increase fee proposal is for patentees seeking to extend the patent term under 35 U.S.C. 156 in conjunction with the Food and Drug Administration/U.S. Department of Agriculture approval process. **The PPAC supports this fee in principle**, however we suggest the USPTO consider if such a large jump in fees is optimal, particularly the initial fee given start-up companies may be resource constrained.

Request for Continued Examination

This fee increase raises the fee for a first RCE by 10% and splits the current fee for second and subsequent RCEs into an increased fee for a second RCE and a new, higher fee for a third and subsequent RCE. **The PPAC supports this increase** as this allow the costs of continued examinations to be recovered directly from those applicants requesting multiple RCEs, instead of relying on other fees to subsidize the costs. The proposal continues to set the first RCE below cost.

Suspension of Action

This fee increase creates a tiered system in which the fees for subsequent suspensions are charged at a higher rate. This fee increase would not affect fees for suspensions of action requested at the time of filing a CPA or RCE. **The PPAC supports this fee increase** as the fee increases encourages efficient applicant behavior and examination and costs associated with suspension of action should not be subsidized by other fees.

Terminal Disclaimer

The PPAC does not support this fee increase. The stated justification is that an earlier terminal disclaimer submission permits the USPTO to reduce unnecessary examination costs, reduce appeal costs, provide greater certainty for the public, and promote overall efficiency of operations. PPAC does not agree that a fee increase will achieve these objectives. Furthermore, the fee increase will place an unfair burden to filers with limited resources. The increase will pressure such filers to give up patent term in exchange for a less expensive more compact prosecution while those with more resources can wait to see if they need to file a terminal disclaimer until allowable claim scope is identified.

Unintentional Delay Petitions

The PPAC supports this fee increase. The fee increase for a petition with a delay less than or equal to two years is designed to offset the costs of processing the petition. The creation of a higher tier aligns with increased costs to the USPTO when deciding a petition with a longer delay.

AIA Trial Fees

The PPAC supports this fee increase. The costs associated with IPR have continued to increase as a result of recent court cases and higher operating costs caused, in part, by inflation.

The AIA fee increase supports aggregate cost recovery for USPTO operations.

Word Count

The PPAC does not support this fee, as the fee increase favors well-resourced petitioners. Even if the small inventor is granted the same number of words, the expense to prepare longer, responsive papers is a significant burden. We believe the USPTO should set a reasonable word limit, and if the petitioner needs additional words, the petitioner can request additional words with the appropriate showing of cause.

Director Review of PTAB Decisions

The PPAC does not support this fee. Director review should be encouraged to ensure that all PTAB decisions are consistent. Adding a fee for this previously free service, may adversely affect individual inventors and small company applicants.

Conclusion

To support its role in the country's innovation system, the USPTO requires adequate funding. Timely, high-quality search and examination require an appropriately compensated work force with adequate time to complete the same, supported by state of the art and reliable IT infrastructure. The lack of reliability and certainty of the patent right has led to growing frustration among the public. The more prevailing view is that innovation is hindered by uncertainty about which patents are in fact valid. This has led to more litigation, consuming valuable and limited resources for both inventors and companies.

As noted above, the PPAC has not supported some individual fee increases and has asked for further refinement for others. It is believed that the PPAC unsupported fees will negatively impact individual inventors and could incentivize them to abandon the patent system completely, no longer seeking to protect their inventions. This is not helpful to our nation's goal of increasing our economic and technological competitiveness.

The PPAC views the biennial fee review process as successful in providing the USPTO the autonomy it needs to set its own fees, while importantly considering input from the public. The USPTO is in the best position to assess its own needs and balance the tradeoffs in setting individual fees. The PPAC notes with appreciation the efforts of the USPTO staff in conducting the biennial fee review and developing the fee proposal that we have reviewed. The PPAC also thanks all of those in the public who submitted comments and participated in the hearing on May 18th. We hope that the end result will be a fee structure that addresses the user community's concerns as well as expectations regarding the USPTO's operations and functionality providing the capabilities that the USPTO needs to fulfill its goal of providing reliable and certain patent rights.


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