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PTAB Bar Association

PTAB Judges Panel – An Inside Perspective

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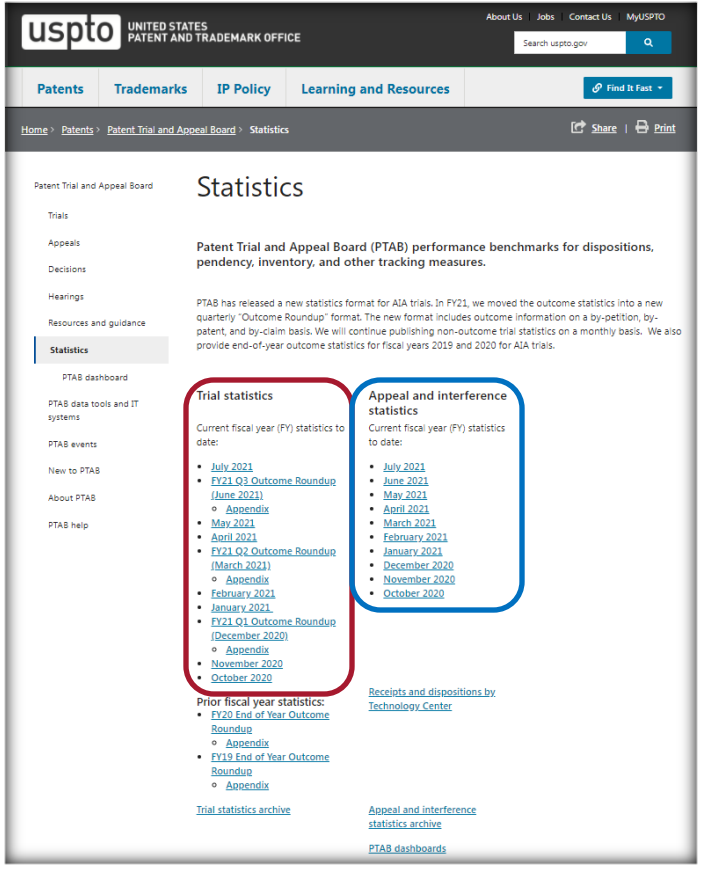
Agenda

- Latest PTAB statistics
- Important changes to PTAB practice
- New to PTAB resources
- Current status of discretionary denials in AIA proceedings
- Post-*Arthrex*—how/when to request Director review
- Fast track appeal pilots
- MTA pilot status
- Practice tips for parties
- Questions

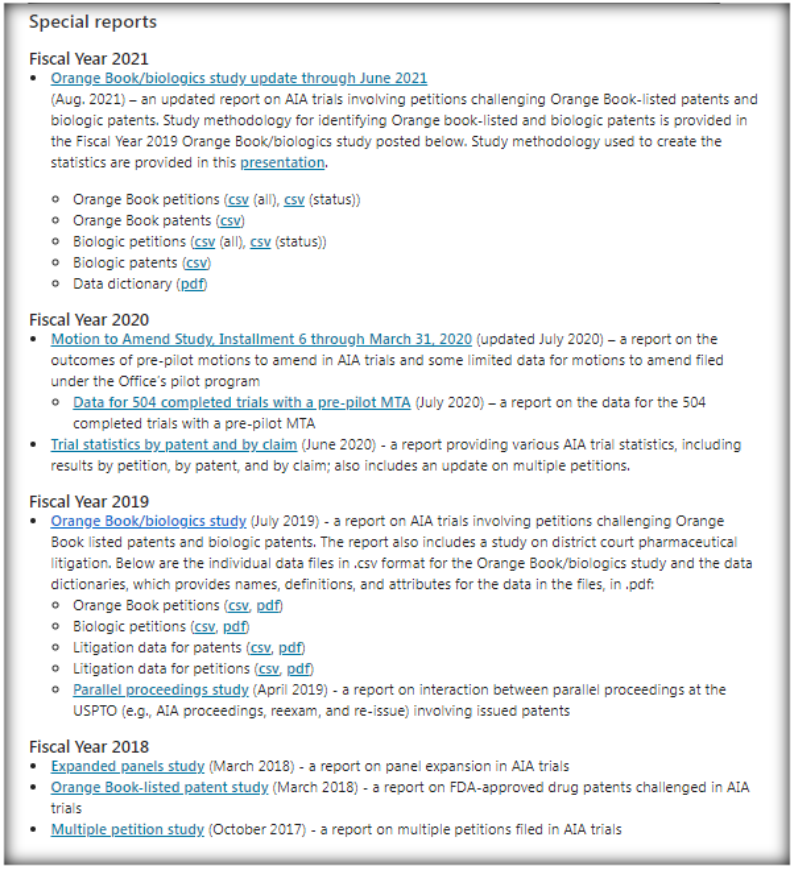
Latest PTAB statistics

PTAB statistics



- PTAB statistics are available at
  - https://www.uspto.gov/patents/ptab/statistics
- Latest statistics (FY21) relating to:
  - AIA proceedings
  - *Ex parte* appeals and interferences

PTAB statistics



Special reports

Fiscal Year 2021

- Orange Book/biologics study update through June 2021
  (Aug. 2021) – an updated report on AIA trials involving petitions challenging Orange Book-listed patents and biologic patents. Study methodology for identifying Orange book-listed and biologic patents is provided in the Fiscal Year 2019 Orange Book/biologics study posted below. Study methodology used to create the statistics are provided in this presentation.
  - Orange Book petitions (csv (all), csv (status))
  - Orange Book patents (csv)
  - Biologic petitions (csv (all), csv (status))
  - Biologic patents (csv)
  - Data dictionary (pdf)

Fiscal Year 2020

- Motion to Amend Study, Installment 6 through March 31, 2020 (updated July 2020) – a report on the outcomes of pre-pilot motions to amend in AIA trials and some limited data for motions to amend filed under the Office's pilot program
  - Data for 504 completed trials with a pre-pilot MTA (July 2020) – a report on the data for the 504 completed trials with a pre-pilot MTA
- Trial statistics by patent and by claim (June 2020) - a report providing various AIA trial statistics, including results by petition, by patent, and by claim; also includes an update on multiple petitions.

Fiscal Year 2019

- Orange Book/biologics study (July 2019) - a report on AIA trials involving petitions challenging Orange Book listed patents and biologic patents. The report also includes a study on district court pharmaceutical litigation. Below are the individual data files in .csv format for the Orange Book/biologics study and the data dictionaries, which provides names, definitions, and attributes for the data in the files, in .pdf:
  - Orange Book petitions (csv, pdf)
  - Biologic petitions (csv, pdf)
  - Litigation data for patents (csv, pdf)
  - Litigation data for petitions (csv, pdf)
  - Parallel proceedings study (April 2019) - a report on interaction between parallel proceedings at the USPTO (e.g., AIA proceedings, reexam, and re-issue) involving issued patents

Fiscal Year 2018

- Expanded panels study (March 2018) - a report on panel expansion in AIA trials
- Orange Book-listed patent study (March 2018) - a report on FDA-approved drug patents challenged in AIA trials
- Multiple petition study (October 2017) - a report on multiple petitions filed in AIA trials

- Also on PTAB statistics website
  - https://www.uspto.gov/patents/ptab/statistics
- Special reports over the years, including:
  - Orange book/biologics study and updates
  - Motion to Amend study and updates
  - Study of parallel proceedings at USPTO
  - Other studies and statistics relating to AIA proceedings from prior fiscal years

Important changes to PTAB practice

Important changes to PTAB practice

- Revised claim construction standard used in AIA proceedings (Nov. 2018)
- Standard Operating Procedures (Sept. 2018)
  - SOP 1 (paneling)
  - SOP 2 (two new processes to designate decisions precedential or informative, including POP review on rehearing)
- Motion to amend practice pilot program initiated in March 2019 and extended until September 16, 2022
- Notice explaining reissue and reexamination options (April 2019)
- 2019 revised patent subject matter eligibility guidance
  - Impacting *ex parte* appeals and AIA cases

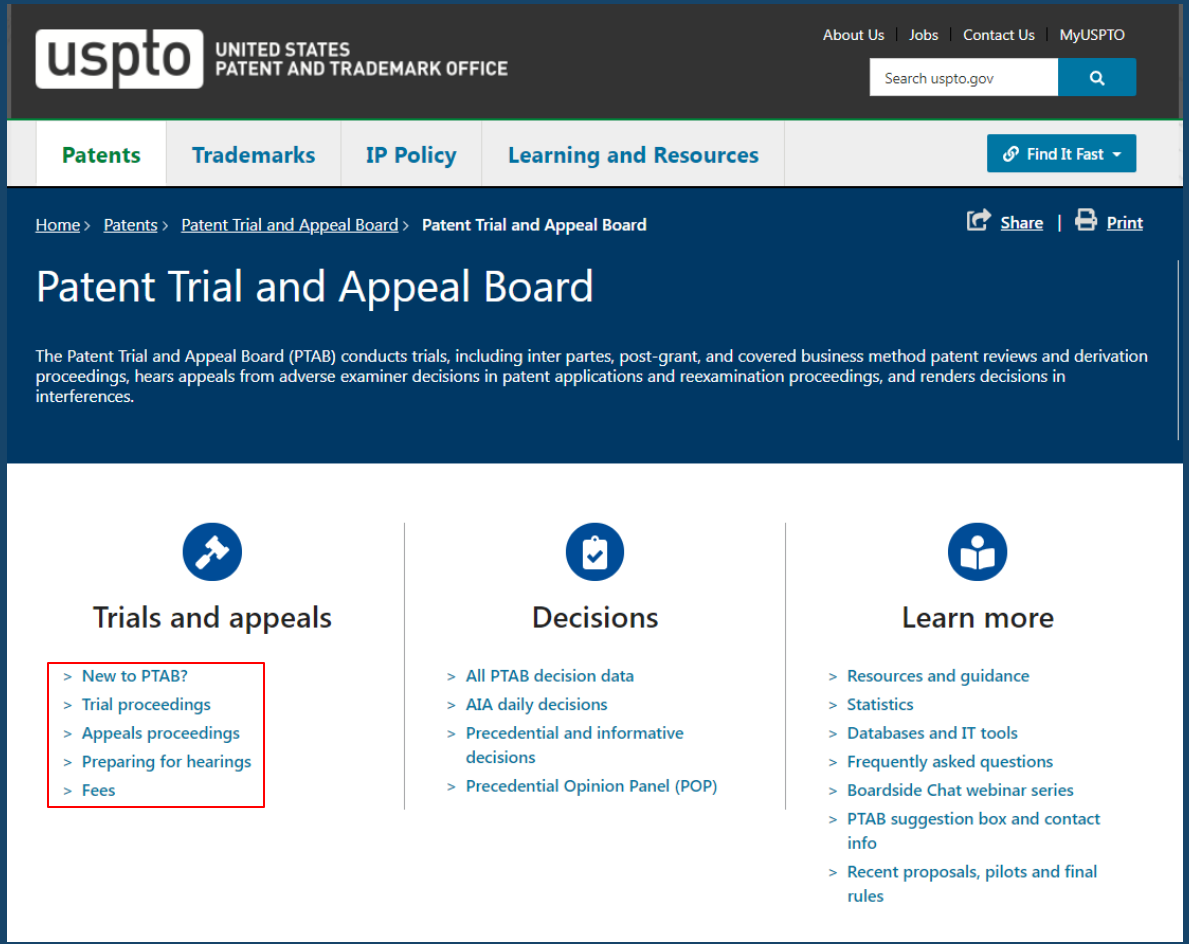
Important changes to PTAB practice

- Updates to Trial Practice Guide (consolidated in Nov. 2019)
- Designated precedential and informative decisions
  - Covering issues such real parties-in-interest; joinder; printed publications; and discretionary denials of institution under 35 U.S.C. § 314(a) and § 325(d)
  - Precedential Opinion Panel (POP) issued four notable precedential decisions
- Extended deadlines under the CARES Act
- Legal Experience and Advancement Program (LEAP) (May 2020)
- Fast-Track Appeals Pilot Program (July 2020)
  - Extended through February 2022
  - COVID Fast-Track Appeals Pilot Program (April 2021)

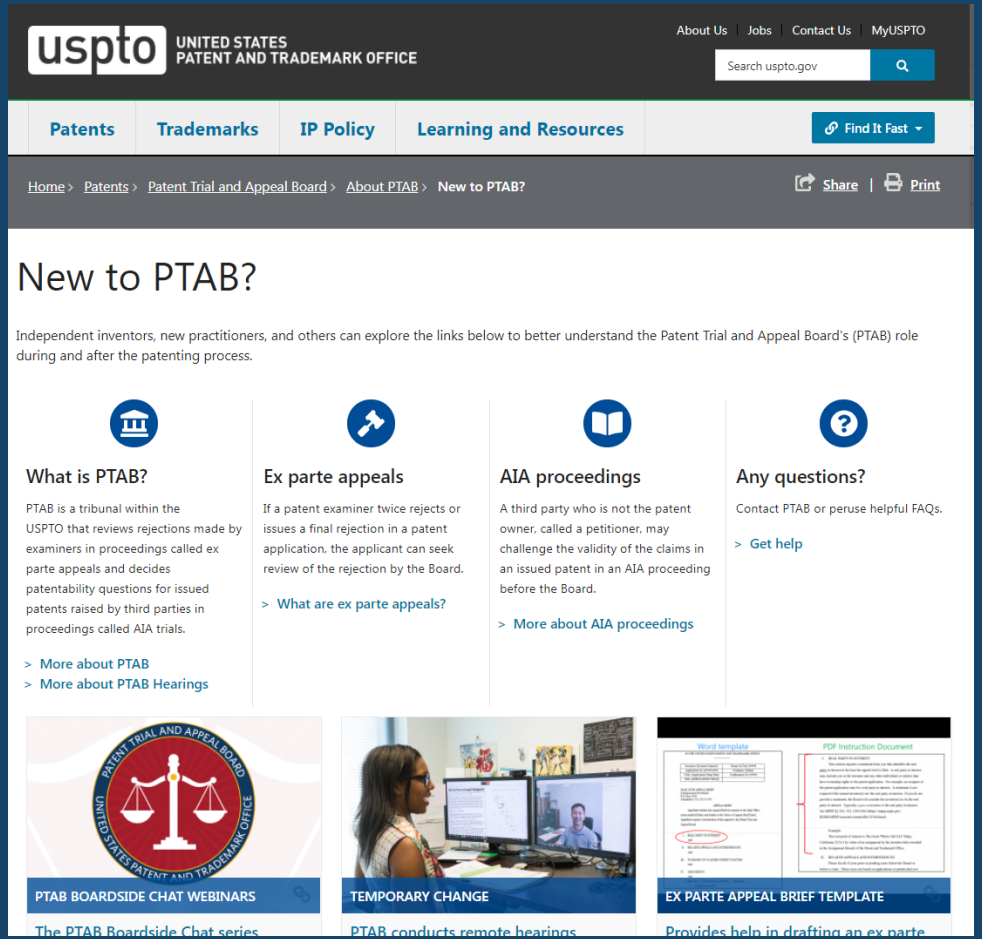
Important changes to PTAB practice

- Rulemaking on AIA trial institution and responsive briefing (Dec. 2020)
- Rulemaking to allocate burdens of persuasion on motions to amend in AIA trial proceedings (Dec. 2020)
- Director issued two memoranda clarifying:
  - Interpretation of § 311(b) in relation to applicant admitted prior art (Aug. 2020)
  - Approach to indefiniteness in AIA proceedings (Jan. 2021)

New to PTAB resources



uspto.gov/patents/ptab



uspto.gov/patents/ptab/ptab-inventors

35 U.S.C. § 314(a) and § 325(d)

Current status of discretionary denials

Current status of discretionary denials

- Serial/parallel petitions, and proceedings in other tribunals
- § 325(d)

Request for Comments (RFC) Discretion to Institution AIA trials

- In October 2020, the USPTO issued a request for comments seeking public input on whether to promulgate rules with case-specific analyses on deciding whether to institute a trial for
  - (1) petitions on claims that have been previously challenged in another petition,
  - (2) more than one petition filed at or about the same time on the same patent,
  - (3) petitions on patents that have been subject to proceedings in a U.S. district court or the ITC, and
  - (4) any other considerations regarding discretion to institute

Request for Comments (RFC) Discretion to Institution AIA trials

- Comment period closed on November 19, 2020
- The USPTO issued an Executive Summary of comments in January 2021:
  - 822 comments received
  - 3 U.S. Senators submitted comments
  - The RFC generated extensive interest from stakeholders—more comments than prior AIA post-grant proceeding rulemaking.

Supreme Court decision

United States v. Arthrex

United States v. Arthrex

- On June 21, 2021, the Supreme Court issued its decision in *United States v. Arthrex*.
- The Court addressed the Constitution's Appointments Clause as it relates to administrative patent judges ("APJs").
- The Court considered whether APJs are "principal officers" who must be appointed by the President with the Senate's advice and consent, or, as the USPTO and the U.S. government argued, whether they are "inferior officers" who can be appointed by the Secretary of Commerce.

United States v. Arthrex

- The Court held that "the unreviewable authority wielded by APJs during *inter partes* review is incompatible with their appointment by the Secretary to an inferior office."
- The Court's remedy provides that the Director "may review final PTAB decisions and, upon review, may issue decisions himself on behalf of the Board."
- Although the decision comprises four separate opinions on the constitutionality issue, seven Justices agree that the Court's tailored remedy addresses the identified problem.

United States v. Arthrex

- The lead opinion by Chief Justice Roberts
  - Vacates the Federal Circuit's decision holding that APJs are unconstitutionally appointed by the Secretary, and states that "Arthrex is not entitled to a hearing before a new panel of APJs."
  - Vacates the Federal Circuit's remedy of severing Title 5 removal protections for PTAB judges.
  - Holds that APJs can function as inferior officers so long as the Director "may review final PTAB decisions and, upon review, may issue decisions himself on behalf of the Board."
  - States "that 35 U.S.C. § 6(c) is unenforceable as applied to the Director insofar as it prevents the Director from reviewing the decisions of the PTAB on his own." Instead, the Director may unilaterally "engage in such review and reach his own decision."

Implementation of interim procedure

Director review

Director review

- *Arthrex* provided the Director authority to review a PTAB final decision in an *inter partes* review by rehearing.
- The Office has implemented an interim procedure for Director review, consistent with the *Arthrex* decision.
- In this interim procedure, such a review may be initiated *sua sponte* by the Director or requested by a party to a PTAB proceeding.

Director review

- If initiated *sua sponte* by the Director, the parties to the proceeding will be given notice and may be given an opportunity for briefing.
- The Director's review may address any issue, including issues of fact and issues of law, and will be *de novo*.

Director review - procedure

- A party may request Director review of a final written decision in an *inter partes* review or a post-grant review by concurrently:
  - filing a request for rehearing by the Director of a PTAB decision, and
  - submitting a notification of that request by email to Director_PTABDecision_Review@uspto.gov, and copying counsel for the parties.

Director review - procedure

- After a panel issues a final written decision in an *inter partes* review or a post-grant review, a party may request either Director review or rehearing by the original PTAB panel, but may not request both.
  - If a party requests panel rehearing, and the panel grants rehearing, a party may subsequently request Director review of that decision.
  - If a party requests both Director review and panel rehearing (either together, or in the alternative), the Office will treat such a request as a request for Director review.

Director review - requirements

- A request for rehearing by the Director must satisfy the timing requirements of 37 C.F.R. 42.71(d).
  - Must be filed within 30 days of the entry of a final written decision or a decision on rehearing by a PTAB panel.
- A timely request for rehearing by the Director will be considered a request for rehearing under 37 C.F.R. 90.3(b) and will reset the time for appeal or civil action as set forth in that rule.

Director review - requirements

- As a general matter, the Director will not consider untimely requests for rehearing of decisions.
- However, the Director may choose to extend the rehearing deadline for good cause if a party requests such an extension before the due date for a request for rehearing.
- Parties whose deadline for requesting rehearing had expired at the time *Arthrex* issued may request a waiver of the deadline, so long as they request the waiver before the due date for filing a notice of appeal under 37 C.F.R. 90.3.

Director review

- The Precedential Opinion Panel (POP) process will remain in effect and unchanged at this time.
  - However, the Office will be reviewing the POP process in view of the Director review process and welcomes public suggestions regarding potential changes.
- Only a party to a case may submit a request for Director review. Third party requests for Director review are not permitted.
- During implementation of the interim procedure, the USPTO will not charge a fee.

Director review – future plans

- The current process is envisioned as an interim procedure that may change based on input from the public and experience with conducting Director reviews.

- Suggestions about the Director review process may be submitted to Director_Review_Suggestions@uspto.gov.

Director review – further information

- For more details on the interim Director review procedure:
  - USPTO *Arthrex* information webpage
    - www.uspto.gov/patents/patent-trial-and-appeal-board/procedures/uspto-implementation-interim-director-review
  - *Arthrex* Q&As
    - www.uspto.gov/patents/patent-trial-and-appeal-board/procedures/arthrex-qas
  - July 1, 2021, Boardside Chat presentation
    - www.uspto.gov/about-us/events/learn-about-interim-director-review-process-following-us-v-arthrex-inc

Director review – email contact info

- Director_PTABDecision_Review@uspto.gov
  - Where a party submits a notification of a Request for Rehearing by the Director (copying counsel for all parties)
    - Must be done concurrently with entering a Request for Rehearing by the Director into PTAB E2E
- Director_Review_Suggestions@uspto.gov
  - Where the public may provide feedback and suggestions about the interim Director review process
- Trials@uspto.gov
  - Where parties may submit case-specific questions (e.g., request a call with the Board) regarding implications of Arthrex
  - Where the public may submit general Arthrex-related questions

Fast-track appeals pilot programs

Fast-track appeals pilot program

- Expedited decisions for *ex parte* appeals
- Running until July 2, 2022
- Petition and $420 fee
- Six-month pendency goal
- 125-granted-petition limit per quarter (500 total)
- Hearings permitted, with some restrictions
- https://www.uspto.gov/patents/ptab/fast-track-appeals-pilot-program

Fast-track pilot program for appeals related to COVID-19

- Expedited decisions for *ex parte* appeals related to COVID-19
- Running until April 15, 2022
- Petition but no fee
- Six-month pendency goal
- https://www.uspto.gov/patents/patent-trial-and-appeal-board/covid-fast-track-appeals-pilot-program

Motion to Amend (MTA) Pilot

MTA Pilot overview

- MTA Pilot program provides PO with two options:
  1. PO may choose to receive preliminary guidance (PG) from Board on its MTA
     - If PO requests it, Board will provide PG within 4 weeks of due date for Opp. to MTA
  2. PO may file a revised MTA after receiving petitioner's opposition to initial MTA and/or after receiving Board's PG (if requested)
     - Based on Pet. Opp. to MTA and/or PG, PO may file:
       - Reply to opposition to MTA and PG (if requested); or
       - Revised MTA; or
       - Nothing (Board treats it like a normal MTA)
  3. Option 1 is not a predicate for Option 2

MTA Pilot: Mar. 15, 2019 to August 31, 2021

- POs file MTAs in about the same % of cases as before pilot (~10%)
- As of August 31, 2021:
  - ~164 MTA, qualifying for pilot, filed so far
  - PTAB decided ~78 MTAs on merits in FWD
- POs have elected one or both pilot options in vast majority of cases
- Bottom-line so far: POs filing MTAs under the pilot program are more likely to have MTAs granted for at least one substitute claim
  - Pre-pilot = 14% granted or granted in part
  - Pilot overall = 27% granted or granted in part

Practice tips

Questions/comments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