MEMORANDUM

DATE: July 31, 2025

TO: Members of the Patent Trial and Appeal Board ("Board")

FROM: Coke Morgan Stewart
Acting Under Secretary of Commerce for Intellectual Properly and Acting Director of the United States Patent and Trademark Office

SUBJECT: ENFORCEMENT AND NON-WAIVER OF 37 C.F.R. § 42.104(B)(4) AND PERMISSIBLE USES OF GENERAL KNOWLEDGE IN INTER PARTES REVIEWS

The United States Patent and Trademark Office (USPTO) will enforce and no longer waive the requirement of 37 C.F.R. § 42.104(b)(4) (Rule 104(b)(4)) that a petition for inter partes review (IPR) "must specify where each element of the claim is found in the prior art patents or printed publications relied upon."[1] As a practical matter, enforcement of Rule 104(b)(4) means that applicant admitted prior art (AAPA), expert testimony, common sense, and other evidence that is not "prior art consisting of patents or printed publications" (collectively, "general knowledge") may not be used to supply a missing claim limitation. Per 35 U.S.C. § 312(a)(4), the Board shall deny an IPR petition that fails to comply with Rule 104(b)(4). General knowledge may still be used in an IPR to support a motivation to combine or to demonstrate the knowledge of a person having ordinary skill in the art. *See, e.g.*, *Unification Techs. LLC v. Micron Tech. Inc.*, 2024 WL

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[1] The August 18, 2020 Memorandum entitled "Treatment of Statements of the Applicant in the Challenged Patent in Inter Partes Reviews Under § 311" (2020 Memorandum), and the June 9, 2022 Memorandum entitled "Updated Guidance on the Treatment of Statements of the Applicant in the Challenged Patent in Inter Partes Reviews Under § 311" (2022 Memorandum) both indicated that the Board was waiving enforcement of Rule 104(b)(4). *See* 2020 Memorandum at 8-9; 2022 Memorandum at 6. In particular, as indicated in both the 2020 Memorandum and the 2022 Memorandum, the USPTO has discretion to waive, suspend, relax, or modify its procedural rules. *Id.*; *see Am. Farm Lines v. Black Ball Freight Serv.*, 397 U.S. 532, 539 (1970) ("it is always within the discretion of a court or an administrative agency to relax or modify its procedural rules adopted for the orderly transaction of business before it"); *see also* 37 C.F.R. § 42.5(b) (stating that "[t]he Board may waive or suspend a requirement of parts 1, 41, and 42").

Janssen Biotech, Inc.
Exhibit 2033
Accord v. Janssen
IPR2026-00256, -00257, -00258, -00259

3738401, at *7 (Fed. Cir. Aug. 9, 2024) (affirming use of general knowledge in an IPR proceeding in the form of expert testimony and AAPA to demonstrate how a skilled artisan would have understood a prior art reference's disclosure as teaching a claim limitation).

This Memorandum supersedes the 2020 Memorandum and the 2022 Memorandum—both of which are no longer consistent with Federal Circuit precedent concerning the use of AAPA to supply a missing claim limitation. *See Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367, 1373-77 (Fed. Cir. 2022) (vacating and remanding to determine whether AAPA improperly formed the "basis" of petitioner's patentability challenge); *Qualcomm Inc. v. Apple Inc.*, 134 F.4th 1355, 1364-65 (Fed. Cir. 2025) (rejecting USPTO's "in combination" rule that requires the Board to consider AAPA whenever an IPR petition combines AAPA with prior art patents or printed publications because "it cannot be that AAPA *never* forms the basis of a ground under § 311(b) whenever AAPA is combined with prior art patents or printed publications.").

Under 35 U.S.C. § 312(a)(3), an IPR petition must identify, "in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim." 35 U.S.C. § 312(a)(4) further requires that a "petition filed under section 311 may be considered only if . . . the petition provides such other information as the Director may require by regulation." Rule 104(b)(4), promulgated in 2012, instructs petitioners on what information is required in a petition, namely that an IPR petition "must specify where each element of the claim is found in the prior art patents or printed publications relied upon." This is consistent with the Director's broad discretion to prescribe regulations to ensure the "integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings." 35 U.S.C. § 316(b). As noted above, past efforts by the Office to permit limited use of general knowledge to satisfy a missing claim limitation are no longer consistent with Federal Circuit precedent. *See Qualcomm*, 24 F.4th at 1373-77; *Qualcomm*, 134 F.4th at 1364-65. Rather than attempt to navigate these

limited uses and risk further litigation on this point in the Federal Circuit, enforcement of Rule 104(b)(4) as provided in this Memorandum will provide a clear means for (i) identifying the petitioner's legal and factual basis for satisfying the threshold for instituting IPR, and (ii) providing the patent owner with notice as to the basis for the challenge to the claims. While Rule 104(b)(4), as applied in some cases, may be narrower than 35 U.S.C. § 311(b),[2] enforcing Rule 104(b)(4) is the best course of action to provide certainty to the parties, the Board, and the public, and to allow for the efficient administration of the Office. *See* 35 U.S.C. §§ 312(a)(4), 316(b). Further, although Rule 104(b)(4) does not address what can serve as the "basis" of an IPR under § 311(b) (*see* 2020 Memorandum at 8–9 & n. 5; 2022 Memorandum at 5–6 & n.2), the rule does impose on petitioners a procedural requirement to identify in the petition where each claim element is found in the prior art patents or printed publications relied upon.

This Memorandum will apply to any petition for IPR filed on or after September 1, 2025.

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[2] *See Shockwave Medical, Inc. v. Cardiovascular Systems, Inc.*, -- F.4th --, 2025 WL 1922023, at *4 (Fed. Cir. July 14, 2025) (finding that IPR petition did not violate § 311(b) where petitioner "properly relied on general background knowledge to supply missing claim limitations (which [patent owner] does not argue were novel to the invention) and used AAPA as evidence of that general background knowledge").