UNITED STATES
PATENT AND TRADEMARK OFFICE

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Neurocrine EX1110
NEUROCRINE v. SPRUCE
PGR2026-00059

Patent Trial and Appeal Board Boardside Chat: Updates to interim Director Review and related processes

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Question/comment submission

- To send in questions or comments during the webinar, please email:
  - PTABBoardsideChat@uspto.gov

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Agenda

I. Background
II. Standard Operating Procedure 2 Revision 11
III. Revised Interim Director Review Process
IV. Delegated Rehearing Panel
V. Appeals Review Panel

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I. Background

Background – SOP 2

Sept. 2018: Standard Operating Procedure 2 (SOP 2) Rev. 10 (**currently superseded by Revision 11 that has retired the POP process**)

- Created Precedential Opinion Panel (POP)
  - Receive requests for review of Board decisions
  - Decide issues of exceptional importance through precedential decisions
- Revised procedures for designating existing Board decisions as precedential
  - Provides for designation of previously-issued cases as precedential or informative by the Director, as well as de-designation of previously designated cases
  - Provides for input from a Screening Committee and PTAB

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Background – Director Review

- On June 21, 2021, the Supreme Court issued its decision in *United States* v. *Arthrex, Inc.*, 141 S. Ct. 1970, 1986 (2021)
  - Addressed the Constitution's Appointments Clause as it relates to administrative patent judges ("APJs")
  - 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"

Background – Director Review

- "Decisions by [APJs] must be subject to review by the Director" addressing concerns of the "Director's ability to supervise APJs in adjudicating petitions for inter partes review."
  - *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1986-87 (2021)
- The Director has an interest in
  - Issuing guidance to increase fairness and efficiency
  - Establishing consistency across Board proceedings

Background – Interim Director Review process

- On June 29, 2021, the Office implemented an **interim process for Director Review**, consistent with *Arthrex*
  - The interim process furthers the USPTO's goal of promoting innovation through consistent and transparent decision-making and the issuance and maintenance of strong patents
  - The interim process complemented three other PTAB procedures that promote the same goals: panel rehearing; internal review; and the POP
- Under the interim process
  - Only a party to a proceeding may request Director review of a **final written decision** (FWD) or a decision **granting rehearing of a FWD** in an AIA proceeding
  - The Director also may grant review ***sua sponte***

Background – Interim Director Review process

- On April 22, 2022, the USPTO published two webpages to increase openness as it formalized the interim Director review process.
  - Interim process for Director review webpage, setting forth more details on the interim process and some additional suggestions for parties who wish to request Director review.
  - Status of Director review requests webpage, providing information about the proceedings in which Director review has been granted, and a spreadsheet, updated monthly, with the status of all Director review requests.

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Background – Request for Comments

- Published a Request for Comments (RFC) seeking public input to inform rulemaking on July 20, 2022; comment period closed October 19, 2022
  - Over 4,300 comments received
- Plan to engage in policy making in 2023 and formalize processes through notice and comment rulemaking

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Background – RFC questions

1. Should any **changes** be made to the interim Director review process, and if so, what changes and why?
2. Should **only the parties** to a proceeding be permitted to request Director review, or should third-party requests for Director review be allowed, and if so, which ones and why?
3. Should requests for Director review be **limited to final written decisions** in IPR and PGR? If not, how should they be expanded and why?
4. Should a party to a proceeding be able to request **both Director review and rehearing by the merits panel**? If so, why and how should the two procedures interplay?

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Background – RFC questions

5. What **criteria** should be used in determining whether to initiate Director review?
6. What **standard of review** should the Director apply in Director review? Should the standard of review change depending on what type of decision is being reviewed?
7. What **standard** should the Director apply in determining whether or not to grant ***sua sponte*** Director review of decisions on institution? Should the standard change if the decision on institution addresses discretionary issues instead of, or in addition to, merits issues?

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Background – RFC questions

8. Should there be a **time limit** on the Director's ability to reconsider a petition denial? And if so, what should that time limit be?
9. Are there considerations the USPTO should take with regard to the fact that decisions made on Director review are not **precedential** by default, and instead are made and marked precedential only upon designation by the Director?
10. Are there any **other considerations** the USPTO should take into account with respect to Director review?

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Background – RFC questions

11. Should the POP review process **remain** in effect, be modified, or be eliminated in view of Director review? Please explain.
12. Are there any **other considerations** the USPTO should take into account with respect to the POP process?

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RFC comments received

- The majority of commenters preferred that
  - Only parties should be able to request Director Review,
  - Director Review should be available for final written decisions and decisions on institution,
  - The Director should apply *de novo* review to all issues on review,
  - The same standard of review should apply for all Director Review decisions,
  - There should be a set time limit on Director Review, and
  - Director Review decisions should be routine by default.

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Overview of current changes

Overview of current changes

In response to RFC comments and USPTO's experience:

- Updates to SOP 2 (Revision 11)
  - Retirement of the Precedential Opinion Panel
- Revised interim Director Review process
  - Expansion to institution decisions
  - Introduction of the Delegated Rehearing Panel
- Creation of the Appeals Review Panel

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II. SOP 2 Revision 11

Updates to SOP 2 Revision 11

- On July 24, 2023, SOP 2 Revision 11 replaced Revision 10
- SOP 2 Revision 11
  - Retires the Precedential Opinion Panel process
  - Focuses on the processes for designating or de-designating Board decisions as precedential or informative
  - No substantive change to designation process of Revision 10

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Reminder: Effect of designation

- The Board enters thousands of routine decisions every year
  - Routine decisions only bind that specific case
- SOP 2 explains the procedures for designating decisions as precedential or informative
  - Helps ensure consistency in decisions across Board jurisdictions including ex parte appeals and AIA proceedings
  - A precedential decision is binding Board authority in subsequent matters involving similar facts or issues
  - Informative decisions set forth Board norms that should be followed in most cases, although it is not binding authority on the Board

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Reminder: Effect of designation

- A **precedential decision** establishes binding Board authority concerning
  - major policy or procedural issues,
  - issues of exceptional importance, including constitutional questions, or
  - issues regarding statutes, rules, and regulations, case law, or issues of broad applicability to the Board
- An **informative decision** provides
  - Board norms on recurring issues,
  - guidance on issues of first impression to the Board,
  - Board rules and practices, or
  - guidance on issues that may develop through analysis of recurring issues in many cases
- No case will be designated without Director approval

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Reminder: Nomination process

- Any person, including anyone from the public or the USPTO, may nominate a routine Board decision for designation as precedential or informative
- Nominations for designation must
  - set forth with particularity the reasons for the requested designation,
  - identify any other Board decisions of which the person nominating is aware that may conflict with the nominated decision, and
  - be submitted by email to PTAB_Decision_Nomination@uspto.gov or through PTAB's online Decision Nomination form at www.uspto.gov/patents/ptab/ptab-decision-nomination

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Reminder: Review of nominations

- Each nomination is reviewed by the Director's Advisory Committee and PTAB Executive Management
- The Advisory Committee is comprised of at least 11 members from various USPTO business units
  - The Advisory Committee prepares an advisory recommendation for each nominated decision, including any dissenting views

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Reminder: Review of nominations

- PTAB Executive Management reviews each nominated decision and provides a recommendation to the Director
  - PTAB Executive Management also solicits and considers feedback from Board judges

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Reminder: Designating a decision

- If the Director determines that the decision should be designated as precedential or informative, the Director will notify the Chief Judge
  - No designation without the Director's approval
  - SOP 2 does not limit the authority of the Director to designate or de-designate at any time, in their sole discretion
- Any decision designated as precedential or informative will be posted on the Board's Precedential and Informative Decisions Webpage

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Question/comment submission

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III. Revised interim Director Review process

Revised interim Director Review process – Availability

On July 24, 2023, the USPTO released its revised Interim Director Review process

- A party may **now** request Director Review of:
  1. A decision on institution **(NEW)**,
  2. A final written decision, or
  3. A decision granting a request for rehearing of either of the above
- No change: a party may request Director Review *or* rehearing by the Board, but not both
- No change: the Director can initiate Director Review *sua sponte*

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Revised interim Director Review process – Availability

(NEW) Party requests for Director Review are limited to the following issues:

Decisions on Institution*	Final Written Decisions
An abuse of discretion	An abuse of discretion
Important issues of law or policy	Important issues of law or policy
	Erroneous findings of material fact
	Erroneous conclusions of law

* Both discretionary and merits-based issues may be raised, subject to limitations above

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Revised interim Director Review process – Requests

- No change: A party must
  - file a timely Request for Director Review ("Request") in the Patent Trial and Appeal Case Tracking System, P-TACTS
    - Timing governed by 37 C.F.R. 42.71(d)
  - email Director_PTABDecision_Review@uspto.gov ("Notification Email"), copying counsel for all parties

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Revised interim Director Review process – Requests

(NEW) The Notification Email must include

- a priority-ranked list of issues for which the party seeks review, and
- an express identification of the alleged (a) abuse of discretion, (b) important issue of law or policy, (c) erroneous finding of material fact, and/or (d) erroneous conclusions of law

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Revised interim Director Review process – Requests

- No change:
  - Requests are subject to
    - length limitations (i.e., 15 pages) of 37 C.F.R. § 42.24(a)(1)(v), and
    - formatting requirements of 37 C.F.R. § 42.6(a)
  - No new evidence or argument unless authorized by the Director
  - No response to the request is permitted unless authorized by the Director
  - A timely request for Director Review is considered a request for rehearing under 37 C.F.R. § 90.3(b) and resets the time for appeal or civil action

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Revised interim Director Review process – Standard of review

(NEW) Standard of review

- Decisions on institution
  - reviewed for abuse of discretion ***unless*** they raise important issues of law or policy, which are reviewed de novo
- Final written decisions
  - reviewed de novo

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Revised interim Director Review process – Advisory Committee

No Change: Advisory Committee assists Director by:

- Evaluating each Director Review request
- Provides a recommendation to the Director

- The Advisory Committee includes at least 11 members from various USPTO business units who serve at the discretion of the Director, subject to conflicts of interest

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Revised interim Director Review process – Director decision

- The Director, upon review of the evidence, arguments, and Advisory Committee recommendation may:
  - grant review,
  - deny review, or
  - **(NEW)** delegate review

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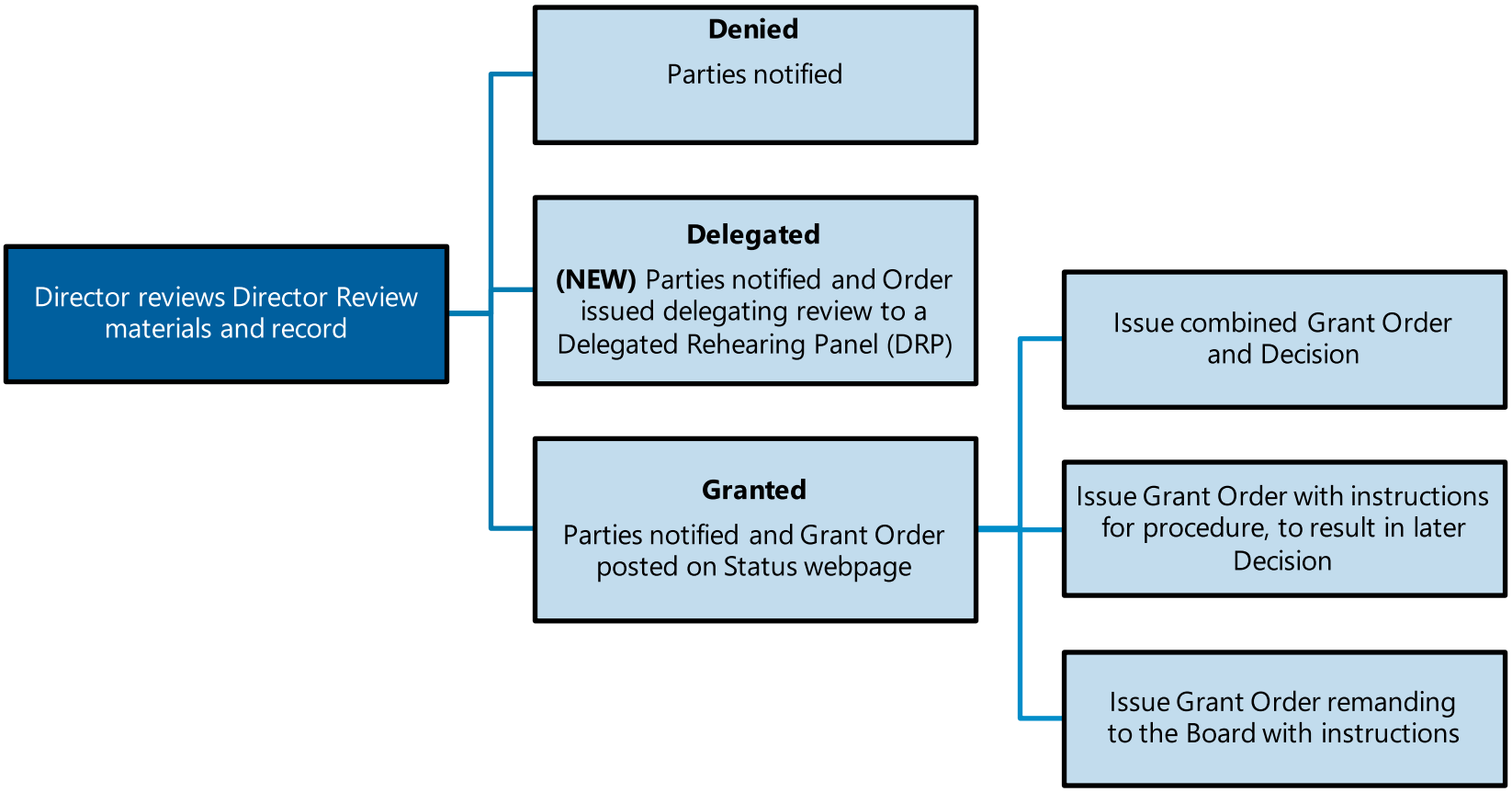
Revised Interim Director Review process



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Revised interim Director Review process – *Sua sponte*

- The Director may grant review *sua sponte*
  - **(NEW)** Typically reserved for issues of exceptional importance
  - **(NEW)** Initiation of *sua sponte* review will be within 21 days after the period for filing a request for rehearing, absent exceptional circumstances, and
  - before a notice of appeal under 37 C.F.R. § 90.3 is filed
- No change:
  - if review is initiated *sua sponte*, the parties will be given notice and may be given an opportunity for briefing
  - resets the time for appeal or civil action to no later than sixty-three (63) days after final resolution of the Director Review process,
  - the Director may seek an Advisory Committee recommendation

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Revised interim Director Review process – Outcomes

- No change:
  - The Director may, in whole or in part:
    - affirm,
    - reverse,
    - modify,
    - vacate,
    - and/or remand the decision to the Board for further proceedings
  - The Director may make any findings or conclusions that the Director deems proper based on the record
  - The Director maintains authority over all issues in the case unless ordered otherwise, but a grant of Director Review does not stay the underlying proceeding before the Board

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Revised interim Director Review process – Effects

- No change: Director Review decisions are **routine** by default
  - The Director may issue a decision as precedential or informative
  - All decisions may be nominated for designation per SOP 2

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Revised interim Director Review process – Further review

Director Review Decisions of:	Requests for Rehearing Available?
Final Written Decisions*	Yes
Decisions on Institution*	Yes

*including decisions granting rehearing of such type

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Revised interim Director Review process – Statistics
(July 1, 2023)

- 232 total requests
  - 228 completed
    - 206 denied
    - 15 dismissed
    - 1 withdrawn
    - 6 granted
  - 37 Director Review grants
    - 6 from requests
    - 31 *sua sponte*

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Question/comment submission

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IV. Delegated Rehearing Panel (DRP)

(NEW) Delegated Rehearing Panel

- The Director may delegate review of a Board decision to a Delegated Rehearing Panel (DRP)
  - Delegation may occur after a party's Director Review request or *sua sponte*
  - For cases that warrant further consideration by an independent panel
    - For example, to consider whether a material issue of law or fact was misapprehended or overlooked

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(NEW) Delegated Rehearing Panel - Composition

- The DRP is selected from:
  - Chief Judge,
  - Deputy Chief Judge,
  - Vice Chief Judges, and
  - Senior Lead Judges
- Paneling otherwise occurs per SOP 1

*Persons serving in an acting capacity for the above identified positions may serve on a DRP.

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(NEW) Delegated Rehearing Panel – Criteria for delegation

- The Director is not limited as to which decisions may be delegated for review
- Expected to focus on decisions in which a potential issue may have been misapprehended or overlooked

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(NEW) Delegated Rehearing Panel - Delegation

- If the Director delegates a requested Director Review, the Director will issue an order delegating review to the DRP
  - The Board will enter an order identifying the DRP panel to which the proceeding has been delegated

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(NEW) Delegated Rehearing Panel – Standard of review

- The DRP may determine if the original Board decision misapprehended or overlooked any issue that was previously before the Board
  - The DRP has discretion to determine whether to grant or deny rehearing
  - The Director, in the order delegating review, may identify a specific issue for the DRP to consider

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(NEW) Delegated Rehearing Panel - Decisions

- The DRP may:
  - determine that the decision does not present an issue warranting correction,
  - render a decision correcting an issue(s) presented, or
  - remand to the Board for further proceedings
- DRP decisions are routine decisions by default
  - DRP decisions may be designated precedential or informative pursuant to SOP 2

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(NEW) Delegated Rehearing Panel – Further review

DRP decisions involving:	Requests for Rehearing Available?	Additional Director Review?
Final Written Decisions*	Yes	No, unless *sua sponte*
Decisions on Institution*	Yes	No, unless *sua sponte*

*including decisions granting rehearing of such type

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V. Appeals Review Panel (ARP)

(NEW) ARP review

- The Director may convene the ARP *sua sponte* to review a decision in an *ex parte* appeal, reexamination appeal, or reissue appeal

- Requests for ARP Review are not accepted or considered

(NEW) ARP – Composition

- By default, the ARP includes:
  - Director,
  - Commissioner for Patents, and
  - PTAB Chief Judge

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(NEW) ARP – Timing

- The ARP aims to issue decisions as soon as possible
  - typically within three months of the grant of ARP review

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(NEW) ARP – Effect

- ARP review decisions are routine decisions by default
  - ARP decisions may be designated precedential or informative pursuant to process set forth in SOP 2

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Next Boardside Chat

- Thursday, September 21 at noon ET
- In-house counsel perspectives on AIA trial proceedings, featuring:
  - Yen Florczak, 3M
  - Henry Hadad, Bristol Myers Squibb
  - Samir Pandya, SAP

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