

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEOGENOMICS LABORATORIES, INC.,
Petitioner

v.

NATERA, INC.,
Patent Owner

Case IPR2025-00455
Patent 11,319,596

**PATENT OWNER'S BRIEF IN SUPPORT OF
DISCRETIONARY DENIAL UNDER 35 U.S.C. §314(a)**

LIST OF EXHIBITS

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I. Introduction

This Petition asks the Board to commence precisely the kind of wasteful, duplicative Patent Office litigation that the Director's restored *Fintiv* policy and precedent were designed to prevent: an IPR requiring the PTAB to decide, *again*, the validity of the same '596 patent claims (based on overlapping arguments using four identical prior art references) that will already have been decided in a *District Court jury trial set to take place 10 months before any Final Written Decision deadline here*. Indeed, Petitioner takes its invitation to waste still more party, District Court, and Board resources a step further—admitting in its Petition that a critical limitation the Examiner concluded was missing from the prior art of record during prosecution is *still not disclosed by the duplicative prior art* that Petitioner now urges in both forums. Failure to exercise its discretion here to deny institution would be an arbitrary departure from the Board's clear policy and precedent, and would directly contradict the rationale underlying discretionary denial—compelling significant wasted efforts duplicating the work in the parallel Court proceeding that will be nearly complete even by the time of institution. It would also further risk inconsistent Court and PTAB findings. And Petitioner's attempts to avert discretionary denial by unfounded speculation¹ about a possible stay of parallel

¹ PO will address additional Petitioner misstatements in its forthcoming POPR.

litigation are flatly contradicted by (1) Petitioner’s own express disavowal of any intent to request a stay, (2) Petitioner’s affirmative insistence (with PO’s explicit agreement) on maintaining the scheduled October 10, 2025 trial date, and (3) the repeated embrace and confirmation *by both parties and the Court* of that scheduled time for trial a mere six months from now.

Patent Owner Natera, Inc. (“PO”) submits this brief in support of discretionary denial of NeoGenomics Laboratories, Inc.’s (“Petitioner”) Petition pursuant to the Board’s March 26, 2025 “Interim Processes for PTAB Workload Management” (“Interim Processes Memo”). Each and every factor enumerated in the Board’s precedential *Fintiv* decision favors denial of institution, and Petitioner has not met its §314(a) burden—a burden that never shifts to Patent Owner—to show that institution should be granted.² The Board should exercise its discretion to deny institution here to prevent the unnecessary, burdensome, and wasteful duplication of effort that would otherwise result, to give effect to the intent of Congress (reflected in *Fintiv*) that IPR proceedings be a “‘true alternative’ to... district court proceeding[s],” *Motorola Solutions, Inc. v. Stellar, LLC*, IPR2024-01205, Pap.19,

² Unless stated, statutory and regulatory citations are to 35 U.S.C. or 37 C.F.R., as context indicates, internal citations omitted, and emphases/annotations are added.

3-4 (Mar. 28, 2025), and to “improve PTAB efficiency [and] maintain PTAB capacity to conduct AIA proceedings.” Interim Process Memo, 3.

II. The Parallel District Court Litigation

Almost two years ago, in July 2023, PO sued Petitioner for infringing PO’s patents with Petitioner’s RaDaR™ 1.0 assay. PO immediately sought and obtained a Preliminary Injunction against Petitioner’s continuing infringement, while it continued actively litigating the merits in District Court. PO initially asserted U.S. Patent Nos. 11,530,454, entitled “Detecting Mutations and Ploidy in Chromosomal Segments” (the “’454 patent”), and 11,519,035, entitled “Methods for Simultaneous Amplification of Target Loci” (the “’035 patent”). Notably, the ’454 patent shares the same specification as the ’596 patent at issue here and is part of the same patent portfolio. EX2012, 1; Pet.60 n.11.³ Petitioner was fully aware of this relevant patent portfolio by at least April 2024, when Petitioner described its own “ongoing... discovery” into Natera’s “substantial intellectual property portfolio with over 150

³ In addition to this proceeding, Petitioner previously filed IPR petitions as to both the ’454 (IPR2024-00346) and ’035 patents (IPR2024-00812). Institution of the ’454 IPR was denied under §325(d) on June 21, 2024 (Pap.15, 5-18), and the ’035 IPR was terminated in October 2024 pursuant to the parties’ partial settlement agreement (Pap.11).

issued patents and over 220 pending patents applications as of December 31, 2022.”

EX2026, 28 n.5. The ’596 patent issued May 3, 2022, with the same title as the ’454 patent (“Detecting Mutations and Ploidy in Chromosomal Segments”). The ’596 patent was added to the complaint once discovery revealed that Petitioner’s “RaDaR 1.1 assay” would infringe. The RaDaR 1.1 assay is an updated version of Petitioner’s initially-accused RaDaR 1.0 assay.

PO’s motion for a Preliminary Injunction, filed three days after its Complaint⁴ (EX2013), was extensively briefed (*see* EX2014; EX2017; EX2018) before a hearing on November 27, 2023, featuring live testimony from a PO expert. EX2019. The Court granted PO’s injunction in a written order on December 27, 2023 (EX2020; *see also* EX2070), and Petitioner appealed that same day. EX2021. Over the next three months, both parties *again* extensively briefed and argued these Preliminary Injunction issues at the U.S. Court of Appeals for the Federal Circuit. EX2062; EX2063; EX2064; EX2065. The Federal Circuit affirmed PO’s Preliminary Injunction on July 12, 2024, and issued its mandate on August 19, 2024.

⁴ Petitioner answered PO’s July 28, 2023 complaint (EX2012) on September 11, 2023 (EX2015), and then amended that original Answer on October 6, 2023 and again on October 20, 2023. EX2016; EX2069.

EX2032, 21-22 (“The district court deftly parsed through excessive arguments and the evidence....”); EX2033.

Fact discovery opened soon after the filing of PO’s motion for a Preliminary Injunction (EX2068), and claim construction on disputed terms of the ’035 and ’454 patents was completed between March and May 2024, with extensive briefing and expert declarations submitted by both parties. *See, e.g.*, EX2022; EX2024; EX2025; EX2027; EX2028; EX2029; EX2030; EX2071. The Court conducted a claim construction hearing and issued a 14-page claim construction order in May 2024 (EX2031), making determinations it would later rely on again to resolve similar issues concerning construction of the ’596 patent, which is related to the ’454 patent. EX2055, 5, 8 n.4; *see also* EX2051, 1 (denying Petitioner’s motion to modify the Court’s construction of a previously-construed term based on statements PO made in Petitioner’s non-instituted IPR against the related ’454 patent, stating that “NeoGenomics takes the statements made by Natera out of context and interprets those statements in a way that is unfair and inaccurate”).

On July 11, 2024, Petitioner served Final Invalidity Contentions. These contentions were 480 pages long and referred to 15 prior-art references. EX2010; EX2011.

After the Federal Circuit’s affirmance of the Preliminary Injunction, the parties reached a partial settlement concerning Petitioner’s RaDaR 1.0 assay.

EX2035. As part of that agreement, Petitioner agreed not to contest that: (1) its RaDaR 1.0 assay infringed certain claims of the '035 patent and all claims of the '454 patent; (2) those claims are valid and enforceable; (3) the stipulated infringement of those claims would irreparably harm PO, the balance of the harms favors the grant of the injunction, and the public interest weighs in favor of the injunction. EX2035, 1-2. On September 23, 2024, the court entered a stipulated order and permanent injunction enjoining NeoGenomics from

making, using, selling, or offering for sale in the United States (a) the RaDaR 1.0 Assay or (b) any assay or product not more than colorably different from the RaDaR 1.0 Assay whose manufacture, use, importation, offer for sale, or sale would infringe any of the Asserted Claims.

EX2035, 2-3. Litigation was, however, not resolved as to Petitioner's then-under-development RaDaR 1.1 assay—a modified version of the originally-accused RaDaR 1.0 assay—that PO first learned of on July 1, 2024.

After “document productions from [Petitioner] NeoGenomics, including productions as recently as October 31, 2024, revealed new information concerning RaDaR 1.1 evidencing infringement of” PO's '596 patent, as well, PO moved to amend its complaint on November 4, 2024, to include the '596 patent and to expressly accuse RaDaR 1.1 of infringing both the '596 and the '454 patents. EX2036, 1-2. In exchange for agreeing not to oppose the addition of the '596 patent

to the litigation, Petitioner insisted upon a commitment from PO that “the current trial date, October 13-17, 2025, [would be] maintained.” EX2037, 2; *see also* EX2038.

Indeed, the Court has also consistently expressed its intention to maintain the October 2025 trial date. *E.g.*, EX2001; EX2040, 1. For example, noting its “extensive experience with this case,” the Court granted PO’s motion to amend on December 6, 2024, finding “there is no unfair prejudice to [Petitioner] so long as the trial is not delayed. This can be accomplished.” EX2040, 1. PO formally filed the amended complaint on December 10, 2024, and Petitioner Answered on December 20, 2024. EX2041; EX2042. Consistent with the Court’s directive, neither PO nor Petitioner has requested any delay of the October trial date.

PO served Preliminary Infringement Contentions regarding the RaDaR 1.1 assay’s infringement of the ’454 and ’596 patents on November 25, 2024, before the motion to amend was granted. EX2039. Claim construction for the ’596 patent—again featuring extensive briefing, discovery, and testimony—was completed between January and March 2025, with the submission of two expert declarations from Petitioner’s expert (who is also Petitioner’s expert in this proceeding), an expert declaration from PO’s expert, and depositions of both experts, as well as a *Markman* hearing with live testimony from PO’s expert. EX2044; EX2045; EX2046; EX2072; EX2047; EX2073; EX2048; EX2049; EX2052; EX2054. The

Court, relying in part on its previously-concluded construction process for the '454 and '035 patents, issued its claim construction order for the '596 patent on March 17, 2025. EX2055, 5, 8 n.4.

On March 14, 2025, Petitioner filed its Amended Final Invalidity Contentions, alleging invalidity of the asserted claims of the '454 and '596 patents under §§102 and 103, as well as other grounds. EX2002. In its litigation contentions, Petitioner relies on four of the same five references asserted in the Petition's Grounds. EX2002, 35 (discussing Diaz and Kinde 2013); EX2002, 5, 41 (discussing Rabinowitz and Bettgowda).

Fact discovery, having started before the Federal Circuit affirmed the Preliminary Injunction in 2024, closed on April 4, 2025. EX2068; EX2056. Over the course of discovery, the parties served and responded to over 320 discovery requests. *E.g.*, EX2057; EX2058; EX2059; EX2060; EX2061. The parties produced a combined total of over 81,000 pages of documents, and have conducted some 28 fact depositions, including Rule 30(b)(6) depositions. Fact discovery closed on April 4, 2025. EX2056, 1.

Trial in the District Court litigation is currently scheduled to begin on October 10, 2025 (EX2001, 1)—a date set well before the Petition was filed, and repeatedly affirmed (before and after the Petition) by both parties and the Judge in the District Court. This trial date is less than two months after the *institution decision* is due on

this Petition (August 14, 2025), and *more than 10 months before any Final Written Decision* deadline here (August 14, 2026). EX2001, 1; EX1022, 8. Thus, even by the time of potential *institution*, the parties will have finished all discovery (including expert discovery), dispositive motions will have been fully briefed and argued, and final pretrial exchanges will be underway. And by the time of any Final Written Decision, the District Court trial will have been long over. EX2001, 1; EX1022, 8.

III. Institution Should Be Denied Under 35 U.S.C. §314(a)

A. The Parallel Litigation Will Not Be Stayed (Factor 1)

The parallel litigation here will not be stayed. This factor therefore favors denial of institution. The Petitioner makes vague assertions about the potential for a stay (Pet.59-60), but neither Petitioner nor PO has ever requested a stay of the parallel litigation pending the IPR, and neither has suggested to the District Court that any stay of the October 10, 2025 trial date would be appropriate.⁵ And, the Court has been clear about maintaining the trial date.

⁵ The parties jointly requested a temporary stay from August 22, 2024, to September 20, 2024, for Petitioner and PO to “finalize a resolution related to RaDaR 1.0” following the conclusion of injunction proceedings and the resulting appeal

Contrary to Petitioner’s speculation that a stay might be “possible” (Pet. 60), Petitioner itself asserted that it “[would] be prejudiced if the addition of the ’596 patent delays the trial date,” and emphasized a “central term of the parties’ partial settlement agreement—[was] agreeing on a case schedule that allows for trial within 6-8 months, which the Court set for October 2025.” EX2037, 8. Petitioner further fails to mention that, in granting PO’s motion to amend the complaint, the Court affirmatively found “that the need for the amendment is based in part on information Natera learned after September 12, 2024, that there has not been bad faith, that amendment would not be futile, and that there is no unfair prejudice to [Petitioner], so long as *trial is not delayed. This can be accomplished.*” EX2040, 1. Further, since then, Petitioner has affirmatively represented to the District Court that it “intends to abide by the current case schedule and does not intend to request a continuance of the trial date,” and confirmed that “NeoGenomics is ready to proceed on the current case schedule.” EX2050, 11-12.

PO likewise does not intend to request a stay (indeed, PO would *oppose* any such request), and the Court has repeatedly indicated (as recently as February 12,

(EX2034, 1), but thereafter affirmed to the Court that this partial settlement contemplated keeping the existing trial date. EX2037, 8.

2025) that it expects to proceed with trial as currently scheduled on October 10, 2025. EX2050, 9, 11; EX2001, 1.

Considering Petitioner’s representations to the Court that it would not request a continuance of the trial date and would in fact be prejudiced by such a continuance, PO’s agreement that the trial date be maintained, the Court’s repeated statements about maintaining the trial date, and the advanced stage of the litigation proceedings, the October 2025 trial date—less than two months after the institution decision here when almost all the work of the Court and parties will have been completed (and some ten months before any Final Written Decision)—is not in doubt. Thus, the cases cited by Petitioner purportedly standing for the proposition that “[t]he Middle District of North Carolina tends to stay proceedings if the Board institutes *inter partes* review” (Pet.59-60) have no bearing here.

As the trial is imminent, both parties have repeatedly stated that the schedule should be maintained, and the Court has indicated that trial will proceed as scheduled, it is clear that no stay will issue and institution should be denied. *Motorola*, Pap.11, 10-11 (finding this factor favored denial where “the court has entered an order setting trial to begin shortly [(3.5 weeks)] after a Decision to Institute would be entered in this proceeding”), *vacated on other grounds*, *Motorola*, Pap.19, 4 (denying institution and explaining that the Board had previously found factor 1 “weighed in favor of denial”); *Google LLC v. Uniloc 2017 LLC*, IPR2020-

00115, Pap.8, 7 (Mar. 27, 2020) (finding factor 1 “weigh[s] in favor of denying institution,” noting “[t]here is no evidence that the district court has granted (or would grant) a stay pending *inter partes* review”); *see also Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Pap.11, 10 (Mar. 20, 2020) (discussing factor 3 and explaining that “more work completed by the parties and court in the parallel proceeding tends to support the arguments that... a stay may be less likely...”); *infra*, §III.C (*Fintiv* factor 3).

B. Trial Is Scheduled to Begin 10 Months Before the Deadline for Any Final Written Decision (Factor 2)

The jury trial in the parallel litigation is scheduled to begin on October 10, 2025—*10 months before the projected August 14, 2025, due date for any Final Written Decision in this proceeding*. EX2001, 1. Petitioner attempts to evade this reality through incorrect characterization of the record of the parallel proceeding and speculation about the potential for a continuance of the trial date that no one seeks (*see* Pet.59-61; *see also* §III.A). But, as discussed above, both Petitioner and PO have repeatedly represented to the District Court that they expect to meet all pre-trial deadlines, and that trial will proceed as scheduled on October 10, 2025. *E.g.*,

EX2050, 11; EX2053, 2; EX2056, 1. The Court, too, has made clear that it expects trial to proceed on October 10. *E.g.*, EX2001, 1; EX2040, 1.⁶

Given the clear statements from the parties and the Court about maintaining the current October 10, 2025 trial date (*e.g.*, EX2050, 11), the advanced posture of this proceeding (with *Markman* and fact discovery completed), and the proximity of that trial date, there is no basis to resort here to some generic median-time-to-trial statistic. *See Fintiv*, Pap.15, 13 (May 13, 2020) (informative) (“We generally take courts’ trial schedules at face value absent some strong evidence to the contrary.”); *cf.* Pet.61. But even if the Board were to consider such statistics, this, too, would

⁶ The Petition speculates about potential delay based on its own motion for foreign discovery (Pet.61)—a delay that never came to pass, as the discovery at issue is now complete. But Petitioner neglects to mention that in support of its motion Petitioner argued it was not necessary to change the deadlines to accommodate this discovery, noting “this case [is] on an expedited track” (EX2043, 4) and “to the extent the [discovery] process is delayed, and the depositions cannot be taken before the close of fact discovery, the Court has discretion to permit *de bene esse* depositions up until trial.” EX2043, 5, 6 (“[T]he most prudent course would be for the court to grant the motion now, and if it turns out that the process is delayed beyond the close of discovery, decide then whether to allow the depositions prior to trial.”).

favor denial: for the 12 months ending September 30, 2024, median time-to-trial for civil actions in the Middle District of North Carolina was 30.5 months. EX2067, 22; EX1021, 22. Based on this figure and the original complaint’s July 28, 2023 filing date (EX2013), trial would be expected on February 13, 2026—still ***5 months before the projected due date for any Final Written Decision here.***

First, Petitioner attempts, without basis—and contrary to the facts—to move the filing date of the parallel litigation from the actual date in July 2023 to December of 2024. Citing the now-***rescinded*** “Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation,” the Petition argues that “[b]ecause Patent Owner first asserted the ’596 patent on December 10, 2024, these data indicate a median time-to-trial date in June 2027—nearly a year after the FWD deadline.” Pet.60. But the Petition offers no legal or factual basis for using the filing date of the *amended* complaint for its calculation here, particularly given:

- Petitioner’s explicit insistence that no amendment be allowed “if the addition of the ’596 patent delays the trial date” (EX2037, 7);
- Petitioner’s own report of the parties’ mutual “agree[ment] on a case schedule that allows for trial within 6-8 months, which the Court set for October 2025” (EX2037, 8);

- Petitioner’s representation that it would be “prejudiced” by any delay in the trial date (EX2037, 7);
- the Court’s explicit finding—in light of “its extensive experience with this case”—that adding the ’596 patent “can be accomplished” *without delaying the trial date* (EX2040, 1; *see also* EX2001, 1); and
- the actual state of discovery here: as discussed in connection with *Fintiv* Factor 3, below, fact discovery has been completed, claim construction proceedings have been completed, final infringement and invalidity contentions have been served, and expert discovery is beginning—none of which would be true if the case were proceeding as if it had been first filed in December 2024, as Petitioner urges.

To make the false suggestion that amending the ’596 patent into the parties’ ongoing litigation was equivalent to starting a completely new case from scratch (Pet.60), the Petition ignores the parties’ express commitments, what Petitioner itself

told the Court, and the Court’s own statements—as well as the substantial overlap between litigating the ’596 patent and the related’454 patent.⁷

Second, the Petition also strikingly ignores the vast number of Board decisions finding that similar or *smaller* gaps between trial and final written decision dates heavily favor denial. *See, e.g., Cisco Sys., Inc. v. Estech Sys., Inc.*, IPR2021-00332, Pap.11, 10-12 (July 7, 2021) (finding *11-month* gap between trial date and due date for final written decision “strongly favors exercising our discretion to deny institution”; further noting that “the investment of time and effort in the [parallel litigations]... has been substantial, and therefore, this factor also strongly favors exercising our discretion to deny institution”); *Motorola*, Pap.19, 3-4 (*11-month* gap between trial and final written decision favored denial); *Samsung Elecs. Co. v. Ancora Techs., Inc.*, IPR2020-01184, Pap.11, 15 (Jan. 5, 2021) (“*Ancora*”) (“Because the currently scheduled District Court trial is scheduled to begin *eight*

⁷ Petitioner’s misleading arguments are also contradicted by the median-time-to-trial statistics it cites: the “Explanation of Selected Terms” accompanying those statistics states that, “[f]or civil cases, median times from filing to trial are computed using the period *from the date a case was filed* to the date trial began,” (EX2066, 2), and makes no mention of using the date of an amended complaint—or *any* date other than the original case filing (here, July 28, 2023). EX2012.

and a half months before our deadline to reach a final decision, we find that [factor 2] weighs in favor of exercising our discretion to deny institution under § 314(a).”); *Immersion Sys. LLC v. Midas Green Techs., LLC*, IPR2021-01176, Pap.16, 12-13 (Jan. 6, 2022) (finding factor 2 weighed in favor of denial where trial was scheduled for approximately *three months* before due date for final written decision); *see also Toyota Motor Corp. v. Emerging Auto. LLC*, IPR2024-00785, Pap.13, 13 (Mar. 11, 2025) (finding “[f]actor 2 weighs heavily in favor of discretionary denial” where trial is scheduled to begin “approximately *eight months* before the Board would issue its Final Decision”). Petitioner’s discussion of this factor cites *no cases at all*, let alone any case applying the original *Fintiv* policy where the Board instituted trial despite a 10-month gap between trial and the due date for a final written decision.

Here, the 10-month gap between trial and the projected Final Written Decision due date, together with the substantial investment of time, effort, and resources in the parallel litigation that has already been made and will be further increased by the time of institution (*see infra* discussion of factor 3), weighs strongly in favor of exercising discretion to deny institution.

C. The Court and Parties Have Already Invested Substantially in the Parallel Litigation (Factor 3)

The advanced stage of the parallel litigation also weighs strongly in favor of discretionary denial. *Motorola*, Pap. 19, 2. By agreement of the parties and the orders of the Court (*see supra* §III.B), this litigation has already reached its final

stages and is heading rapidly for trial just six months from the date of this brief. As detailed below, fact discovery is complete, claim construction is complete, all contentions have been exchanged, and a Preliminary Injunction (later converted into a stipulated permanent injunction, EX2035) involving the earlier RaDaR 1.0 assay⁸ has already been fully (indeed, “excessive[ly]”) litigated both in the District Court and at the Federal Circuit. *See supra* §II; *see also* EX2032, 21-22 (“The district court deftly parsed through excessive arguments and the evidence....”).

Further, expert discovery is ongoing, and dispositive motions are due two months from now. By the time of the due date for an institution decision here (four months from now, on August 14, 2025), all that will remain for the litigation are certain pre-trial exchanges and the October 10, 2025 trial itself. EX1022, 6-8. As can plainly be seen, the investment of time and resources by the Court and parties in the parallel proceeding is already extremely substantial today, and by the time of an institution decision it will be as complete as in any suit that has not already been tried. Nearly all substantive work other than trial itself will be complete by the time of that institution decision date. For example:

Claim construction has issued. The parties provided, and the District Court considered, extensive *Markman* briefing, testimony, and arguments concerning

⁸ The RaDaR 1.1 assay was fashioned on the earlier RaDaR 1.0 assay.

construction of not only the '596 patent, but also the related '454 patent—and the Court itself expressly relied on the results of the prior construction efforts concerning the '454 patent to construe limitations of the '596 patent. EX2055, 5, 8 n.4; *see also* §II. Even looking just to efforts specific to the '596 patent, the parties supplied and the Court assessed significant briefing, two expert declarations from Petitioner's expert (who is also serving as Petitioner's expert in this proceeding), an expert declaration from PO's expert, and depositions of those experts; the Court held a *Markman* hearing with the parties on March 11, 2025 (including in-court testimony of PO's expert); and the Court issued a claim construction order on March 17, 2025. EX2044; EX2045; EX2046; EX2047; EX2048; EX2049; EX2052; EX2054; EX2055. *Motorola*, Pap.19, 3; *Ancora*, Pap.11, 17.

Final infringement and invalidity contentions have been served. PO and Petitioner served their respective final infringement and invalidity contentions, a month before the filing of this brief, on March 14, 2025. EX2002, 88; EX1022, 5. Petitioner's litigation invalidity contentions rely in part on four wholly duplicative references that Petitioner also included as four of the five references supporting the Grounds in its IPR Petition: (1) Diaz (EX1006) and (2) Kinde 2013 (EX1007) (both asserted in Grounds 1-3 here); and (3) Rabinowitz (EX1009) (also in Ground 2 here) and (4) Bettgowda (EX1008) (together with Rabinowitz, the only two references in Ground 4 here). EX2002, 38; EX2003, 1; EX2004, 36; EX2005, 3. *Motorola*,

Pap.19, 3; *Ancora*, Pap.11, 17. Indeed, the **only** reference from the Grounds that Petitioner did **not** also repeat in its litigation contentions is Fleishhacker (EX1010), which is cited here only as a third combination reference in Ground 3 to challenge only claim 15 (a claim not asserted in the litigation).

Fact discovery is complete. Fact discovery closed on April 4, 2025 (and the parties actually concluded the final fact deposition on April 7, 2025, after agreeing to that exception “to accommodate the availability of counsel and the witnesses”). EX2056. In total, the parties produced over 81,000 documents and conducted 28 depositions (including Rule 30(b)(6) depositions and two depositions under the Hague Convention, EX2050, 2) during fact discovery, and invested substantial time in producing technical documents, and financial information. *Toyota*, Pap.13, 13-14 (on rehearing, finding factor three “weighs heavily in favor of discretionary denial” where fact discovery was closed and expert discovery was set to close several weeks after the rehearing decision).

Expert discovery is underway and will be complete before the institution decision is due. Expert discovery is set to close on June 6, 2025, and the parties have recently confirmed to the District Court that expert depositions “will be completed during the [scheduled] expert discovery period and in advance of the current June 6, 2025 expert discovery deadline.” EX2053, 2; *Cisco*, Pap.11, 9-10 (finding that the “investment in the [parallel litigations] strongly favor[s] exercising

our discretion to deny institution” where the “cutoff dates for completion of fact and expert discovery... have passed” and “validity and infringement expert discovery has closed, and expert depositions have already been conducted as of the time of the Preliminary Response.”); *Toyota*, Pap.13, 13-14; *Ancora*, Pap.11, 17.

Dispositive motions and motions to exclude will be filed, fully briefed, and heard by the Court before institution. Dispositive motions and motions to exclude expert testimony are due June 20, 2025, with oppositions due July 3, 2025, and replies due July 18, 2025. And these motions are all scheduled to be argued at an August 8, 2025 hearing—a week before the institution deadline. EX1022, 6. *Pharaoh Energy Servs. v. Flex-Chem Holding Co.*, IPR2024-00822, Pap.6, 11 (Sept. 20, 2024) (finding that “the advanced state of the Parallel Litigation [] weigh[ed] strongly in favor of discretionary denial” where fact and expert discovery were complete, claim construction was briefed but not yet ruled on, and dispositive and *Daubert* motions were to be filed less than three weeks after the institution decision).

Numerous pre-trial exchanges will be complete before institution. Witness lists, deposition designations, exhibit lists, a draft of the joint pre-trial order, proposed jury instructions, verdict forms, and *voir dire* questions will be exchanged on August 13, 2025, ***before*** the due date for institution. EX1022, 6. The only remaining pre-trial exchanges will be completed shortly afterwards, with all motions *in limine* fully briefed and the trial brief submitted by September 19, 2025, with trial

itself to follow only a few weeks later. EX1022, 7-8. This, too, weighs in favor of discretionary denial. *Pharaoh*, Pap.6, 11.

There is no way to describe these efforts and investment by the Court and the parties over the past two years—and ongoing today—as anything short of heavy and substantial, and this points directly and clearly in favor of discretionary denial. *Motorola*, Pap.19, 3; *Duplo U.S.A. Corp. v. MGI Digital Tech. S.A.*, IPR2023-00936, Pap.8, 18 (Dec. 5, 2023) (“We agree with Patent Owner that there has been substantial investment by the parties and the district court in the parallel proceeding, including the completion of preliminary disclosures and claim construction, and the near-completion of discovery. Under the circumstances, we find that the third *Fintiv* factor ***weighs heavily in favor of discretionary denial*** of institution.”); *Ancora*, Pap.11, 17. Indeed, as of the institution deadline, the parallel litigation here will be at a stage nearly identical to the parallel proceedings in *Motorola*, where the Acting Director overruled the original Board panel to deny institution just a month ago. There—as will be the case here—claim construction was complete, fact and expert discovery were closed, dispositive motions were fully briefed, and pretrial exchanges were underway before the institution decision issued. *Motorola*, Pap.8, 12-14. The Acting Director vacated the Board’s decision and denied institution, finding that “[t]he Board did not give enough weight to the investment in the parallel proceeding,” and, “[g]iven the substantial time and effort the parties and the district

court had invested in the parallel proceeding, factor 3 strongly favors discretionary denial.” *Motorola*, Pap.19, 2-3. Here, as in *Motorola*, the parties and court have invested substantial time and effort in the district court proceedings. EX1022, 5-6.⁹

⁹ Any later attempt by Petitioner to argue it filed the Petition expeditiously would not tip this factor against denial. *See The Hillman Grp., Inc. v. Hy-Ko Prods. Co.*, IPR2022-00168, Pap.8, 10-11 (May 9, 2022) (“***Despite the lack of delay***, we view the advanced state of the [parallel] [l]itigation as tipping this factor overall slightly in favor of denial.”). Moreover, such an argument ignores the facts. As detailed above, Petitioner here was long aware of PO’s portfolio of related patents, including the ’596 patent, and (unlike PO) Petitioner was certainly aware of the details its own contemplated RaDaR 1.1 assay. *See, e.g.*, EX2026, 28 n.5 (Petitioner stating in April 2024 that it was conducting “ongoing... discovery” into Natera’s ““substantial intellectual property portfolio with over 150 issued patents and over 220 pending patent applications as of December 31, 2022.””). But while Petitioner filed other IPRs to challenge both the ’454 and ’035 patents in December 2023 (IPR2024-00346) (denied under §325(d) on June 21, 2024, Pap.15, 5-18) and April 2024 (IPR2024-00812) (terminated pursuant to the parties’ partial settlement agreement, Pap.11), respectively, Petitioner ***made the choice to wait on the ’596 patent***: “faced with the prospect of a looming trial date,” Petitioner “wait[ed] until the district court

It is unsurprising that Petitioner’s discussion of this factor cites no Board precedent finding that it weighed against denial of institution, let alone any case finding it weighed against denial where the parallel litigation had progressed as far as the proceedings here. Pet.61-62.¹⁰

The substantial investment made here by both the Court and the parties in parallel litigation strongly favors discretionary denial.

trial has progressed significantly before filing” its IPR. *Ancora*, Pap.11, 17; EX2012.

¹⁰ Rather than Board decisions under *Fintiv*, Petitioner’s discussion of factor 3 instead cites an Eastern District of Texas case granting a motion to stay following claim construction and the near-completion of discovery. Pet.62 (citing *CyWee Grp. Ltd. v. Samsung Elecs. Co.*, No. 2:17-CV-00140-WCB-RSP, 2019 WL 11023976, at *6 (E.D. Tex. Feb. 14, 2019) (Bryson, J.)). But as detailed above, no party has requested a stay here, nor has the District Court suggested one. *See supra* §III.A. How a court in the Eastern District of Texas—having no connection to the parallel litigation here—might react to a request for a stay has no bearing on whether the Board should exercise its discretion here, where it is undisputed that the parallel litigation is at an advanced stage.

D. There Is Significant Overlap Between Issues Raised in the Petition and in the Parallel Litigation (Factor 4)

1. There Is Significant Overlap Between the Asserted Prior Art References Raised In Each Proceeding

There is significant overlap between the art Petitioner relies on for its unpatentability arguments in the Petition and the art Petitioner has asserted for invalidity purposes in the parallel litigation.

Here, the Petition Grounds assert obviousness based on: (1) Diaz in view of Kinde 2013; (2) Diaz in view of Kinde 2013 and Rabinowitz; (3) Diaz in view of Kinde 2013 and Fleischhacker; and (4) Rabinowitz in view of Bettegowda. In the parallel litigation, Petitioner's invalidity contentions rely on four of these five identical references. As to the Diaz and Kinde 2013 references, Petitioner's invalidity contentions in parallel litigation assert (1) Diaz and Forshew, optionally in view of Kinde 2013 or Young, and optionally further in view of Bashashati; (2) Forshew, optionally in view of Gerstung or Kukita, and optionally further in view of Bashashati; and (3) Bashashati and Patel. EX2002, 38. As to the Rabinowitz and Bettegowda references, all of Petitioner's District Court invalidity contentions (1)-(3) also explicitly cite and rely on Rabinowitz (EX2002, 17-18; EX2003, 41; EX2004, 36; EX2005, 3), and contention (1) also explicitly cites and relies on Bettegowda. EX2002, 28, 31, 33; EX2003, 5. Indeed, the only reference asserted in a Petition Ground that is *not* discussed in Petitioner's District Court invalidity

contentions is Fleischhacker, on which Petitioner relies solely in connection with a limitation of non-asserted dependent claim 15.¹¹ Pet.10.

To argue against discretionary denial, Petitioner stipulates here that, “should the Board institute this proceeding... Petitioner will not pursue *these same grounds* in the North Carolina action.” Pet.62 (citing *Sand Revolution*). But this is wholly insufficient.

First, Petitioner’s inclusion of *additional* references in its parallel litigation arguments as compared to its combinations in the IPR proceedings does not mitigate the significant overlap with respect to its four duplicative references invoked in IPR Petition Grounds here. *Fintiv*, Pap.15, 14, 15 (finding “Petitioner’s assertion of additional invalidity contentions in the District Court” that are not included in the IPR Grounds doesn’t negate this significant “overlap”); *Pharaoh*, Pap.6, 12-13 (finding factor 4 “strongly favors discretionary denial” where, in addition to two overlapping references, petitioner relied on an additional reference in district court not asserted in the IPR: “[t]hat Petitioner also relies on [another reference] in addition to [the references asserted in both proceedings] to assert invalidity in the Parallel Litigation does not change the analysis here” because the assertion of

¹¹ Even with Petitioner’s strategic challenge of claim 15 with Fleischhacker, there remains substantial material overlap.

additional invalidity contentions in district court beyond the overlapping IPR grounds “is not relevant to the question of the degree of overlap for this factor” (citing *Fintiv*, Pap.15, 14-15)).

Second, Petitioner has structured the grounds in both proceedings such that its *Sand Revolution* stipulation (Pet.62) is essentially meaningless: it would not mitigate the duplicative work that will result if this proceeding is instituted. Despite the stipulation, Petitioner will still be relying in litigation on four of the five references asserted here, favoring denial of institution. *Samsung Elecs. Co. v. Secure Wi-Fi LLC*, IPR2024-01366, Pap.10, 14-17 (Mar. 24, 2025) (“*Secure Wi-Fi*”) (finding that petitioner’s *Sand Revolution* stipulation would permit petitioner to “create a ground that is not one of the ‘same grounds asserted in this Petition,’ but still would result in the exact same central issue needing to be decided based on the exact same evidence... and arguments presented in the Petition”); *Apple Inc. v. Maxell, Ltd.*, IPR2020-00408, Pap.13, 10-15 (Aug. 11, 2020) (finding differing grounds asserted in district court and in petition “substantially similar” and therefore “favor[ing] the exercise of discretionary denial”); *Ancora*, Pap.11, 19, 21-22 (finding that petitioner’s stipulation that, “should an IPR be instituted, the art used in the grounds in this Petition will not be raised during trial in the related litigation” was “narrow” such that “there will likely be overlap between the issues raised in the Petition and the parallel litigation” because “overlapping claims are challenged based on the

same prior art in both the Petition and in the parallel litigation”); *Samsung Elecs. Co. v. Clear Imaging Rsch., LLC*, IPR2020-01402, Pap.12, 24-25 (Mar. 4, 2021) (“*Clear Imaging*”) (finding “factor 4 weighs slightly in favor of exercising our discretion to deny institution” “notwithstanding the [*Sand Revolution*] stipulation,” because “overlapping claims are challenged based on the same prior art” and noting that the district court “would be analyzing and interpreting the same pieces of prior art, duplicating effort and potentially reaching inconsistent results”).

That both the Board and the District Court “would be analyzing and interpreting the same pieces of prior art, duplicating effort and potentially reaching inconsistent results” confirms that institution should be denied. *Clear Imaging*, Pap.12, 24; *Secure Wi-Fi*, Pap.10, 16.

2. There is Significant Overlap Between the Asserted *Arguments* In Each Proceeding

The extensive overlap between the Petition’s Grounds and Petitioner’s litigation contentions is not limited to the identity of the four duplicated *references*. Instead, as is apparent from an examination of the grounds themselves, Petitioner’s *arguments* concerning the four overlapping references are also substantially similar in both proceedings, indicating the appropriateness of discretionary denial. *Clear Imaging*, Pap.12, 20-21, 24-25 (finding factor 4 supports denial notwithstanding Petitioner’s argument that an overlapping reference “is used quite differently in the petition than in the litigation” (because it is used as a secondary reference to a

particular primary reference “for features of two claims... no longer asserted [in the litigation,]” whereas “in the litigation, [the overlapping reference] would be used as a secondary reference to support [two different references] not relied upon in the petition”); “[t]ellingly, Petitioner does not assert that the same prior art disclosures would not be relied upon in both proceedings,” which “may result in duplication of work and create the potential for inconsistent decisions”).

As just one example, Petitioner attempts to fill a key gap concerning the claimed sensitivity of detection in the context of a multiplex assay, an inventive gap that formed a basis for the Examiner’s allowance of the claims of the ’596 patent (EX1003, 62-63, 334), and in doing so Petitioner argues in **both** the Petition (at 22) and in its District Court contentions (EX2002; EX2003) that:

- the Diaz reference would purportedly have motivated a skilled artisan to detect a mutation present in less than or equal to 0.015% of the cell-free DNA. *See* Pet.22 (quoting Diaz (EX1006), 2); EX2003, 3 (also quoting Diaz (EX1006), 2);
- Diaz purportedly would have so motivated a skilled artisan because Diaz states that “the fraction of circulating DNA contributed from the tumor varies greatly, between 0.01% and more than 90%.” *See* Pet.22 (quoting Diaz (EX1006), 2); EX2003, 3 (also quoting Diaz (EX1006), 2);

- that Kinde 2013’s *non-multiplexed* Safe-SeqS assay is purportedly “capable of detecting 1 mutant template among 5000 to 1,000,000 wild-type templates” and purportedly “compatible with multiplex PCR.” Pet.24-25 (citing Kinde 2013 (EX1007), 4); EX2003, 4-5 (citing Kinde 2013 (EX1007), 4); *see also* Pet.23 (“Kinde 2013 demonstrates detection of an SNV present at less than 0.015% [in a non-multiplexed assay]”); EX2003, 36 (“Kinde [2013] also discloses a [non-multiplexed] method for detecting an SNV that is present in less than or equal to 0.015% of the cell-free DNA comprising the SNV locus”); and
- that a skilled artisan would purportedly have been motivated to combine Diaz and Kinde 2013 to achieve the claimed sensitivity because both relate to detection of cancer-associated variants, including SNVs, and because Diaz cites a previous Kinde paper (Kinde 2011 (EX1049)) discussing an earlier version of Safe-SeqS. Pet.16-17; EX2003, 4.

As these examples concerning the same critical gap in the prior art make clear, institution here would “result in the exact same central issue needing to be decided based on the exact same evidence... and arguments” in both proceedings. *Secure Wi-Fi*, Pap.10, 16 (finding factor 4 favored denial where ground in parallel litigation

that differed but involved two overlapping references “would result in the exact same central issue needing to be decided based on the *exact same* evidence... and *arguments* presented in the Petition”); *compare, e.g.*, Pet.16-17 (“[b]oth references relate to detection of tumor-specific SNVs” and “Diaz points to Safe-SeqS (citing Kinde 2011) as a solution ‘aimed at increasing overall sensitivity’ for detecting mutations in ctDNA in the context of next-generation sequencing.”), *with* EX2003, 4 (“both Diaz and Kinde [2013] relate to the field of cancer detection... to detect rare cancer-associated variants, including SNVs” and “Diaz cites the original Safe-SeqS method [in Kinde 2011], a precursor of the Safe-SeqS method disclosed in Kinde, as an example of one such approach for improved sensitivity”).

The same recycling of arguments occurs with respect to Petitioner’s Rabinowitz (Grounds 2 and 4) and Bettgowda (Ground 4) references. For example, Petitioner argues in parallel litigation that, based on Rabinowitz, “as Natera has admitted, multiplex amplification of 50 to 100 target loci in a single reaction for detection of mutations in the amplified DNA using high-throughput sequencing was known in the prior art.” EX2003, 41. Likewise, Petitioner asserts here that “[i]n Rabinowitz, the inventors of the ’596 patent admit that ‘the prior art includes disclosures of successful multiplexed PCR reactions involving pools of up to about 50 or 100 primers. . . .’” Pet.28. And as to Bettgowda, Petitioner claims in both proceedings that Bettgowda was “able to detect one mutant template in the DNA

purified from up to 5 ml of plasma” and that—“[a]lthough Bettegowda uses alternative units to describe the mutant allele fraction”—“a POSA would have understood that” this was a disclosure of detecting an SNV “present in less than or equal to 0.015% of the” cfDNA having the SNV locus. Pet.50; EX2003, 5.

The significant overlap in Petitioner’s arguments concerning the prior-art disclosures duplicated in each proceeding thus also confirms that institution should be denied. *Clear Imaging*, Pap.12, 24-25; *Apple*, Pap.13, 10-13 (finding that factor 4 favored denial even where the underlying litigation obviousness ground used a reference not asserted in the petition, explaining that “Petitioner does not argue, nor do we see based on the present record, that the proposed combination of [2 references] in the underlying litigation differs materially from the obviousness ground based on [one of the district court references] and the knowledge of a person of ordinary skill in the art asserted in the Petition.”).

3. There Is Significant Overlap Between the Claims at Issue In Each Proceeding

Petitioner notes that its Petition has challenged more claims (claims 1, 2, 4, 5 and 10-18) than are currently being asserted now in the parallel District Court litigation (claims 1, 11, 12 and 18). Pet. 62. But *every claim being litigated in the District Court is also being challenged in this Petition*. Further, as the Board has explained (but Petitioner ignores), “the mere existence of non-overlapping claims does not support Petitioner’s assertion that ‘[t]here will be no overlap between issues

raised in this Petition and the related litigation.”” *Ancora*, Pap.11, 20 (weighing factor four in favor of denial where the petition challenged claims not at issue in the parallel proceeding). Petitioner does not assert, for example, that “the non-overlapping claims differ significantly in some way” or that they are not “all [] directed to the same subject matter.” *Ancora*, Pap.11, 20; *Next Caller, Inc. v. TRUSTID, Inc.*, IPR2019-00961, Pap.10, 14 (Oct. 16, 2019) (denying institution where petitions jointly challenged all 52 claims of the patent-at-issue and the parallel proceeding involved only seven claims). Petitioner also does not address the fact that every claim challenged in both proceedings depends from claim 1—the ’596 patent’s only independent claim—and that this is the clear focus of Petitioner’s arguments here. *Compare* Pet.17-25, 32-36, 42-52 (25 pages addressing claim 1), *with* Pet.25-28, 37-40, 52-54 (11 pages addressing all dependent claims); *Samsung Elecs. Co. v. Mojo Mobility, Inc.*, IPR2023-01098, Pap.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.”).¹²

¹² The District Court deadline for Natera’s final infringement contentions has passed, and Natera is thus unable to assert additional ’596 patent claims (beyond already-asserted claims 1, 11, 12, and 18) in that ongoing litigation. EX1022, 5.

4. A *Sotera* Stipulation Would Not Mitigate the Duplicative Efforts Required Here

Lastly, even if Petitioner were to offer a *Sotera* stipulation now in the hopes of bargaining against discretionary denial, such a stipulation would not “outweigh the substantial investment in the district court proceeding or *Fintiv* factors 1, 2, and 5,” each of which favors denial as discussed herein. *Motorola*, Pap.19, 4; *Cisco*, Pap.11, 12 (denying institution where petitioner offered *Sotera* stipulation, explaining, “[w]e are not persuaded, however, that the stipulation[] proffered here [is] sufficient when weighed against the other factors”); *SAP Am., Inc. v. Cyandia, Inc.*, IPR2024-01495, Pap.13, 8-9 (Apr. 7, 2025) (finding that factor 4 weighed in favor of denial notwithstanding Petitioner’s *Sotera* stipulation in part because Petitioner asserted system art in parallel litigation, and further explaining that “it appears that all claims being contested as invalid in the Litigation are also subject to a challenge in the Petition. The narrowing of asserted claims in the Litigation, if it occurs, will streamline the parties’ overall dispute on invalidity if we decide to discretionarily deny institution. So, a majority of the parties’ work that would be done here will also be required in the Litigation regardless of whether we institute review. Accordingly, we do not consider the presence of the *Sotera* stipulation in our case to ensure that *inter partes* review would be a ‘true alternative’ to the Litigation.”); *see also Apple Inc. v. Haptic, Inc.*, IPR2024-01475, Pap.11, 17-18 (Apr. 4, 2025) (denying institution even where factor 4 weighed strongly in favor of

not denying including because “the District Court trial is scheduled to begin six months before we would reach a final decision..., the District Court has expended effort resolving substantive issues in the case, [] the defendant in District Court and the Petitioner here are the same party” and “the merits are not particularly strong.”); *HP Inc. v. Universal Connectivity Techs., Inc.*, IPR2024-01428, Pap.12, 7-8, 16 (Apr. 8, 2025) (denying institution even where factor 4 weighed strongly in favor of not denying, explaining that “[b]ecause of the *Sotera* stipulation, factor 4 weighs strongly in favor of not exercising discretion. However, two other factors weigh in favor of exercising discretion, especially the trial date factor. The merits of Petitioner’s challenge are not particularly strong. A balanced assessment of the factors leads us to exercise discretion to deny the Petition.”). §§III.B, III.F.

E. Petitioner Is the Defendant in the Parallel Litigation (Factor 5)

As noted above, Petitioner and Patent Owner are parties to the parallel litigation, where Petitioner is the defendant. Accordingly, this factor weighs in favor of denying institution. *Fintiv*, Pap.11, 13-14. (Indeed, the Petition does not dispute this, but rather attempts to minimize the import of factor 5 by suggesting this “is the norm....” Pet.63.)

F. Other Circumstances that Impact the Board’s Exercise of Discretion, Including the Merits (Factor 6)

As PO’s forthcoming Preliminary Response will confirm,¹³ the Petition fails even to meet Petitioner’s threshold burden for institution, a burden that never shifts to PO (*see* §314(a)), let alone demonstrate “compelling merits”—a determination that, in any event, could not overcome the other factors in the Board’s discretionary denial analysis. “Guidance on USPTO’s rescission of ‘Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation,’” 3 (Mar. 24, 2025) (“compelling merits alone is not dispositive in making the [*Fintiv*] assessment”); *Fintiv*, Pap.11, 14-15. Indeed, as the Petition *admits*, a critical limitation the Examiner concluded was missing from the prior art of record during prosecution (Pet.63) is *still missing here*: the Petition acknowledges that *none of its asserted prior art references ever discloses a multiplex assay with the 0.015% sensitivity as claimed*; instead, Petitioner merely argues its art “teach[es]

¹³ While PO here highlights one of the Petition’s most blatant substantive failures, PO does not understand the Interim Processes Memo’s recent bifurcation of discretionary denial briefing to require that PO provide all of its merits arguments in this paper, rather than in the full Preliminary Response that exists for this purpose, in order to ensure their consideration—particularly for a determination in which the burden to support institution always remains with Petitioner.

the 0.015% limitation [in a non-multiplexed assay that is] *compatible with...* multiplex amplification. . . .” Pet.63.¹⁴ The Petition also touts the fact that it is accompanied by expert testimony, but this gap between the art and the claims is significant, and many cases with expert testimony do not meet the burden for institution, let alone the burden for showing “compelling merits.” *See* Pet.63.

Finally, while the Petition asserts “the public interest favors institution” because continued existence of the ’596 patent puts the eventual public availability

¹⁴ This failure merits discretionary denial under any measure. The Petition itself recognizes that none of its references disclose a multiplexed assay with 0.015% sensitivity as the claims require—instead, the Petition merely asserts “compatibility” of a *non-multiplexed assay* with multiplexing. The Petition thus concedes that none of its asserted references ever discloses a multiplex assay with the requisite 0.015% sensitivity. Petitioner’s asserted art here thus suffers precisely the same failings—and is substantially the same in this critical respect—as the art previously argued, considered, and properly rejected by the Office during original prosecution. EX1003, 62-63, 334. Petitioner has not asserted any error by the Office in allowing the claims over substantially the same art in the prior prosecution, much less any material error. Accordingly, the Board could also exercise its discretion to deny institution under §325(d) based on this same shortcoming.

of Petitioner's RaDaR 1.1 assay at risk (Pet.64), this is no different from the argument of *every* infringer. Petitioner never even attempts to show that the public lacks access to other comparable assays (including PO's own Signatera™ assay) or that PO lacks the capacity to serve Petitioner's patients, and Petitioner tellingly omits that it has already litigated and lost this point before both the District Court and the Federal Circuit. When the Court issued a preliminary injunction based on the '035 patent against further infringement by Petitioner's RaDaR 1.0 assay, it concluded (after briefing and argument by Petitioner) that "[a]nyone in need of a tumor informed MRD test will be able to get one from [PO] Natera." EX2020, 20; EX2032, 21-22 ("The district court deftly parsed through excessive arguments and the evidence....").

IV. Conclusion

The *Fintiv* factors overwhelmingly favor denial here, both individually and considered (as they must be) as a whole: both parties have stated they will not request a stay, both parties confirmed their mutual reliance on the existing trial schedule in a joint agreed submission to the Court, Petitioner has stated that it would be prejudiced by any delay in reaching trial, and the Court has confirmed its intention to keep the October 2025 trial date—all confirming there is no likelihood of a stay (factor 1); there is a 10-month gap after the trial date before the due date for any Final Written Decision (factor 2); by the time of any institution decision here, the

Court and the parties will have expended tremendous time and resources in the parallel litigation, with only certain final pretrial exchanges and the trial itself remaining to be completed (factor 3); four of the five prior art references asserted by Petitioner here are also relied on by Petitioner to make substantially overlapping invalidity arguments in the parallel litigation, and Petitioner's litigation contentions are structured in such a way that its proffered stipulation will not actually avoid the extremely wasteful, duplicative efforts that will result if this proceeding is instituted (factor 4); the parties are the same in both proceedings (factor 5); and there are no other circumstances that counsel against discretionary denial (factor 6). And the merits cannot be strong because none of the Petition's asserted prior art references ever discloses a multiplex assay with the requisite sensitivity. As in *Motorola*, "the efficiency and integrity of the system are best served by denying review" under *Fintiv*. Pap.19, 4.

For the foregoing reasons, the Board should exercise its discretion to deny the Petition.

Respectfully submitted,

Dated: April 14, 2025

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CERTIFICATE OF WORD COUNT

The undersigned certifies that the foregoing Patent Owner’s Brief In Support Of Discretionary Denial Under 35 U.S.C. §314(a) complies with the type-volume limitation in 37 C.F.R. §42.24(c)(1) and the “Interim Processes for PTAB Workload Management” (Mar. 26, 2025). According to the word-processing system’s word count, the brief contains 9,004 words, excluding the parts of the brief exempted by 37 C.F.R. §42.24(a)(1).

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of Patent Owner's Brief In Support Of Discretionary Denial Under 35 U.S.C. §314(a) and the accompanying exhibits have been served in their entirety on April 14, 2025, by causing the aforementioned documents to be electronically mailed to the following attorneys of record for the Petitioner listed below.

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