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Request for Comments on Director Review, Precedential Opinion Panel Review, and Internal Circulation and Review of Patent Trial and Appeal Board Decisions

A Notice by the Patent and Trademark Office on 07/20/2022

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Department of Commerce
Patent and Trademark Office

Neurocrine EX1111
NEUROCRINE v. SPRUCE
PGR2026-00061

[Docket No. PTO-P-2022-0023]

AGENCY:

Patent Trial and Appeal Board, United States Patent and Trademark Office, U.S. Department of Commerce.

ACTION:

Request for Comments.

SUMMARY:

The United States Patent and Trademark Office (USPTO or Office) seeks public comments on practices and policies for the review of Patent Trial and Appeal Board (PTAB or Board) decisions. The USPTO has implemented a number of processes that promote the accuracy, consistency, and integrity of PTAB decision-making in Leahy-Smith America Invents Act of 2011 (AIA) proceedings. The USPTO plans to formalize those processes through notice-and-comment rulemaking. To inform such rulemaking, and to inform any modifications to the interim processes pending formalization, the USPTO seeks public comments. Specifically, the USPTO seeks input on the current interim Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (Director) review process that allows a party to request Director review of a PTAB final written decision in inter partes review (IPR) or post-grant review (PGR) proceedings, and also provides the Director the option to sua sponte initiate the review of any PTAB decisions (at the Director's discretion), including institution decisions and decisions on rehearing. The USPTO also seeks input on the Precedential Opinion Panel (POP) process. Finally, the USPTO seeks input on the current interim process for PTAB decision circulation and internal PTAB review. These processes, implemented by the PTAB prior to issuing decisions and implemented without Director input, are modeled after practices of the U.S. Court of Appeals for the Federal Circuit.

DATES:

Comment Deadline Date: Written comments must be received on or before September 19, 2022, to ensure consideration.

ADDRESSES:

For reasons of Government efficiency, comments must be submitted through the Federal eRulemaking Portal at *www.regulations.gov (http://www.regulations.gov)*. To submit comments via the portal, enter docket number PTO-P-2022-0023 on the homepage and click “Search.” The site will provide a search results page listing all documents associated with this docket. Find a reference to this Request for Comments and click on the “Comment Now!” icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal (*www.regulations.gov (http://www.regulations.gov)*) for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions regarding how to submit comments by mail or by hand delivery, based on the public's ability to obtain access to USPTO facilities at the time.

FOR FURTHER INFORMATION CONTACT:

Kalyan Deshpande, Vice Chief Administrative Patent Judge; Amanda Wieker, Acting Senior Lead Administrative Patent Judge; or Melissa Haapala, Vice Chief Administrative Patent Judge, at 571-272-9797.

SUPPLEMENTARY INFORMATION:

Background

Development of This Request for Comments

On September 16, 2011, the AIA was enacted into law (Pub. L. 112-29 (https://www.govinfo.gov/link/plaw/112/public/29), 125 Stat. 284 (2011)). The AIA established the PTAB, which is made up of administrative patent judges (APJs) and four statutory members, namely the USPTO Director, the USPTO Deputy Director, the USPTO Commissioner for Patents, and the USPTO Commissioner for Trademarks. 35 U.S.C. 6(a) (https://www.govinfo.gov/link/uscode/35/6). The Director is appointed by the President, by and with the advice and consent of the Senate. 35 U.S.C. 3(a)(1) (https://www.govinfo.gov/link/uscode/35/3). APJs are appointed by the Secretary of

Commerce in consultation with the Director. *Id.* 6(a). The PTAB hears and decides ex parte appeals of adverse decisions by examiners in applications for patents; appeals of reexaminations; and proceedings under the AIA, including IPRs, PGRs, covered business method (CBM) patent reviews,[1] and derivation proceedings, in panels of at least three members. *Id.* 6(b), (c). Under the statute, the Director designates the members of each panel. *Id.* 6(c). The Director has delegated that authority to the Chief Judge of the Board. *See* PTAB Standard Operating Procedure 1 (Rev. 15) (SOP1), Assignment of Judges to Panels, *https://go.usa.gov/xtdt2 (https://go.usa.gov/xtdt2)*.

35 U.S.C. 6(c) (https://www.govinfo.gov/link/uscode/35/6) states that "[o]nly the Patent Trial and Appeal Board may grant rehearings" of Board decisions. In *United States* v. *Arthrex, Inc.,* the U.S. Supreme Court (Court) held that the Appointments Clause of the Constitution (art. II, sec. 2, cl. 2) and the supervisory structure of the USPTO require that the Board's final decisions must be subject to review by the Director, a principal officer of the United States. *See United States* v. *Arthrex, Inc.,* 141 S. Ct. 1970, 1986 (2021). The Court determined that "35 U.S.C. 6(c) (https://www.govinfo.gov/link/uscode/35/6) is unenforceable as applied to the Director insofar as it prevents the Director from reviewing the decisions of the PTAB on his own." *Id.* at 1987. The Court explained that:

this suit concerns only the Director's ability to supervise APJs in adjudicating petitions for inter partes review. We do not address the Director's supervision over other types of adjudications conducted by the PTAB, such as the examination process for which the Director has claimed unilateral authority to issue a patent.

Id. The Court thus held that the Director has the discretion to review IPR final written decisions rendered by APJs, and, upon review, the Director may issue decisions on behalf of the Board. *Id.* at 1988.

On June 29, 2021, the USPTO implemented an interim process for Director review. At that time, the interim Director review process provided that the Director may initiate Director review of any PTAB final (🗋 printed page 43250) written decision sua sponte, and a party to a PTAB proceeding may request Director review of an IPR or PGR final written decision. To request Director review, a party to a final written decision must concurrently: (1) enter a Request for Rehearing by the Director into PTAB E2E, the PTAB's filing system, and (2)

submit a notification of the Request for Rehearing by the Director to the USPTO by email to *Director_PTABDecision_Review@uspto.gov (mailto:Director_PTABDecision_Review@uspto.gov)*, copying counsel for all parties. *Id.*

The USPTO further published *Arthrex* Q&As, updated on December 4, 2021, available at *https://go.usa.gov/xtDnS (https://go.usa.gov/xtDnS)* (superseded on April 22, 2022, by the "Interim process for Director review" web page, available at *https://go.usa.gov/xuHwP (https://go.usa.gov/xuHwP)*). As explained in the *Arthrex* Q&As, Director review is a de novo review that may address any issue of fact or law. A party may not make new arguments or submit new evidence with a request for Director review unless permitted by the Director. Also, a party may only request Director review of a final written decision issued in an IPR or PGR. At this time, the USPTO does not accept requests for Director review of other decisions, including decisions on institution and Board ex parte appeal decisions. Third parties may not request Director review or submit comments concerning Director review of a particular case unless comments are requested by the Director. Further, the POP review process outlined in the Board's Standard Operating Procedure 2 (Rev. 10), available at *https://go.usa.gov/xu4PT (https://go.usa.gov/xu4PT)*, remains in effect and unchanged.

On April 22, 2022, the USPTO published two web pages to increase openness as it formalizes the Director review process. The USPTO published an "Interim process for Director review web page," setting forth more details on the interim process and some additional suggestions for parties who wish to request Director review. The suggestions include guidance on focusing and prioritizing issues, and strongly encourage parties to provide a priority-ranked list of the issues being raised, with a brief explanation of each issue and a brief explanation of the rationale for the prioritized-ranking of them. The USPTO also published a web page providing the status of all Director review requests, available at *https://go.usa.gov/xuHwE (https://go.usa.gov/xuHwE)*. The status web page includes a spreadsheet that is updated monthly, as well as information about the proceedings in which Director review has been granted.

On May 25, 2022, and June 17, 2022, the USPTO further updated the "Interim process for Director review" web page. The first update explains that although the Office does not accept requests for Director review of institution decisions in AIA proceedings, the Director has always retained and continues to retain the authority to review such decisions sua sponte after issuance. If the Director sua sponte initiates Director review of an institution decision, the parties and the public will be notified, and the Director may order

party and amicus briefing. The second update made two modifications. First, the update specifies that if a requesting party believes that the issue presented for Director review is an issue of first impression, the party should indicate that in the email requesting Director review. Second, the update explains that, in anticipation of this Request for Comments, any preliminary feedback to the Director review suggestion email box (*Director_Review_Suggestions@uspto.gov (mailto:Director_Review_Suggestions@uspto.gov)*) could be submitted through July 11, 2022.

The Interim Director Review Process

The interim Director review process follows existing PTAB rehearing procedures under 37 CFR 42.71(d) (https://www.ecfr.gov/current/title-37/section-42.71#p-42.71(d)) and Standard Operating Procedure 2. Under the interim process, a Request for Rehearing by the Director must be filed within 30 days of entry of the Board's final written decision or a decision by the Board granting rehearing of a final written decision. *See*37 CFR 42.71(d)(2) (https://www.ecfr.gov/current/title-37/section-42.71#p-42.71(d)(2)). A request for Director review of a decision remanded by the Federal Circuit for further proceedings consistent with *Arthrex* must be filed within 30 days of the remand order, unless the Federal Circuit sets a different deadline for filing the Director review request. The Director may choose to extend the rehearing deadline for good cause on a party's request before the due date. A timely Request for Rehearing by the Director will be considered a request for rehearing under 37 CFR 90.3(b) (https://www.ecfr.gov/current/title-37/section-90.3#p-90.3(b)) and will reset the time for appeal or civil action as set forth in that rule. Requests for Rehearing by the Director are limited to 15 pages (*see*37 CFR 42.24(a)(1)(v) (https://www.ecfr.gov/current/title-37/section-42.24#p-42.24(a)(1)(v))), and the Director will not consider new evidence or arguments submitted with a Director review request. At this time, there is no fee for requesting Director review.

Moreover, under the interim process, parties are limited to requesting either: (1) Director review, or (2) rehearing by the original Board panel. Parties may also request Director review of a Board decision that results from a rehearing grant, but not a Board decision to deny rehearing. Requests for both Director review and panel rehearing of the same decision are treated as a request for Director review only.

When a party submits a request for Director review, the USPTO catalogs the request and reviews it to ensure compliance with the interim Director review requirements. If the request is compliant, it is entered into the record of the corresponding proceeding as

"Exhibit 3100—Director Review Request." If the request is not compliant, the USPTO will attempt to work with the party making the request to rectify any areas of noncompliance. If the request is not compliant, for example, because it was submitted after the deadline, it will not be considered because it will be untimely.

Each request for Director review is then routed to and considered by an Advisory Committee that the Director has established to assist with the process. The Advisory Committee currently has 11 members and includes representatives from various business units within the USPTO, who serve at the discretion of the Director. The Advisory Committee currently comprises members from the Office of the Under Secretary (not including the Director), the PTAB (not including members of the original panel for each case under review), the Office of the Commissioner for Patents (not including any persons involved in the examination of the challenged patent), the Office of the General Counsel, and the Office of Policy and International Affairs. The Advisory Committee meets periodically to evaluate each request for Director review and recommends to the Director which decisions to review. Advisory Committee meetings may proceed with less than all members in attendance, as long as a quorum of seven members is present for each meeting.

The Advisory Committee reviews each Director review request for, among other things, issues that involve an intervening change in the law or USPTO procedures or guidance; material errors of fact or law in the PTAB decision; matters that the PTAB misapprehended or overlooked; novel issues of law or policy; issues on which PTAB panel decisions are split; issues of particular importance to the USPTO or the patent community; or inconsistencies with USPTO procedures, guidance, or decisions.[2] The Advisory Committee (🗋 printed page 43251) then presents the Director with each Director review request, the associated arguments and evidence, and the recommendation of the Advisory Committee to determine whether to grant or deny the request. The Director also may consult others in the USPTO on an as-needed basis, so long as those individuals do not have a conflict. Although the Advisory Committee and other individuals in the USPTO may advise the Director on whether a decision merits review, the Director has sole discretion to grant or deny review.[3] The Director's decision to grant or deny a request will be communicated directly to the parties in the proceeding through PTAB E2E. Director review grants will be posted on the Director review status web page. Director review denials can be found on the Director review status spreadsheet, which is updated monthly and posted on the Director review status web page.

In addition to allowing parties to request Director review under the interim process, the Director may choose to conduct a sua sponte Director review. The Director may initiate a sua sponte review of any PTAB decision, including institution decisions, or a corresponding decision on rehearing (whether denying or granting rehearing). As explained in more detail below, PTAB Executive Management (the PTAB Chief Judge, Deputy Chief Judge, Vice Chief Judges, and Senior Lead Judges) may identify decisions as candidates for sua sponte Director review. The Director may also convene the Advisory Committee to make recommendations on decisions that the Director is considering for sua sponte Director review. If the Director initiates a sua sponte review, the parties will be given notice and may be given an opportunity for briefing. The public also will be notified, and the Director may request amicus briefing. If briefing is requested, the USPTO will set forth the procedures to be followed.

At this time, the USPTO does not accept requests for Director review of decisions on institution in AIA proceedings or appeal decisions. To request review of those types of decisions (and other decisions), parties may request review by the POP, which, by default, includes the Director, the Commissioner for Patents, and the PTAB Chief Judge. As a general matter, the interim process for Director review does not alter the current POP process. As explained above and below, however, the USPTO seeks comments on the POP process in view of the Director review process.

On July 6, 2022, the USPTO further updated the "Interim process for Director review" web page to make clear that: (1) decisions made on Director review are not precedential by default, and instead are precedential only upon the Director's designation; and (2) final written decisions by the Director after Director review are appealable to the U.S. Court of Appeals for the Federal Circuit using the same procedures for appealing Board final written decisions. *See* "Interim process for Director review" web page, §§ 2, 14; 37 CFR 90.3 (https://www.ecfr.gov/current/title-37/section-90.3).

As of July 5, 2022, the USPTO had received 204 requests for Director review under the interim process. Of those requests, the Director review process was completed for 198 requests. Of the 198 completed requests, 5 requests were granted, 1 request was withdrawn, and the remaining requests were denied. Eleven requests did not meet the requirements for Director review and were not considered. Additionally, Director Kathi Vidal has initiated sua sponte Director review in four cases. Andrew Hirshfeld, former Commissioner for Patents, who was performing the functions and duties of the Director

prior to Director Vidal's confirmation, granted Director review and rehearing in *Ascend Performance Materials Operations LLC* v. *Samsung SDI Co.,* IPR2020-00349, Paper 57 (Nov. 1, 2021) (Order granting Director review request); *Proppant Express Investments, LLC* v. *Oren Technologies, LLC,* IPR2018-00733, Paper 95 (Nov. 18, 2021) (Order granting Director review request); and each of *Apple Inc.* v. *Personalized Media Communications LLC,* IPR2016-00754, Paper 50 (Mar. 3, 2022), and IPR2016-01520, Paper 47 (Mar. 3, 2022) (Orders granting Director review requests).[4] Recently, Director Vidal sua sponte ordered a Director review of the Final Written Decisions in each of *MED-EL Elektromedizinische Geräte Ges.m.b.H.* v. *Advanced Bionics AG,* IPR2020-01016, Paper 43 (June 1, 2022), and IPR2021-00044, Paper 41 (June 1, 2022) (Orders initiating Director review); and of the Decisions on Institution in *OpenSky Industries, LLC* v. *VLSI Technology LLC,* IPR2021-01064, Paper 41 (June 7, 2022) (Order initiating Director review), and *Patent Quality Assurance, LLC* v. *VLSI Technology LLC,* IPR2021-01229, Paper 31 (June 7, 2022) (Order initiating Director review). Director Vidal also granted a request for Director review of the Final Written Decision in *Nested Bean, Inc.* v. *Big Beings USA Pty Ltd.,* IPR2020-01234, Paper 36 (June 17, 2022) (Order granting Director review and authorizing additional briefing).

The USPTO plans to formalize the Director and POP review processes through notice-and-comment rulemaking. To inform such rulemaking, and to inform any modifications to the interim processes pending formalization, the USPTO seeks public comments.

The Interim Process for PTAB Decision Circulation and Internal PTAB Review

Since May 2022, the USPTO has been using an interim process for PTAB decision circulation and internal PTAB review to promote consistent, clear, and open decision-making. *See* "Interim process for PTAB decision circulation and internal PTAB review," available at *https://go.usa.gov/xJ7fq (https://go.usa.gov/xJ7fq)*. Under the interim process, certain categories of PTAB decisions are circulated to a pool of non-management judges (the Circulation Judge Pool (CJP)) prior to issuance. These decisions include all AIA institution decisions; AIA final written decisions; AIA decisions on rehearing; decisions on remand from the Federal Circuit; inter partes reexamination appeal decisions; and designated categories of ex parte appeal, ex parte reexamination appeal, and reissue appeal decisions. Judges may, at their option, circulate other types of decisions for CJP review.

The CJP comprises a representative group of at least eight non-management PTAB judges who collectively have technical/scientific backgrounds and legal experience representative of the PTAB judges as a whole. The CJP is modeled after both the Federal Circuit's previous office of the Senior Technical Assistant and the Federal Circuit's 10-day circulation process for precedential decisions. *See* United States Court of Appeals for the Federal Circuit, Internal Operating Procedures, Redlined Copy, 18 (Mar. 1, 2022), available at *https://go.usa.gov/xJ7fx (https://go.usa.gov/xJ7fx)* (describing the previous office of the Senior Technical Assistant); and United States Court of (🗋 printed page 43252) Appeals for the Federal Circuit, Internal Operating Procedures, 10.5 (Mar. 1, 2022), available at *https://go.usa.gov/xJ7fg (https://go.usa.gov/xJ7fg)* (describing the 10-day circulation process for precedential decisions).

For each reviewed PTAB decision, the CJP provides the panel with information regarding potential conflicts or inconsistencies with relevant authority, including PTAB precedential decisions, Director-written guidance, and other USPTO policies. The CJP also provides the panel with information regarding potential inconsistencies with informative or routine PTAB decisions and suggestions for improved readability and stylistic consistency. The panel has the final authority and responsibility for the content of a decision and determines when and how to incorporate feedback from the CJP. Judges are required to apply pertinent statutes, binding case law, and written guidance issued by the Director or the Director's delegate that is applicable to PTAB proceedings. There is no unwritten guidance applicable to PTAB proceedings that judges are required to apply.

The CJP also identifies, and brings to the attention of PTAB Executive Management, notable draft decisions, such as decisions that address issues of first impression or that appear to be inconsistent with USPTO policy or involve areas where policy clarification may be needed. PTAB Executive Management may discuss decisions after issuance with the Director and/or the Director review Advisory Committee for consideration for sua sponte Director review, or with the POP Screening Committee [5] for consideration for POP review. The CJP has periodic meetings with PTAB Executive Management to discuss potentially conflicting panel decisions and general areas for potential policy clarification. PTAB Executive Management may discuss these issues with the Director for the purpose of considering whether to issue new or updated policies through regulation, precedential or informative decisions, and/or a Director guidance memorandum.

Any panel member, at his or her sole discretion, may also optionally consult with one or more members of PTAB management (*i.e.,* PTAB Executive Management and Lead Judges) regarding a decision prior to issuance. If consulted, PTAB management may provide information regarding the consistent application of USPTO policy, applicable statutes and regulations, and binding case law. Adoption of any suggestions provided by PTAB management based on such consultation is optional. Unless consulted by a panel member, PTAB management does not make suggestions to the panel on any pre-issuance decisions, either directly or indirectly through the CJP.

The Office recognizes that it is important that the PTAB maintain a consistent and clear approach to substantive areas of patent law and PTAB-specific procedures, while maintaining open decision-making. The interim PTAB decision circulation and internal review processes promote decisional consistency and open decision-making by reinforcing that the adoption of all CJP and requested PTAB management feedback is optional, that members of PTAB management do not provide feedback on decisions pre-issuance unless they are a panel member or a panel member requests such feedback, and that the PTAB panel has the final authority and responsibility for the content of a decision. Additionally, the process provides a mechanism by which the Director may be made aware of decisions to consider for sua sponte Director review or POP review, and of areas to consider for issuing new, or modified, USPTO policy to promote a strong intellectual property system. The interim process makes clear that the Director is not involved, pre-issuance, in directing or otherwise influencing panel decisions.

The USPTO seeks feedback on the PTAB decision circulation and internal review processes.

Request for Public Comments

The USPTO seeks written public comments on the interim Director review process, the POP review process, and the PTAB decision circulation and internal review processes. The USPTO welcomes any comments from the public on the processes and is particularly interested in the public's input on the questions and requested information noted below.

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?

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?

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?

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?

13. Should any changes be made to the interim PTAB decision circulation and internal review processes, and if so, what changes and why?

14. Are there any other considerations the USPTO should take into account with respect to the interim PTAB decision circulation and internal review processes?

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

Footnotes

1. Under section 18 of the AIA, the transitional program for post-grant review of CBM patents sunset on September 16, 2020. AIA 18(a). Although the program has sunset, existing CBM proceedings, based on petitions filed before September 16, 2020, remain pending.
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2. No member of the Advisory Committee may participate in considering a request for Director review if that member has a conflict of interest under the U.S. Department of Commerce USPTO Summary of Ethics Rules, available at https://go.usa.gov/xJ7wF (https://go.usa.gov/xJ7wF). PTAB APJs who are Advisory Committee members will also follow the guidance on conflicts of interest set forth in the Board's SOP1, and will recuse themselves from any discussion involving cases on which they are paneled.
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3. If the Director has a conflict with the parties, patent, or counsel in the decision, she will be recused, and the required action will be taken by the Deputy Director. If the position of the Deputy Director is vacant, or if the Deputy Director also has a conflict of interest, the required action will be taken by the Commissioner for Patents.
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4. The U.S. Court of Appeals for the Federal Circuit upheld Mr. Hirshfeld's authority to decide requests for Director review, finding that the delegation of the function of Director review did not violate the Appointments Clause (U.S. Const. art. II, § 2, cl. 2); the Federal Vacancies Reform Act (5 U.S.C. 3345 (https://www.govinfo.gov/link/uscode/5/3345) et seq.); or the Constitution's separation of powers (U.S. Const. art. II, § 2, cl. 2) [Is it correct that this citation should be the same as the one for the Appointments Clause?]. See Arthrex, Inc. v. Smith & Nephew, Inc., 35 F.4th 1328, 1333-1340 (Fed. Cir. 2022).
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5. The POP Screening Committee provides recommendations to Precedential Opinion Panel. The Screening Committee comprises of the members of the Precedential Opinion Panel, or their designees, typically in equal numbers (for example, 3 designees of each of the Chief Judge, Commissioner for Patents, and Director). See PTAB Standard Operating Procedure 2 (Rev. 10) (SOP2), Precedential Opinion Panel to Decide Issues of Exceptional Importance Involving Policy or Procedure and Publication of Decisions and Designation or De-Designation of Decisions as Precedential or Informative, https://go.usa.gov/xPMqx (https://go.usa.gov/xPMqx).

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