

2023 Changes in Director Review

BY JON E. WRIGHT*

On July 24, 2023, the United States Patent and Trademark Office (USPTO or Office) promulgated a revised interim process for Director Review of Patent Trial and Appeal Board (PTAB or Board) decisions in proceedings under the America Invents Act (AIA).¹ The revised interim process follows stakeholder input received in 2022 in response to a Request for Comments on Director Review via the Precedential Opinion Panel (POP) and on pre-issuance internal circulation and review of Board decisions.

The revised interim process, along with a new Appeals Review Panel process,² replaces the old Precedential Opinion Panel procedures and will remain in effect, with possible modifications, until a final process is formalized via rulemaking. According to the Office, the interim process furthers the “goals of promoting innovation through consistent and transparent decision-making, and the issuance and maintenance of reliable patents.” To facilitate the review process, the Director has assigned former USPTO Solicitor Thomas Kraus in a new “director review executive” position to oversee the process.³

Background

In *United States v. Arthrex, Inc.*, 141 S.Ct. 1970 (2021), the Supreme Court held that Administrative Patent Judges’ ability to render final decisions on patentability on behalf of the Executive Branch is “incompatible with their status as inferior officers.” As a result, the Court determined that the Director must have *discretion* to review PTAB decisions. In exercising that discretion, the Court made clear that “the Director need not review every decision of the PTAB,” nor did it require the Director to accept requests for review or issue a decision in every case.

The 2023 interim process for review reflects the Director’s ongoing efforts to comply with *Arthrex*. They give the Director the discretion to review PTAB decisions, they provide a vehicle for a party to request director review of certain decisions, and they outline the internal processes for effecting review.

Which Decisions Can Be Reviewed Under the New Interim Process?

There are three types of decisions for which a party can request review under the new interim process: (1) institution decisions under 35 U.S.C. §314, (2) final written decisions under 35 U.S.C. §318, and (3) decisions granting a request for rehearing of (1) or (2). Although *Arthrex* only requires that the Director have discretion to review final written decisions, parties may also request review of institution decisions and rehearing decisions. According to the Office, review of these decision is included for decisional “consistency and uniformity.” Importantly, the Director retains unilateral discretion to initiate, *sua sponte*, Director Review of these, and any other Board decisions.

What is the Scope of Review?

The scope of Director Review depends on the type of decision for which review is sought.

Institution decisions: Review of institution decisions is limited to decisions presenting (a) an abuse of discretion or (b) important issues of law or policy. Both discretionary and merits-based issues may be raised, subject to limitations (a) and (b) above.

Final written decisions: Review of final written decisions is more robust and includes decisions presenting (a) an abuse of discretion, (b) important issues of law or policy, (c) erroneous findings of material fact, or (d) erroneous conclusions of law.

How Does a Party Request Director Review in an AIA Proceeding?

A party⁴ dissatisfied with a Board panel decision has two options: (1) request panel rehearing, or (2) request Director Review. A party cannot do both, and an improper request for both will be treated as a request for Director Review only. The process for requesting panel rehearing has not changed. The process for requesting director review is set forth below.

To request director review, a party must concurrently (1) file Request for Director Review in P-TACTS; and (2) email the Director,⁵ with a cc to counsel for all parties to the proceeding. Both submissions are required to perfect a request for Director Review.

The Director may also initiate review, *sua sponte*. Absent exceptional circumstances, the Director may initiate review within 21 days after the expiration of the period for filing a request for rehearing under Rule 42.71(d). *Sua sponte* Director Review is reserved for issues of “exceptional importance.” Such issues may be surfaced by the PTAB’s internal post-issuance review team, which may alert the Director that an issued decision may warrant Director Review. If the Director *sua sponte* initiates review, the parties to the proceeding will be notified and may given an opportunity for briefing.

We describe the content, timing, formatting and processing of requests next.

Content

Notification email: The notification email is important. The interim procedure requires the following:

1. A priority-ranked list of the issues for which the party seeks review, in the rare instance where a party has more than one issue to raise. This list shall include 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, as appropriate to the type of decision for which review is sought.

2. A brief explanation of the issue(s) and a brief explanation of the rationale for the prioritized-ranking of the issue(s). The brief explanation should not exceed a few sentences and is not a substitute for formal arguments on the record.
3. If the requesting party believes that the request presents an issue of first impression, the notification email must so indicate.

*Request for Review*³: The request filed with PTACS is, effectively, a motion and should be structured as such. Substantively, it should cover what is set forth in the summary email, but in more depth.

Importantly, a request for Director Review may not introduce new evidence and, accordingly, exhibits may not be entered in support of the request. The Director will not consider new evidence or new arguments not part of the official record. If a party believes that additional evidence is necessary, prior permission must be sought via an email to the Director. Exceptions regarding new evidence or arguments may be warranted in cases addressing issues of first impression or issues involving intervening changes in the law or USPTO procedures, guidance, or decisions. As with any paper submitted to the Board, any argument not made within the Request may be deemed waived.

Unless authorized by the Director, no response to the Director Review request is permitted.

Timing

A request for Director Review must be filed within the time prescribed for a request for rehearing under 37 C.F.R. § 42.71(d), as appropriate to the type of decision for which review is sought. If a request is untimely, it is not considered. This means a dissatisfied party must request review (1) within 14 days of the entry of a decision to institute a trial as to at least one ground of unpatentability asserted in the petition; or (2) within 30 days of the entry of a final decision or a decision not to institute a trial. The Director may, upon a showing of good cause, extend the time period set forth above.

A timely request for Director Review is considered a request for rehearing under 37 C.F.R. § 90.3(b). It therefore resets the time for noticing an appeal to the U.S. Court of Appeals for the Federal Circuit, as set forth in that rule.

Formatting and Fees

Requests for Director Review must conform to the applicable formatting requirements for motions under 37 C.F.R. § 42.6(a). There are currently no fees to request Director Review.

Processing

After a party submits a request for Director Review, the Office will docket the request and review it to ensure compliance with the applicable requirements. If the request is compliant, the Office will enter the notification email and the Request for Director Review into the record of the corresponding proceeding as "Exhibit 3100 – Director Review Request."

If the request is not compliant, the Office will attempt to work with the party making the request to rectify any areas of non-compliance. However, if the request is not compliant because it was submitted after the deadline, it will not be considered absent a good cause extension as discussed above.

Communications

Finally, as with other communications with the Board during AIA proceedings, all communications from a party to the Office during the pendency of Director Review must copy (cc) counsel for all parties to the proceeding. All communications will be entered into the record of the proceeding.

What Happens After a Party Request Director Review?

Advisory Committee

(i) *Advisory Committee*: All compliant requests for Director Review in AIA trials first go to an Advisory Committee. The Advisory Committee is composed of at least 11 members (7 for a quorum). The Advisory Committee consists of representatives from various USPTO business units who serve at the discretion of the Director. It meets periodically to evaluate each request for Director Review. The Director may also convene an Advisory Committee to make recommendations on decisions that the Director is considering for *sua sponte* Director Review. The Advisory Committee will provide a consensus recommendations to the Director for each request for review at regular intervals. If there are differing views among the members, that may be noted in the recommendation. The Director then receives each request for Director Review, the underlying decision, and the recommendation of the Advisory Committee. Then, at the Director's sole discretion, they may grant or deny Director Review.

Delegated Rehearing Panel

(ii) *Delegated Review Panel*: After receiving a recommendation from the Advisory Committee, the Director *may* delegate further consideration to a delegated rehearing panel (DRP). For example, the Director may designate a DRP to consider whether the Board overlooked or misapprehended a material issue of fact or law. When the Director determines to delegate review of a decision to the DRP, the Director will issue an order notifying the parties. In the event that the Director delegates a decision to the DRP to conduct review, including when the Director delegates review of a decision *sua sponte* to the DRP, the DRP panel will determine whether to grant rehearing. The DRP has three members selected from Chief Judge, Deputy Chief Judge, Vice Chief Judges, and Senior Lead Judges. A judge from the original panel or a judge with conflict may not participate.

If the Director (or a delegate like the DRP) denies review, they are under no obligation to provide a reason.

If the Director (or the DRP acting on her behalf) grants review, they may issue an initial order that identifies

the issue(s) to be addressed. Alternatively, the Director may issue a singular order that both grants review and resolves the issue(s) based on the existing record.

What is the Standard of Review?

Under Director Review, the Board's decision whether to institute trial in an AIA proceeding, or a decision granting rehearing of such a decision, is reviewed for abuse of discretion unless the review engages important issues of law or policy, which are reviewed *de novo*. All other decisions are reviewed *de novo*.

Will the Director Entertain Amicus Briefing?

Generally, no, unless the Director has requested such briefing. Any amicus brief submitted by a party with whom the Director has a conflict will be struck. This process is consistent with Federal Rule of Appellate Procedure 29(a)(2) as adopted by the United States Court of Appeals for the Federal Circuit.

Has the Director Granted Requests for Review Under the New Procedures?

Yes. As of this writing, the Director has granted review in at least four cases since the new revised interim procedures have become active. In three instances, review has been from a decision denying institution, and in one instance review is from a final written decision. We briefly describe three of those decisions below.

1. *DK Crown Holdings Inc. v. Diogenes Limited*, IPR2023-00268

In *DK Crown Holdings*, the Board denied institution with one of the panel members dissenting. The Patent Owner sought Director Review. It argued that the panel majority "abused its discretion by: (1) improperly importing claim limitations to avoid prior art; (2) construing 'continuously' such that independent claim 1 is narrower than one of its dependent claims and an element of that dependent claim is rendered superfluous; and (3) characterizing the prior art inaccurately and contrary to its disclosure." The Advisory Committee referred the request for review to the Director. The Director, in turn, determined that "the Decision warrants review by an independent Delegated Review Panel ("DRP") to review the fact-intensive issues presented in this case." The Order states that: "[t]he DRP shall make its decision independently and without direction from me." The DRP will now determine whether to grant rehearing. If the DRP grants review, it "may issue a decision, or, if appropriate, may remand to the Board for further proceedings." It may also request additional briefing. DRP review is still pending.

2. *SynAffix B.V. v. Hangzhou DAC Biotech Co., Ltd.*, IPR2022-01531

In *SynAffix B.V.* the Board denied institution. The patent in this case is entitled "Hydrophilic Linkers and Their Uses for Conjugation of Drugs to Cell Binding Molecules" and involves protein/drug conjugates for targeted delivery of drugs to specific cells. The Patent Owner presented highly fact intensive arguments against institution, arguing that the panel misapprehended the claimed chemical formulas and related prosecution history that underlie the denial of institution. The Patent Owner also argued that the Decision reflects an abuse of discretion in finding and relying upon an alleged prosecution history disclaimer that is not only unsupported but directly contradicted by the record evidence. The case is similar to *DK Crown Holdings* in that the Director delegated the fact-intensive review to a Delegated Review Panel.

3. *ResMed Corp. v. Cleveland Medical Devices Ind.*, IPR2023-00565

In *ResMed*, the Board exercised its discretion under 35 U.S.C. § 314(a) and the *Fintiv* factors to deny institution. The denial was based on the advanced state of a related litigation pending in the United States District Court for the District of Delaware where Judge Williams was presiding. The rehearing dispute centered on Judge William's median time to trial and whether the Petitioner should have been able to address Patent Owner's evidence on that point. In denying review, the Board relied on a Director-vacated institution denial that had presented similar facts. Accordingly, the Director determined that "[t]he Board would benefit from additional briefing by the parties on these issues." The Director then granted review, vacated the decision denying institution, and remanded the case to the panel for further proceedings.

Key Takeaways: Some early themes seem to have emerged under the new procedures. *First*, three of the four granted reviews involve institution decisions. Although not required under *Arthrex*, these early cases show the Director is perfectly willing to review institution decisions, even though they are insulated from further appellate review. It is here that the Director can best implement policy and we expect healthy review of institution decisions into the future. *Second*, we see from the review of *DK Crown* and *SynAffix* that the Director will delegate to a DRP those requests for review that pass Advisory Committee screening, but that are highly fact intensive. This makes sense as a DRP is in the best position to evaluate fact-intensive reviews, which would be time consuming for the Director.

Overall, parties not satisfied with a decision, whether at institution or after the merits trial, should continue to test the boundaries of revised interim process for Director Review because the current Director has shown a willingness to direct review where she deems necessary.

1. This summary draws heavily from the USPTO website's description of the "Revised Interim Director Review Process." Additional information may be found here: <https://www.uspto.gov/patents/ptab/decisions/revised-interim-director-review-process>

2. The Appeals Review Panel (ARP) process is available only at the Director's sua sponte discretion for review of ex parte appeals decisions. As of publication, the Director had not yet convened the ARP to review any decisions. More information about the ARP can be found here: <https://www.uspto.gov/patents/ptab/appeals-review-panel>

3. <https://news.bloomberglaw.com/ip-law/ex-patent-solicitor-takes-on-director-review-amid-rising-demand>

4. Third parties may not request Director Review. Nor may they submit comments concerning review of a decision, unless amici curiae briefing is requested by the Director.

5. The paper itself is subject to the length limitations (i.e., 15 pages) for motions to the Board provided in 37 C.F.R. § 42.24(a)(1)(v).