

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEOGENOMICS LABORATORIES, INC.
Petitioner,

v.

NATERA, INC.
Patent Owner.

Patent No. 11,319,596

Inter Partes Review No. IPR2025-00455

**PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR
DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(a)**

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**Petitioner’s Exhibits 1001 - 1106 were previously filed and are listed again here based on 37 C.F.R. § 42.63.*

***Petitioner’s Exhibit 1107 through 1110 are newly filed.*

I. INTRODUCTION

The Director should not grant Patent Owner's request to discretionarily deny review under 35 U.S.C. § 314(a).

First, the Petition presents compelling merits. The four Grounds in the Petition meet all the limitations of the twelve challenged claims, including the 0.015% limitation that led to their allowance. Moreover, each primary reference provides express disclosures pointing to combinations with secondary references. Patent Owner does not challenge any of the reasons for combining the references in its Patent Owner's Discretionary Denial Brief (Paper 10). Its *sole* argument against the merits of the Petition—that the art does not disclose the 0.015% limitation in the context of multiplex amplification—is undercut by disclosures in Kinde 2013 and Bettegowda indicating otherwise.

Second, the Petition presents materially different art, arguments and challenged claims than in the co-pending litigation. The Petition relies on two primary references—Diaz and Rabinowitz—whereas the district court invalidity challenge relies on Forshew 2012 or on Bashashati and Patel. As a result, the arguments presented in the two proceedings are materially different. Patent Owner emphasizes some overlapping references, but does not (and cannot) establish that the same references predominate in the litigation given the litigation's focus on

Forsheew 2012. Nor does Patent Owner have any compelling response that the Petition seeks to cancel eight more claims than in the district court action.

Third, as discussed *infra*, numerous panels have found an expeditious filing of a petition to mitigate investment by the parties and the court in a co-pending litigation. Here Petitioner filed expeditiously. On December 10, 2024, Patent Owner amended its complaint to add U.S Patent No. 11,319,596 (the “’596 patent”). About *five weeks* later, on January 15, 2025, Petitioner filed its Petition. This mitigates the investment by the parties and the Court in the co-pending litigation, especially given that the Court may not decide any summary judgment motion on invalidity before institution as discussed below.

Fourth, the Court recently indicated at a hearing that it may not rule on summary judgment in time for an October trial. Despite Patent Owner having submitted over 70 exhibits from the co-pending litigation, it omitted the hearing transcript where the Court discussed that the judges in her district were “kind of swamped.”

Balancing all these factors, including public health considerations, the Board should not exercise its discretion to deny review as discussed in more detail *infra*.

II. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(a) IS NOT WARRANTED

A. Factor 6: Compelling Merits And The Public Health Interests Strongly Weigh Against Denial

Under *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 14–15 (Mar. 20, 2020) (precedential), “if the merits of a ground raised in the petition seem particularly strong on the preliminary record, this fact has favored institution.” *See also* Memorandum from Scott R. Boalick, Chief Administrative Patent Judge, Guidance on USPTO’s rescission of “Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation,” 3 (March 24, 2025) (“[A]s stated in *Fintiv*, the factors considered in the exercise of discretion are part of a balanced assessment of all the relevant circumstances in the case, including the strength of the merits.”). The merits of the Petition are particularly strong for three reasons.

First, the Petition presents art teaching the 0.015% limitation that was the basis for allowance, none of which was before the Examiner during prosecution. Second, Patent Owner’s assertion that the art in the Petition fails to teach the 0.015% limitation in the context of multiplex amplification is incorrect. (Paper 10, 36–37.) Third, Patent Owner’s broad reading of the asserted claims in the co-pending litigation is inconsistent with its arguments during prosecution and further

strengthens the unpatentability arguments for the challenged claims in this proceeding.

1. The Petition presents strong grounds based on art that meets every challenged claim limitation

During prosecution, the Examiner allowed the '596 patent after Patent Owner amended the independent claim to recite that “an SNV mutation that is present in less than or equal to 0.015% of the cell-free DNA having the SNV locus is detected from the sequence reads” (the “0.015% limitation”). (Paper 2, 4–7.) This limitation and the remaining limitations of the challenged claims are met by the four straightforward grounds in the Petition.

For Ground 1, Diaz discloses various methods for performing “liquid biopsies” involving genotyping circulating tumor DNA at multiple time points. (Ex. 1006, 1.) For example, it describes tumor-informed cfDNA assays comprising “identifying a specific mutation or mutations in the tumor tissue” and then targeting and quantifying the level of ctDNA at a particular time point. (*Id.*, 4.) Diaz also discusses the problem of distinguishing mutations from errors to detect rare mutations in cfDNA. (*Id.*, 3.) To address this challenge, Diaz points to barcode-based error correction methods such as Safe-SeqS as a solution “aimed at increasing overall sensitivity” for detecting mutations in ctDNA in the context of next-generation sequencing. (*Id.*, 3 (citing Ex. 1049 (Kinde 2011, which discloses an early version of Safe-SeqS).) ***Diaz thus provides express motivation to***

combine its disclosure of tumor-informed cfDNA assays with barcode-based error correction methods, and with Safe-SeqS in particular. None of this is challenged in Patent Owner’s Discretionary Denial Brief.

The other reference in Ground 1, Kinde 2013, discloses *an improved version of the Safe-SeqS method cited by Diaz*, and its application in *multiplex PCR* assays “performed in a similar fashion” to the single-plex Safe-SeqS assays. (Ex. 1007, 5, 8, 18.) Kinde 2013 further disclosed that its improved Safe-SeqS approach is capable of detecting 1 mutant template among as many as 1,000,000 wild-type templates, including a specific example of *detecting a mutation present at 0.01%* of the DNA having the locus, thereby meeting the 0.015% limitation. (*Id.*, 4, 6.) The Petition explains in detail how the remaining limitations of claims 1, 2, 5, and 10–18 are met by the three grounds based on Diaz and Kinde 2013. (Paper 2, 13–39.)

The fourth ground, Rabinowitz (Ex. 1009) in combination with Bettgowda (Ex. 1008), also meets all the limitations of claims 1, 2, 10–13, and 15–18 of the ’596 patent in a straightforward manner. Rabinowitz is a U.S. patent application published in 2012, listing multiple named inventors of the ’596 patent as inventors. Rabinowitz discloses methods for “highly efficient highly multiplexed targeted PCR to amplify DNA followed by high throughput sequencing to determine the allele frequencies at each target locus,” including the ability to multiplex even

more than 50 or 100 PCR primers in one reaction “in a way that most of the resulting sequence reads map to targeted loci.” (Ex. 1009, [0064].) Rabinowitz further teaches applying its multiplex PCR assays to cfDNA and suggests their application to cancer patient plasma. (Ex. 1009, [0267], [0209], [0284].)

Bettegowda discloses tumor-informed assays for ctDNA using Safe-SeqS, and that Safe-SeqS achieved sensitivities comparable to BEAMing, which *detects mutations in ctDNA at levels as low as 0.005%*, thereby meeting the 0.015% limitation. (Ex. 1008, 15; *see also* Ex. 1072, 1.) Bettegowda also teaches use of Safe-SeqS in a “*multiplexed*, sequencing-based assay to query known mutated hotspots of several genes in the EGFR pathway.” (Ex. 1008, 4, 15–16.)

Rabinowitz and Bettegowda provide express motivation and reasonable expectation of success for the combination. *Bettegowda teaches that Safe-SeqS enables highly sensitive mutation detection using barcode-based error correction.* (Ex. 1008, 2, 16.) And *Rabinowitz discloses a molecular barcoding approach* that “entails targeting one or more specific loci and generating a tagged copy of the original molecules such manner [*sic*] that most or all of the tagged molecules from each targeted locus will have a unique tag and can be distinguished from one another upon sequencing of this barcode using clonal or single molecule sequencing.” (Ex. 1009, [0488].) Thus, Rabinowitz suggests that molecular barcodes can be used to identify sequences that originate from the same original

DNA template. A similar principle underlies the Safe-SeqS error correction method of Bettegowda. (*See* Ex. 1008, 16.) Again, none of this is challenged by Patent Owner in its discretionary denial brief.

2. Patent Owner’s assertion that the art in the Petition fails to disclose the 0.015% limitation in the context of multiplex amplification is wrong

Patent Owner raises only one argument as to the merits of the Petition.¹ It argues that the art in the Petition fails to disclose the 0.015% limitation in the context of a multiplex amplification and argues in a footnote that the cited art is “substantially the same in this critical respect” as the art considered during prosecution. (Paper 10, 36–37.) Not so. During prosecution, the Examiner

¹ Patent Owner notes that it has reserved its remaining merits arguments for the Preliminary Response due on May 14, 2025, the same day as this Brief. (Paper 10, 36 n.13.) Patent Owner could have filed its Discretionary Denial Brief concurrently with its Preliminary Response. (*See* Paper 9 (extending time to file Patent Owner’s Discretionary Denial Brief to May 14, 2025).) If Patent Owner had done so, Petitioner would have been able to address all of Patent Owner’s merits arguments, as this Brief’s deadline would have been extended to June 14, 2025. But, as it stands now, the Board will be considering a limited briefing record in deciding discretionary denial.

identified only one reference as teaching detection of an SNV present at levels less than or equal to 0.015%: Kennedy *et al.* (Ex. 1036). (Ex. 1003, 62–63.)

According to the Examiner, Kennedy taught “detection of mutations with frequencies around 10^{-6} ” (0.0001%, more than 150-fold lower than the level required by the claims). (Ex. 1003, 62–63.) But the error correction method of Kennedy could not be performed in the context of the claims based on the express teachings of the reference. (*Id.*) Specifically, the Examiner noted that Kennedy’s method “***relies*** on sequencing both strands of DNA fragments which are amplified using barcode-specific primers”² and enriching the libraries by hybridization, ***not by PCR-based enrichment methods***. (*Id.*) On this basis, the Examiner found that “the claimed method cannot be used for double-strand sequencing of Kennedy *et al.*” (*Id.*)

The Examiner correctly understood that duplex sequencing was incompatible with PCR to enrich for specific target loci. According to Kennedy itself, duplex sequencing is “not compatible” with PCR-based enrichment methods, because “the targeted duplex DNA is melted into its single-stranded components during PCR, and the complementarity of the original DNA is lost.” (*Id.*, 8.) This lost information prevents tracing sequences of both complementary strands back to the original DNA duplex, which is required for Kennedy’s method. (*See id.*, 2.)

² All emphases in quotations are added unless otherwise noted.

In contrast to Kennedy, both Kinde 2013 and Bettegowda teach detection of an SNV present in the input DNA at levels below 0.015% *using PCR-based enrichment*. And both Kinde 2013 and Bettegowda teach performing their versions of the Safe-SeqS method using *multiplex PCR*. (Ex. 1007, 5, 8, 18; Ex. 1008, 4, 15–16.) Thus, Kinde 2013 and Bettegowda are *not* “substantially the same” as Kennedy.³

Nor is Patent Owner correct in taking issue with Kinde 2013 and Bettegowda’s highly sensitive assays being “compatible” with multiplex amplification. (Paper 10, 36–37.) Patent Owner focuses on the Petition’s explanation that the cited art fills the gap identified by the Examiner during prosecution, the 0.015% limitation, in an assay “compatible” with multiplex-PCR. (*Id.*, 37 (citing Paper 2, 63).) Patent Owner however ignores the reasoning for this statement in the Petition. Kinde 2013 taught a higher limit of detection (0.1%) using *more stringent SNV detection parameters for a mutation “agnostic” screening assay*, which also used multiplex PCR. (Paper 2, 24.) Kinde 2013 itself

³ Patent Owner references 35 U.S.C. § 325(d) in a footnote. (Paper 10, 37 n.14.) This half-hearted attempt to raise another basis for discretionary denial should be rejected. Patent Owner’s brief is squarely based on discretionary denial under § 314(a) and follows the *Fintiv* framework.

explains that those different “detection” parameters were used because the “mutations are not known *a priori in a screening environment.*” (Ex. 1007, 19.) Other than the different analytical parameters used to account for mutations being *unknown* in the screening context, Kinde 2013 teaches that “[the] multiplexed assay was performed in a similar fashion” to its single-plex version of Safe-SeqS. (*Id.*, 18.) Moreover, Kinde 2013’s more stringent *unknown* mutation detection approach is not required by the claims, where “target SNVs and their precise positions are known and selected in advance” as Patent Owner’s expert admits. (Ex. 2047, ¶68.)

Given the express prior art disclosures and the scope of the claims (which have been further broadened by Patent Owner in the co-pending litigation as discussed *infra*), it appears that Patent Owner is demanding a level of unpatentability not required under obviousness case law. Both Kinde 2013 and Bettegowda teach multiplex versions of Safe-SeqS and their versions of Safe-SeqS detect an SNV present in less than or equal to 0.015% of the DNA having the SNV, thereby teaching the claim limitation. (Ex. 1007, 4–6, 8, 18; Ex. 1008, 4, 15–16.)

Thus, Kinde 2013 and Bettegowda—which were not before the Examiner during prosecution—fill the gap in the art identified by the Examiner and meet the

claim limitation that Patent Owner asserts is purportedly missing from the Petition art.

3. Patent Owner's broad reading of the claims is inconsistent with its arguments during prosecution and indicates an even stronger argument against patentability

After the Petition was filed, Patent Owner argued in the co-pending litigation that “detecting is part of the high-throughput sequencing happening in the sequencer” when single bases are detected as they are incorporated into DNA template strands. (Ex. 2044, 15.) About two weeks later, Patent Owner's expert, Dr. Metzker, also opined that “[o]ne of ordinary skill in the art would have understood that, as soon as the base call is made for a sequence read at the SNV mutation position, the sequencer detects whether the tumor-specific SNV is present or not.” (Ex. 2047, 39.) This change in claim scope undercuts Patent Owner's assertions of the patentability of the challenged claims for at least two reasons.

First, Patent Owner's arguments are inconsistent with the arguments that were the basis for allowance. During prosecution, Patent Owner distinguished over one reference, Diehn *et al.* (Ex. 1031), by arguing that Diehn *et al.* only actually demonstrated that fractions of cancer DNA were “***accurately detected*** at fractional abundances of at least 0.025%.” (Ex. 1003, 474.) But in the co-pending litigation, Patent Owner has abandoned the suggestion that the claims require detection of an SNV with any reasonable accuracy. (*See* Ex. 2047, 52–53

(asserting that “Claim 1 of the ’596 Patent (Babiarz) does not require correctness”).) Indeed, according to Dr. Metzker, SNV detection occurs as part of sequencing, even if the “SNV” detected is actually an error and not a true SNV. (See Ex. 2052, 113:23–114:11, 142:25–143:14⁴.) Dr. Metzker also maintains that detection has occurred even if the “SNV” base call is later filtered out as an error. (See *id.*, 96:22–97:3 (“Q. Okay. Well, what you're saying is, in the real world, you will detect many, many, many instances of SNV mutations and do back-end processing to determine whether any of them are errors, right? A. You -- you might do some downstream analysis to figure out errors from real SNV mutations. You might. You might do that.”).)

Second, Patent Owner’s broad reading of the claims—*i.e.*, not requiring that the detection of an SNV present in less than or equal to 0.015% of the cfDNA is performed with scientifically reasonable accuracy or confidence—strengthens the Petition’s Grounds. For example, both Kinde 2013 and Bettgowda disclose the 0.015% limitation for SNV detection with ***reasonable real-world confidence intervals***. Kinde 2013 only considered a mutation to be “detected” if the barcode associated with the mutation was supported by more than one sequencing read and

⁴ Citations to Ex. 2052 are based on the page and line numbers of the original deposition transcript.

more than 50% of the reads sharing the same barcode contained the identical mutation. (Ex. 1007, 19.) And Bettegowda reported detection of ctDNA templates using 95% confidence intervals. (Ex. 1008, 16.) Rare mutations that were present in the sequence reads could not be confidently distinguished from errors were not “detected” according to Kinde 2013 or Bettegowda. But *those same mutations would be successfully detected under Patent Owner’s broad reading of the claims*. The Petition grounds thus teach all claim limitations with superior confidence beyond what the claim requires under Patent Owner’s new claim scope arguments.

As another example, Diaz teaches cfDNA assays for tumor-specific mutations using PCR and high-throughput sequencing and discusses the problem of distinguishing mutations from errors, which imposes a technical limit on sensitivity. (Paper 2, 2, 13; *see also* Ex. 1006, 3.) Kinde 2013 and Bettegowda provide a solution. But according to Patent Owner’s recent arguments discussed above, errors impose *no technical limit for the 0.015% limitation as recited in the claims*. Patent Owner’s recent arguments thus indicate an even higher reasonable expectation of success for performing the claimed method based on the cited references in the Petition Grounds.

4. Public health interests direct against discretionary denial

There are public health interests at stake in this proceeding, because Patent Owner's assertion of the '596 patent may limit the public's access to Petitioner's cancer detection assay called RaDaR 1.1. Previously, Patent Owner sought a preliminary injunction on an earlier version of RaDaR (1.0) based on a different patent (U.S. Patent No. 11,519,035 (Ex. 1029, "the '035 patent")). In doing so, it put RaDaR 1.0 out of the public's reach for head and neck cancers. (Ex. 1108, 1–2.) Studies to show clinical equivalency between the approved version of RaDaR 1.0 and RaDaR 1.1 are currently well underway. (Ex. 1110, 13.) But Patent Owner now seeks to put RaDaR 1.1 out of reach based on a different patent, the '596 patent. The Board's review of the '596 patent is thus important to ensure that the public has access to Petitioner's new assay.

Patent Owner argues that Petitioner has "already litigated and lost this point" (Paper 10, 38.) But the preliminary injunction was based on a different patent, the '035 patent, as discussed above. That patent claims an earlier priority date and has a different claim scope.⁵ RaDaR 1.0's approval for head and neck cancers also was

⁵ The preliminary injunction stage also concerned U.S. Patent No. 11,530,454 (Ex. 1028, "the '454 patent"). This patent recites a method "capable of detecting an SNV that is present in less than or equal to 0.015% of the cell-free DNA

not before the District Court at the time of the preliminary injunction, and there is no indication that the Federal Circuit considered this evidence. (Ex. 1109, 1 (Patent Owner’s 28(j) letter arguing that because the Federal Circuit was “limited to the evidence before the district court at the time of the preliminary injunction hearing, later events are irrelevant to the issue” before the Court).)

* * *

Thus, given the straightforward Petition Grounds, including their disclosure of the 0.015% limitation, the Patent Owner’s broader reading of claim scope in the district court action and the public health interests at stake, Factor 6 strongly weighs against the Board denying review. *Samsung Elecs., Co., Ltd. v. Headwater Research LLC*, IPR2024-01396, Paper 13, 8–9 (April 1, 2025) (“Petitioner’s obviousness grounds are clear and persuasive [W]e determine that the merits

comprising the SNV locus” (Ex. 1028, 172:27–31) and shares the same specification as the ’596 patent. But the Court did not rule on the ’454 patent at the preliminary injunction stage. (Ex. 1107, 67:11–15.) Recently, the Court noted that, while it had “punted” the obviousness question regarding the ’454 patent, there appeared to be an “obviousness problem” in view of Dr. Metzker’s new arguments that error rates do not matter in the context of the 0.015% limitation. (Ex. 1107, 67:4–23.)

of at least one ground raised in the Petition are particularly strong. Thus, this factor weighs against exercising discretion to deny institution.”).

B. Factor 4: The Petition Includes Materially Different Grounds, References, And Claims From The District Court Action

The *Fintiv* Board explained that “if the petition includes materially different grounds, arguments, and/or evidence than those presented in the district court, this fact has tended to weigh against exercising discretion to deny institution under *NHK*.” *Fintiv*, IPR2020-00019, Paper 11, 12–13. Because that description squarely applies to this proceeding, Factor 4 also weighs against denial.

1. The art and arguments are materially different across the two proceedings

As discussed above, the Petition seeks cancellation of claims 1, 2, 5, and 10–18 of the ’596 patent based on five references in four grounds:

Ground	35 U.S.C. §	Claims	Prior Art
1	103	1, 2, 5, 10, 12–14, 16–18	Diaz (Ex. 1006) & Kinde 2013 (Ex. 1007)
2	103	1, 2, 5, 10–14, 16–18	Diaz, Kinde 2013, & Rabinowitz (Ex. 1009)
3	103	15	Diaz, Kinde 2013, & Fleischhacker (Ex. 1010)
4	103	1, 2, 10–13, 15–18	Rabinowitz & Bettgowda (Ex. 1008)

The district court action involves three different grounds of invalidity: (1) Diaz and Forshew 2012⁶, optionally in view of Kinde 2013 or Young, and optionally further in view of Bashashati; (2) Forshew 2012, optionally in view of Gerstung or Kukita, and optionally further in view of Bashashati; and (3) Bashashati and Patel. (Paper 10, 25.) The second and third grounds have *no* overlapping art with any of the Petition Grounds. The first ground in the district court action only has *some* overlapping art with Petition Grounds 1–3, namely Diaz and Kinde 2013. But that first ground as presented in the litigation is significantly different from Petition Grounds 1–3. *See Klein Tools, Inc. v. Milwaukee Elec. Tool Corp. et al.*, IPR2024-01400, Paper 17, 17 (Apr. 8, 2025) (emphasizing that *Fintiv* Factor 4 focuses on the grounds, arguments and evidence “as *presented in the parallel proceeding*”) (emphasis in original).

Forshew 2012—a reference not even mentioned in the Petition—is the focal point of the first ground in the district court action. (Ex. 2002, 38.) It alone is cited as teaching all limitations of the claims asserted in the parallel litigation. (*Id.*; *see also* Ex. 2004.) The combination of Forshew 2012 with Diaz in the district

⁶ Forshew et al., *Noninvasive Identification and Monitoring of Cancer Mutations by Targeted Deep Sequencing of Plasma DNA*, 4 Sci. Transl., Med. 136, 10 (May 30, 2012) (“Forshew 2012”).

court action also cites Forshew 2012 as supplying every limitation of the asserted claims. (Ex. 2003.) And Kinde 2013 is only cited as an optional reference for limitations already disclosed by Forshew.

The remaining Petition Ground—Ground 4—relies on Rabinowitz and Bettegowda, which are *not* used as the basis for any invalidity ground in the district court action. Ignoring the differences between the grounds in the litigation and the Petition, Patent Owner asserts that the invalidity contentions in the litigation “explicitly cite and rely on Rabinowitz.” (Paper 10, 25.) But the grounds in the district court action cite Rabinowitz only as evidence of the state of the prior art, including that Patent Owner previously admitted that multiplex amplification of 50 to 100 target loci in a single reaction was known in the prior art. Rabinowitz is *not* cited to supply any missing claim limitations. (Ex. 2003, 41–42; Ex. 2004, 36; Ex. 2005, 3.); *see also* *POSCO Co., Ltd. v. Arcelormittal*, IPR2024-01376, Paper 11, 15–16 (Mar. 18, 2025) (“[T]he VinFast entities presented [Petition Art] Engels and Takagi alongside many other references as evidence of the ‘State of the Art.’ This is, therefore, not a situation where the ITC investigation will ‘resolve key issues in the petition.’”) (internal citations omitted). Rather, the litigation grounds rely on Forshew 2012 or Patel—references not even mentioned in the Petition—to teach multiplex amplification of 10 to 50 of the target loci. (Ex. 2003, 40–42; Ex. 2004, 34–36; Ex. 2005, 22.)

Similarly, Patent Owner asserts that the invalidity contentions explicitly cite and rely on Bettegowda. (Paper 10, 25.) But there Bettegowda is cited *only* as evidence of the state of the prior art—not as the basis for invalidity. (Ex. 2002, 28, 31, 33; Ex. 2003, 5.) Specifically, Bettegowda is cited only as evidence that SafeSeqS had been applied to cfDNA before the priority date of the asserted patents (Ex. 2002, 28; Ex. 2003, 5), and as one of many examples of prior art references teaching MRD assays and whole exome sequencing (Ex. 2002, 31, 33). The Petition presents an entirely different basis for unpatentability, demonstrating that the combination of Rabinowitz and Bettegowda alone teaches each and every limitation of claims 1, 2, 10–13, and 15–18 of the ’596 patent.

To the extent there is any material overlap between the Petition and the district court grounds, that overlap is mitigated by Petitioner’s *Sand Revolution* stipulation. (Paper 2, 62.) Patent Owner argues that “Petitioner will still be relying in litigation on four of the five reference asserted here” (Paper 10, 27.) As discussed *supra*, Patent Owner’s framing of the overlap is unnuanced and does not accurately reflect how those four references are *presented* in the co-pending litigation.

2. The cases cited by Patent Owner are distinguishable

In *Pharaoh Energy Servs. v. Flex-Chem Holding Co.*, IPR2024-00822, Paper 6, 12 (Sept. 20, 2024), cited by Patent Owner in Paper 10 at 26–27, the

Board found substantial overlap of issues where the invalidity contentions cited **only** the same two references that formed the basis of the petition grounds and one additional reference. That is not the case here, where entirely different references (Forshew 2012 or Bashashati and Patel) are the central focus of the invalidity contentions. The Board also noted the *Pharaoh* petitioner had “not entered into **any** type of stipulation, *Sotera*-style **or otherwise**, that would minimize the inefficiencies.” (*Id.*, 13 (quoting preliminary response).) The facts weighing for denial in *Pharaoh* do not apply to this Petition.

Apple Inc. v. Maxell, Ltd., IPR2020-00408, Paper 13 (Aug. 11, 2020) (“*Maxell*”) and *Samsung Elecs. Co. v. Secure Wi-Fi LLC*, IPR2024-01366, Paper 10 (Mar. 24, 2025) (“*Secure Wi-Fi*”) are similarly inapposite. (Paper 10, 27.) In *Maxell*, the asserted grounds in the petition and the litigation relied on the same **primary** reference. *Apple Inc.*, IPR2020-00408, Paper 13, 11–14. For example, the **only** difference between two grounds was that the litigation ground cited a secondary reference (Murayama) merely as additional support for one claim limitation. (*Id.*, 12.) Similarly, in *Secure Wi-Fi*, the Board found that the petition and litigation contentions shared the same “central issue” (whether two overlapping references—Vardi and IEEE802.11—disclosed the claim limitations). *Samsung Elecs. Co.*, IPR2024-01366, Paper 10, 16. In contrast to *Apple*, the **non-overlapping** references in the present litigation are cited for all asserted claim

limitations, and the ***only overlapping*** references (Diaz and Kinde 2013) are cited as additional support. More importantly, the “central issue” is different between the Petition and the litigation grounds given the focus on Forshew 2012 in the litigation, as discussed *supra*.

Patent Owner also relies on *Samsung Elecs. Co. v. Ancora Techs., Inc.*, IPR2020-01184, Paper 11 (Jan. 5, 2021) (“*Ancora*”) to argue that Petitioner’s *Sand* stipulation does not mitigate the limited overlap in the cited references. (Paper 10, 27–28.) But Patent Owner ignores that, in *Ancora*, the Board found that a stipulation did not mitigate overlap because it ***would not bind Petitioner’s co-defendants*** in the parallel litigation. *Ancora*, IPR2020-01184, Paper 11, 21. No such risk applies here.

Finally, Patent Owner relies on *Samsung Elecs. Co. v. Clear Imaging Rsch., LLC*, IPR2020-01402, Paper 12, 25 (Mar. 4, 2021) (“*Clear Imaging*”) (finding “factor 4 weighs ***slightly*** in favor of exercising our discretion to deny institution.”). (Paper 10, 28.) But Patent Owner ignores that, in *Clear Imaging*, the Board found that the claims in the petition and in the parallel litigation recited “similar subject matter,” with the non-overlapping claims challenged in the petition *all* reciting steps similar to the functions performed by the apparatus recited in the asserted claims. *Clear Imaging*, IPR2020-01402, Paper 12, 21–23. That is not the case here—a fact which Patent Owner never acknowledges.

3. The challenged claims are materially different across the two proceedings

The differences between the district court action and the Petition do not end with the art or arguments. The Petition seeks to cancel *eight more claims* of the '596 patent than at issue in the parallel litigation. The Board has found such a difference to direct against denial, even if a trial precedes a final written decision. *Apple Inc. et al. v. Neodron Ltd.*, IPR2020-00778, Paper 10, 19 (Sept. 14, 2020) (weighing Factor 4 against discretionary denial because “the ITC will not consider the validity of challenged claims 13 and 14”); *PUMA North America, Inc. v. Nike, Inc.*, IPR2019-01043, Paper 8, 9–10 (Oct. 31, 2019) (“the Litigation only addresses challenged claims 1, 5, and 6” whereas “the Litigation *does not address* challenged claims 9, 10, 13, 14, or 17 Accordingly, even if trial in the Litigation were to conclude prior to the statutory due date for the Final Written Decision in this proceeding, questions regarding the patentability of the majority of challenged claims would remain unresolved.”) (emphasis in original).

Patent Owner tries to side-step this material difference by referencing sole independent claim 1 and arguing that the claims are “all directed to the same subject matter.” (Paper 10, 33.) But Patent Owner ignores that the dependent claims have differing scope, necessitating for example an entire separate ground for claim 15. *Klein Tools*, IPR2024-01400, Paper 17, 18–19 (finding factor weighs against discretionary denial when six claims—all dependent from sole independent

claim 1—were not challenged in the co-pending litigation); *Hanwha Solutions Corp. v. Maxeon Solar Pte. Ltd.*, IPR2024-01199, Paper 17, 18 (Feb. 26, 2025) (“While some overlap of issues may exist, complete overlap does not exist and resolution of the companion trial will not address *the non-overlapping claims or grounds.*”).

As above, the cases that Patent Owner cites are all distinguishable from the facts here. (Paper 10, 33.) In *Next Caller, Inc. v. TRUSTID, Inc.*, IPR2019-00961, Paper 10, 6–14 (Oct. 16, 2019), all of the invalidity grounds asserted in the district court litigation and in the petition relied on the *same primary reference* (Martin). And the petition grounds challenging the additional claims were based on the *same references* (Martin, Goldman, Abramson, Kealy, and Schwartz) that were the *basis* for the invalidity contentions of the asserted claims in the litigation—no additional references or different references were asserted to challenge the non-overlapping dependent claims. (*Compare id.*, 7–8 (petition grounds citing various reference combinations for all challenged claims) *with id.*, 12 (litigation grounds citing the same references and one additional reference)). In contrast, the Petition here relies on Fleischhacker or Bettegowda for the bladder cancer limitation of claim 15, *neither of which* is the basis for a ground in the district court litigation.

Finally, Patent Owner cites *Samsung Elecs. Co. v. Mojo Mobility, Inc.*, IPR2023-01098, Paper 11, 11 (Feb. 9, 2024) (“The claim that it is the focus of the

parties’ arguments in this proceeding, independent claim 1, is common to both proceedings, *and Patent Owner has stipulated not to assert infringement of the additional claims in the Petition.*”). (Paper 10, 33.) But the Patent Owner here has filed no such stipulation with respect to the additional claims challenged in the Petition. Instead, it merely argues in a footnote that, based on the schedule of the parallel litigation, it is “unable to assert additional ’596 patent claims (beyond already-asserted claims 1, 11, 12, and 18) *in that ongoing litigation.*” (*Id.*, n.12.)

Factor 4 thus weighs strongly against discretionary denial given the material differences in art, arguments and challenged claims between this proceeding and the co-pending litigation.

C. Factor 3: The Lack Of Any Decision On Validity Combined With Petitioner’s Expeditious Filing Of The Petition Direct Against Discretionary Denial

Factor 3—which focuses on the investment in the co-pending district court action—directs against discretionary denial. According to *Fintiv*, this factor considers whether a district court has issued “substantive orders” related to the challenged patent. *Fintiv*, IPR2020-00019, Paper 11, 9–10. To provide guidance on a “substantive order,” the *Fintiv* Board cited a preliminary injunction decision on validity. (*Id.*, n.16.) The Court here has not issued any substantive orders related to the validity of the ’596 patent. Dispositive motions, such as summary judgment, have not yet been briefed, and their hearing—*not* decision—will be near

the deadline of the institution decision as Patent Owner admits.⁷ (Paper 10, 21.)

As discussed *infra*, the Court has indicated that it may *not* rule on any summary judgement motion in time before trial. (Ex. 1107, 100:16–24.)

Patent Owner emphasizes the investment made in district court with respect to the '596 patent, including discovery, claim construction briefing, and the *Markman* order. (Paper 10, 17–21.) The Board, however, has balanced such investment with whether substantive decisions on validity have in fact been made. For example, in *Medtronic Corevalve LLC v. Colibri Heart Valve LLC*, IPR2020-01454, Paper 11, 15–16 (Mar. 10, 2021) (“*Medtronic Corevalve*”), the Board recognized that “the parties and court have invested substantial time and resources” but also found “no evidence that any substantive determinations on validity issues have been made in the CDCA case.”

Moreover, Factor 3 tips against discretionary denial because Petitioner filed the Petition expeditiously. *Fintiv*, IPR2020-00019, Paper 11, 11 (“If the evidence shows that the petitioner filed the petition expeditiously, such as promptly after

⁷ The Board issued the Notice of Filing Date (Paper 5) on February 14, 2025—a month after the Petition was filed on January 15, 2025. Had the Notice been issued near the Petition’s actual filing date, the briefing would not have been completed before institution.

becoming aware of the claims being asserted, this fact has weighed against exercising the authority to deny institution under *NHK.*”). Patent Owner filed its amended complaint—formally adding the ’596 patent into the litigation—on December 10, 2024. (Ex. 2041.) About ***five weeks*** after that filing and service, Petitioner filed its Petition on January 15, 2025. The Board has routinely found ***much later*** filed petitions to be reasonable or expeditious:

- *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, 17 (Dec. 1, 2020) (finding timing of the Petition was reasonable even though “Petitioner filed its Petition approximately two months after serving its initial invalidity contentions, and ***approximately two weeks before the statutory deadline.***”);
- *Cellco Partnership v. Huawei Device Co, Ltd.*, IPR2020-01117, Paper 10, 22 (Feb. 3, 2021) (“We also credit Petitioner’s diligence in filing the Petition in this case within a relative short time (less than ***three months***) after being served infringement contentions in the parallel case. . . .”);
- *Samsung Elecs. America, Inc. v. SNIK LLC*, IPR2020-01324, Paper 9, 9 (Mar. 9, 2021) (“Moreover, Petitioner was diligent in filing its petitions ***nearly three months*** before the statutory bar.”);

- *Medtronic, Inc. et al. v. Teleflex Innovations S.A.R.L.*, IPR2020-01341, Paper 11, 12 (Feb. 9, 2021) (“*Medtronic*”) (“We do not consider, based on the current record, the filing of the Petition ***within 6 months of the filing of the Amended Complaint*** that asserted the ’413 patent to be unjustified.”);
- *Ability Opto-Elecs. Tech. Co., LTD., v. Largan Precision Co., Ltd.*, IPR2020-01339, Paper 10, 22 (Feb. 22, 2021) (finding filing a petition ***three months*** after patent owner identified allegedly infringing claims and noting that “it is often reasonable for a petitioner to wait to file its petition until learning specifics about infringement allegations, such as which claims are being asserted against it.”); and
- *Medtronic Corevalve*, IPR2020-01454, Paper 11, 14 (“We find no unreasonable delay in Petitioner’s prompt filing of the Petition ***only four months after the complaint was served.***”) (citing cases for support).

Patent Owner does not, and cannot, dispute that Petitioner filed its Petition expeditiously. Patent Owner merely asserts—in a footnote—that Petitioner’s expeditious filing should not tip this factor. (Paper 10, 23–24 n.9.) It argues that Petitioner was somehow aware that Patent owner was going to assert the ’596 patent from a portfolio of over 150 patents but waited to file the present Petition.

(*Id.*) There is no evidence that Petitioner knew Patent Owner would assert the '596 patent until November 2024 when Patent Owner sought to amend the complaint. (Ex. 2036.)

Even if Petitioner was generally aware of the '596 patent as part of Patent Owner's portfolio, the operative trigger for Factor 3 is the service of the amended complaint, when the claims of the newly added patent are officially asserted. *Medtronic Corevalve*, IPR2020-01454, Paper 11, 14 (although petitioner was aware of patent through the *filing* of a complaint, the "claims were not 'being asserted' until a complaint was served" and there was "no unreasonable delay in Petitioner's prompt filing of the Petition only four months after the complaint was served.")). In contrast, under Patent Owner's approach to Factor 3's expeditious requirement, a petitioner would have to file random IPR petitions—in this case, over 150—to challenge any patent in a portfolio that could ultimately be asserted in an amended complaint in order to be expeditious. That makes no sense.

Patent Owner also references Petitioner's earlier filed petitions against two other patents that were asserted in the original complaint. (Paper 10, 23–24 n.9.) The earlier filings are irrelevant for Factor 3 here. In *Medtronic*, a patent owner asserted a first set of patents against petitioner, who filed a first set of IPR petitions in response. Then, the patent owner amended its complaint to add a new patent, and the petitioner filed an IPR petition on the new patent—just as in this present

case. The *Medtronic* Board held that “the filing of the Petition within 6 months of the filing of the Amended Complaint that asserted the ’413 patent to be justified.” *Medtronic*, IPR2020-01341, Paper 11, 12. That is, the Board’s focus was, correctly, on the filing of the amended complaint.

Following the amended complaint here in December 2024 (Ex. 2041), the parties faced claim construction and discovery deadlines related to the ’596 patent. But Petitioner did not wait for this litigation to progress significantly—it instead filed the Petition on January 15, 2025, about five weeks after the amended complaint was filed and served. That Petitioner here filed its Petition within *five weeks*, as opposed to the six months in *Medtronic*, tips Factor 3 in Petitioner’s favor.

D. Factors 1, 2 And 5: These Factors Relating To When Trial Will Commence Are Collectively Neutral

Patent Owner repeatedly argues that Petitioner, as Defendant in the co-pending litigation, has sought a trial commencing on October 10, 2025. (Paper 10, 10–17, 35.) Because Patent Owner also has sought an October trial, it argues that the trial date is “not in doubt.” (*Id.*, 11.) But the *Court*’s most recent statements on whether trial will commence in October is far less unequivocal than Patent

Owner’s “not in doubt” assertion and renders Factors 1, 2 and 5 collectively neutral.⁸

On March 11, 2025, at the end of a Markman hearing, the Court discussed the status of the case. It explained that, while it would do its “absolute best” to try the case in October, “[w]e have had another judge take senior status” and that “[w]e’re kind of swamped” in the Middle District of North Carolina (“M.D.N.C.”). (Ex. 1107, 100:5–9.) The Court then stated that there was “more of a chance than usual” that it will *not* be able decide summary judgment in time for an October trial:

If I figure out that I am not going to be able to get summary judgment done in time for us to try it in October, I will let you know that early,

⁸ See Paper 10, 9 (neither party requesting a stay); *Fintiv*, IPR2020-00019, Paper 15, 12 (May 13, 2020) (finding Factor 1 neutral when neither party has requested a stay and the court has not ruled on the issue); *Cisco Sys., Inc. v. Ramot at Tel Aviv Univ.*, IPR2020-00122, Paper 15, 10 (May 15, 2020) (APJ Crumbley, dissenting) (“In cases such as the one at hand, where the parties are the same, the factor is neutral. To hold otherwise—that the factor weighs in favor of denial if the parties are the same—would, in effect, tip the scales against a petitioner merely for being a defendant in district court.”).

because I respect your time and I know you have other things going on.

So I don't expect it to happen, *but there is more of a chance than usual that it might happen* because of our situation here and the national situation involving budget cuts, primarily to our facilities. That's how we're experiencing it in the moment. So there we are.

(*Id.*, 100:16–24.)

Patent Owner did not submit the Court's statements about being "swamped" or that "there is more of a chance than usual" of delay, even though it submitted over 70 other exhibits from the co-pending litigation. It instead cites two orders regarding what the Court expects to do. (Paper 10, 11, 13, 15; Ex. 2040, 1; Ex. 2001, 1.) But the first order (Ex. 2040) issued on December 6, 2024, *before* the Court's more recent statements at the Markman hearing. The second order (Ex. 2001), which was a text order, issued before the Markman hearing as well. There, the Court said that it "remains of the *tentative view* that the case can be tried fairly during the week of October 14, *but* will make a *final decision* on trial time *later*, after any summary judgment briefing." (Ex. 2001, 1.) At the Markman hearing, about a month later, the Court explained that it may not be able to get

“summary judgment done in time for us to try in October.”⁹ (Ex. 1107, 100:16–19.)

This statement places the text order in proper context. The “final decision on trial time” mentioned in the text order has still not been made. In fact, “there is more of a chance than usual” that summary judgment, mentioned in the text order, may end up delaying trial. *See also* Ex. 1022, 8 (trial date is “subject to the Court’s availability and subject to adjustment based on the Court’s criminal court schedule”).

Patent Owner’s failure to address the Court’s most recent statements undermines its remaining arguments. It asserts that M.D.N.C. case law and statistics are inapplicable. (Paper 10, 11, 13–14.) But its dismissal of M.D.N.C. case law is premised on *uncited* “repeated statements” from the Court. (Paper 10, 11.) To the extent Patent Owner is referring to Ex. 2040 and Ex. 2001, those do not reflect the Court’s most recent statements as discussed above. Patent Owner’s dismissal of M.D.N.C. time-to-trial statistics is similarly premised on *uncited* “clear statements” from the Court. (*Id.*, 13.) Nowhere does Patent Owner address the Court’s recent statements that it is “kind of swamped.” (Ex. 1107, 100:5–7.)

⁹ The Court explained that, while it could promptly issue a claim construction decision, “summary judgment is a different ball of wax.” (Ex. 1107, 100:5–8.)

Patent Owner spends pages arguing that the time-to-trial analysis should be based on the filing date of the original complaint as opposed to the amended complaint. (Paper 10, 14–16.) It misses the point. There is no dispute that the complaint was amended on December 10, 2024, to include the ’596 patent for the first time, thereby starting a new round of briefing. (Ex. 2041.) For example, the parties submitted claim construction briefing for the ’035 patent and the ’454 patent (Exs. 2022, 2024–2025, 2027–2030, 2071), and the Court issued a claim construction order (Ex. 2031) in 2024—only for the parties to redo the claim construction briefing (Exs. 2044–2048, 2072–2073) and for the Court to issue a new claim construction order (Ex. 2055) for the ’596 patent in 2025. *See also* Paper 10, 18–19 (referring to “significant briefing” assessed by the Court). As it now stands, regardless of Patent Owner’s assertions about the correct “filing date,” there is “more of a chance than usual” that dispositive motions, such as summary judgment, may not be done in time to “try the case in October.” (Ex. 1107, 100:16–23.)

Finally, even if the trial were to proceed on October 10, 2025, numerous panels have instituted review even though the trial date preceded a final written decision by *many months*:

- *Apple Inc. v. Seven Networks, LLC*, IPR2020-00506, Paper 11, 7, 18–19 (Sept. 1, 2020) (although “trial is scheduled to begin on November

2, 2020, *ten months before*” the final written decision deadline, factors such as 4 and 6 “outweigh the earlier scheduled trial date in the District Court and the investment in the District Court litigation.”) (italics emphasis in original; internal quotes omitted);

- *Cellco Partnership*, IPR2020-01117, Paper 10, 18–20 (instituting review even though parties agreed to trial date *four months* before the final written decision deadline);
- *Samsung Elecs. America*, IPR2020-01324, Paper 9, 9–10 (declining to deny review where “the district’s scheduled trial date predates our projected final written decision deadline by approximately *seven months*”);
- *Medtronic Corevalve*, IPR2020-01454, Paper 11, 12–13 (instituting review even though the trial date preceded the final written decision by *nearly six months* and the district court conveyed that the trial date “would not move under any circumstances.”) (internal quotation omitted); and
- *Google LLC v. EcoFactor, Inc.*, IPR2021-00054, Paper 9, 9 (May 10, 2021) (not invoking Board’s authority to deny institution even when scheduled trial date is “approximately *five months* before a Final Written Decision would be due.”); and

- *Uniden America Corp. v. Escort Inc.*, IPR2019-00724, Paper 6, 6–7 (Sept. 17, 2019) (instituting review when the “Texas litigation is moving quickly towards a one week trial” scheduled “*three months before* a final written decision likely will be issued”) (italics emphasis in original).

Patent Owner does not address any of these cases in its brief, even though it had three months from the Petition’s filing to consider the case law and thousands of additional words available to explain. (Paper 10, 16–17, 42.) And the cases that Patent Owner cites are all distinguishable from the facts here.

In *Cisco Sys., Inc. v. Estech Sys., Inc.*, IPR2021-00332, Paper 11, 9–10, 14 (July 7, 2021), the Board could not “say that Petitioner was diligent in filing the Petition” nor did it find the merits of the challenge outweighed the other factors. As discussed *supra*, Petitioner was diligent in filing a petition with compelling merits. Similarly, in *Ancora*, the Board found that petitioner “chose to wait until the very last day of the one-year period in late June 2020 to file the Petition,” and that petitioner’s “challenges contain certain weaknesses.” *Ancora*, IPR2020-01184, Paper 11, 18, 24 (internal quotation omitted). The petitioner in *Immersion Sys. LLC v. Midas Green Techs., LLC*, IPR2021-01176, Paper 16, 14–16 (Jan. 6, 2022) also waited to the last possible day (“mere hours” before the deadline) to file a petition that was a “*complete overlap*” with the validity issues raised in district

court. (Emphasis in original; internal quotation omitted.) No such overlap exists in this proceeding as also discussed *supra*.

In *Toyota Motor Corp. v. Emerging Auto. LLC*, IPR2024-00785, Paper 13, 15 (Mar. 11, 2025), the Board did not find “the merits to be particularly strong on the current record” given the petitioner’s reliance on a single sentence in a reference. And, most recently in *Motorola Solutions, Inc. v. Stellar, LLC*, IPR2024-01205, Paper 19, 3 (Mar. 28, 2025), the original panel had misapprehended the relevant inquiry by relying on the volume of infringement filings in the co-pending litigation. Petitioner’s arguments here do not rely on the volume of infringement filings.

In short, Factors 1, 2 and 5 are collectively neutral, given the Court’s most recent statements relating to the October trial. And, in any event, panels have not denied review even when a trial date precedes a final written decision.

III. THE DIRECTOR’S MARCH 26, 2025 MEMORANDUM VIOLATES THE ADMINISTRATIVE PROCEDURE ACT

On March 26, 2025, the Acting Director issued a memorandum entitled “Interim Processes for PTAB Workload Management” (“Memorandum”). The Memorandum sets forth the procedure under which Patent Owner has filed its Discretionary Denial Brief on April 14, 2025. Petitioner respectfully submits that the Memorandum violates the Administrative Procedure Act (“APA”). First, as binding agency policy that affects private interests, the Memorandum is a

substantive rule that had to be promulgated through notice-and-comment rulemaking. *Mendoza v. Perez*, 754 F.3d 1002, 1020 (D.C. Cir. 2014). Second, the Acting Director is not authorized under AIA, including § 314(a), to deny the Petition based on the factors referenced in the Memorandum. 5 U.S.C. § 706(2)(C). Third, the application of those factors has currently led to agency action that is arbitrary and capricious under the APA. 5 U.S.C. § 706(2)(A).

IV. CONCLUSION

Factors 6 and 4 strongly weigh against discretionary denial, because the merits of the Petition are particularly strong, the art, arguments and claims challenged are materially different from the co-pending litigation and there are public health interests at stake. Petitioner's expeditious filing of the Petition within five weeks of the amended complaint tips Factor 3 in its favor. Factors 1, 2 and 5 are collectively neutral given that "there is more of a chance than usual" that the Court will not decide summary judgment in time for an October trial. Thus, on balance, Petitioner respectfully requests that the Director decline to exercise discretion to deny institution and let the panel decide whether to institute based on the compelling merits of the Petition.

IPR2025-00455

Dated: May 14, 2025

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Certification of Word Count

Pursuant to 37 C.F.R. § 42.24 and the Memorandum on Interim Processes for PTAB Workload Management, dated March 26, 2025, Petitioner certifies that the word count of the foregoing PETITIONER’S OPPOSITION TO PATENT OWNER’S REQUEST FOR DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(a) is as measured by Microsoft Word is 8,275 words, excluding those portions identified in 37 C.F.R. § 42.24(a).

Dated: May 14, 2025

By /Mehran Arjomand/
Mehran Arjomand

Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached PETITIONER'S OPPOSITION TO
PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL UNDER 35
U.S.C. § 314(a) was served on the below date via e-mail (by consent) to the
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