

## PTAB Acting Director Denies IPR Merely Because Petitioner Knew of the Challenged Patent Over a Decade Ago

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We previously reported how the PTAB's institution rate has fallen to approximately 40% in the new administration, with many of those denials stemming from the PTAB's increased usage of its discretionary denial processes to deny IPR challenges without otherwise addressing the merits of the identified prior art. See [here](#). The latest grant of discretionary denial continues that trend and exemplifies the current challenges in pursuing IPR/PGR invalidity challenges at the U.S. Patent Office.

In *IRHYTHM TECHNOLOGIES, INC. v WELCH ALLYN, INC.*, IPR2025-00363, -00374, -00376, -00377, and -00378, the Patent Owner (Welch) brought an infringement suit in the District of Delaware on February 20, 2024 (Case No. 1:24-cv-224) and the accused infringer (iRhythm) responded by filing several IPR invalidity challenges ten months later in December 2024. Welch availed itself of the new PTAB process for requesting a discretionary denial (see [here](#)) by filing a 35-page request for discretionary denial within a few months after the IPR petitions were filed. The lengthy request argued that the PTAB should exercise its discretion to deny the IPR challenges primarily because iRhythm knew about one of the asserted patents (US8214007) but waited until it was sued before challenging the patent at the PTAB. This delay, Welch argued, "create[ed] an expectation between the parties." As proof, Welch submitted exhibits demonstrating that iRhythm had identified the asserted patent (and its earlier pending patent application) in information disclosure statements (IDSs) submitted in connection with prosecuting one of iRhythm's patent applications in 2013-2015. Welch also argued for a discretionary denial by alleging (i) iRhythm's supporting expert declaration was too long, which improperly shifts the burden to the PTAB and Welch to determine the "actual opinions from the morass of irrelevant and inapplicable information muddled together in his 500+ pages" and (ii) the *Fintiv* factors favor denial, among other arguments.

iRhythm filed a 36-page response about a month later. The lengthy response focused on the PTAB's guidance as stated in the Consolidated Trial Practice Guide (Nov. 2019) identifying the following six exemplary factors that parties may address in their discretionary denial briefing: (1) whether the PTAB or another forum has already adjudicated validity/patentability; (2) whether legal changes since issuance bear on patentability; (3) the strength of the unpatentability challenge; (4) the extent of the petition's reliance on expert testimony; (5) settled expectations of the parties; and (6) compelling economic, public health, or national security interests. The response argued that Welch had only addressed three of those factors, and those arguments were largely based on mischaracterizations of iRhythm's expert declaration. The response argued that the *Fintiv* factors do not support a discretionary denial, for example, because the related district court trial matter was in its early stages and trial was scheduled to occur six

months after a final IPR decision. The response rebutted Welch’s “settled expectations” argument as “fail[ing] as a matter of common sense” because Welch’s failure to sue iRhythm after it received FDA clearance for its accused devices in 2012, 2017, and 2021 demonstrated the settled expectation that the asserted patent had “nothing to do with” iRhythm’s products and therefore iRhythm “did not need to expend resources contesting” the allegedly invalid patent.

The PTAB Acting Director’s three-page discretionary denial opinion issued less than a month after iRhythm’s response. The short opinion exercised the PTAB’s discretion to deny the IPR challenges (for all of the challenged patents) primarily because iRhythm was aware of one of the challenged patents in 2013, as shown by the submitted iRhythm IDS statement. The decision found persuasive Welch’s argument that this intervening time period created “settled expectations [that] favor denial of institution.” The decision noted that it applied “a holistic assessment of all of the evidence and arguments presented” and that even though “[s]everal arguments weigh against discretionary denial”—including that (i) the related district court is in its early stages, (ii) trial will occur months after the IPR final decision issues, (iii) there was a “high-likelihood” of a district court staying pending IPR resolution and (iv) iRhythm’s expert declaration properly provided citations to the record without attempting to merely “fill gaps in the prior art”—a discretionary denial was warranted here. The decision summarized that “Petitioner’s awareness of Patent Owner’s applications and failure to seek early review of the patents favors denial and outweighs the above-discussed considerations.”

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## Related Capabilities

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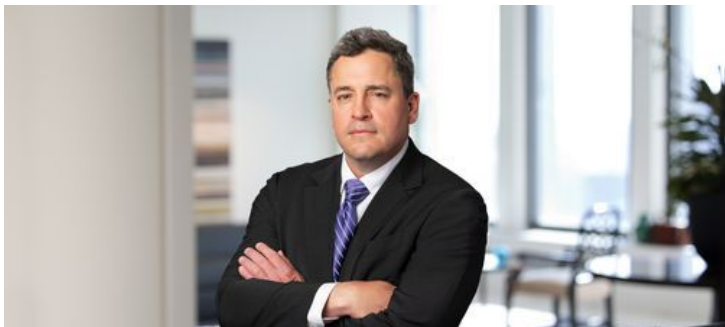
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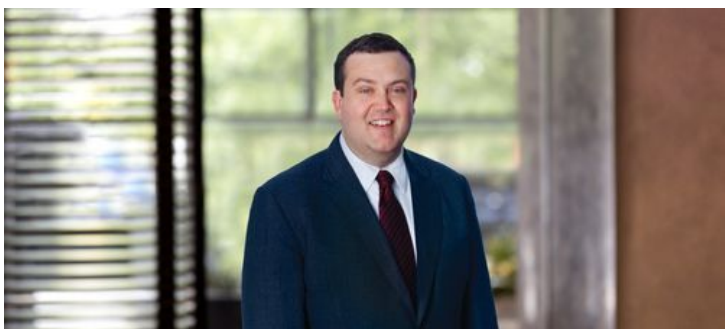
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