

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FOUNDATION MEDICINE, INC.,
Petitioner,

v.

GUARDANT HEALTH, INC.,
Patent Owner.

Case IPR2019-00652
Patent 9,834,822 B2

Before SUSAN L. C. MITCHELL, TINA E. HULSE, and
KRISTI L. R. SAWERT, *Administrative Patent Judges*.

SAWERT, *Administrative Patent Judge*.

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

I. INTRODUCTION

Foundation Medicine, Inc. (“Petitioner”)¹ filed a Petition (Paper 2, “Pet.”) to institute an *inter partes* review of claims 1–13 and 17–20 of U.S. Patent No. 9,834,822 B2 (Ex. 1001, “the ’822 patent”). Guardant Health, Inc. (“Patent Owner”) timely filed a Preliminary Response (Paper 6, “Prelim. Resp.”). On our authorization (Paper 9), Petitioner filed a Reply (Paper 11, “Reply”) limited to issues raised by Patent Owner as to our discretion to institute under 35 U.S.C. § 314(a).

We have authority under § 314(a) to determine whether to institute an *inter partes* review. To institute an *inter partes* review, we must determine that the information presented in the Petition shows “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314(b) may not institute review on less than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018). Also, in accordance with USPTO Guidance, “if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition.” *See Guidance on the Impact of SAS on AIA Trial Proceedings* (April 26, 2018) (available at <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial>).

Applying those standards, and upon consideration of the information presented in the Petition, the Preliminary Response, and the Reply, and for

¹ Petitioner identifies Foundation Medicine, Inc., as well as Roche Holdings, Inc., Roche Finance Ltd, and Roche Holding Ltd, as real parties-in-interest. Pet. 73.

the reasons explained below, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one claim of the '822 patent is unpatentable. Accordingly, we institute an *inter partes* review of all challenged claims (1–13 and 17–20) of the '822 patent, based on the ground raised in the Petition.

II. BACKGROUND

A. *Related Proceedings*

Patent Owner has asserted the '822 patent against Petitioner in *Guardant Health, Inc. v. Foundation Medicine, Inc.*, Case No. 17-cv-1616-LPS-CJB (D. Del.). Pet. 74; Paper 4, 2–3. Patent Owner has also asserted the '822 patent against Personal Genome Diagnostics, Inc. (“PGDx”) in *Guardant Health, Inc. v. Personal Genome Diagnostics, Inc.*, Case No. 17-cv-1623-LPS-CJB (D. Del.). *Id.*

Petitioner has filed a petition seeking *inter partes* review of the '822 patent, designated IPR2019-00653. Paper 4, 2. Petitioner has also filed several petitions seeking *inter partes* review of patents related to the '822 patent, including: IPR2017-01170, IPR2017-01447, and IPR2017-01448 (challenging U.S. Patent No. 9,340,830); IPR2019-00130 (challenging U.S. Patent No. 9,598,731); IPR2019-00634 (challenging U.S. Patent No. 9,840,743); and IPR2019-00636 and IPR2019-00637 (challenging U.S. Patent No. 9,902,992). *Id.*

PGDx also filed petitions seeking post-grant review of the '822 patent, designated PGR2018-00058, and of U.S. Patent No. 9,840,743, designated PGR2018-00057. *Id.* Both petitions were dismissed before a decision on institution.

B. The '822 Patent (Ex. 1001)

The '822 patent involves a system and method for detecting rare mutations and copy number variations in cell free polynucleotides. Ex. 1001, Abstract. The '822 patent indicates that cell free DNA (“cfDNA”) found in different types of bodily fluids may be used to detect and monitor disease. *Id.* at 1:29–45. For instance, cfDNA may contain genetic aberrations—like a change in copy number variations and/or single or multiple sequence variations associated with a particular disease—that may be used to detect or monitor such disease. *Id.* at 1:29–45, 30:8–14.

The '822 patent states that this system and method generally “comprise[s] sample preparation, or the extraction and isolation of cell free polynucleotide sequence[s] from a bodily fluid; subsequent sequencing of cell free polynucleotides by techniques known in the art; and application of bioinformatics tools to detect rare mutations and copy number variations as compared to a reference.” *Id.* at 30:4–14. The '822 patent further describes two tools for detecting genetic variation in a sample of cfDNA with high sensitivity. *Id.* at 32:33–35. These tools are described as follows:

First, the efficient conversion of individual polynucleotides in a sample of initial genetic material into sequence-ready tagged parent polynucleotides [is done], so as to increase the probability that individual polynucleotides in a sample of initial genetic material will be represented in a sequence-ready sample. This can produce sequence information about more polynucleotides in the initial sample. Second, high yield generation of consensus sequences for tagged parent polynucleotides [is done] by high rate sampling of progeny polynucleotides amplified from the tagged parent polynucleotides, and collapsing of generated sequence reads into consensus sequences representing sequences of parent tagged polynucleotides. This can reduce noise introduced by amplification bias and/or sequencing errors, and

can increase sensitivity of detection. Collapsing is performed on a plurality of sequence reads, generated either from reads of amplified molecules, or multiple reads of a single molecule.

Id. at 32:36–53.

Parent polynucleotides as described above are tagged with barcodes that may be unique or non-unique. *Id.* at 37:44–49.

[T]he use of non[-]unique barcodes, in combination with sequence data at the beginning (start) and end (stop) portions of individual sequencing reads and sequencing read length may allow for the assignment of a unique identity to individual sequences. Similarly, fragments from a single strand of nucleic acid having been assigned a unique identity, may thereby permit subsequent identification of fragments from the parent strand.

Id. at 37:46–52.

C. Illustrative Claim

Claim 1 is the only independent claim. Claims 2–13 and 17–20 depend directly from claim 1. *See* Ex. 1001, 62:51–64:22. Claim 1 is illustrative and reproduced below:

1. A method, comprising:
 - a) providing a population of cell-free DNA (“cfDNA”) molecules obtained from a bodily sample from a subject;
 - b) converting the population of cfDNA molecules into a population of non-uniquely tagged parent polynucleotides, wherein each of the non-uniquely tagged parent polynucleotides comprises (i) a sequence from a cfDNA molecule of the population of cfDNA molecules, and (ii) an identifier sequence comprising one or more polynucleotide barcodes;
 - c) amplifying the population of non-uniquely tagged parent polynucleotides to produce a corresponding population of amplified progeny polynucleotides;
 - d) sequencing the population of amplified progeny polynucleotides to produce a set of sequence reads;

- e) mapping sequence reads of the set of sequence reads to one or more reference sequences from a human genome;
- f) grouping the sequence reads into families, each of the families comprising sequence reads comprising the same identifier sequence and having the same start and stop positions, whereby each of the families comprises sequence reads amplified from the same tagged parent polynucleotide;
- g) at each genetic locus of a plurality of genetic loci in the one or more reference sequences, collapsing sequence reads in each family to yield a base call for each family at the genetic locus;
- h) determining a frequency of one or more bases called at the locus from among the families.

Ex. 1001, 62:18–48.

D. The Prior Art

Petitioner advances the following references as prior art on which it relies for the asserted grounds challenging the claims of the '822 patent:

1. Michael Schmitt et al., U.S. Patent No. 9,752,188 B2 (Sept. 5, 2017) (Ex. 1011, “Schmitt”);
2. Michael W. Schmitt et al., *Detection of Ultra-rare Mutations by Next-generation Sequencing*, 109(36) PROC. NATL. ACAD. SCI. 14508–513 (2012) (Ex. 1047, “Schmitt 2012”);
3. H. Christina Fan et al., *Noninvasive diagnosis of fetal aneuploidy by shotgun sequencing DNA from maternal blood*, 105(42) PROC. NATL. ACAD. SCI. 16266–271 (2008) (Ex. 1048, “Fan”); and
4. Tim Forshew et al., *Noninvasive Identification and Monitoring of Cancer Mutations by Targeted Deep Sequencing of Plasma DNA*, 4(136) SCI. TRANSL MED. 1–34 (2012) (Ex. 1004, “Forshew”).

E. The Asserted Ground of Unpatentability

Petitioner challenges the patentability of the claims 1–13 and 17–20 of the '822 patent based on the following ground:

References	Basis	Claims challenged
Schmitt in view of Schmitt 2012, and further in view of Fan or Forshew	35 U.S.C. § 103	1–13 and 17–20

Petitioner further relies upon the declaration of Stacey Gabriel, Ph.D., to support its challenge. *See* Ex. 1002.

III. PATENTABILITY ANALYSIS

We organize our patentability analysis into four sections. First, we address the level of ordinary skill in the art. Second, we address claim construction. Third, we provide an overview of the asserted references. And fourth, taking account of the information presented, we consider whether the grounds asserted in the Petition meet the threshold showing for instituting an *inter partes* review under 35 U.S.C. § 314(a).

A. Level of Ordinary Skill in the Art

Relying on Dr. Gabriel’s declaration, Petitioner contends that a person of ordinary skill in the art for the '822 patent “would have had a Ph.D. in genetics, molecular biology, bioinformatics or a related field, and at least five years of research in an academic or industry setting, including at least two to three years of research experience in the field of cancer genomics.” Pet. 20 (citing Ex. 1002 ¶ 72). Petitioner further contends that an ordinarily skilled artisan “would have had knowledge of DNA sequencing, including NGS [next-generation sequencing] and related sequencing methods, and related sample preparation techniques, bioinformatics methods for grouping

and comparing sequence reads and mapping sequence reads onto genomes, and methods for identifying genetic variants in a sample.” *Id.*

Patent Owner does not propose a definition for the level of ordinary skill in the art in its Preliminary Response, or otherwise dispute Petitioner’s definition. *See generally* Prelim. Resp. Petitioner’s definition appears consistent with the level of ordinary skill in the art reflected in the prior art, and we will apply it for this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown” (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

B. 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).² 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.* Furthermore, at this stage in the proceeding,

² The Office has changed the claim construction standard to be applied in AIA proceedings to replace the broadest reasonable interpretation (“BRI”) standard with the same claim construction standard used in a civil action in federal district court. *Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51340 (Oct. 11, 2018). The change applies to petitions filed on or after November 13, 2018. *Id.* Because the present Petition was filed on February 1, 2019, we construe the claims in accordance with the federal district court standard, now codified at 37 C.F.R. § 42.100(b).

we need only construe the claims to the extent necessary to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e 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))).

Petitioner proposes constructions for the terms “barcode,” “non-uniquely tagged,” “parent polynucleotide,” “plurality of genetic loci,” and “selectively enriching.” Pet. 21. Patent Owner responds that “no term needs construction in order to deny the petition.” Prelim. Resp. 19. For this Decision, we determine that we need only construe the claim term “non-uniquely tagged.”

Claim 1 requires the generation of “non-uniquely tagged parent polynucleotides.” Ex. 1001, 62:22–24. Petitioner contends that “[t]he term ‘non-uniquely tagged’ means that ‘the number of different identifiers attached to the polynucleotides is at least 2 and fewer than the number of polynucleotides.’” Pet. 21 (citing Ex. 1002 ¶ 75). We agree.

As discussed above, the ’822 patent describes parent polynucleotides that are tagged with “unique” or “non-unique” identifiers. *See* Ex. 1001, 6:26–28 (stating that, in some embodiments, “each tagged parent polynucleotide in the set is uniquely tagged,” whereas in other embodiments, “the tags are non-unique”). In the context of “non-unique” identifiers, the ’822 patent follows the words “non-uniquely tagged” with “*that is*, the number of different identifiers can be at least 2 and fewer than the number of polynucleotides that map to the mappable base position.” Ex. 1001, 41:42–46 (emphasis added).

We read this description in the '822 patent as setting forth an express definition of “non-uniquely tagged.” Specifically, “that is” (or “i.e.”) “signals an intent to define the word to which it refers.” *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1334 (Fed. Cir. 2009). Here, by using the phrase “that is,” the '822 patent defines “non-uniquely tagged” as meaning that the number of different identifiers attached to the parent polynucleotides is at least 2, and the number of different identifiers is fewer than the number of parent polynucleotides. *See Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324, 1330 (Fed. Cir. 2003) (holding that a patentee “explicitly defined” a term by using “i.e.” followed by an explanatory phrase).

As to the latter portion of that definition, we further agree with Petitioner that, because the number of different identifiers is fewer than the number of parent polynucleotides, not every parent polynucleotide is tagged with a unique identifier. Pet. 11–12; Ex. 1001 ¶¶ 50–51. For example, in a population of 1000 parent polynucleotides and only 500 different identifiers, at least some parent polynucleotides will share the same identifier, and thus, the parent polynucleotides are “non-uniquely tagged.” Pet. 12; Ex. 1002 ¶ 51. Conversely, in a population of 1000 parent polynucleotides and 1000 different identifiers, each parent polynucleotide will have its own unique identifier, and thus, the parent polynucleotides are “uniquely tagged.” Pet. 11; Ex. 1002 ¶ 50.

C. The Prior Art

Before turning to Petitioner’s asserted grounds of unpatentability, we provide a brief summary of the asserted references.

1. *Schmitt (Ex. 1011)*

Schmitt relates to a method called Duplex Consensus Sequencing (“DCS”) that, according to Schmitt, greatly reduces sequencing errors by independently tagging and sequencing each of the two strands of a DNA duplex. Ex. 1011, Abstract. Because the two strands of DNA are complementary, true mutations can be found at the same position on both strands, as opposed to on a single strand if PCR or sequencing errors occur. *Id.*

According to Schmitt’s DCS method, sheared double-stranded DNA that has been end-repaired and T-tailed is combined with A-tailed single molecule identifier (SMI) adaptors and ligated. *Id.* at 3:44–47. In one embodiment, every adaptor contains a unique, double-stranded, complementary n-mer random tag on each end, such that every DNA fragment becomes labeled with two distinct SMI sequences. *Id.* at 3:47–53. The labeled DNA fragments are amplified by PCR, resulting in two types of PCR products, each with a distinct SMI sequence. *Id.* at 3:53–60.

For error correction through DCS, sequence reads sharing a unique set of SMI tags are grouped into paired families, each pair reflecting one double-stranded DNA fragment. *Id.* at 4:4–10. Mutations present in only one or a few family members, or mutations occurring in only one of the two strands represent sequencing mistakes or PCR-introduced errors. *Id.* at 4:10–18. True mutations are present on both strands and appear in all members of a family pair. *Id.* at 4:18–20.

2. *Schmitt 2012 (Ex. 1047)*

Schmitt 2012 also relates to the DCS method, and uses the same library preparation techniques and sequencing methods disclosed in Schmitt.

Ex. 1047, Abstract, 14509 (Fig. 1). Schmitt 2012 discloses a “data processing” workflow comprising the steps of filtering sequence reads, aligning reads to a reference genome, grouping reads containing identical tag sequences to form single-strand consensus sequence reads (“SSCS”), re-aligning reads to the reference genome, and identifying and comparing partner strands among SSCS reads compared to form DCS reads. *Id.* at 14513, SI1–SI2; *see also* Ex. 1002 ¶ 91.

3. *Fan (Ex. 1048)*

Fan relates to a method for diagnosing fetal aneuploidy by directly sequencing cell-free DNA from the plasma of pregnant women with high-throughput shotgun sequencing technology. Ex. 1048, Abstract. In doing so, Fan was able to measure the over- and under-representation of chromosomes from an aneuploidy fetus. *Id.*

4. *Forshew (Ex. 1004)*

Forshew relates to a method for identifying cancer mutations present in cell-free DNA using tagged-amplicon deep sequencing (“TAm-Seq”). Ex. 1004, Abstract. Tagged amplicon deep sequencing allows amplification and deep sequencing of genomic regions spanning thousands of bases. *Id.* at 1. Forshew applied the technique to both abundant and rare mutations in circulating DNA from blood plasma of ovarian and breast cancer patients. *Id.* at 1–2.

D. Obviousness Over Schmitt in View of Schmitt 2012, and Further in View of Fan or Forshew

Petitioner asserts that claims 1–13 and 17–20 of the ’822 patent are unpatentable as obvious over Schmitt, Schmitt 2012, and Fan or Forshew. Pet. 30–70. Specifically, Petitioner argues that the combination of prior-art

references teaches each limitation of the challenged claims. *Id.* at 41–70. Relying on Dr. Gabriel’s Declaration, Petitioner also argues that a person of ordinary skill in the art would have been motivated to combine the teachings of the references, and would have had a reasonable expectation of success. *Id.* at 32–41 (citing Ex. 1002 ¶¶ 99–106, 108–113, 115–120). Patent Owner opposes. Prelim. Resp. 22–40. Having considered the arguments and evidence before us, we find that the record establishes a reasonable likelihood that Petitioner would prevail on its asserted ground of obviousness over Schmitt, Schmitt 2012, and Fan or Forshew, for at least claim 1.

1. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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 said 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) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). “Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant’s disclosure.” *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

In that regard, an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for

a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418; *see also In re Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). In *KSR*, the Supreme Court also stated that an invention may be found obvious if trying a course of conduct would have been obvious to a person having ordinary skill:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

550 U.S. at 421. “*KSR* affirmed the logical inverse of this statement by stating that § 103 bars patentability unless ‘the improvement is more than the predictable use of prior art elements according to their established functions.’” *In re Kubin*, 561 F.3d 1351, 1359–60 (Fed. Cir. 2009) (citing *KSR*, 550 U.S. at 417).

We analyze the asserted grounds of unpatentability in accordance with the above-stated principles.

2. *Prior-Art Status of Schmitt*

As an initial matter, Patent Owner argues that the Petition should be denied because it fails to establish that Schmitt is prior art to the ’822 patent. Pet. 19–22. Schmitt was filed as Application No. 14/386,800 on September 20, 2014, and issued as U.S. Patent No. 9,752,188 B2 on September 5, 2017. Ex. 1011, (10), (86). Both of these dates are after the September 4, 2012, priority date of the ’822 patent. *See* Ex. 1001, (60) (claiming priority to

provisional application filed on September 4, 2012). Petitioner contends Schmitt is prior art under 35 U.S.C. § 102(a)(2) because it “claims the benefit of U.S. Provisional Application 61/613,413 filed on March 20, 2012.” Pet. 22 (citing Ex. 1012 (“the ’413 provisional”)). Petitioner contends that Schmitt “is entitled to claim a right of priority under 35 U.S.C. § 119 to the ’413 [p]rovisional” because the ’413 provisional “provides written description support and enablement of at least one claim in Schmitt, as identified in a table of the Gabriel Declaration.” Pet. 22 (citing Ex. 1002 ¶ 81).

In the Declaration, Dr. Gabriel states that she has “reviewed the Schmitt ’413 Provisional and compared it to the disclosure of Schmitt, and in my opinion, the Schmitt ’413 Provisional provides a written description of the invention in sufficient detail to have enabled a person of ordinary skill in the part to practice at least one of the claims set forth in Schmitt.” Ex. 1002 ¶ 81. Patent Owner argues that this showing is insufficient because “[a]rguments must not be incorporated by reference from one document into another document.” Prelim. Resp. 10 n.21 (quoting 37 C.F.R. § 42.6(a)(3)). Patent Owner also argues that Petitioner’s showing is insufficient because it “is simply not true.” Prelim. Resp. 20–21. In particular, Patent Owner points out that Figure 4 of Schmitt, upon which Petitioner relies in the Petition, is absent from in the ’413 provisional. *Id.* at 21–22 (citing Pet. 27, 43–44).

In *Dynamic Drinkware LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015), the Federal Circuit explained that “[f]or a patent to claim priority from the filing date of its provisional application, it must satisfy 35 U.S.C. § 119(e)(1).” “In other words, the specification of the

provisional must ‘contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms,’ 35 U.S.C. § 112 ¶ 1, to enable an ordinarily skilled artisan to practice the invention claimed in the nonprovisional application.” *Id.* (quoting *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002) (emphasis omitted)). Of particular note, the Federal Circuit explained that the burden of persuasion is always on Petitioner to prove unpatentability by a preponderance of the evidence, although the burden of production, which initially falls on Petitioner, may shift to Patent Owner under certain circumstances. *Id.* at 1378–79; *see Apple, Inc. v. OpenTV, Inc.*, Case IPR2015-00969, slip op. at 12–14 (PTAB Sept. 23, 2015) (Paper 8) (discussing the shift of the burden of production described in *Dynamic Drinkware*). In addition, the Federal Circuit required the petitioner in *Dynamic Drinkware* to “compare the claims of the Raymond patent to the disclosure in the Raymond provisional application” before finding that the Raymond patent, which the petitioner relied upon for its unpatentability challenge, was “entitled to claim the benefit of the filing date of its provisional application.” *Dynamic Drinkware*, 800 F.3d at 1381.

We have reviewed Dr. Gabriel’s Declaration and Petitioner’s arguments and, on this record, find that they are sufficient for making a threshold showing that at least one claim in Schmitt is entitled to the priority to the ’413 provisional. *See* Pet. 22–23; Ex. 1002 ¶ 81; *see also Medtronic, Inc. v. Niazi Licensing Corp.*, IPR2018-00609, slip op. at 9–11 (PTAB Aug. 20, 2018) (Paper 8) (explaining that a non-provisional application is entitled to the benefit of the provisional application’s filing date if the provisional application “support[s] just one claim” in the non-provisional). Although

Petitioner cites to Figure 4 of Schmitt, we do not find reliance on that figure necessary for Petitioner to establish a reasonable likelihood that it would prevail with respect to at least one challenged claim. The parties are invited to address this issue further during trial, to the extent necessary, taking into account the burden-shifting framework articulated in *Dynamic Drinkware*.

3. *The Claimed Limitations*

Taking claim 1 as illustrative, we are satisfied on this record that Petitioner establishes sufficiently for institution that the combination of Schmitt and Schmitt 2012, and Fan or Forshew, teaches each and every limitation of the claim. *See* Pet. 41–56.

a. Step (a) of claim 1

The first step of claim 1 recites “providing a population of cell-free DNA (“cfDNA”) molecules obtained from a bodily sample from a subject.” Ex. 1001, 62:19–21. We agree with Petitioner, on this record, that Fan and Forshew teach this limitation. Pet. 41–42. Fan describes extracting cfDNA from the plasma of pregnant women to detect fetal aneuploidy. *See* Ex. 1048, 16266 (“We directly sequenced cell-free DNA with high-throughput shotgun sequencing technology from plasma of pregnant women”), 16270 (stating that “DNA was extracted from cell-free plasma”). Specifically, Fan extracted between 1.2 and 8 ng of cfDNA from plasma samples ranging from 1.3 to 3.2 ml. *Id.* at SI7 (Table S1); *see also* Ex. 1002 ¶ 122. Similarly, Forshew describes extracting cfDNA from plasma samples to identify mutations in cancer patients. *See* Ex. 1004, 1 (stating that “[p]lasma of cancer patients contains cell-free tumor DNA”), 10 (stating that “[c]irculating DNA was extracted from between 0.85 and 2.2 ml of plasma”). As shown in Table S6, Forshew obtained amounts ranging from

0.9 to 19.7 ng of cfDNA from plasma samples of cancer patients. *Id.* at 32 (Table S6); *see also* Ex. 1002 ¶ 23.

b. Step (b) of claim 1

The first portion of step (b) recites “converting the population of cfDNA molecules into a population of non-uniquely tagged parent polynucleotides.” Ex. 1001, 62:22–24. Schmitt teaches that, in the DCS method, SMI adaptors comprising a “sequence (or ‘tag’) of nucleotides” are ligated to the ends of parent polynucleotides. Ex. 1011, 6:46–51. Schmitt also refers to the sequences of the SMI adaptors as “n-mer” sequences. *Id.* at 6:46–66.

The parties dispute whether Schmitt teaches that those parent polynucleotides are “non-uniquely tagged.” In particular, Petitioner contends that Schmitt discloses both “uniquely tagged” and “non-uniquely tagged” parent polynucleotides, Pet. 42–46, whereas Patent Owner contends that Schmitt fails to disclose “non-uniquely tagged” parent polynucleotides as claimed, Prelim. Resp. 23–32. Having reviewed the record, we are satisfied that Petitioner establishes sufficiently for institution that Schmitt discloses “non-uniquely tagged” parent polynucleotides.

As explained above, we construe “non-uniquely tagged” to mean that the number of different identifiers attached to the parent polynucleotides is at least 2, and the number of different identifiers is fewer than the number of parent polynucleotides. *Supra* § III.B. Schmitt discloses a “hybrid method” of tagging parent polynucleotides that uses “a combination of sheared ends and a shorter n-mer tag (such as 1 or 2 or 3 or 4 or more degenerate or semi-degenerate bases) in the adaptor.” Ex. 1011, 9:9–11 (emphasis added); *see also* Pet. 43–46; Ex. 1002 ¶¶ 126–127. We understand that the n-mer tag

used in the hybrid method is not “unique” for each parent polynucleotide—i.e., the number of different n-mer tags is fewer than the number of parent polynucleotides—because Schmitt explicitly distinguishes the n-mer from an SMI (or single molecular identifier) tag. *See* Ex. 1011, 9:1–4 (stating that the DCS method “does *not strictly require the use of an SMI tag*, as the sheared ends can be used as identifiers to differentiate unique individuals molecules from PCR duplicates” (emphasis added)).

On this record, we are not persuaded by Patent Owner’s arguments to the contrary. *See* Prelim. Resp. 23–32. Although we agree with Patent Owner that the disclosure of Schmitt is directed, in the main, to the use of *unique* identifiers, *see* Prelim. Resp. 24–28, Schmitt’s disclosure does not appear, at least on this record, to be limited to unique identifiers.³ Indeed, Schmitt states that, in the hybrid approach, only the *combination* of the sheared ends and the short n-mer tag that “serve[s] as [a] *unique* molecular identifier[],” Ex. 1011, 9:12–13 (emphasis added), thus suggesting that the short n-mer tag itself is not unique for each parent polynucleotide. Put differently, in the hybrid approach, more than one parent polynucleotide will share the same short n-mer tag, but the tagged parent polynucleotides are nevertheless uniquely identifiable based on the additional information provided by the sheared ends. *See* Pet. 11–12; Ex. 1002 ¶¶ 51–53.

³ Patent Owner appears to suggest that Petitioner’s arguments are not credible because, in IPR2019-00130, Petitioner repeatedly characterized the Schmitt references as using unique tags. Prelim. Resp. 24–26 (citing Ex. 2004, 42, 44, 52, 54, 60). Schmitt is prior art for all that it teaches. *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1378 (Fed. Cir. 2013). Thus, we cannot ignore Schmitt’s disclosure of an embodiment using non-unique, short n-mer tags.

We also understand from Dr. Gabriel’s currently unrebutted testimony that n-mer tag is “non-unique,” because, for example, a 4-mer yields 4^4 , or 256, different tag sequences, which when ligated at both ends of a parent polynucleotide, yield 256^2 , or 65,536 different or “unique” identifiers. Ex. 1002 ¶ 127 & n.7; Pet. 44–45. This number of unique identifiers is less than the number of parent polynucleotides that would result from a selection of parent polynucleotides ranging from 200 to 500 base pairs. *Id.* Although we acknowledge Patent Owner’s argument that Dr. Gabriel’s testimony presents “a contrived scenario based on a series of unsubstantiated assumptions and illogical mathematical calculations,” Prelim. Resp. 29–32, this argument at most raises a disputed issue of fact best resolved following trial with the benefit of a full record.

Finally, we also acknowledge that Schmitt expressly describes the hybrid approach as providing a “*unique* molecular identifier.” Ex. 1011, 9:12–13 (emphasis added); *see also* Prelim. Resp. 28 (stating that “the hybrid approach [is] expressly described as producing ‘*unique molecular identifiers*.’”). Even so, it appears to us that the parent polynucleotide, once ligated to the short n-mer tag, nevertheless remains—in substance—a “non-uniquely tagged” parent polynucleotide, as that phrase is used in claim 1. *See* Pet. 44–45; *see also* Ex. 1002 ¶¶ 126–127. This understanding appears to be consistent with the ’822 patent’s explanation that “non-uniquely tagged” polynucleotides can nevertheless be uniquely identifiable:

[A] plurality of barcodes may be used such that *barcodes are not necessarily unique to one another* in the plurality. In this example, the barcodes may be ligated to individual molecules such that the *combination of the bar code and the sequence it may be ligated to creates a unique sequence that may be individually tracked*. As described herein, detecting of

non[-]unique barcodes in combination with sequence data of beginning (start) and end (stop) portions of sequence reads may *allow assignment of a unique identity to a particular molecule.*

Ex. 1001, 39:13–22 (emphases added); *see also* Pet. 45–46; Ex. 1002 ¶ 130. Moreover, although claim 1 recites that the parent polynucleotides are “non-uniquely tagged,” the parent polynucleotides are nevertheless uniquely identifiable because their amplified copies are grouped into families, “whereby each of the families comprises sequence reads amplified from the same tagged parent polynucleotide.” Ex. 1001, 62:40–42. It is unclear, at least on this record, how the approach set forth in claim 1 differs from that taught by Schmitt.

The second portion of step (b) provides that “each of the non-uniquely tagged parent polynucleotides comprises (i) a sequence from a cfDNA molecule of the population of cfDNA molecules, and (ii) an identifier sequence comprising one or more polynucleotide barcodes.” Ex. 1001, 62:24–28. We agree with Petitioner, on this record, that Schmitt teaches this limitation. Pet. 45. For example, Schmitt describes embodiments (a–c) in Figure 3, in which sequence reads are derived from parent polynucleotides comprising both a “strand identifier” and a sequence derived from the parent DNA molecule. Ex. 1011, 4:4–54; *see also* Ex. 1002 ¶ 129.

c. Steps (c) through (h) of claim 1

Turning to the remaining limitations of claim 1, we have reviewed Petitioner’s contentions and supporting evidence about steps (c) through (h) of the claimed method, and find them sufficient based on the current record. *See* Pet. 47–56. In particular, we agree with Petitioner’s contentions that Schmitt, either alone or in combination with Schmitt 2012, discloses:

- amplifying the tagged polynucleotides and sequencing the amplified progeny (steps (c) and (d) of claim 1), *see* Pet. 47; Ex. 1011, 3:10–20 (disclosing “amplifying the double-stranded SMI-target nucleic acid complex, resulting in a set of amplified SMI-target nucleic acid products; and sequencing the amplified SMI-target nucleic acid products”); *see also id.* at 21:55–57; Ex. 1002 ¶¶ 132–133;
- mapping the sequence reads to a reference sequence (step (e) of claim 1), *see* Pet. 47–49; Ex. 1011, 20:39–64 (teaching aligning sequence reads “to the human genome with the Burrows Wheeler Aligner (BWA)”); *id.* at 23:10–14, 24:33–37; Ex. 1047, SI1 (“Reads were then aligned to the reference genome with the Burrows Wheeler aligner (BWA) and nonmapping reads were discarded. . . . Reads sharing identical tag sequences were then grouped together and collapsed to consensus reads.”); *see also* Ex. 1002 ¶¶ 134–137, 139;
- grouping the sequence reads into families (step (f) of claim 1), *see* Pet. 40–51; Ex. 1011, 4:9–10, 9:9–14, 17:61–18:2, 20:39–64, 21:55–61; *see also* Ex. 1002 ¶¶ 140–144;
- collapsing sequence reads in each family to yield a “base call” (step (g) of claim 1), *see* Pet. 51–55; Ex. 1011, 4:20–29, 4:55–66, 18:44–61, 20:50–56; 22:50–53, 23:19–22, 23:61–24:1, 25:20–30, Figures 3 and 5C; *see also* Ex. 1002 ¶¶ 145–152; and
- determining the frequency of bases called at the locus from among the families (step (h) of claim 1), *see* Pet. 55–56; Ex. 1011, 4:25–29, Figure 3; *see also* Ex. 1002 ¶¶ 154–155.

d. Summary

For all the above reasons, and on this record, we are satisfied that Petitioner establishes sufficiently for institution that the combination of Schmitt and Schmitt 2012, and Fan or Forshew, satisfies each and every limitation of claim 1. We have reviewed Petitioner’s contentions and supporting evidence regarding claims 2–13 and 17–20 as well, and find them sufficient based on the current record. *See* Pet. 57–70. Patent Owner does not present separate arguments for any of the dependent claims. *See generally* Prelim. Resp.

4. Motivation to Combine/Reasonable Expectation of Success

Even “[i]f all elements of the claims are found in a combination of prior art references,” “the factfinder should further consider whether a person of ordinary skill in the art would [have been] motivated to combine those references, and whether in making that combination, a person of ordinary skill would have [had] a reasonable expectation of success.” *Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 833 (Fed. Cir. 2015). The “motivation to combine” and “reasonable expectation of success” factors are subsidiary requirements for obviousness subsumed within the *Graham* factors. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). Relying on Dr. Gabriel’s Declaration, Petitioner contends that an ordinarily skilled artisan would have had a reason to combine the teachings of the Schmitt references with either Fan or Forshew, with a reasonable expectation of success. Pet. 32–41.

Petitioner contends that an ordinarily skilled artisan, at the time of the ’822 patent, would have been prompted to combine “the teachings of Schmitt and Schmitt 2012 regarding the DCS method” with “the teachings

of either Fan or Forshew regarding sequencing and analysis of cell free DNA.” Pet. 37 (citing Ex. 1002 ¶ 111). Petitioner contends that Schmitt “provides explicit motivation to combine” with the teachings of Fan, because Schmitt cites to Fan when discussing “deep sequencing”—i.e., the use of massively parallel sequencing to detect minor variants within heterogeneous mixtures. Pet. 32 (citing Ex. 1011, 1:28–55; Ex. 1002 ¶ 99).

Petitioner also contends that the ordinarily skilled artisan would have understood that genetic mutations in cfDNA occur at low frequencies compared to wild-type DNA, and thus represent only a minute portion of the heterogeneous mixture of DNA in circulation. According to Petitioner, the skilled artisan, wishing to detect genetic mutations in cfDNA “with accuracy and sensitivity,” would have looked to Schmitt for its disclosure of an improved next-generation sequencing technique (i.e., duplex consensus sequencing or DCS) that reduces “sequencing artifacts” and detects genetic variation “with high sensitivity.” Ex. 1001, 31:60–32:52; Ex. 1002 ¶ 104. Indeed, Petitioner contends, “Schmitt states that next-generation deep sequencing has been implemented in a variety of fields, including clinical applications such as prenatal screening for fetal aneuploidy and early detection of cancer.” Pet. 34 (citing Ex. 1011, 1:28–55).

Having considered the arguments and evidence before us, we are satisfied on this record that Petitioner has shown sufficiently for institution that an ordinarily skilled artisan would have had a reason to combine the disclosures of the Schmitt references with Fan or Forshew; that is, to use Schmitt’s DCS method to detect low-frequency genetic mutations in cfDNA, with a reasonable expectation of success. Pet. 36–37. Specifically, we agree with Petitioner that Schmitt suggests applying the DCS method to “prenatal

screening for fetal aneuploidy.” Pet. 36 (citing Ex. 1011, 1:42–43). An ordinarily skilled artisan screening for fetal aneuploidy, as described by Fan, Ex. 1048, Abstract, 16266, would have been prompted to look to Schmitt’s improved DCS method to reduce amplification and sequencing errors, and to improve detection of rare genetic mutations, Pet. 36–37. *See also, e.g.*, Ex. 1011, 2:56–62 (stating that DCS “allow[s] rare variants . . . to be detected with unprecedented sensitivity”); *id.* at 2:56–62 (stating that DCS “greatly reduces errors” from PCR or sequencing); Ex. 1002 ¶¶ 103–108. We further agree with Petitioner an ordinarily skilled artisan screening for cell-free tumor DNA, as described by Forshew, Ex. 1004, Abstract, 1–2, would have also looked to Schmitt’s improved DCS method for the same reasons, Pet. 37. *See* Ex. 1011, Abstract, 1:28–5; Ex. 1002 ¶¶ 109–110.

Although we acknowledge Patent Owner’s arguments to the contrary, we are not persuaded on this record. *See* Prelim. Resp. 32–40. For example, Patent Owner argues that Schmitt is directed to the analysis of cellular DNA, and discloses nothing about the application of DCS for prenatal screening for fetal aneuploidy. *Id.* at 32–39. We do not read the disclosure of Schmitt so narrowly on this record. Schmitt teaches that “deep sequencing” has been used “in a variety of fields,” including in “prenatal screening for fetal aneuploidy” and in “early detection of cancer.” Ex. 1011, 1:38–45. Schmitt further teaches that deep sequencing “has limitations” resulting from amplification and sequencing errors. *Id.* at 1:56–2:6. Schmitt also teaches that its disclosed DCS method (which includes the “hybrid” embodiment discussed above) “reduces or eliminates” the problems associated with the prior art. Thus, although Patent Owner is correct that Schmitt does not expressly recite “cfDNA,” it is our view on this record that an ordinarily

skilled artisan reading Schmitt would have understood that Schmitt’s DCS method was a reasonable substitute for the deep sequencing techniques used in the prior art—such as those techniques Fan and Forshew used for prenatal cfDNA screening and for tumor cfDNA screening, respectively.

We are also not persuaded, on this record, by Patent Owner’s argument that the technical difficulties associated with cfDNA would have discouraged an ordinarily skilled artisan from using Schmitt’s DCS method to analyze cfDNA. Prelim. Resp. 34–40. For example, Patent Owner argues that “part of the innovation” of the ’822 patent is its disclosure of “methods for high-efficiency conversion of cell-free DNA into tagged parent polynucleotides.” *Id.* at 35 (citing Ex. 1001, 33:1–10, 36:36–61). Patent Owner argues that, because Schmitt does not teach such a high-efficiency conversion, the ordinarily skilled artisan would not have had a reasonable expectation of success in achieving that feature of the invention. *Id.* But “[t]he reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the *limitations of the claimed invention.*” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (emphasis added). And here, “high-efficiency conversion” is not recited in claim 1 of the ’822 patent. *See* Ex. 1001, 62:17–48.⁴ Patent Owner’s argument, therefore, is not persuasive.

We have considered Patent Owner’s other arguments, and find that they raise disputed issues of fact about whether an ordinarily skilled artisan would have been led away from analyzing cfDNA for genetic mutations

⁴ In contrast, claim 1 of U.S. Patent 9,902,992 B2, at issue in related proceedings IPR2019-00636 and IPR2019-00637, expressly recites “tag[ging] at least 20% of the cfDNA molecules.”

using Schmitt’s DCS method, based on the teachings of other prior-art references. Again, we conclude that this issue is best resolved following trial with the benefit of a full record.

5. Summary

In sum, we are satisfied that Petitioner establishes a reasonable likelihood that it would prevail in showing that claim 1 is unpatentable as obvious over the combination of Schmitt, Schmitt 2012, and Fan or Forshew. In light of *SAS* and USPTO Guidance, we also institute an *inter partes* review of dependent claims 2–13 and 17–20 on the same ground.

IV. 35 U.S.C. § 314(a) ANALYSIS

Patent Owner argues that we should exercise discretion under 35 U.S.C. § 314(a) to deny the Petition. Prelim. Resp. 3–16. Petitioner disagrees. *See generally* Reply. Section 314(a) does not require the Director to institute an *inter partes* review. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.”). Rather, a decision whether to institute is within the Director’s discretion, and that discretion has been delegated to the Board. *See* 37 C.F.R. § 42.4(a); *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.”).

In *General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, Case IPR2016-01357 (PTAB Sept. 6, 2017) (Paper 19) (precedential as to Section II.B.4.i) (“*General Plastic*”), the Board articulated a non-exhaustive list of factors to consider in evaluating whether to exercise discretion under § 314(a) to deny a petition that challenges a patent that was previously

challenged before the Board. *See also* Office Patent Trial Practice Guide Update (available at https://www.uspto.gov/sites/default/files/documents/2018_Revised_Trial_Practice_Guide.pdf) (“TPGU”) at 9–11 (stating that the Board will consider the *General Plastic* factors when determining whether to institute a trial). These factors are:

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 filings of 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.

Gen. Plastic, slip op. at 9–10; see also TPGU at 9–10. These factors are “a non-exhaustive list” and “additional factors may arise in other cases for consideration, where appropriate.” *Gen. Plastic*, slip op. at 16, 18; see also TPGU at 10 (stating that “[t]he *General Plastic* factors are also not

exclusive” and that “[t]here may be other reasons” that “favor[] denying a petition”).

A. Whether the Same Petitioner Previously Filed a Petition Directed to the Same Claims of the Same Patent

As Patent Owner points out, the claims of the '822 patent were previously challenged in PGR2018-00057 by petitioner PGDx. Prelim. Resp. 6. Before Patent Owner filed its preliminary response in that case, the Board granted, with prejudice, PGDx's motion to terminate. *Id.* at 5 (citing PGR2018-00058, Paper 9 at 2).

According to Patent Owner, PGDx and Petitioner “are co-defendants in the same co-pending litigation, where both are accused of infringing the subject '822 patent.” *Id.* at 6. Patent Owner suggests that Petitioner and PGDx have “coordinated efforts⁵ in seeking dismissal of the previously filed PGR with an understanding that the same challenges would be repackaged here to better accommodate identified defects in the PGR petition.” *Id.* Relying on *Valve Corp. v. Electronic Scripting Products, Inc.*, Case IPR2019-00062, slip op. at 9–10 (PTAB April 2, 2019) (Paper 11) (precedential), Patent Owner contends that “the complete overlap in the challenged claims” between this Petition and PGDx's petition, as well as “the significant relationship between” Petitioner and PGDx “favor denying institution.” Prelim Resp. 10–11.

Petitioner responds that the first *General Plastic* factor weighs heavily against denying the Petition, because Petitioner has not previously filed a

⁵ Specifically, Patent Owner contends that, should this Petition be granted and trial instituted, “reasonably tailored discovery and briefing” will be needed to address “the extent to which Petitioner and PGDx” have acted in concert. Prelim. Resp. 6.

challenge to the '822 patent. Reply 3. Petitioner also contends that Patent Owner has failed to provide any evidence that PGDx and Petitioner are related or acting in concert, and further contends that the facts of this case are distinguishable from those in *Valve*. *Id.* at 4–7.

Having considered respective arguments and evidence of the parties, we determine that the first *General Plastic* factor does not weigh in favor of denial. In particular, we find that the arguments and evidence before us do not support a reasonable inference that PGDx and Petitioner are coordinating their activities before the Office. Indeed, to the extent PGDx and Petitioner are coordinating their activities in the underlying district court litigations, such coordination appears to have been mandated by the Scheduling Orders in their respective district-court litigations. *See* Ex. 2010 (requiring the parties make simultaneous submissions to the court); *see also* Reply 2 n.3 (stating that, “over their objections, the [District] Court required [Petitioner] and PGDx to participate jointly in certain pre-trial activities”).

We also agree with Petitioner that the facts of this case are distinguishable from those in *Valve*. In *Valve*, the Board found that the first *General Plastic* factor weighed against institution because the petitioner’s licensee had previously filed a petition for *inter partes* review challenging the same claims of the same patent. Slip op. at 10–11. Here, however, Petitioner represents that it and PGDx “are competitors who market different cancer diagnostic assays.” Reply 4–5. We agree with Petitioner that it and PGDx, as competitors, do not share a “significant relationship” similar to that of the licensor and licensee in *Valve*.

B. 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

Patent Owner contends that the second *General Plastic* factor weighs in favor of denial because both Petitioner and PGDx knew of, or should have known of, the prior art relied upon by Petitioner in this Petition. Prelim. Resp. 12. In this regard, Patent Owner points out that both Schmitt 2012 and Forshew were previously asserted in PGR2018-00057, and contends that Petitioner, at a minimum, should have known of Fan because that reference is cited in Schmitt. *Id.*

Petitioner responds that Patent Owner provides no persuasive evidence showing that Petitioner was aware of the references at the time PGDx filed its petition. Reply 7. Petitioner also contends that, in any event, “whether PGDx knew of the art subsequently cited in Petitioner’s Petition is irrelevant because PGDx and Petitioner never communicated about the Petition.” *Id.* at 7–8.

Having considered respective arguments and evidence of the parties, we determine that the second *General Plastic* factor does not weigh in favor of denial. As discussed above, Patent Owner’s arguments and evidence do not support a reasonable inference that Petitioner and PGDx are acting in concert, or that Petitioner was aware of PGDx’s prior petition before it was filed. *See* Reply 7 n.8. Thus, we agree with Petitioner that whether Petitioner knew of, or should have known of, the prior art relied upon in this Petition at the time PGDx filed its petition is not relevant.

C. 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 to the third *General Plastic* factor, Patent Owner acknowledges that no preliminary response was filed in PGR2018-00057. But, Patent Owner contends, this *General Plastic* factor nevertheless weighs in favor of denial because “[f]ollowing discussions with Patent Owner regarding its positions, PGDx moved to dismiss . . . on the eve of the due date for filing [the] Patent Owner Preliminary Response[.]” Prelim. Resp. 12–13. In response, Petitioner contends that “[b]ecause PGDx withdrew its PGR petition[] before Patent Owner filed a preliminary response, this factor weighs in favor of institution.” Reply 8.

We agree with Petitioner. The third *General Plastic* factor is designed to prevent a challenger from using Patent Owner's Preliminary Response as a guide for formulating a subsequent challenge. *See Toyota Motor Corp. v. Cellport Sys., Inc.*, Case IPR2015-01423, slip op. at 8 (PTAB Oct. 28, 2015) (Paper 7) (“[T]he opportunity to read Patent Owner's Preliminary Response in IPR2015-00634, prior to filing the Petition here, is unjust.”). Here, Petitioner had no such opportunity because the proceeding was terminated before Patent Owner filed a preliminary response. Moreover, although Patent Owner represents that “Patent Owner engaged in discussions with PGDx regarding the pending PGR and spent considerable resources preparing the preliminary response,” Prelim. Resp. 12, Patent Owner presents no evidence that Petitioner had knowledge of those discussions.

D. 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; Whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent

Patent Owner contends that the fourth and fifth *General Plastic* factors weigh in favor of denial, because “the currently asserted art was known or should have been known to Petitioner at least as of the March 26th, 2018[,] filing date” of PGDx’s petition, but Petitioner waited roughly 10 months before filing its own Petition on February 1, 2019. Prelim. Resp. 14. Patent Owner contends that “there is no reason why [Petitioner] could not have” filed its Petition “contemporaneous with the filing[] of its co-defendant.” *Id.* Contemporaneous filings, Patent Owner contends, would have “better mitigat[ed] prejudice and harassment of the Patent Owner, as well as the inefficient drain on Board resources.” *Id.* In response, Petitioner contends that these factors do not weigh in favor of denial, because its Petition in this proceeding was filed within the one-year statutory period of 35 U.S.C. § 315(b). Reply 8–9.

We agree with Petitioner that these factors do not weigh in favor of exercising our discretion to deny institution. Even if Petitioner could have filed its Petition earlier, “we have no reason to believe, on this record, that Petitioner *delayed* by filing when it did, or that Petitioner gained any particular advantage by filing when it did.” *Samsung Elecs Co. v. Immersion Corp.*, Case IPR2018-01499, slip op. at 20–21 (PTAB Mar. 6, 2019) (Paper 11). Here, although Patent Owner alleges harassment and waste, Patent Owner has not pointed to any particular advantage enjoyed by Petitioner by its alleged delay.

E. The finite resources of the Board; 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

Patent Owner contends that the sixth and seventh *General Plastic* factors weigh in favor of denial because the patentability issues here are also at issue in the underlying district-court litigations—the first of which is scheduled for trial in May 2020. Prelim. Resp. 15. Patent Owner contends that this trial date is several months before a final written decision would issue in this case. *Id.* Relying on *NHK Spring Co. v. Intri-Plex Techs., Inc.*, Case IPR2018-00752, slip op. at 20 (PTAB Sept. 12, 2018) (Paper 8) (precedential), Patent Owner contends that “it is an inefficient use of resources to evaluate the same art and arguments when these same issues will be decided by the district court before the conclusion of any *inter partes* review.” Prelim. Resp. 15. In response, Petitioner contends that the existence of a pending district-court litigation does not necessarily weigh against institution, especially where, as here, Petitioner has not filed any previous petition challenging the same claims of the ’822 patent. Reply 9–10. Having considered the arguments and evidence advanced by the parties, we determine that the sixth and seventh *General Plastic* factors do not weigh in favor of denying institution.

“[T]he intent of the [sixth] factor . . . is to conserve *Board* resources from repeat or multiple staggered petitions challenging the same claims of the same patent before the Board.” *Samsung*, slip op. at 17. The present proceeding is not part of a series of multiple, staggered proceedings, but rather is only one of two challenges to the ’822 patent that Petitioner filed (and the only successful challenge). The Board terminated PDGx’s petition

challenging the '822 patent before the Board issued a decision on institution.
Reply 10.

Moreover, we acknowledge Patent Owner's representation that the underlying district-court litigations involve the same issues raised in the Petition, but we also observe that the start date for the first district-court litigation is over eight months in the future, thus calling into doubt Patent Owner's assertion that those issues will be resolved before a trial on the Petition concludes.

F. Weighing the Factors

For the reasons discussed above, we determine that all the factors in this particular case do not weigh in favor of exercising our discretion under 35 U.S.C. § 314(a). Therefore, we decline Patent Owner's request to deny the Petition under 35 U.S.C. § 314(a).

V. CONCLUSION

After considering the arguments presented in the Petition, the Preliminary Response, and the Reply, as well as the evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one claim of the '822 patent is unpatentable. Thus, in accordance with USPTO Guidance and *SAS*, we institute an *inter partes* review of all the challenged claims on the ground set forth in the Petition. Our determinations at this stage of the proceeding are based on the evidentiary record currently before us. This decision to institute trial is not a final decision as to patentability of any claim for which we have instituted an *inter partes* review. We will base any final decision on the full record developed during trial.

VI. ORDER

Accordingly, it is:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–13 and 17–20 of U.S. Patent No. 9,834,822 B2 is instituted with respect to the ground set forth in the Petition;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, an *inter partes* review of the '822 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

Case IPR2019-00652

Patent 9,834,822 B2

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