

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ILLUMINA, INC.,
Petitioner,

v.

RAVGEN, INC.,
Patent Owner.

IPR2021-01272
Patent 7,332,277 B2

Before ZHENYU YANG, TIMOTHY G. MAJORS, and DAVID COTTA,
Administrative Patent Judges.

MAJORS, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Illumina, Inc. (“Petitioner” or “Illumina”),¹ on July 20, 2021, filed a Petition to institute *inter partes* review of claims 55–63, 66–69, 80–91, 94–96, 126–130, 132, and 133 of U.S. Patent No. 7,332,277 B2 (Ex. 1001, “the ’277 patent”). Paper 1 (“Pet.” or “Petition”). Ravgen, Inc. (“Patent Owner”)² filed a Preliminary Response. Paper 7 (“Prelim. Resp.”). With our authorization given via e-mail, Petitioner and Patent Owner filed a respective Preliminary Reply and Preliminary Sur-Reply addressing certain matters raised in the Preliminary Response; Paper 8 (“Prelim. Reply”); Paper 9 (“Prelim. Sur-Reply”).

Under 35 U.S.C. § 314(a), *inter partes* review may not be instituted unless the Petition “shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” It is reasonably likely that Petitioner will prevail in showing that one or more of the challenged claims are unpatentable. We decline to deny the Petition on a discretionary basis as requested by Patent Owner. Thus, for reasons explained below, we institute *inter partes* review of claims 55–63, 66–69, 80–91, 94–96, 126–130, 132, and 133 of the ’277 patent.

A. Related Patents & Proceedings

The ’277 patent issued February 19, 2008, from U.S. Patent Application No. 10/661,165 (“the ’165 Application”), filed September 11,

¹ Petitioner identifies itself, Illumina Cambridge, Ltd., and Verinata Health, Inc., as the real parties-in-interest. Pet. 3.

² Patent Owner identifies itself as the real party-in-interest. Paper 4, 1.

2003. Ex. 1001, codes (21), (22), (45). The '165 Application claims priority to several other applications including, as the earliest application listed in '277 patent's priority chain, U.S. Provisional Patent Application No. 60/360,232, filed on March 1, 2002. *Id.* at code (60).

Related U.S. Patent No. 7,727,720 ("the '720 patent"), which also lists the '165 Application in its priority chain, issued on June 1, 2010. *See* IPR2021-00791, Paper 20 at 2–3 (citing, as Exhibit 1001, the '720 patent).

Petitioner identifies multiple lawsuits involving the '277 patent. Pet. 3. Those lawsuits include: *Ravgen, Inc. v. Illumina, Inc.*, No. 20-1644 (D. Del.) ("the Illumina lawsuit"); *Ravgen, Inc. v. Natera, Inc. and NSTX, Inc.*, No. 1:20-cv-00692-ADA (W.D. Tex.) ("the Natera lawsuit"); *Ravgen, Inc. v. Laboratory Corp. of America Holdings*, No. 6:2020-cv-00969-ADA (W.D. Tex.) ("the Labcorp lawsuit"); and *Ravgen, Inc. v. Quest Diagnostics*, No. 6:20-cv-00972-ADA (W.D. Tex.) ("the Quest lawsuit").³ *Id.* (identifying additional lawsuits against PerkinElmer Inc., Myriad Genetics, Inc., Progenity, Inc., and Ariosa Diagnostics, Inc., in the Western District of Texas or the District of Delaware).

Petitioner and Patent Owner also identify other matters involving the '277 patent pending before the Patent Office. Pet. 3–4; Paper 4, 1–2; Paper 6, 1. Claims of the '277 patent have also been challenged in IPR2021-00788, -00789 and -00790 (all filed by Quest), IPR2021-00902 and -01054

³ The Quest lawsuit has since been transferred to another district. Paper 10, 1 (identifying *Ravgen v. Quest Diagnostics*, No. 2:21-cv-09011-RGK-GJS (C.D. Cal.)); Prelim. Reply 4. Herein we use "the Quest lawsuit" to refer to the proceedings before both courts.

(both filed by Labcorp), and IPR2021-01577 (filed by Streck, Inc.). Pet. 3–4; Paper 4, 1; Paper 6, 1. On October 19, 2021, we instituted trial in IPR2021-00788, Paper 23 (covering claims 55–63, 66–69, 80–94, 96, and 126–133), and denied institution in IPR2021-00789 and IPR2021-00790. On November 5, 2021, we instituted trial in IPR2021-00902 and -01054 (covering, collectively, claims 55–63, 66–69, 80–96, and 127–133). In addition, Patent Owner identifies Ex Parte Reexamination Control No. 90/014,792 as related to the ’277 patent. Paper 4, 2.

The related ’720 patent is also challenged in IPR2021-00791 (filed by Quest), -01026 (filed by Labcorp), and -01271 (filed by Illumina). Natera’s challenge to the ’720 patent in Ex Parte Reexamination Control No. 90/014,703 is, as of December 15, 2021, stayed. IPR2021-00791, Paper 25.

B. Asserted Grounds of Unpatentability

Petitioner asserts four grounds of unpatentability in this Petition (Pet. 5–6), which are provided in the table below:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
55–59, 61–63, 66–69, 80–89, 94, 96, 126–130	102(a), (e) ⁴	Landes ⁵

⁴ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. §§ 102 and 103. Based on the filing date of the ’277 patent, we apply the pre-AIA versions of §§ 102 and 103.

⁵ Landes et al., WO 03/062441 A1, published July 31, 2003 (Ex. 1003, “Landes”).

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
95	103(a)	Landes, Marx ⁶
55–63, 66–69, 80–91, 94, 96, 126–130, 132, 133	103(a)	Lo, ⁷ Valli ⁸
95	103(a)	Lo, Valli, Marx

Petitioner relies on the declaration of Dr. Brynn Levy, among other evidence. Ex. 1056. Patent Owner responds with testimony from Dr. Glenn D. Prestwich, along with other evidence. Ex. 2001.

C. Technology Overview and the '277 Patent

The '277 patent relates to non-invasive methods for sampling DNA and detection of genetic disorders in a fetus. Ex. 1001, 1:31–39. The '277 patent explains that a variety of invasive and non-invasive techniques are available for prenatal diagnosis, including amniocentesis, and analysis of fetal blood cells in maternal blood. *Id.* at 2:53–57. According to the patent, however, “techniques that are non-invasive are less specific, and the techniques with high specificity and high sensitivity are highly invasive.” *Id.* at 2:57–60; *see also id.* at 3:33–37 (citing increased fetal mortality risk with amniocentesis).

⁶ G. Marx et al., *Reducing white cells in platelet units*, 31:8 TRANSFUSION 743–747 (1991) (Ex. 1029, “Marx”).

⁷ Lo et al., WO 98/39474, published Sept. 11, 1998 (Ex. 1033, “Lo”).

⁸ V.E. Valli et al., *An Anticoagulant for Transport of Bovine Blood*, 21 CAN. VET. J. 252–257 (1980) (Ex. 1034, “Valli”).

We provide a brief overview of the components of blood, which is helpful in understanding the claims of '277 patent, as well as the cited prior art. Blood is composed of plasma and other blood components suspended in plasma. Ex. 2001 ¶ 38. The major blood components in plasma include red blood cells ("RBCs"), white blood cells ("WBCs") and platelets. *Id.* Most DNA is typically found inside cells (within the cell membrane and nucleus) but some DNA may also be found outside the cells circulating freely in the plasma. *Id.* ¶¶ 37–38. Such circulating DNA is known as "cell-free DNA" ("cfDNA"). *Id.* WBCs, unlike RBCs, include an individual's cellular DNA, and when WBCs are subjected to various stresses (e.g., biological, physical, or chemical), the WBCs may lyse and release additional cfDNA into the plasma. *Id.* ¶¶ 40–41; Ex. 1056 ¶ 23; Ex. 1035.

By the late 1990s, and prior to the '277 patent, researchers had known that pregnant women have cell-free *fetal* DNA ("cffDNA") along with maternal cfDNA circulating in maternal plasma. Ex. 2001 ¶ 39; Ex. 1056 ¶ 21. For example, in studies by Dr. Dennis Lo, researchers determined that cffDNA was present in maternal plasma in a range of about 3.4%–6.2% (as a percent of total circulating DNA), with the percentages corresponding to early and late pregnancy, respectively. Ex. 2001 ¶ 54 (citing Ex. 1033, 26–28). Although intact fetal *cells* may also be found in maternal plasma, most fetal DNA in maternal plasma exists in its cell-free form. Ex. 1036, 1612; Ex. 1056 ¶ 24 (noting that blood processing affects the total cell-free DNA (mostly maternal DNA) but not cell-free fetal DNA); Ex. 2001 ¶ 42.

In order to analyze cell-free DNA from blood, a blood sample is ordinarily collected (e.g., from a subject's vein) and then further processed.

Ex. 2001 ¶ 41. A common mode of processing for such blood samples involves the use of centrifugation to separate the cellular components and plasma within the sample. Ex. 2001 ¶¶ 53–54 (discussing the plasma separation protocols in Landes and Lo); Ex. 1056 ¶ 25.

Dr. Levy explains that, when processing maternal blood samples, it was routine to use one or more preservative agents in appropriate blood collection tubes. Ex. 1056 ¶¶ 25–26 (citing, e.g., Exs. 1003 and 1033). According to Dr. Levy, an exemplary blood collection tube used for this purpose was Becton, Dickinson’s Acid Citrate Dextrose (“ACD”), also known as an Acid Citrate Dextrose Solution A (“ACDA”), blood collection tube. *Id.* ¶ 26 (citing references). ACD tubes contain dextrose—the naturally-occurring enantiomer of glucose. *Id.* (“Dextrose is the naturally-occurring dextrorotatory form of glucose, and is often referred to as glucose.”).

The ’277 patent acknowledges the prior non-invasive use of fetal cells and cell-free fetal DNA, both isolated from maternal blood, for prenatal diagnosis. Ex. 1001, 5:7–59. With regard to fetal cells, the patent notes that the “presence of fetal nucleated cells in maternal blood makes it possible to use these cells for noninvasive prenatal diagnosis,” and that such “cells can be sorted and analyzed by a variety of techniques to look for particular DNA sequences.” *Id.* at 5:8–13. Yet the patent states that “it is still difficult” to get many fetal cells from maternal blood and “[t]here may not be enough to reliably determine anomalies of the fetal karyotype or assay for other abnormalities.” *Id.* at 5:30–34. The ’277 patent states that fetal DNA “has been detected and quantitated in maternal plasma and serum” and that “fetal

DNA present in the maternal serum and plasma is comparable to the concentration of DNA obtained from fetal cell isolation protocols.” *Id.* at 5:39–49. “However,” according to the patent, “the diagnostic and clinical applications of circulating fetal DNA is limited to genes that are present in the fetus but not in the mother” and “a need still exists for a non-invasive method that can determine the sequence of fetal DNA and provide definitive diagnosis of chromosomal abnormalities in a fetus.” *Id.* at 5:53–59.

The ’277 patent describes a method that is said to increase the proportion or percentage of the cffDNA component in a sample from a pregnant female for subsequent analysis. According to the ’277 patent, the ability to detect chromosomal abnormalities has been “hindered by the low percentage of free fetal DNA” in maternal samples. *Id.* at 89:1–6. “Increasing the percentage of free fetal DNA would enhance the detection” of genetic abnormalities. *Id.* at 89:6–11.

With the aim of increasing the percentage of cffDNA relative to circulating maternal DNA in a maternal sample, the ’277 patent describes adding an agent that inhibits cell lysis. Ex. 1001, 219:38–44 (Example 15) (“[T]he use of cell lysis inhibitors, cell membrane stabilizers, or cross-linking reagents can be used to increase the percentage of fetal DNA in the maternal blood.”); *id.* at 89:11–13 (“The percent of fetal DNA in plasma obtained from a pregnant female was determined both in the absence and presence of inhibitors of cell lysis”). The ’277 patent explains that, “[w]hile lysis of both maternal and fetal cells is inhibited, the vast majority of cells [in a maternal blood sample] are maternal, and thus by reducing the lysis of maternal cells, there is a relative increase in the percentage of free fetal

DNA.” *Id.* at 32:36–39. The patent identifies numerous agents as cell lysis inhibitors, cell membrane stabilizers, or cross-linking reagents. *See, e.g., id.* at 31:57–32:21 (listing, for example, formaldehyde, formalin, cholesterol, and glucose).

The ’277 patent provides results on the use of formalin (i.e., formaldehyde in aqueous solution) as the lysis-inhibiting agent. Ex. 1001, 89:1–91:50 (Example 4), 219:38–226:26 (Example 15). In Example 4, the patent describes collecting a 5 ml blood sample from a pregnant subject, separating the sample into two tubes (each containing EDTA⁹), and adding formaldehyde (25µl/ml) to one of the tubes. *Id.* at 89:18–25. The samples were centrifuged and 800 µl of each maternal plasma sample was then used for DNA purification and further processing to determine the relative amount of cffDNA in the samples. *Id.* at 89:25–91:13. According to the ’277 patent, “the percentage of fetal DNA present in the sample that was treated with only EDTA was 1.56%” and the “percentage of fetal DNA present in the sample treated with formalin and EDTA was 25%.” *Id.* at 91:14–20. The percent of total cffDNA in eighteen blood samples with and without formalin was then calculated, with the results (mean percentage

⁹ The ’277 patent states that EDTA is a “magnesium chelator.” Ex. 1001, 31:52–54.

cffDNA) provided in Table V. *Id.* at 91:35–43 (reporting, *inter alia*, 19.47% with formalin and 7.71% without formalin), 219:38–226:26 (Example 15).

D. Challenged Claims

Independent claims 55 and 81 are illustrative and read as follows:

55. A method comprising determining the sequence of a locus of interest on free fetal DNA isolated from a sample obtained from a pregnant female, wherein said sample comprises free fetal DNA and an agent that inhibits lysis of cells, if cells are present, wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor.

81. A method for preparing a sample for analysis comprising isolating free fetal nucleic acid from a the sample, wherein said sample comprises an agent that inhibits lysis of cells, if cells are present, and wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor.

Ex. 1001, 472:66–473:5, 474:52–57.

To illustrate some of the challenged dependent claims, claim 56 depends from claim 55 and adds that “said sample is selected from the group consisting of: blood, serum, plasma, urine, and vaginal secretions.” *Id.* at 473:6–8. Claim 60 depends from claim 55 and adds that “said cell lysis inhibitor is selected from the group consisting of: glutaraldehyde, derivatives of glutaraldehyde, formaldehyde, derivatives of formaldehyde, and formalin.” *Id.* at 473:15–18. Claim 82 depends from claim 81 and adds that said sample “is obtained from a source selected from the group consisting of human, non-human, mammal, reptile, cattle, cat, dog,” and further recites many other types of animals. *Id.* at 474:58–62.

E. Prosecution History

During prosecution, the Examiner rejected pending claims as anticipated by Lo, or for obviousness based on Lo combined with other references.¹⁰ Ex. 2064, 1228, 1231. In response, applicant argued that the Examiner had provided no evidence that EDTA in Lo's samples inhibits cell lysis. *Id.* at 1194–1196 (“[T]he Office has provided absolutely no documentary evidence or rationale in support of its assertion that EDTA is an agent that inhibits cell lysis.”), 1199–1200.

Applicant also argued that “the assertion by the Office that EDTA is a cell lysis inhibitor is simply incorrect.” *Id.* at 1196. Applicant stated:

EDTA is not an “agent that inhibits cell lysis.” Rather, EDTA is a well-known chelator of calcium and magnesium. EDTA is routinely added to blood during the blood collection process as an anticoagulant due to its ability to chelate calcium. In fact, EDTA is sometimes included as an ingredient in cell lysis buffers. . . . EDTA is clearly referred to as a chelator in Applicant's specification, not as a cell lysis inhibitor (see, e.g., paragraph [0165] of Applicant's specification), whereas multiple examples of agents that inhibit cell lysis are provided separately (see, e.g., paragraphs [0165] to [0167]).

Id. at 1196. As such, applicant argued that Lo's teaching of EDTA does not satisfy the limitation of “an agent that inhibits cell lysis” as claimed. *Id.*

The Examiner withdrew the rejections based on Lo, but entered new rejections for obviousness based on the combination of “Amicucci” or

¹⁰ Claims 55 and 81 correspond, respectively, to pending claims 58 and 87 in prosecution. Ex. 2064, 530. The citations to Exhibit 2064 are to the page numbers added to the exhibit copy, not the original pagination.

“Umansky,” with “Kiessling.” *Id.* at 927–928, 931, 958–961. The Examiner found that Amicucci and Umansky taught all the claim limitations except “an agent that inhibits cell lysis,”¹¹ which the Examiner found was taught in Kiessling based on its disclosure on formaldehyde as an agent to fix (i.e., inhibit the lysis of) white blood cells. *Id.* at 928, 959.

In response, applicant argued that there was no motivation to combine the newly cited references. *See, e.g., id.* at 574–575. Among other things, applicant argued that the DNA analyzed in the methods of Umansky and Kiessling was “quite distinct” because Umansky analyzed fetal DNA circulating outside a cell, “while the DNA in Kiessling is in and/or released from a fixed cell.” *Id.*; *see also id.* at 593 (advancing similar argument for the Amicucci combination). Applicant also argued that the claimed method addressed a long-felt need and produced unexpected results. *Id.* at 573–574, 591–592. More specifically, applicant argued that its method was an alternative to invasive prenatal testing, and that, by adding formalin as an agent that inhibits lysis, the percentage of free fetal DNA was 25%, compared to 1.56% without formalin. *Id.* at 574 (asserting that, based on prior reports, “the mean percentage of free fetal DNA in a maternal sample was expected to be about 3%”).

The Examiner, on September 26, 2007, entered a Notice of Allowability. *Id.* at 523–525. The Examiner stated that the claims are

¹¹ Patent Owner notes that Amicucci disclosed use of EDTA tubes for collection of maternal blood. Prelim. Resp. 6 n.1.

“deemed to be allowable in light of the applicant’s amendment filed 30 MAY 07 and the persuasive argument(s) therein.” *Id.* at 525.

Patent Owner also references the related ’720 patent’s prosecution history. Prelim. Resp. 7–9. The Examiner initially asserted Kiessling against the pending claims (but in combination with different references than discussed above). *See, e.g.*, Ex. 2041, 1145, 1149–1157. Patent Owner emphasizes that the Examiner subsequently withdrew those rejections and “stated that ‘*[t]he most persuasive argument(s) related to the applicant assertion that there was a long felt need and the evidence of an unexpected result*’ on pages 13 and 14 of the applicant’s response.” Prelim. Resp. 7 (quoting (with Patent Owner’s emphasis) Ex. 2041, 1191–1192).

The Examiner, however, later entered a new round of rejections. Ex. 2041, 2168–2173. Those rejections included combinations based on, *inter alia*, either Amicucci or Holodniy, in further combination with Kiessling, which the Examiner determined taught the addition of formaldehyde as the claimed agent. *Id.* Patent Owner points out that the Examiner, in making these rejections, stated: “these authors [e.g., Amicucci or Holodniy] do not teach that their samples comprise an agent that impedes cell lysis, if cells are present, and wherein said agent is selected from a defined group which includes a cell lysis inhibitor.” Ex. 2041, 2170; Prelim. Resp. 7–8. Patent Owner notes, however, that Amicucci disclosed that blood samples were processed in EDTA-containing tubes and Holodniy disclosed that blood samples were collected in tubes that include ACD. Prelim. Resp. 8 n.2 (citing Ex. 2046, 1, and Ex. 2075, 2).

Applicant further amended the claims, argued that there were no reasons to combine the references, and argued that the claimed methods solved a long-felt need and produced unexpected results. Ex. 2041, 2238, 2249–2250. Ultimately the claims were allowed. *Id.* at 2286–2290.

II. DISCRETION UNDER 35 U.S.C. § 314(a)

A. Standards for Exercising Discretion under Section 314(a)

Under Section 314(a), the Director has discretion to deny institution. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”). Indeed, “the PTO is permitted, but never compelled, to institute an IPR proceeding.” *Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016).

The Director, and the Board under the Director’s delegated authority, may deny institution based on a number of considerations and in a variety of circumstances. For example, it is within the Board’s discretion to deny serial petitions or to deny one or more concurrently-filed (i.e., parallel) petitions that challenge the same patent. Such discretion is explained in *General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sep. 6, 2017) (precedential as to Section II.B.4.i) (“*General Plastic*”) as well as in the Board’s Consolidated Trial Practice Guide (“CTPG”). *General Plastic* at 16–19 (discussing factors the Board considers); CTPG 56–61 (discussing the *General Plastic* factors and considerations that inform discretion based on parallel-petitioning activity).

When deciding whether discretionary denial based on serial-petitioning activity is appropriate, we consider the factors set forth in *General Plastic*, which include:

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition;
4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
5. whether the petitioner provides adequate explanation for the time elapsed between the filing of the multiple petitions directed to the same claims of the same patent;
6. the finite resources of the Board; and
7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

General Plastic at 16–19. The above seven factors are non-exclusive and, thus, not limiting. *Id.*

The Board may also deny institution of a petition based on parallel proceedings before the courts where the validity of the subject patent is already at issue. In *NHK*, the Board denied institution relying, in part, on § 314(a) because the parallel district court proceeding was scheduled to

finish before the Board reached a final decision. *NHK Spring Co. v. Intriplex Techs., Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential). “*NHK* applies to the situation where the district court has set a trial date to occur earlier than the Board’s deadline to issue a final written decision in an instituted proceeding.” *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 3 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv*”). When determining whether to exercise discretion to deny institution under *NHK* due to an earlier trial date, we consider the following *Fintiv* factors:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board’s exercise of discretion, including the merits.

Id. at 6. “These factors relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding.” *Id.* In evaluating these factors, we take “a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.” *Id.*

Patent Owner argues, applying the factors set forth in *General Plastic* or *Fintiv* to the circumstances here, that we should deny the Petition on a discretionary basis under § 314(a). We decline to do so for the reasons explained below.

B. Analysis of the General Plastic Factors

1. Factor 1: Whether the same petitioner previously filed a petition directed to the same claims of the same patent

This Petition is Illumina’s first and only petition challenging the claims of the ’277 patent. Pet. 66. Under such circumstances, standing alone, the Board ordinarily weighs *General Plastic* Factor 1 against discretionary denial. *See Unified Patents, Inc. v. Certified Measurement, LLC*, IPR2018-00548, Paper 7 at 7–8 (PTAB Sept. 5, 2018).

Nevertheless, “our application of the *General Plastic* factors is not limited solely to instances when multiple petitions are filed by the same petitioner.” *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00062, Paper 11 at 2 (PTAB April 2, 2019) (precedential) (“*Valve*”). Where “different petitioners challenge the same patent, we consider any relationship between those petitioners when weighing the *General Plastic* factors.” *Id.* And, in some case, it may be appropriate to deny a follow-on petition on a discretionary basis even if the follow-on petition is filed by a different party. *Id.* at 10. This is explained in the *Valve* decision, where the Board weighed “[t]he complete overlap in the challenged claims and the significant relationship between Valve [(follow-on petitioner)] and HTC [(first petitioner)] [to] favor denying institution.”

Petitioner contends that it “is not a party, real party-in-interest, or privy to the other Patent Office proceedings” challenging the ’277 patent. Pet. 67. Petitioner also notes that its challenge presents different prior art and unpatentability theories than in any earlier filings with the Board challenging the ’277 patent. Prelim. Reply 1–2 (noting reliance on Landes as anticipating prior art).

Patent Owner cites the petitions from Quest (filed in April) and Labcorp (filed in May/June) and the reexamination request from Natera (filed July 2, 2021), all of which predate Illumina’s Petition filed on July 20, 2021. Prelim. Resp. 45. According to Patent Owner, “because a significant relationship exists between Petitioner and the prior challengers, and there is significant overlap between the challenged claims and invalidity theories,” Factor 1 favors denial. *Id.* In support of the alleged “significant relationship,” Patent Owner contends that Illumina, Quest, Labcorp, and Natera have each been charged with infringement in various lawsuits based on “similar noninvasive genetic tests” that “include[] the same key component—blood collection tubes sourced from Streck, Inc.” *Id.* at 46 (citing Exs. 2086, 2087, 2088, and 2089 (complaints in each lawsuit)). Patent Owner argues that Streck “appears to be assisting the defendants” because Streck allegedly helped Natera run experiments in support of a noninfringement defense in the Natera lawsuit. *Id.* Moreover, Patent Owner argues, Natera, Quest, and Labcorp “have entered into supply agreements with Illumina for sequencing technology used in genetic testing, including accused test.” *Id.* (citing Exs. 2091–2093 (press releases)); Prelim. Sur-

Reply 1 (asserting that the “earlier challengers source gene-sequencing technology from Petitioner”).

Petitioner responds that Patent Owner’s argument about the alleged “significant relationship” is unsupported. Prelim. Reply. 1. Petitioner states that it “has not received any assistance from Streck . . . and is not involved in any of the ongoing litigations or proceedings that relate to Natera, Quest, and LabCorp.” And, Petitioner explains, the number and staggered nature of the challenges to the ’277 patent “is a result of [Patent Owner’s] own making—[Patent Owner] sued Petitioner well after it sued the other third parties.” *Id.*

We do not agree with Patent Owner that Factor 1 weighs in favor of discretionary denial here. To the extent there is any relationship between Illumina and the earlier challengers, we find that such relationship is not a “significant” one, such as contemplated by *Valve*. First, although Illumina, Natera, Quest, and Labcorp are each defendants accused of infringing the ’277 patent, unlike *Valve*, they are not co-defendants in the same case. *Valve* at 9–10. Nor were Illumina and the other parties sued at the same time—Patent Owner instead sued those parties in seriatim district court complaints filed over approximately six months starting in mid-2020. Exs. 2086, 2087, 2088, and 2089. Thus, the staggered nature of the alleged follow-on challenges by those parties can be reasonably explained by Patent Owner’s elected timetable for suing the defendants.

Second, the “significant relationship” in *Valve* turned in large part on the fact that co-defendants and serial petitioners in that case, HTC and Valve, were each accused of infringement based on the same device—

HTC's VIVE device. *Valve* at 9–10. Indeed, there was evidence that Valve not only licensed its technology to HTC but that Valve helped HTC design the accused VIVE device. *Id.* at 10. Here, by contrast, Illumina and, for example, Natera were sued based on *their own* alleged infringing prenatal tests. *See, e.g.*, Ex. 2086 ¶¶ 40–41 (identifying Illumina's "Verifi® Plus Prenatal Test"), Ex. 2087 ¶ 5 (identifying Natera's "Panorama" pre-natal test and various other tests for non-prenatal uses, such as in transplant rejection). And there is no persuasive evidence to show that Illumina co-developed Natera's (or the other parties') accused tests, or vice-versa.

Patent Owner contends that Illumina and others use Streck's tubes as a "key component" of the alleged infringing tests because those tubes include an agent that inhibits cell lysis as claimed. Prelim. Resp. 46. But Illumina is not Streck and there is no evidence of a "significant relationship" between them. Illumina also represents, with only Patent Owner's conjecture in opposition, that "Petitioner has not received any assistance from Streck with respect to the '277 patent." Prelim. Reply 1. Even accepting Patent Owner's contention that Streck has helped Natera, we see no basis to impute that alleged relationship to Illumina. Also, that Illumina and Natera (or others) may have executed supply agreements years ago under which Illumina agreed to supply sequencing kits/consumables is not clearly connected to the infringement asserted by Patent Owner or, at most, only at an attenuated level. *See, e.g.*, Ex. 2087 (complaint against Natera mentioning Illumina only once ("Illumina HiSeq 2500 Rapid Run" used to

sequence amplicons), in paragraph 29, in a long string cite about Natera's Prospera test for transplant rejection)¹²; Exs. 2091–2093 (press releases).

On the question of overlap, we agree with Patent Owner that there is substantial overlap among the claims challenged by Illumina and prior petitioners, and moderate overlap on the obviousness grounds. Illumina's Petition is, however, the first petition challenging independent claims 55 and 81 for anticipation. That challenge is based on Landes, which was not asserted, alone or in combination with other references, in the previous IPR proceedings. Prelim. Reply 1–2.

Patent Owner cites to Natera's reexamination request against the '277 patent and draws parallels between theories advanced by Natera there and Illumina's here. Prelim. Resp. 47. That reexamination, which was filed only a few weeks before Illumina's Petition, does not weigh significantly in our analysis for at least the following reason. Patent Owner has moved to stay the reexamination, that motion is unopposed, and there is a strong likelihood it will be granted and the reexamination stayed pending completion of the IPRs challenging the '277 patent. IPR2021-00902, Paper 19; Exhibits 3002 and 3003 in IPR2021-00902.

There are other material differences between this case and the “substantial relationship” and circumstances in *Valve* that ultimately favored denial. For example, in *Valve*, both HTC and Valve had retained the same expert in support of their respective serial petitions, Valve had joined related

¹² Streck, in contrast, features more prominently in Ravgen's infringement allegations against Natera. Ex. 2087 (referencing Streck tubes with the alleged lysis inhibiting agent over thirty-five times).

instituted proceedings filed by HTC, and Valve had clearly used the Board's denial of HTC's earlier petition as a roadmap for Valve's follow-on petition (we address the absence of road-mapping under Factor 3 below). *Valve* at 3, 12–13. None of those considerations are present with Illumina's Petition. The facts here simply do not resemble, indeed they are far from, those in *Valve* that weighed in favor of discretionary denial.

For the reasons above, we find that Factor 1 weighs against denial of Illumina's Petition.

2. Factors 2, 4, and 5

Factors 2, 4, and 5 relate, in general, to a petitioner's knowledge of prior art asserted in a later petition when an earlier petition was filed, the time between a petitioner learning of the later-asserted art and the later-filed petition, and a petitioner's explanation for any delay between filings. *General Plastic* at 16–19. We agree with Petitioner, however, that where a later petitioner is not the same party as, or significantly related to, the earlier petitioner(s), Factors 2, 4, and 5 are less relevant in the overall *General Plastic* analysis. Prelim. Reply 2–3; cf. *Unified Patents, Inc. v. Certified Measurement, LLC*, IPR2018-00548, Paper 7 at 7-8 (PTAB Sept. 5, 2018).

Patent Owner argues that Petitioner could, with diligence, have located Landes and the other relied-upon references in April or May 2021, when Quest and Labcorp filed their petitions. Prelim. Resp. 48–49 (asserting that Illumina had Quest's and Labcorp's IPR petitions “one-and-half” and “two-and-a-half months” before Illumina filed). Patent Owner further contends that Illumina has not adequately explained the delay in filing Illumina's own petition (in late July 2021). *Id.* at 50; Prelim. Sur-

Reply 2–4 (arguing that Illumina knew or should have known of the asserted prior art earlier and noting date stamps on some of Petitioner’s exhibits to suggest Illumina gathered such evidence in March 2021).

As noted above, because we determine that Illumina is sufficiently unrelated to the prior petitioners, these factors carry less weight in the analysis. But even if Patent Owner’s characterizations of what Illumina knew (or should have known) and when it should have known it are accurate, we find that a few-months gap between the first petition and the Illumina Petition is not unreasonable under the circumstances. Prelim. Reply 3 (“While PO’s assertion is pure speculation, even if true, a two-to-three month timeframe to prepare a detailed request for *inter partes* review is entirely reasonable.”).

Patent Owner’s criticisms relevant to these factors hinge mostly on the notion that Illumina should have filed its petition at about the same time as the other petitioners, or not at all. Those criticisms are weak when the petitioners are unrelated parties and were not sued at the same time or in the same lawsuit. Of course, had all the petitions against the ’277 patent been filed at about the same time, we may have consolidated proceedings and recognized efficiencies. Nevertheless, as Patent Owner did not or could not, coordinate the filing of its various lawsuits to approximately the same date, it cannot on this record fairly criticize unrelated petitioners for filing petitions on a schedule staggered by a few months. Patent Owner staggered the filing of its lawsuits over about six months, with Illumina being sued last. This provides a reasonable explanation for the timing of Illumina’s filing relative to the earlier filings.

Factors 2, 4, and 5 do not weigh in favor of discretionary denial for the reasons discussed above.

3. Factor 3: whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition

As pointed out by Patent Owner, “[u]nder the third *General Plastic* factor, the Board considers the extent to which a later petitioner had the opportunity to ‘tailor its arguments to address issues identified by patent owner and/or the Board during a prior proceeding.’” Prelim. Resp. 49 (quoting *NetApp v. Realtime Data*, IPR2017-01354, Paper 16 at 11 (PTAB Nov. 14, 2017)). Illumina did not, however, tailor its arguments to address any issues addressed by Patent Owner or the Board because, at the time Illumina filed its Petition, Patent Owner had not yet filed any response in any related proceeding and the Board had not issued a decision instituting or denying institution of any proceeding. Illumina’s Petition was filed July 20, 2021, but the earliest patent owner preliminary response or decision on institution for the ’277 patent was in IPR2021-00788—on July 28, 2021, and October 19, 2021, respectively. See IPR2021-00788, Papers 10 and 23.

Patent Owner contends that Illumina’s “delayed filing enabled it to tailor its arguments in response to issues addressed by Patent Owner, the Board, and/or the Patent Office Central Reexamination Unit during earlier filed proceedings.” Prelim. Sur-Reply 3. Illumina could not have used materials that did not exist as a roadmap to preparing this Petition. Again, Patent Owner had not filed any response nor had the Board issued any

decision on institution when Illumina filed, and the request for reexamination had only been filed a few weeks earlier with no action from the Patent Office on the request at the time.¹³

Patent Owner contends that Illumina had access to the papers filed by the other petitioners and that “[t]hose papers gave Illumina a road map for preparing its own challenge.” Prelim. Resp. 49. Even if that was accurate, it is not the sort of alleged road-mapping about which *General Plastic* is primarily concerned. *General Plastic* at 17 (criticizing follow-on petitions that seek to “us[e] our [(i.e., the Board’s)] decisions as a roadmap, until a ground is found that results in the grant of review”); *see also id.* at 17 n.14 (citing cases that explain “a decision on a petition . . . is not simply part of a feedback loop by which a petitioner may perfect its challenges through a subsequent filing”) (citation omitted). We decline to weigh factor 3 in favor of denial here merely based on some substantive similarities in some of the grounds presented by unrelated petitioners.

Under the circumstances, Factor 3 weighs against discretionary denial of the Petition.

4. Factors 6 and 7

General Plastic Factors 6 and 7 relate to the Board’s resources and the requirement to issue a timely final written decision. *General Plastic* at 16.

¹³ Insofar Patent Owner is alluding to the reexamination of the ’720 patent, that matter is stayed. Prelim. Sur-Reply 3; IPR2021-00791, Paper 25. Moreover, Patent Owner provides no comparison between Illumina’s Petition and any action in this other reexamination that would suggest Illumina used that proceeding as a roadmap.

Patent Owner contends that we should deny institution because the Board's limited resources are generally better spent focusing on initial petitions as compared to follow-on petitions, and the Board can no longer realistically coordinate the schedules of Illumina's challenge with the earlier proceedings. Prelim. Sur-Reply 4; Prelim. Resp. 50.

To some extent we agree with Patent Owner. Inasmuch as there are some similarities in the various petitioners' obviousness theories, it is arguably inefficient and wasteful to institute yet another trial—now four, counting Illumina's Petition—challenging substantially the same claims on those bases. And the opportunity for coordinated schedules has passed.

On the other hand, Illumina's primary ground, which is based on anticipation by Landes and covers most all the challenged claims, is a newly advanced theory against the '277 patent before the Board. All the prior challenges to the '277 patent at the Board are based on obviousness and none involved Landes. Even if Illumina agreed with the prior petitioners' obviousness contentions, Illumina was foreclosed from both joining any earlier proceeding and asking the Board to resolve Illumina's anticipation ground via joinder. *Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1335–36 (Fed. Cir. 2020) (holding that introduction of new issues in IPR proceedings via joinder is not permitted). In other words, Illumina's desire to have the Board resolve its anticipation challenge and an alternative filing strategy that might have produced more efficiencies are in tension. Every new instituted proceeding takes from the Board's finite resources, but we also consider, in fairness, Petitioner's desire to have the Board decide its unique unpatentability challenge raised here.

It is true that Illumina might have filed the Petition earlier and possibly allowed us to put its trial on the same schedule as the other ongoing proceedings against the '277 patent. Because it did not do so, it places a somewhat greater burden on Board resources. At the same time, the panel is already familiar with the '277 patent and certain prior art, so there are efficiencies gained.¹⁴ And we perceive at present no specific obstacle to reaching a final written decision in this matter within one year from institution.

Altogether, on this record, Factors 6 and 7 are neutral to only marginally weighing in favor of denial.

5. Conclusion

After considering all the *General Plastic* factors, we decline to deny the Petition on this discretionary basis. Factors 1 through 5 weigh against denial. Factors 6 and 7 are neutral to marginally weighing toward denial, which does not override the other factors on this record.

¹⁴ In looking to overall efficiencies, it may well be inefficient for the Board, which is already familiar with the '277 patent and the prior art, to deny institution of Illumina's Petition on a discretionary basis, increasing inefficiencies for the district court in Delaware should it otherwise be inclined to grant a motion to stay pending resolution of the IPRs, which Illumina represents it will seek upon institution. *See General Plastic* at 16–17 (explaining that an objective of the AIA was to “provide an effective and efficient alternative to district court litigation”).

C. Analysis of the Fintiv Factors

1. Factor 1: Whether a Stay Exists or Is Likely to Be Granted if a Proceeding Is Instituted

Fintiv factor 1 recognizes that a stay of litigation pending resolution of a PTAB trial allays concerns about inefficiency and duplication of efforts, which strongly weighs against discretionary denial. *Fintiv* at 6.

Petitioner represents that it will seek a stay in court if we institute *inter partes* review. Pet. 68. Petitioner contends that given the timing, “there is a strong likelihood such a stay will be granted.” *Id.* Patent Owner responds that Petitioner has not yet filed a motion to stay, so this factor should be neutral. Prelim. Resp. 52. It is unclear how the court may rule on Petitioner’s yet-to-be-filed motion. Thus, this factor is neutral. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12 (PTAB May 13, 2020) (informative) (explaining that factor 1 generally “does not weigh for or against discretionary denial” when neither party has requested a stay).

2. Factor 2: Proximity of the Court’s Trial Date to the Board’s Projected Statutory Deadline

Fintiv factor 2 looks to the “proximity of the court’s trial date to the Board’s projected statutory deadline.” *Fintiv* at 9. “If the court’s trial date is earlier than the projected statutory deadline, the Board generally has weighed this fact in favor of exercising authority to deny institution under *NHK*.” *Id.*

Petitioner represents that trial in the Illumina lawsuit is not scheduled to begin until September 11, 2023. Pet. 68. According to Petitioner, this

weighs against discretionary denial because a final written decision will precede trial in the Illumina lawsuit by many months. *Id.*

Patent Owner does not dispute that a final written decision on Illumina’s Petition would precede trial in the Illumina lawsuit, but argues that such final written decision would come well after trial in three third-party lawsuits—the Natera lawsuit, the Quest lawsuit, and the Labcorp lawsuit (collectively, “the third-party lawsuits”). Prelim. Resp. 52–55; Prelim. Sur-Reply 5. We address Patent Owner’s arguments regarding the third-party lawsuits below, including issues of timing and overlap, in connection with *Fintiv* Factor 6.

The September 11, 2023, trial date relative to the Board’s projected statutory deadline weighs against discretionary denial because we expect to render a final written decision in this matter roughly eight months before any trial of Illumina’s lawsuit in Delaware.

3. Factor 3: Investment in the Parallel Proceeding by the Court and Parties

Factor 3 considers the “investment in the parallel proceeding by the court and parties,” including “the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision.” *Fintiv* at 9.

Petitioner argues that it is early in the Illumina lawsuit and “[t]here is still significant investment required in the district court litigation.” Pet. 68. Petitioner explains that “[c]laim construction, discovery, pre-trial motions, preparing for trial, going through the trial process, and engaging in post-trial motions practice, all lie in the future.” *Id.* (citing Ex. 1051, 16–18).

Patent Owner argues that “the parties and the district court have already invested significant effort in the Illumina Litigation and will invest quite a bit more by the time the Board issues its institution decision in January 2022.” Prelim. Resp. 56 (“The parties have already exchanged infringement and invalidity contentions, exchanged claim terms for *Markman*, and will be in the middle of claim construction briefing at the time of the institution decision.”).

We agree with Petitioner that investment in the Illumina lawsuit, particularly as related to validity issues, has not been substantial. Based on the scheduling order, fact discovery will not close until August 16, 2022. Ex. 2076, 6. The parties have exchanged preliminary contentions, but final contentions are not due until the summer of 2022. *Id.* at 5. Claim construction briefing has begun, but a *Markman* hearing is not scheduled until April 12, 2022. *Id.* at 10–11. It, thus, appears that moderate investment has been made so far, and most of the investment lies ahead. *See generally, id.*

Overall, this factor weighs against discretionary denial of the Petition.

4. Factor 4: Overlap between Issues Raised in the Petition and in the Parallel Proceeding

Factor 4 considers whether “the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding.” *Fintiv* at 12. If the issues in the Petition overlap substantially with those in the parallel proceeding, “this fact has favored denial.” *Id.* “Conversely, if the petition includes materially

different grounds, arguments, and/or evidence . . . this fact has tended to weigh against exercising discretion to deny institution.” *Id.* at 12–13.

Patent Owner argues that “there is significant overlap between the claims challenged in the Petition and those asserted in the Illumina Litigation.” Prelim. Resp. 58. According to Patent Owner, “[t]hirty of the thirty-five Challenged Claims in the Petition are asserted in the Illumina Litigation.” *Id.* Patent Owner does not, however, direct us to evidence showing that the invalidity arguments presented in the Petition overlap with those at issue in the Illumina lawsuit. Prelim. Resp. 58–60; Prelim. Sur-Reply 5.

Petitioner also stipulates that “it will not pursue, in district court, invalidity based on any instituted IPR ground.” Prelim. Reply 4. This stipulation echoes the one made in *Sand Revolution II, LLC v. Continental Intermodal Group-Trucking LLC*, IPR2019-01393, Paper 24 at 16 (PTAB June 16, 2020) (informative), which the Board weighed as marginally against discretionary denial because such stipulation mitigated to some degree concerns over duplication of efforts and inconsistent results to the extent there otherwise was overlap between parallel proceedings.

Given the absence of evidence on this record of significant overlapping issues, and Petitioner’s stipulation, we find that this factor weighs against exercising our discretion to deny institution.

5. Factor 5: Whether the Petitioner and the Defendant in the Parallel Proceeding Are the Same Party

Petitioner is a defendant in the Illumina lawsuit. Because our final written decision in this matter will likely precede the date for trial scheduled in the Illumina lawsuit by many months, this factor weighs against discretionary denial. *Google LLC v. Parus Holdings, Inc.*, IPR2020-00846, Paper 9 at 21 (PTAB Oct. 21, 2020) (“Here, . . . Petitioner is the defendant in the parallel proceeding. This fact could weigh either in favor of, or against, exercising discretion to deny institution, depending on which tribunal was likely to address the challenged patent first.”).

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

Factor 6 looks to whether “other circumstances” exist that might “impact the Board’s exercise of discretion.” *Fintiv* at 14. Such other circumstances include, for example, the merits. *Id.*

Petitioner argues that this factor favors institution based on the “significant public interest against ‘leaving bad patents enforceable.’” Pet. 69. Petitioner further argues that it “has presented strong grounds for anticipation and obviousness of the challenged claims.” Prelim. Reply 5.

Patent Owner argues that the “merits of the instant Petition are far from strong.” Prelim. Resp. 61. Patent Owner argues that the existence of “serially-filed petitions by similarly situated defendants . . . favors denial.” *Id.* And Patent Owner argues that “trials are scheduled of the ’277 patent in *three* other litigations before the FWD would be due in this proceeding.” *Id.* at 52–53. According to Patent Owner, the courts and the parties have made

significant investments in these other lawsuits and there is substantial overlap between the arguments presented in the Petition and in the third-party lawsuits. *Id.* at 52–60.

We begin with Petitioner’s argument that the merits are strong and that policy considerations against leaving “bad patents” enforceable counsel against discretionary denial. For the reasons discussed below, we find that Petitioner has met its institution burden. Our determination is preliminary, and we are not prepared at present to characterize Petitioner’s challenge as especially “strong.” Nor, on this preliminary record, do we characterize the ’277 patent as a “bad patent.” Although Petitioner has met the institution burden, we weigh the merits as neutral for purposes of the *Fintiv* analysis.

We turn next to Patent Owner’s argument regarding the third-party petitions. We have considered Patent Owner’s arguments with respect to serially-filed petitions in the context of the *General Plastics* factors. For the reasons discussed above (Section II(B)), we do not agree on this record that the existence of additional and earlier petitions against the ’277 patent merit discretionary denial. That determination does not change even if considered along with the arguments made here under *Fintiv*.

Finally, we consider the arguments regarding the third-party lawsuits. We consider each of the three third-party lawsuits (none of which, to our knowledge, is stayed) in turn.

Starting with the Natera lawsuit under the *Fintiv* rubric, factor 2 (proximity to trial) weighs against denial or is at most neutral. Patent Owner repeatedly argued, as it did in related proceedings, that trial in the Natera lawsuit was set to begin on December 13, 2021. Prelim. Resp. 53; *see also*

id. at 56 (arguing “the court in the Natera Litigation will have concluded a jury trial—scheduled for December 13, 2021—by the time the Board issues its institution decision in January 2022”); *see* IPR2021-00902, Paper 9 at 15–16, 47, 49. We know now that trial in the Natera lawsuit did not take place on December 13, 2021. At this point, it is unclear when trial will occur in the Natera lawsuit because the trial date was cancelled and the matter has since been transferred to a new judge. Prelim. Reply 4; Ex. 3003 (order canceling trial); Ex. 3004 (docket report for Natera lawsuit).

We agree with Patent Owner that *Fintiv* factor 3 (investment) weighs against instituting trial on this Petition when considering the Natera lawsuit. Prelim. Resp. 56–57. Although trial has been taken off calendar, the parties and the court made substantial investments in that proceeding in the lead-up to trial. *Id.*

With respect to factor 4 and the degree of overlap with the Natera lawsuit, Landes, Marx, and Valli, all of which Petitioner asserts here, are not identified as a basis for invalidity in the Natera litigation. Prelim. Resp. 59–60. Patent Owner argues, however, that Lee is asserted in the Natera lawsuit, that Lee collects blood samples in tubes containing ACD (allegedly like Landes). *Id.* Therefore, Patent Owner contends, the Petition and the Natera lawsuit will both “address and resolve the same key argument:” whether the glucose/dextrose component of ACD is an “agent” that inhibits cell lysis as claimed. *Id.*¹⁵ We credit Patent Owner’s argument insofar as

¹⁵ Whether claims of the ’720 patent are unpatentable over Lee is also being addressed in already instituted proceedings before the Board in IPR2021-01206, filed by Labcorp. *See generally* IPR2021-01206, Paper 11.

there does appear to be some substantive overlap, both as to anticipation and obviousness, in issues raised in the Petition and the Natera lawsuit.

Although that overlap, along with the investment discussed above, weighs in favor of denial, that weight is diminished to a degree because Illumina is unrelated to Natera (*Fintiv* factor 5) and due to uncertainty about when and if trial in the Natera lawsuit will occur.

Patent Owner also cites the Labcorp lawsuit as having an earlier trial date, and as a source of overlap and duplication of efforts. Prelim. Resp. 53–58. Considering the Labcorp lawsuit, factor 2 is neutral. Trial was originally scheduled to take place (in an unsigned proposed order) on July 11, 2022. Prelim. Resp. 53 (citing Ex. 2053). Now, however, the parties have proposed moving the trial date later to September 19, 2022, which would be four months before the due date of our final written decision. Exs. 3001, 3002; Prelim. Sur-Reply 5. Still, no firm trial date has been established—the court has not acted on the proposal for a September 19, 2022 trial date, which remains only an estimate. *Id.* Although we usually take courts’ trial schedules at “face value,” that is not necessarily so with trial dates that are mere estimates. *See, e.g., Progenity, Inc. v. Natera, Inc.*, IPR2021-00279, Paper 12 at 29 (PTAB June 11, 2021) (concluding “there is no trial date scheduled for the parallel proceeding” based on an email from the court’s clerk merely providing an estimated trial date); *Intel Corp., v. FG SRC LLC*, IPR2020-01449, Paper 13 at 15 (PTAB Mar. 3, 2021) (explaining that estimated trial dates are not firm trial dates). Therefore, “[w]hether the trial takes place before, contemporaneously with, or after our final written

decision statutory deadline involves speculation.” *Progenity*, IPR2021-00279, Paper 12 at 29.¹⁶

With respect to factor 3 for the Labcorp lawsuit, we are unpersuaded that investment in the litigation, particularly as related to validity issues, has been substantial. Even taking the more recent unsigned, proposed scheduling order as a guide about potential case deadlines, as of this institution decision, fact discovery opened on September 16, 2021, and will not close until April, 2022. Ex. 3001, 2–3. Expert discovery will not open until April and closes in June, at the earliest. *Id.* A *Markman* order has been entered but most of the investment from the court and the parties in the Labcorp lawsuit, especially on the invalidity issues, lies ahead.

With respect to factor 4 and the Labcorp lawsuit, it is difficult on this record to determine to what extent the arguments presented in the Petition overlap with those presently at issue in the Labcorp lawsuit. Patent Owner devotes a single sentence to addressing the alleged overlap, asserting that “[s]ignificant overlap also exists between the Petition and the LabCorp and Quest Litigations.” Prelim. Resp. 58 (citing Ex. 2055 (Quest’s Invalidity Contentions), 2). That does not persuade us of overlap to a degree that justifies weighing factor 4 in favor of denial, especially against Illumina as an unrelated party (factor 5).

¹⁶ Labcorp has also apparently moved to transfer the Labcorp lawsuit from the Western District of Texas to the Southern District of California. Prelim. Reply 4; *Ravgen, Inc. v. Lab. Corp of Am. Holdings*, 6:20-cv-969-ADA, Dkt. 72 (W.D. Tex. Nov. 23, 2021). On the present record, it is not clear how the court in Texas might resolve that motion.

Finally, Patent Owner cites the Quest lawsuit as a source of potential overlap and duplication of efforts. Prelim. Resp. 53. Regarding the Quest lawsuit, *Fintiv* factor 2 weighs against denial or is at most neutral because the case was recently transferred from the Western District of Texas to the Central District of California, and no trial date has been set by the new court. Ex. 3005 (docket from the Western District of Texas in Quest lawsuit); Ex. 3006 (docket from the Central District of California in the Quest lawsuit); *In re Quest Diagnostics Inc.*, No. 2021-193, 2021 WL 5230757 (Fed. Cir. Nov. 10, 2021) (directing, on petition for writ of mandamus, transfer of the matter to the District Court for the Central District of California). Factor 3 weighs the same as in the Labcorp lawsuit because, before it was transferred, the Quest lawsuit was before the same judge and on the same schedule as the Labcorp lawsuit. And the extent of investment by the transferee court has not been shown to be significant at this time.

With respect to factor 4, it is unclear to what extent the arguments in the Petition overlap with those presently at issue in the parallel Quest lawsuit. As with the Labcorp lawsuit, Patent Owner does not identify any areas of significant overlap between the grounds raised in Illumina's Petition and those being pursued by Quest in its lawsuit against Patent Owner. Prelim. Resp. 58. But even assuming that there is some degree of overlap, the weight given to such overlap is diminished because Quest and Illumina are unrelated and it is not apparent that trial in the new transferee court will precede a final written decision on Illumina's Petition.

Overall, we consider *Fintiv* factor 6 to be neutral on this record.

7. Balancing the *Fintiv* Factors

Altogether, considering and balancing the *Fintiv* factors holistically, we decline to invoke our authority to deny the Petition on a discretionary basis under § 314(a).

III. ANALYSIS

A. *Principles of Law*

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3)).

To show anticipation under 35 U.S.C. § 102, each and every claim element, arranged as in the claim, must be found in a single piece of prior art. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations of nonobviousness when presented. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. Person of Ordinary Skill in the Art (“POSA”)

In determining the level of skill in the art, we consider the problems encountered in the art, the art’s solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Petitioner proposes the following POSA definition:

[A POSA] would have had an “a M.D. and/or Ph.D. in a related area such as genetics, biochemistry, molecular biology, cell biology, or microbiology and at least one to two years of work in one of those related areas . . . [or] a Bachelor’s degree in one of the foregoing areas and at least three to four years of work in that area.” . . . Based on this asserted level of skill, a POSA would have had academic or industry experience collecting and analyzing cell-free DNA from blood samples.

Pet. 13 (quoting Ex. 1020 ¶ 15). Patent Owner proposes substantially the same definition. Prelim. Resp. 11 (citing Ex. 2001 ¶ 32). To the extent there are minor differences in the proposals, Patent Owner’s declarant testifies that such differences are not material and his “opinions . . . would not change if Dr. Levy’s [i.e., Petitioner’s] proposed level of ordinary skill were adopted.” Ex. 2001 ¶ 34.

The parties are in substantial agreement on the POSA level, and we adopt Petitioner’s proposal for this Decision. Our determinations below would not change if we adopted Patent Owner’s minimally different level.¹⁷

¹⁷ We adopted a somewhat differently phrased definition for the POSA in the Quest and Labcorp cases based on the parties’ positions in those matters.

C. Claim Construction

We interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b) (2020). Under this standard, we construe the claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*

Petitioner does not identify any claim terms as needing construction. Pet. 21–22. Patent Owner argues that in applying *Landes* to the challenged claims, Petitioner interprets the claims too broadly. Prelim. Resp. 12. In particular, Patent Owner argues that Petitioner’s interpretation of the claims to encompass anticoagulant chelators, such as EDTA or ACD (acid citrate dextrose) is “impermissibly broad.” *Id.* at 13.

At this stage, we do not find it necessary to further construe the claims to determine whether they encompass anticoagulant chelator compounds such as EDTA and ACD because Petitioner relies on glucose, which is an undisputed component of ACD, as the “agent that impedes cell lysis.” *See, e.g.*, Pet. 1–2, 26 (“*Landes* expressly discussed the use of ‘an agent that inhibits lysis of cells’ (i.e., glucose) according to the ’277 patent.”), 28 (explaining, with citation to evidence, that “glucose is necessarily present in

See, e.g., IPR2021-00788, Paper 23 at 42–43; IPR2021-01054, Paper 11 at 33–35. On this record, we do not see that such differences are material or would alter the outcome of this Decision.

the ACDA blood collection tube described in *Landes*'s 'Plasma Separation Protocol'").

We recognize that the glucose in *Landes* is introduced to the samples as a component of ACD (or ACDA), a known anticoagulant. Ex. 1056 ¶ 62 (testimony of Dr. Levy that "*Landes* . . . described the same method as is claimed in the '277 patent, where 'an agent that inhibits lysis of cells' is present in a maternal blood sample by virtue of the glucose ingredient present in the ACDA^[18] blood collection tube"). The challenged claims, however, use the transitional phrase "comprising." *See supra* Section I(D). Accordingly, the challenged claims are open-ended and do not exclude the presence of additional elements or agents beyond those recited in the claim. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1319 (Fed. Cir. 2009) ("The claim uses the term 'comprising,' which is well understood in patent law to mean 'including but not limited to.'").

Consistent with the use of the transitional term "comprising," we do not understand Patent Owner to argue that the sample used in the methods claimed cannot contain any anticoagulant. Rather, we understand Patent Owner to argue that one cannot satisfy the claim element requiring "an agent that impedes cell lysis" by pointing solely to an anticoagulant. Petitioner does not do so and, thus, we do not find it necessary to further construe the claims at this stage of the proceeding. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e

¹⁸ According to Dr. Levy, *Landes* uses the acronym ACDA to refer to Becton, Dickinson's Acid Citrate Dextrose Solution A. Ex. 1056 ¶ 42.

need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))); *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy’”).¹⁹

If the parties believe that further argument on claim construction is needed to resolve issues in dispute, they may provide such argument in briefing permitted in trial.

D. Overview of the Asserted Prior Art

1. Landes (Exhibit 1003)

Landes is an international patent application that published July 31, 2003. Ex. 1003, code (43). Landes claims priority to a U.S. provisional patent application (No. 60/349,877) that was filed January 18, 2002 (hereafter “the Landes Provisional” (Ex. 1006)).

Landes relates generally to non-invasive methods used to distinguish circulating fetal DNA from maternal DNA in samples from maternal blood, and thereby to detect fetal aneuploidies and alleles. Ex. 1003, code (57). Landes teaches, for example, that “maternal serum or plasma may be a relatively rich source of fetal DNA based on PCR determinations,” that “fetal DNA can be consistently detected in maternal serum as early as 7

¹⁹ As understood, Patent Owner’s position also does not account adequately at this stage for a compound that may have more than one functionality (e.g., chelation and cell membrane stabilization).

weeks,” and that such DNA increases during gestation. *Id.* at 2:19–25 (disclosing that “the lowest fetal DNA concentration in plasma as measured by PCR was greater than 20 fetal cell equivalents per mL of maternal blood with some instances where fetal DNA constituted as much as 5% of the total DNA in plasma”).

Landes discloses a plasma separation and fetal DNA isolation protocol where maternal blood is first collected into ACDA tubes from Becton, Dickinson. *Id.* at 10:26–12:6. Landes teaches that, following centrifugation and plasma removal, DNA can be isolated from the plasma sample using commercially available kits. *Id.* Landes teaches that the DNA may then be treated with bisulfite to distinguish fetal and maternal DNA,²⁰ and the nucleotide sequence of interest may be subsequently amplified (e.g. via fetal-specific PCR) and analyzed. *Id.* at 12:9–15:3.

²⁰ Landes teaches that isolated DNA may be treated “with a reagent which differentially modifies methylated and non-methylated DNA, e.g., bisulfite,” which recognizes that fetal DNA is generally “hypomethylated relative to adult DNA.” Ex. 1003, 8:22–28 (explaining that “[o]ne means of generating fetal-specific PCR products is to identify loci that are unmethylated in fetal DNA and methylated in adult/maternal DNA.”).

2. Marx (Exhibit 1029)

Marx is an article that published in 1991. Ex. 1029, 743. Marx relates to techniques that aim to prepare platelet rich plasma samples with reduced white blood cell contamination. *Id.* Marx teaches, for example, “an effective method of significantly decreasing the WBC content” of platelet units is to prepare a sample “with reduced centrifugation time and with the braking programs disengaged.” *Id.*; *see also id.* at 746 (“[N]o brakes gave much more reasonable yields . . . as well as low WBC contamination.”).

3. Lo (Exhibit 1033)

Lo is an international patent application that published in 1998. Ex. 1033, code (43). Lo relates to a detection method performed on maternal serum or plasma from a pregnant female, which comprises detecting the presence of nucleic acids of fetal origin. *Id.* at Abstr. According to Lo, “[t]he plasma or serum-based non-invasive prenatal diagnosis method according to [Lo’s] invention can be applied to screening for Down’s Syndrome” and other chromosomal abnormalities. *Id.* at 5:3–6.

Lo describes methods for non-invasive prenatal determinations of, for example, fetal RhD status from maternal blood samples, which examples involve isolating and analyzing cell-free fetal DNA. *Id.* at 15:4–19:28 (Example 3). Lo discloses that maternal blood samples were collected in EDTA tubes, and that the samples were centrifuged to separate the plasma from cellular blood components in the buffy coat. *Id.* at 15:20–27.

Lo teaches that the absolute concentrations of fetal DNA in maternal plasma and serum are similar. *Id.* at 30:8–9. However, Lo discloses, the “main difference lies in the presence of a larger quantity of background

maternal DNA in serum compared to plasma, possibly due to the liberation of DNA during the clotting process.” *Id.* at 30:10–12. According to Lo, with some detection methods, such as conventional PCR, “maternal plasma may be preferable to maternal serum for robust foetal DNA detection.” *Id.* at 30:12–17.

4. Valli (Exhibit 1034)

Valli is an article published in 1980 related to studies on various anticoagulants and the effects of such agents on bovine blood in transport. Ex. 1034, 252 (“Various anticoagulants were assessed in order to develop a transport media . . . which would improve leukocyte stability.”). Valli reports that “[t]he purpose of this study was to develop a transport medium for bovine blood which would provide stability during routine shipment through the mail without requiring usual precautions against Canadian climactic conditions.” *Id.* (explaining that such medium “would allow blood samples for mass screening or for diagnostic purposes to be sent to a central laboratory”).

Valli discloses that blood collected in tubes containing EDTA or ACD was tested for leukocyte stability with those agents alone “and in combination with fixative agents (acids, alcohols, and aldehydes).” *Id.*; *see also id.* at n.4 (identifying “formaldehyde and glutaraldehyde”). According to Valli, “pilot studies on various combinations of anticoagulants showed that formaldehyde improved cell preservation but there was marked clumping of platelets and leukocytes after 48 h.” *Id.* at 253.

Valli discloses that, “[f]rom the results of this pilot experiment five anticoagulant combinations were selected” for experimentation. *See id.* at

254 (Table I, listing “FORMULATION OF ANTICOAGULANT COMBINATIONS EVALUATED” including Titriplex I and Titriplex IV, both of which are disclosed as including, *inter alia*, EDTA and formalin). According to Valli, “[a]ll three formalin containing preparations (Titriplex I, IV, and ACD-formalin-ASA) were greatly superior to EDTA without additives for maintaining the stability of leukocytes during transport.” *Id.* at 257. Valli discloses: “The fact that the results of cell counts . . . were so accurate with formalin containing anticoagulants, indicates that these preparations are deserving of a far wider utilization.” *Id.*

E. Ground 1: Anticipation by Landes

Petitioner asserts that claims 55–59, 61–63, 66–69, 80–89, 94, 96, and 126–130 are unpatentable as anticipated by Landes. Pet. 16–19, 22–42.

We gave an overview of Landes above. As a threshold matter, there is a dispute about whether Petitioner has shown that Landes is prior art to the challenged claims, which we address below. *See* Prelim. Resp. 22–26. We will then turn to analysis of the unpatentability of the claims, and Patent Owner’s arguments in response.

1. Prior Art Status of Landes

Petitioner contends that Landes properly claims, and is entitled to, the priority benefit of the Landes Provisional (Ex. 1006), filed on January 18, 2002. Pet. 16. In furtherance of its position, Petitioner provides a chart, breaking down each element of the claims in Landes and providing citations for disclosure in the Landes Provisional that allegedly provides support under 35 U.S.C. § 112, first paragraph, for each of the claims. *Id.* at 17–19.

In addition, Petitioner contends that “each of the anticipatory statements in *Landes* relied on in Section X were carried forward verbatim from the ’877 [*Landes*] provisional.” *Id.* at 19; *see, e.g., id.* at 23 (citing corresponding disclosures in both Ex. 1003 (*Landes*) and Ex. 1006 (“*Landes* Provisional”) for a limitation of claim 55).

Patent Owner responds that Petitioner has not shown that *Landes* is prior art as of its provisional filing date. Prelim. Resp. 22–24. According to Patent Owner, “conclusory assertions” do not show that the claims of *Landes* have § 112 support in the *Landes* Provisional. *Id.* at 22–24, 26 (asserting that Petitioner cites large portions of the disclosure). Patent Owner notes that, even if the claims of *Landes* appear verbatim in the *Landes* Provisional, that does not necessarily mean that the description requirement under § 112 is met. *Id.* at 24–25 (citing *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010)).²¹ Patent Owner also contends that *in ipsius verbis* claim language in the *Landes* Provisional does not necessarily show that *Landes*’s claims are enabled. *Id.* at 5. In support, Patent Owner points out that claims 1 and 2 of *Landes* were rejected for lack of enablement during prosecution and that the application was ultimately abandoned. *Id.* (citing Ex. 2078, 6–12).

²¹ In *Ariad*, appellant argued that the “original claims identify whatever they state” leaving only the question of applicant had enabled use of the invention, but the court “disagree[d] that this is always the case.” *Ariad*, 598 F.3d at 1349 (explaining that, “[a]lthough many original claims will satisfy the written description requirement, certain claims may not” and giving, as an example, claims that recite a broad genus of compounds without sufficient disclosure of representative species).

For a later published patent application to receive the priority date of an earlier filed provisional application from which it claims priority, we ask two questions. First, whether at least one claim of the patent application is supported by the description of the relied-upon provisional application.

Dynamic Drinkware, LLC V. Nat'l Graphics, Inc., 800 F.3d 1375, 1382; *Lyft, Inc. v. Ikorongo Tech LLC*, IPR2021-00422, Paper 10 at 10–12 (PTAB Aug. 19, 2021) (hereafter “*Lyft*”) (explaining, with citation to the MPEP and Board decisions, that “the provisional application must provide sufficient [§ 112] support for at least one claim in the reference patent or published application”). Second, whether the provisional application supports the disclosure relied upon for prior art purposes in the reference patent application. *Lyft* at 11.²²

This second question or requirement is often established if the relied-upon disclosures in the reference patent application appear in substantially

²² In *Lyft*, the Board found that petitioner had not met its burden on the second requirement. Among other things, the reference patent application and the provisional application in that case had materially different disclosures; the relationship between those documents, and satisfaction of the relevant claim limitations by such disclosures was entirely unclear in the petition, such that the Board could not determine the relationship itself from the record. *Lyft* at 13–16. Here, in contrast, the disclosures of Landes and the Landes Provisional are virtually identical, only the first requirement is contested, and, notwithstanding the breadth of Petitioner’s citations, we are able to ascertain the relevance of those cited portions of the specification to the issue of § 112 support without difficulty. It may have been prudent for Petitioner to include a more detailed discussion to accompany its citations but, on this record and without persuasive argument in opposition, we determine Petitioner met its burden to proceed to trial relative to the prior art status of Landes. We discuss further below.

the same form in the provisional application. *Lyft* at 13 (“In a case in which a provisional application is shown to have identical or nearly identical disclosure to the portions of an application or patent relied upon, this may be enough.”). Petitioner has met this second requirement because the disclosures of Landes and the Landes Provisional appear to be nearly identical. Petitioner argues that Landes’s disclosures cited as meeting the limitations of the challenged claims appear verbatim in the Landes Provisional (Pet. 19) and Patent Owner provides no argument to the contrary. Patent Owner’s argument is, instead, aimed at the first requirement—whether Landes’s claims have § 112 support in the Landes Provisional. Prelim. Resp. 24–26.

Based on the current record, we find that Petitioner has met its institution burden in establishing that Landes is entitled to claim the priority benefit of the Landes Provisional and, thus, is prior art to the ’277 patent. On the matter of written description support under § 112, the claims of Landes (claims 1–4) appear unchanged in the Landes Provisional (claims 1–4). *Compare* Ex. 1003, 22–23, *with* Ex. 1006, 21–22. Petitioner also provides citations to the specification of the Landes Provisional that, while broad, correspond to several disclosed alternative embodiments, and the various working examples (Materials and Methods and Experimental Examples 1–5) that describe and explain how to carry out the methods claimed. Pet. 17–19 (citing, e.g., Ex. 1006, 8:7–9:27, and 10:1–20:12). Patent Owner cites precedents for the proposition that, in some circumstances, the presence of the same claim language in an original disclosure may not be enough to satisfy the description requirement. Prelim.

Resp. 23–24. But Patent Owner provides neither specific argument nor evidence that this is one of those circumstances. If Patent Owner believes there is some particular deficiency with respect to Landes’s claims and the written description requirement, Patent Owner leaves it unsaid.

Patent Owner’s position relative to whether the claims of Landes are enabled under § 112 based on the Landes Provisional is a closer call. Here, at least, Patent Owner cited a rejection for lack of enablement of claims 1 and 2 during Landes’s prosecution as possibly illustrating some gap in the disclosure of Landes or the Landes Provisional. Prelim. Resp. 25.

Petitioner’s cited evidence is, however, not limited to claims 1 and 2 of Landes or the Landes Provisional—independent claims 3 and 4 are also identified, and those claims were *not* rejected for lack of enablement.

Ex. 2078, 12–16 (rejecting claims 3 and 4 for anticipation and obviousness, but not under § 112, first paragraph). It is not necessary that all the reference’s claims be supported or enabled by the disclosure of the provisional under § 112 for the reference to receive the priority benefit of the provisional’s filing date. *Lyft* at 10–11; *Ex parte Mann*, 2016 WL 7487271, at *6 (PTAB Dec. 21, 2016); MPEP § 2136(I) (9th ed. rev. 10.2019 (June 2020)). And Petitioner has identified the working examples in the Landes Provisional, which provide further guidance on using the various methods described and claimed in Landes.²³ See Pet. 18–19 (citing, e.g., Ex. 1006,

²³ *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (identifying factors relevant to the enablement inquiry including guidance provided and whether working examples are present in the disclosure).

10:1–20:12). Patent Owner provides no argument on why such disclosures are insufficient in enabling at least claim 3 or 4 of Landes.

For the reasons above, Patent Owner’s argument about the prior art status of Landes is unavailing on this record. Petitioner is reasonably likely to prevail in establishing that Landes is prior art to the ’277 patent.

2. Anticipation Analysis

Petitioner shows, based on this preliminary record, where the limitations of the challenged claims are disclosed in Landes. Pet. 22–42. Petitioner’s assertions are backed by the cited prior art and by the testimony of its declarant, Dr. Levy. *Id.*; Ex. 1056 ¶¶ 51–96.

Petitioner and Dr. Levy show, for example, where Landes discloses each of the limitations of independent claim 55, which is illustrative. Petitioner and its declarant establish, at this stage, that Landes teaches a method as recited in claim 55’s preamble, whether that preamble language is limiting or not. Ex. 1056 ¶ 52; Ex. 1003, Abstract (disclosing non-invasive methods for detecting and distinguishing fetal DNA and alleles). Petitioner shows where Landes discloses claim 55’s “determining the sequence” step. Ex. 1056 ¶¶ 53–58 (citing, *inter alia*, Landes’s methods for isolating fetal DNA from maternal blood samples and detecting a sequence for a loci of interest from fetal DNA); *see, e.g.*, Ex. 1003, Abstr., 3:19–31, 8:25–9:11, 10:26–12:6, 18, 19:15–18).

Petitioner and Dr. Levy further explain Landes’s disclosure of “an agent that inhibits lysis of cells” as claimed: Landes describes collecting maternal blood samples in ACDA blood collection tubes that contain dextrose (i.e., glucose)—glucose being among the lysis-inhibiting agents

identified in the '277 patent. Pet. 25–29; Ex. 1056 ¶¶ 50–51, 60–64; Ex. 1003, 10:28–29 (“Maternal blood is collected into ACDA blood collection tube (Becton Dickinson, Franklin Lakes, NJ) or other appropriate collection tube”), 16:20–21, 19:17–19); Ex. 1007, 4:30–39 (disclosing that ACDA comprises 24.5 gm of dextrose•H₂O, as well as sodium citrate and citric acid); Ex. 1001, 32:4–41 (listing “glucose,” among other compounds, as “an agent that stabilizes cell membranes [that] may be added to maternal blood samples to reduce maternal cell lysis”).²⁴

On this preliminary record, we determine that Petitioner’s arguments and evidence are sufficient for purposes of institution. We focus our remaining discussion on Patent Owner’s counterarguments.

Patent Owner argues that “Petitioner [has] failed to show that ACD is the claimed agent.” Prelim. Resp. 27. Patent Owner contends that “ACD is an anticoagulant chelator that prevents blood from clotting,” and that is allegedly how ACD is used in Landes. *Id.* (citing Ex. 2001 ¶¶ 165–166). According to Patent Owner, the '277 patent “separates anticoagulant chelators from the groups of cell lysis inhibitors,” “the prosecution history consistently excludes anticoagulant chelators,” and “extrinsic evidence

²⁴ See also Ex. 2064 (prosecution history), 1196 (representing that “multiple examples of agents that inhibit cell lysis are provided separately (see, e.g., paragraphs [0165] to [0167]”)), 1381 (paragraph 167 identifying glucose)); Ex. 1020 (declaration of Patent Owner’s expert, Dr. Wayne W. Grody) ¶¶ 37–40 (citing the '277 patent as identifying “glucose” as a membrane stabilizer and as among “the category of agents that prevents or reduces the rupture of cell membranes and release of cellular contents by protecting or preserving the structural integrity of the cell membrane”).

confirms the classification of ACD as an anticoagulant” as allegedly distinct from cell preservatives like formaldehyde. *Id.* at 28.

As discussed above (Section III(C)), the claims are open ended and do not exclude compounds or components that might be added and otherwise characterized as anticoagulants or chelators. Moreover, Petitioner’s challenge is not based on mere addition of any anticoagulant. Petitioner explains that Landes’s tubes include ACDA, which itself includes dextrose/glucose as a distinct component. Pet 1–2, 15, 25–27. At this stage, it is undisputed that the ACDA tubes of Landes include glucose and it is similarly undisputed that the ’277 patent identifies glucose as a cell-membrane stabilizer and inhibitor of cell lysis as claimed. *See, e.g.*, Ex. 1001, 32:4–41 (listing glucose as a membrane stabilizer); *see also id.* at 91:46–49 (“In this example, formaldehyde was used to prevent lysis of the cells, however any agent that prevents lysis of cells or increases the structural integrity of cells can be used”). Patent Owner’s argument above fails to grapple with Petitioner’s theory of unpatentability, which is based on glucose being the claimed “agent” in Landes’s method notwithstanding that glucose is introduced along with other chemical components.

Moving on, Patent Owner argues that Petitioner’s proof is lacking because it “focuses solely on dextrose in isolation, but ACD is a compound comprised of multiple components” that “work together in the composition to provide ACD’s anticoagulant properties.” Prelim. Resp. 28–29. According to Patent Owner, “Petitioner’s focus only on properties that dextrose might have if added independently to a sample does not show what happens when the compound ACD is added to a sample in Landes’ blood

collection tubes.” *Id.* at 29–30. Patent Owner contends that other references categorize ACD as an anticoagulant without mentioning that ACD stabilizes cell membranes. *Id.* at 30.

Patent Owner’s arguments may have merit, but are better evaluated on a full record at trial. The record now supports that dextrose (i.e., naturally-occurring glucose) is present in solution in ACD. Ex. 1043 ¶ 26 (“ACD tubes contain dextrose”); Ex. 1007, 4:30–39; *see also*, Ex. 2001 ¶ 165 (testimony of Dr. Prestwich describing ACD has having three components, one of which is dextrose); Ex. 2074 (identifying ACD as a solution of citric acid, sodium citrate, and dextrose). The record at present also supports that glucose is a membrane stabilizer that impedes cell lysis. *See, e.g.*, Ex. 1001 at 15:58–65 (specification of the ’277 patent, stating: “An agent that stabilizes cell membranes may be added to the sample including but not limited to . . . glucose.”), 32:4–12 (“[A]n agent that stabilizes cell membranes may be added to the maternal blood samples to reduce maternal cell lysis including but not limited to . . . glucose.”); *see also*, Ex. 2001 ¶ 166 (Dr. Prestwich testimony that “glucose by itself . . . is a membrane stabilizer in the context of the ’277 and ’720 Patent inventions because it functions to stabilize membranes by maintaining the health of cells and strengthening the cell membranes”); Ex. 1011, 15–16 (“[G]lucose . . . had the most marked effect on inhibiting [cell] lysis on storage.”).

Patent Owner faults Petitioner for focusing “only on the hypothetical presence of dextrose alone” (Prelim. Resp. 29), but the record supports that dextrose is introduced into Landes’s blood samples as one component in a three component solution (*see e.g.*, Ex. 2074, 1). We do not find support at

present for the proposition that the dextrose (i.e., glucose) component of Landes's ACD solution will act differently on the cells in Landes's sample—and to the exclusion of a cell-stabilizing and lysis-inhibiting effect as reported in the '277 patent—simply because it is combined with a blood sample with two other chemical components.

We recognize Dr. Prestwich's testimony that "the components of the ACD compound work together to prevent coagulation" with dextrose "counter-balanc[ing] the sodium citrate in order to maintain the isotonicity of the sample environment." Ex. 2001 ¶ 166. But it is not apparent that such testimony about the asserted isotonicity-maintenance function of dextrose in ACD precludes dextrose from also acting to stabilize membranes and inhibit lysis, as taught in the '277 patent. *Id.* Indeed, inasmuch as isotonicity refers to maintaining the extracellular sample environment so that it is neither too hypertonic nor hypotonic, such evidence may well further support Petitioner's challenge.²⁵ Such issues raise material questions better resolved on a fully-developed record. At present, without evidence to support that dextrose does not function as a membrane stabilizer when it is introduced in solution with other components versus when it is introduced alone, we find, on this preliminary record, that the presence of dextrose (i.e., glucose) in Landes's sample-collection tubes satisfies the "agent" limitation.

²⁵ FDA prescribing information for ACDA indicates that the following ingredients are the solution's key components: "[c]itric acid for pH regulation," "[s]odium citrate anticoagulates," and "[d]extrose for isotonicity." Ex. 2074, 4.

Patent Owner also contests Petitioner’s anticipation theory to the extent it is based on inherency. Prelim. Resp. 31–32. At this stage, however, we determine that Petitioner has made a threshold showing that dextrose/glucose in Landes’s tubes would necessarily function as a cell-membrane stabilizer. As discussed above, the evidence in support includes at least the ’277 patent, which lists glucose as providing the claimed functionality.²⁶ Whether Landes intended or recognized ACDA’s function as an anticoagulant and not, explicitly, as a cell-membrane stabilizer is not decisive. First, Landes, like the methods disclosed and claimed in the ’277 patent is directed to the same purpose—non-invasive methods for isolating cell-free fetal DNA from maternal samples and detecting sequences of fetal genetic material (e.g., alleles of interest) in those samples, which may be used to determine if genetic abnormalities are present. *See, e.g.*, Ex. 1003, Abstr., 3:1–4:6; Ex. 1001, Abstr., 1:30–39, 472:66–473:5. Second, recognition of an inherent functionality (here, inhibition of cell lysis by glucose in ACD) within the prior art itself is not necessary. *See MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (“Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize

²⁶ *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012) (analyzing inherency based on disclosures of the “patent itself”).

the inherent characteristics or functioning of the prior art.”) (citations omitted).

For the reasons above, Petitioner has established a reasonable likelihood that it will prevail in showing at least one of the challenged claims is unpatentable as anticipated by Landes.

F. Ground 2: Obviousness over Landes and Marx

Petitioner asserts that claim 95 would have been obvious over Landes and Marx. Pet. 42–46. Landes and Marx are summarized above. Claim 95 depends from claims 94 and 81, and adds that “the centrifugation step is performed with the centrifuge braking power set to zero.” Ex. 1001, 475:30–32. Petitioner asserts that Marx discloses zero-brake centrifugation and that setting the braking power to zero was a well-known technique. Pet. 43. Petitioner contends it would have been obvious to use zero-brake centrifugation in Landes’s methods to minimize disturbance of the buffy-coat when processing blood samples. *Id.* at 44–45.

Patent Owner’s arguments against Ground 2 are the same as addressed above on Ground 1. Prelim. Resp. 22 (addressing Grounds 1 and 2 together). Patent Owner’s arguments are unavailing at this stage.

Petitioner also argues that it is not aware of any secondary considerations of nonobviousness relevant to claim 95. Pet. 46. Petitioner does, however, address such considerations relative to its challenge to claim 55 and the combination of Lo and Valli (Ground 3), which challenge is addressed in more detail below. *Id.* at 52–55. There, Petitioner contends that Patent Owner’s claimed invention did not satisfy any long-felt need and

yielded no unexpected results. *Id.* Petitioner contends that Patent Owner markets no product commensurate in scope with the challenged claims and, for the patent's examples, Petitioner contends the results of those examples are unreliable and could not be reproduced by other researchers. *Id.* at 53–55 (citing, *inter alia*, Exs. 1052 (Chinnapapagari) and 1053 (Chung)).²⁷

Objective indicia of nonobviousness receive little weight on this record. As we have elsewhere explained, there is no sufficient nexus yet established between any purported long-felt need, unexpected results, skepticism or praise and the claims of the '277 patent.²⁸ *See* IPR2021-00788, Paper 23 at 55–62; IPR2021-00902, Paper 13 at 52–53 (explaining, among other things, that Patent Owner's objective indicia evidence is limited to methods using formaldehyde as the lysis-inhibiting agent but the claims are much broader); *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999) ("The patentee bears the burden of showing that a nexus exists."). If further argument and evidence is presented on objective indicia of nonobviousness during trial, we will determine the appropriate weight to give it based on a fully-developed record.

²⁷ We addressed similar argument in related proceedings; for guidance moving forward, the parties here may consider developing argument and evidence specific to any alleged objective indicia as discussed in our institution decision in Quest's case (IPR2021-00788, Paper 23 at 55–62).

²⁸ Patent Owner does not expressly argue here that unexpected results, skepticism, etc., qualify as objective indicia of nonobviousness. Instead, Patent Owner's argument on skepticism, for example, allegedly reveals that Petitioner's challenge is based on hindsight and undermines a POSA's expectation of success in combining Lo and Valli for Ground 3. *See, e.g.*, Prelim. Resp. 41–43. We address those arguments under Ground 3.

We have considered Petitioner’s argument and evidence in support of Ground 2 (e.g., Ex. 1056 ¶¶ 97–102) and conclude on this record that Petitioner is reasonably likely to prevail in showing that claim 95 would have been obvious over Landes and Marx. Also, if trial is instituted it must be instituted on all challenged claims and grounds. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1354 (2018).

G. Grounds 3 & 4: Obviousness over Lo and Valli; Lo, Valli, and Marx

Petitioner asserts, for Ground 3, that claims 55–63, 66–69, 80–89, 94, 96, and 126–130 would have been obvious over Lo and Valli. Pet. 46–65. Petitioner asserts that claim 95 would have been obvious over Lo, Valli, and Marx. Pet. 65–66. Lo, Valli, and Marx are summarized above.

We start with Petitioner’s contentions, citing those against claim 55 as representative. We will then proceed to Patent Owner’s arguments, which are directed to the challenged claims as a group.

Petitioner argues, persuasively on this record, that Lo discloses all the limitations of claim 55 except for the “agent” limitation “[t]o the extent EDTA is not” the claimed agent that inhibits cells. Pet. 46–48. Petitioner’s contentions are backed by evidence, including relevant disclosures in the prior art and Dr. Levy’s testimony. *See, e.g.*, Ex. 1033, 4–5, 15–20, 23–33 (describing exemplary non-invasive methods for isolating cell-free fetal DNA from samples of maternal blood and detecting fetal nucleotide sequences of interest for purposes of, for example, determining aneuploidies); Ex. 1056 ¶¶ 104–107. Lo discloses that maternal blood samples were collected in tubes with EDTA and centrifuged to separate the

plasma component from which cell-free DNA is extracted. Ex. 1033, 16:20–17:6 (“Blood samples were collected into tubes containing EDTA”).

According to Petitioner, a POSA would have understood from Lo and other background art that unstable maternal WBCs in a blood sample are subject to lysis and release of maternal cell-free DNA during sample preparation and processing. Pet. 48. Petitioner argues a POSA would thus understand that such lysis makes robust cell-free fetal detection more difficult. *Id.*; Ex. 1003, 308–17 (disclosing “a larger quantity of background maternal DNA in serum compared to plasma, possibly due to liberation of DNA during the clotting process”); Ex. 1035 (Hahn), 1577 (“The contamination of the plasma sample by maternal cells or cell remnants would, however, affect the apparent concentration of maternal DNA in the sample.”); Ex. 1036 (Chiu), 1612 (disclosing that blood processing protocols affect total DNA concentrations but not the amount of fetal DNA); Ex. 1056 ¶ 109. This, Petitioner contends, would have motivated a POSA consider Valli and the cell-stabilizing compositions allegedly described therein, for purposes of modifying Lo’s method. Pet. 48–50.

Petitioner contends that Valli assessed blood collection agents for their capacity to stabilize bovine leukocytes (WBCs) during transport of the blood samples. *Id.* at 48 (citing Ex. 1034, 252). Petitioner contends “the prior art discussed the ability of formalin to further reduce cell lysis in the presence of EDTA” and Petitioner cites Valli’s experiments. *Id.* at 48–51. According to Petitioner, Valli, for example, “tested two formalin-EDTA preparations (Titriplex I and IV) and ACD-formalin-ASA.” *Id.* at 51 (citing Ex. 1034, 253, 257, Table 1). Valli allegedly “concludes that formalin-

EDTA preparations tested [were] ‘greatly superior to EDTA without additives for maintaining the stability of leukocytes during transport.’” *Id.* (citing and quoting Ex. 1034, 257 (disclosing that “these preparations [(i.e., formalin-containing anticoagulants)] are deserving of a far wider utilization”); Ex. 1056 ¶ 114). Thus, Petitioner contends, a skilled artisan carrying out Lo’s method to isolate cell-free fetal DNA from maternal plasma in the presence of EDTA “would have been motivated to substitute a formalin-EDTA preparation, as suggested by Valli, to improve white-blood-cell stability (thereby reducing background cell-free maternal DNA resulting from cell lysis),” and would have done so with a reasonable expectation of success. Pet. 52 (citing, e.g., Ex. 1056 ¶¶ 107–115).

Patent Owner raises several counterarguments. First, Patent Owner argues that EDTA is not the claimed agent. Prelim. Resp. 33. We do not understand Petitioner’s position to be based on EDTA satisfying the agent limitation. Petitioner’s position is that a composition comprising EDTA *plus formalin* (formalin or formaldehyde identified as a preferred lysis inhibitor in the ’277 patent) meets the requirement of claim 55 of “an agent that inhibits lysis of cells.” Pet. 52; Ex. 1001, 89:1–34 (Example 4 (disclosing treatment of a blood sample with EDTA in combination with formaldehyde)).

Second, Patent Owner argues that a POSA would not have been motivated to combine Lo with Valli as argued by Petitioner. Prelim. Resp. 34–39. Patent Owner cites several reasons in support. *Id.* Patent Owner questions whether a POSA would have recognized the problem of maternal cell lysis in a blood sample as argued by Petitioner. Prelim. Resp. 34.

Indeed, Patent Owner contends, Lo “actually presents its methods as already solving potential problems caused by maternal cf DNA contamination.” *Id.* To be sure, Lo’s method is presented as an improvement for noninvasively isolating and analyzing fetal DNA from what came before it. *See, e.g.,* Ex. 1033, Abstr., 1:1–11. But we disagree with Patent Owner’s argument here because it incorrectly presumes that a skilled artisan would not seek to continue to improve upon Lo’s methods. Moreover, it does not account adequately for the other cited background art (e.g., Chiu and Hahn), which indicate that maternal cell lysis had been recognized as an issue and problem when preparing samples with the potential to undesirably increase free maternal and total DNA in the sample background.

Patent Owner also argues that a POSA would not have turned to Valli because Valli does not address the aforementioned lysis problem. Prelim. Resp. 36. According to Patent Owner, Valli describes WBC “stability,” not lysis or resulting DNA release. *Id.* Assuming the skilled artisan is, however, aware of the problem of maternal WDC lysis and sample contamination when carrying out methods like Lo’s as discussed above, the question is whether a POSA would consider Valli at least reasonably pertinent to that problem. At this stage, evidence suggests it is and a POSA would at least have considered Valli for purposes of mitigating lysis and contamination issues recognized elsewhere in the art.

Patent Owner continues, arguing that a POSA would not have modified Lo to include Valli’s anticoagulant compositions because Valli’s data and disclosures are inconclusive, inapplicable, and, in some ways just wrong. Prelim. Resp. 36–39. For example, Patent Owner contends that, in

some of Valli's assays, Valli reports that cell counts increased yet Valli fails to address possible confounding causes for that increase (e.g., cell division); in any event, Patent Owner contends Valli's data are not a reliable metric of cell lysis. *Id.* (citing Ex. 1034, 3). Patent Owner contends that Valli elsewhere offers conclusions about cell counts in certain media and conditions (ACD and EDTA, and under refrigeration) that are at odds with other references Valli cites. *Id.* at 36–37 (citing Ex. 2102, 1–2). Patent Owner contends that the variance reported for some of Valli's data is so high that a POSA would discount Valli, or not rely on it altogether. *Id.* at 37 (citing Ex. ¶¶ 177–178); Ex. 1034, 3 (Table II)). Furthermore, Patent Owner argues that Titriplex I and Titriplex IV *do not* include EDTA, contrary to what Valli teaches. *Id.* at 37–38 (citing, e.g., Ex. 2097, 32 (disclosing that Titriplex I is nitrilotriacetic acid (NTA)) and Titriplex IV is DCTA)); Ex. 1034, 254 (Table 1, indicating that the Titriplex I formulation includes, *inter alia*, EDTA, formalin, and methylene blue). Thus, Patent Owner contends, a POSA reading Valli would not know if Valli misunderstood the contents of Titriplex I and IV or incorrectly applied those trademarks to different solutions. Prelim. Resp. 38.

Based on the above alleged errors and inconsistencies in Valli, Patent Owner contends the POSA would not know whether Valli ever reported results of a test comparing formalin+EDTA against a solution of EDTA alone, which testing forms the crux of Petitioner's theory for modifying Lo. *Id.* at 39–40. According to Patent Owner, the POSA would, in any case, have been skeptical of Valli's disclosures and not have looked to Valli as informative. *Id.* at 38–39. Indeed, Patent Owner contends, this may well

explain why Valli's approach on which Petitioner relies was never adopted in the field since its publication in 1980—rather, researchers like Lo continued to use EDTA tubes. *Id.*

Patent Owner's criticisms of Valli's disclosures appear to have some merit. For example, Valli's teaching that Titriplex I includes EDTA is questionable, if not incorrect, based on Patent Owner's rebuttal evidence. *See, e.g.*, Ex. 2097, 32; Ex. 2099, 1; Ex. 2100, 1. The extent to which the alleged (or actual) errors or inconsistencies in Valli would detract from a POSA's reliance on Valli and undermine the rationale for combining with Lo is, however, a matter better resolved on a full evidentiary record. To preserve the argument, Patent Owner must raise it at trial, and Petitioner will have a chance to respond.

Patent Owner raises substantially the same criticisms about Valli's teachings in arguing that Petitioner has failed to show a reasonable expectation of success. Prelim. Resp. 39–41. Here too, we will make a final determination on this issue based on a full record. Patent Owner also cites to alleged skepticism from others in the field, including Dr. Lo, as undermining Petitioner's showing. *Id.* at 40–41 (citing Ex. 2007; Ex. 1054, 4). This argument has potential merit. Yet, at this point, it is not apparent that the alleged skepticism is about simply adding formaldehyde (whether it would, predictably, have been thought to produce any benefit), or whether it is specific to the results that the inventor, Dr. Dhallan, reportedly achieved with formaldehyde, which others indicated they could not reproduce in their experiments. Ex. 1054, 4.

Lastly, Patent Owner argues that Petitioner's challenge is based on hindsight. Prelim. Resp. 41–44. We do not, at this stage, agree. Petitioner has cited express disclosures in the prior art and evidence-based reasoning for combining the prior art as proposed. Patent Owner cites no disclosure relied upon by Petitioner that comes solely from the '277 patent. Patent Owner's assertions (*id.* at 42–43) about the invention satisfying a long-felt need, producing surprising results, or generating praise are better addressed as alleged objective indicia of non-obviousness. Repackaging those assertions as revealing “hindsight,” with no attempt from Patent Owner to establish an appropriate nexus between the evidence and the claims, is unavailing on this record in rebutting Petitioner's challenge.

Although Patent Owner has raised some potentially meritorious counterarguments to Petitioner's challenge to the claims over Lo and Valli, the record would benefit from further argument and evidence on such matters. We are, in any event, instituting trial on Petitioner's other grounds and must therefore include in trial all grounds raised in the Petition. *SAS*, 138 S. Ct. at 1354.

Petitioner challenges claim 95 based on the combination of Lo, Valli, and Marx. Pet. 65–66; Ex. 1056 ¶¶ 152–153. Petitioner's theory is based on the combination of Lo and Valli, as discussed above, with a further addition of no-brake centrifugation as in Marx (offering similar reasoning to adding Marx as in Ground 2, to avoid disturbance of the buffy coat). Pet. 65–66. Patent Owner does not present any argument on the combination of Lo, Valli, and Marx, separate from the argument about Lo and Valli, which we

addressed immediately above. Accordingly, Petitioner's challenge to claim 95 as unpatentable over Lo, Valli, and Marx is also included in trial.

IV. CONCLUSION

On this preliminary record, Petitioner has established a reasonable likelihood of prevailing in showing that at least one of the challenged claims is unpatentable based on grounds advanced in the Petition.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *granted*, and we institute *inter partes* review of claims 55–63, 66–69, 80–91, 94–96, 126–130, 132, and 133 based on the grounds asserted in this Petition;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is given of the institution of trial, which will commence on the entry date of this Decision.

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