

UNITED STATES
PATENT AND TRADEMARK OFFICE



Welcome

Patent Public Advisory Committee Public Meeting

November 30, 2023
10 a.m. – 12 p.m. ET

Please submit questions to ppac@uspto.gov



UNITED STATES
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Patent Public Advisory Committee Public Meeting

Call to Order and Introduction
Suzanne Harrison
PPAC Chair

Please submit questions to ppac@uspto.gov



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Opening Remarks

Kathi Vidal

**Under Secretary of Commerce for Intellectual Property
and Director of the USPTO**

Please submit questions to ppac@uspto.gov



**UNITED STATES
PATENT AND TRADEMARK OFFICE ®**

2023 PPAC Annual Report

November 30, 2023

Patent Public Advisory Committee meeting



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Agenda

- Introduction
- What is the PPAC?
- Rulemaking
- Finance
- Artificial intelligence
- Working with other government agencies
 - FDA
 - USDA
- Patent Trial and Appeal Board (PTAB)
- Impacting the gross domestic product (GDP)

Introduction

- The PPAC's efforts this year have been focused on helping the USPTO use patents for the benefit of the nation. As such, we have worked with Director Vidal in the following areas:
 - Linking patents and invention to increasing GDP and helping to ensure a robust U.S. economy.
 - Expanding the number and diversity of people who engage with the U.S. patent system, both geographically and demographically.
 - Continuing to be good financial stewards to ensure the patent system is both affordable and accessible to all participants.
 - Working collaboratively with other government agencies to ensure the USPTO has all the relevant data and information it needs to issue robust and reliable patent rights.
 - Increasing stakeholder engagement with numerous requests for comments and rulemaking interactions.

Patents and national competitiveness

"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."

-2023 PPAC Annual Report, page 2 of the PPAC Chair's letter to the President



Preparing for the future

- The PPAC is proud to partner with the USPTO and Director Vidal to help prepare the agency for the challenges it faces in the coming years:
 - Considering 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 Leahy-Smith 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.



What is the PPAC?

- The PPAC was established by the American Inventors Protection Act of 1999 to review the policies, goals, performance, budget, and user fees of the USPTO.
- The Secretary of Commerce 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 for a three-year term. At least 25% of the PPAC must represent “small entity patent applicants.” No PPAC member may serve more than two terms.
- By law, the PPAC must convene two meetings each year that must be open to the public. Either the Director or the PPAC Chair may call non-public meetings where “personnel, privileged, or confidential information” will be discussed.

What is the PPAC?

- The PPAC is authorized by 35 U.S.C. 5(f) to request “records and information” from the Director, except for personnel or privileged information, or information concerning patent applications.
- Each year, the PPAC prepares a published Annual Report, which is transmitted to the President of the United States, the Secretary of Commerce, the Director of the USPTO, and members of the House and Senate Judiciary Committees.
- PPAC members can work no more than 60 days per year.

Rulemaking activities

General rulemaking timeline



FY 2023: Volume of USPTO notices in the Federal Register and written comments

Type of notice	# Notices	# Comments
Final rule	17	N/A
NPRM	2	20
ANPRM (optional)	1	14,530
Request for comments (optional)	32	700
Total	52	15,250



Being good stewards: finance

- FY 2023:
 - 515,000 new patent applications
 - 340,000 patents granted
 - 8,500 patent examiners
 - \$2.9 billion direct costs

Fee funding model

- Fees fully offset the Patents organization's operational costs
- Appropriations still required
- Not cost-for-service:
 - Small/micro entity discounts
 - Below-cost application fees
- Operating reserves

Finance model changes

Changes	Forecasted outcome
Unleashing American Innovators Act: increased discounts	\$74–\$110 million/year decrease in fee revenue
Pay raises and inflation	\$173 million/year spending increase

Fiscal initiatives

- Fee setting process
- Building leases: \$27-\$50 million/year savings
- Technology investments

Key takeaways

- The USPTO is in good financial shape
- Cost recovery and operating reserves are critical
- Greater flexibility in fee setting
- Ongoing efforts to gain access to \$950 million in unavailable collected patent fees

AI and patent classification and searching

- AI tools are already being used in limited ways in patent classification and searching.
 - C*
 - Assistance in finding potential prior art
- AI tools should not be considered an acceptable replacement for POSITA resources.

AI and inventorship

- Current law requires the named inventor or joint inventors to be natural persons.
- The USPTO has engaged with the public and foreign intellectual property (IP) offices to obtain different perspectives on this issue.
- The USPTO decision will impact innovation in developing new AI tools.

Proposal for expanded USPTO-FDA cooperation

- July 2021 Executive Order, which directs a whole-of-government effort to promote competition in the American economy:
 - The FDA communicated with the USPTO to ensure that “the patent system, while incentivizing innovation, does not also unjustifiably delay generic and biosimilar competition.”
 - Similar requests followed from Congress focusing on potential of conflicting statements made during agency review.
- Different roles of the USPTO and the FDA
- The USPTO and the 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.
- The PPAC supports the USPTO’s ongoing efforts to review whether information sharing with the 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.



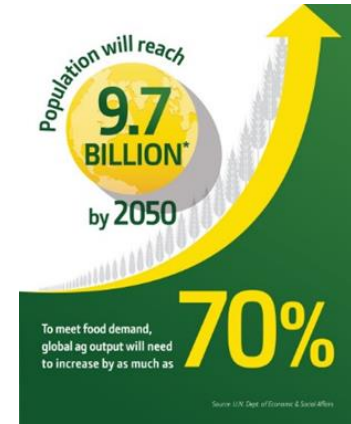
Proposal for expanded USPTO-FDA cooperation

- The PPAC has not been presented with 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.
- The PPAC believes any patent reform proposals should be clearly supported by facts.
 - Senator Tillis requested that the USPTO and the FDA conduct an independent assessment to study data from several data sources about patenting practices in the pharmaceutical industry.
- The PPAC supports the USPTO's and the FDA's ongoing efforts to complete an independent study, 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.



IP around seeds and plant varieties is an issue of national security

According to FBI Director Christopher Wray, 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 the simple act of digging up seeds in a field.



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.
- *Ex parte Hibberd*: Private company investment in plant breeding has skyrocketed, as well as the introduction of new plant varieties. According to conservative estimates, the introduction of patent protection increased the total value of U.S. agricultural land in 2002 by 7.5%, or roughly \$80 billion (\$117 billion in 2020 USD).

Executive Order promoting competition

- July 2021 Executive Order
- USPTO and USDA collaboration
 - Access to off-patent inventions
 - Outreach to farmers to provide education about the role of IP
 - Cooperation between the USDA PVP system and the USPTO patent system
 - Maintain the delicate balance aimed at rewarding and incentivizing those who do the work to create original innovation, as well as protecting the public interest in continued innovation and fair competition.

The patent system

- Per U.S. Const., 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.
 - The patent system is 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.



Patent Trial and Appeal Board (PTAB)

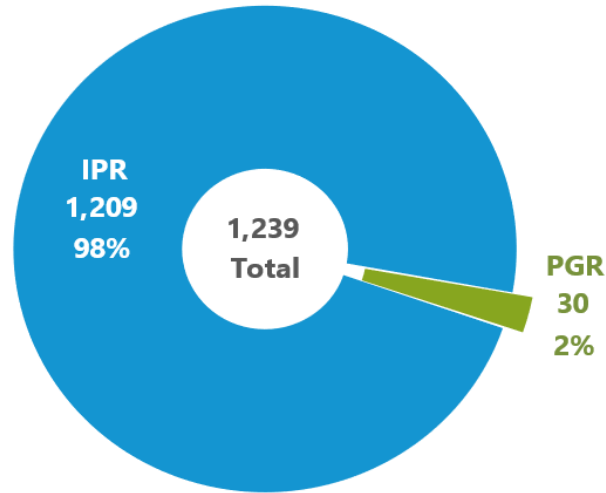
- The AIA—September 16, 2011. The AIA established the PTAB and created post-grant proceedings.
 - The proceedings are intended “to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs.”
 - The USPTO recognized this in the recent ANPRM:

Congress designed the AIA to improve and ensure patent quality by providing ***“quick and cost-effective alternatives to litigation”*** for challenging issued patents while also recognizing 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.”***



Current data indicates that inter partes review (IPR) remains the most prevalent AIA proceeding, with 98% of petitions being filed

Petitions filed by trial type (FY23: Oct. 1, 2022 to Sept. 30, 2023)

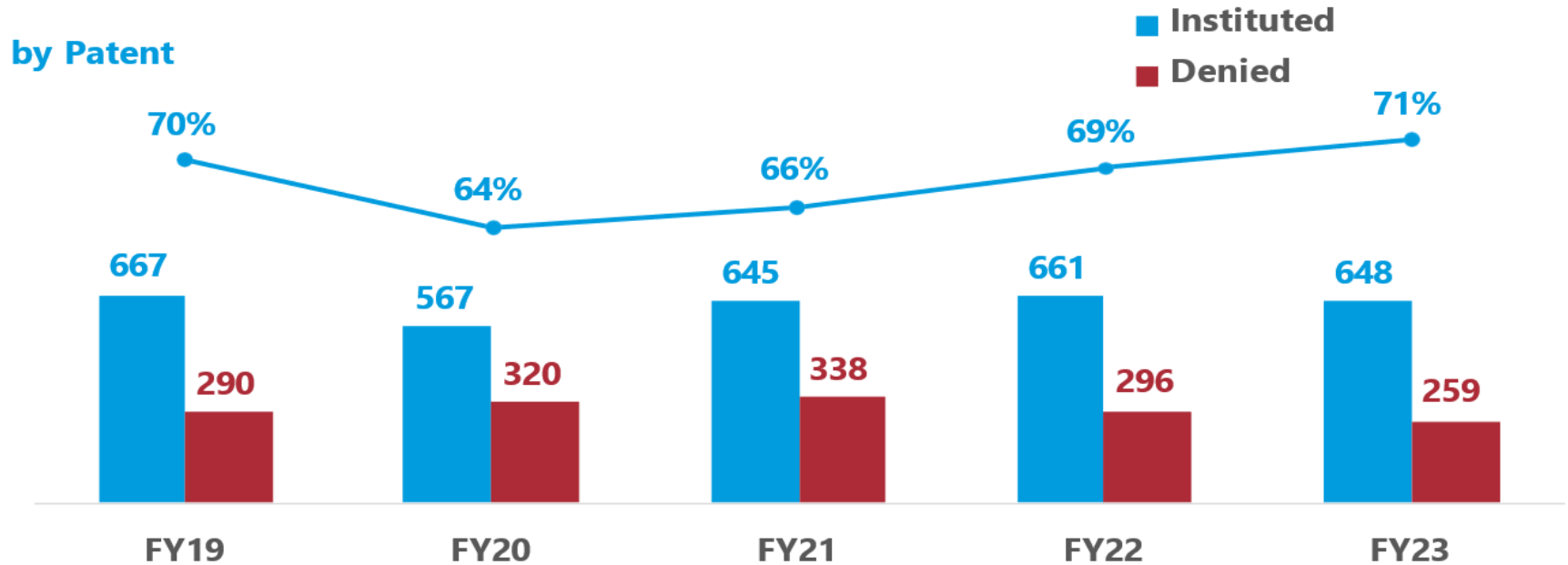


Trial types include Inter Partes Review (IPR) and Post Grant Review (PGR).



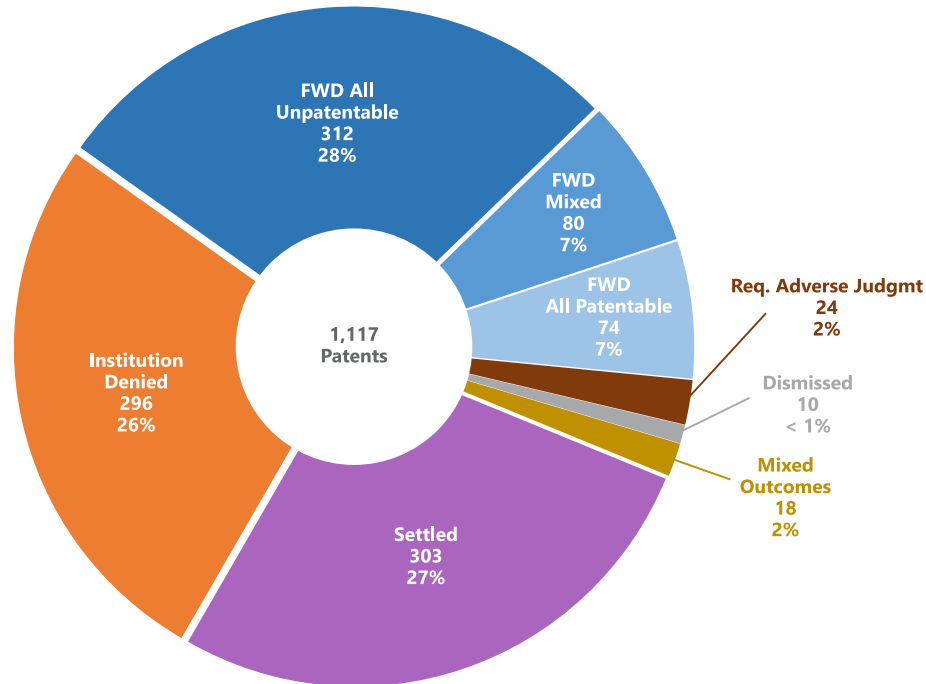
Institution rates by patent

(FY19 to FY23: Oct. 1, 2018 to Sept. 30, 2023)



Outcomes by patent

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



FWD patentability or unpatentability reported with respect to the claims at issue in the FWD. "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.

Office of Patent Quality Assurance study of PTAB outcomes

- 93% of these challenges finding unpatentability of at least one independent claim were based on prior art not cited in prosecution.
 - 74% only new prior art
 - 19% on a mix of new prior art and art previously cited during prosecution
- 7% of the challenges finding at least one independent claim unpatentable were based on prior art cited during the examination of the patent.
 - 82% had more than 100 references cited by the applicant in an information disclosure statement

Key takeaways

- Congress, with support from the USPTO, should continue to study patent and litigation data to ascertain if the AIA legislation achieved its desired goals.
- 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 the sole responsibility for prior art searching and should discuss with stakeholders ways to encourage applicants to provide more prior art references.
- 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 it.



Reaching more inventors

- The USPTO has been successful in increasing 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.



Thank you!

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