

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HANGSEN INTERNATIONAL GROUP LTD.,

Petitioner,

v.

ZANOPRIMA LIFESCIENCES, LTD.,

Patent Owner.

Case IPR2023-00503
Patent 10,913,962

PATENT OWNER'S PRELIMINARY RESPONSE

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PATENT OWNER'S EXHIBIT LIST

<u>No.</u>	<u>Description</u>
2001	Claim Construction Order, <i>Zanoprima v. Hangsen</i> , No. 6:22-cv-00268-ADA, Dkt 54 (W.D. Tex. Feb. 2, 2023)
2002	Amended Scheduling Order, <i>Zanoprima v. Hangsen</i> , No. 6:22-cv-00268-ADA, Dkt 52 (W.D. Tex. Dec. 16, 2022)
2003	Texas Western District—Time to Milestones, DocketNavigator, https://search.docketnavigator.com/patent/court/225/14 (last visited May 6, 2023)
2004	Judge Alan D. Albright—Time to Milestones, DocketNavigator, https://search.docketnavigator.com/patent/judge/16961/15 (last visited May 6, 2023)
2005	Hangsen International Group Ltd's Final Invalidity Contentions, <i>Zanoprima v. Hangsen</i> , No. 6:22-cv-00268-ADA (W.D. Tex. Mar. 21, 2023)

Patent Owner Zanoprima Lifesciences Ltd. (“Zanoprima” or “Patent Owner”) respectfully requests that the Board decline to initiate *inter partes* review of claims 1–14 (the “Challenged Claims”) of U.S. Patent No. 10,913,962 (the “’962 Patent”) as requested by Petitioner Hangsen International Group Ltd. (“Hangsen” or “Petitioner”).

I. INTRODUCTION

The ’962 Patent claims a novel, stereoselective route of synthesis for producing (S)-nicotine that includes (1) reducing myosmine with an enzyme with imine reductase activity to form (S)-nornicotine, and (2) methylating the (S)-nornicotine to form (S)-nicotine. This two-step route of synthesis results in (S)-nicotine with high chemical and enantiomeric purity, which is greatly desired by the pharmaceutical and tobacco replacement industries.

In its considered judgment to grant the ’962 Patent, the U.S. Patent Office recognized the advance that the ’962 Patent signifies in the synthesis of (S)-nicotine with high enantiomeric and chemical purity. Several patent offices around the world, including Korea, Canada, EPO, Japan, India, Australia, and Denmark, have also granted Patent Owner’s patent applications directed to the same novel and non-obvious process, and several more jurisdictions are reviewing similar applications. Presumably, Petitioner’s parent company also found the idea novel, having submitted its own patent application in China, Korea, and the U.S. claiming the same

route of synthesis two years after the effective filing date of the '962 Patent and six months after the application for the '962 Patent published.¹

Nonetheless, Petitioner now argues Patent Owner's claimed route of synthesis would have been obvious. Cognizant of the complete lack of prior art references that disclose the claimed stereoselective reduction of mysomine to (S)-nornicotine using an imine reductase, Petitioner instead relies primarily on a reference that discloses the non-stereoselective reduction of myosmine, and then provides conclusory and unsupported arguments regarding prior art references that vaguely describe commercial services for screening imine reductases with certain imines, none of which are myosmine. Petitioner's combinations are transparent efforts to use hindsight knowledge of the '962 Patent to selectively combine components from the prior art to fit claim elements. Yet, even then, none of the Grounds in the Petition satisfies Petitioner's burden to show a reasonable likelihood that any of the '962 Patent claims are invalid.

The Board should also exercise its discretion to deny institution because all of the *Fintiv* factors weigh in favor of denial and Petitioner's challenges are not compelling. Petitioner has not moved to stay the District Court proceedings and

¹ The '962 Patent was effectively filed on November 16, 2018 and published on May 21, 2020. The Chinese application CN112409327A was filed on November 18, 2020. The U.S. and Korean applications, US20220154231 and KR20220068130A, were filed on July 20, 2021 and August 26, 2021, respectively.

there is no evidence that the Court will grant a stay. Trial is scheduled to occur 6 months before Board will likely issue a final written decision and the Court has already engaged in claim construction, the parties have shared final invalidity and infringement contentions, and the parties have been heavily engaged in fact discovery for months. Petitioner is advancing the same invalidity arguments for the same claims using the same prior art in both proceedings. As such, a holistic analysis of *Fintiv* factors 1–5 strongly favors denial. Moreover, as discussed in detail below, Petitioner’s arguments and evidence fall far short of a “compelling, meritorious challenge.”

II. OVERVIEW OF THE ’962 PATENT

The ’962 Patent recognizes that “there is considerable demand for nicotine products,” specifically for (S)-nicotine with high enantiomeric and chemical purity. *See* ’962 Patent at 1:13–15, 1:38–41, 1:45–51. “(S)-nicotine [that is] obtained by extraction from leaves of the tobacco plant ... typically has a chemical purity less than 95% due to the presence of related alkaloid impurities.” *Id.* at 1:61–64.

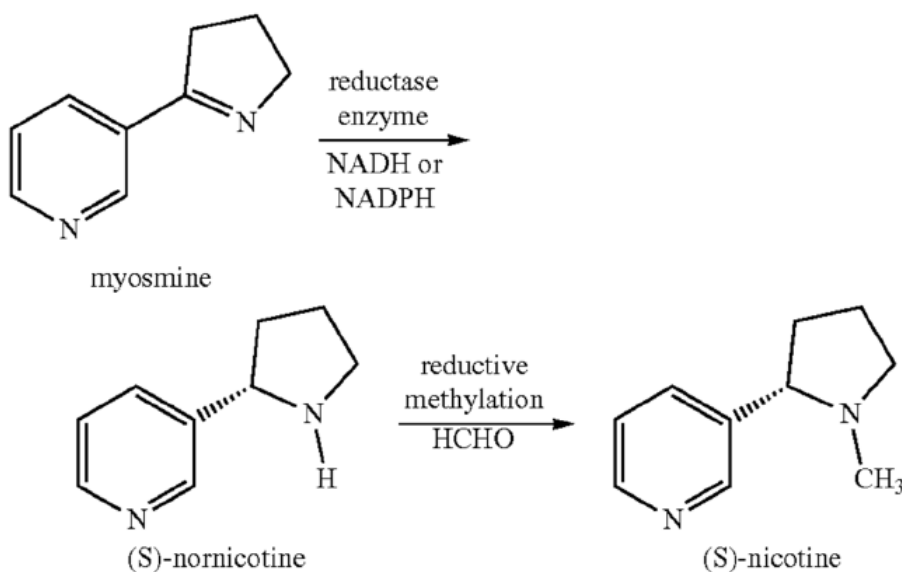
The background of the ’962 Patent acknowledges that synthetically producing (S)-nicotine by first producing a racemic (i.e. equal) mixture of (R)-nicotine and (S)-nicotine, followed by resolution of the racemic mixture was known. ’962 Patent at 2:8–12. The ’962 Patent, however, claims a different and novel route of synthesis for (S)-Nicotine. That is, the ’962 Patent discloses “selectively synthesising (S)-

nicotine in preference to the (R) enantiomer with high enantiomeric selectivity while also achieving high chemical purity.” *Id.* at 2:23–25.

The '962 Patent describes forming (S)-nicotine using a two-step process:

- (i) reducing myosmine with an enzyme with imine reductase activity to form (S)-nornicotine; and
- (ii) methylating the (S)-nornicotine formed from step (i) to form (S)-nicotine.

'962 Patent at 2:32–35. An example of this reaction scheme from the '962 is provided below:



The '962 Patent further describes that step (i) is an “enantiomeric selective synthetic step with preference for the (S) isomer, and that step (ii) is such that this preference is retained in the final nicotine product.” *Id.* at 2:40–43. “This allows the production of (S)-nicotine without having to resort to resolution of a racemic mix.” *Id.* at 2:44–46.

III. CLAIM CONSTRUCTION

Petitioner identifies two phrases of the '962 Patent, one from claim 1 and one from claim 9, that it asserts should be construed by the Board. These are the same two phrases presented for claim construction by the parallel district court litigation. Prior to the filing of this Petition on January 24, 2023, the parties had fully briefed these claim construction issues and presented arguments to the Court at the *Markman* hearing. At that hearing, the Court rejected the very constructions now being presented by Petitioner, which was memorialized by the Court on February 2, 2023. *See* Ex. 2001 (Claim Construction Order).

In any event, none of the Petitioner's arguments or evidence relies on the constructions it proposes. In fact, Petitioner acknowledges that "those constructions do not affect whether the Petition should be instituted." Petition at 12.

Patent Owner contends that no constructions are necessary at this stage of the proceeding.

IV. LEVEL OF ORDINARY SKILL IN THE ART

Petitioner asserts that "[a] POSITA with respect to the '962 Patent would have had a Ph.D. in a relevant field of organic chemistry or biochemistry, with several years of research experience gained during those studies or afterwards in organic synthesis, including chiral synthesis, and the use of enzymes in reactions" and that "[a] POSITA could also include a person with a lesser academic degree, but with

several years' experience sufficient to develop equivalent experience in synthetic organic chemistry, such as in pharmaceutical applications or in the chiral synthesis of compounds with biological activity.” Petition at 13.

At this stage of the proceeding, Patent Owner does not contest Petitioner's proposed level of ordinary skill in the art.

V. PETITIONER FAILS TO MEET ITS BURDEN TO SHOW THE UNPATENTABILITY OF THE CLAIMS OF THE '962 PATENT

Petitioner presents six grounds of unpatentability under 35 U.S.C. § 103.

An invention is obvious when “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 of the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 13 (1966). Obviousness “cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). A “patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 401. Merely identifying “components selectively culled from the prior art to fit the parameters of the patent invention” is insufficient to show obviousness. *Cheese Sys., Inc. v. Tetra Pak Cheese & Powder*

Sys., 725 F.3d 1341, 1352 (Fed. Cir. 2013) (internal citations and quotations omitted). It is the Petitioner’s burden to show “that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009); *see also Artic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017).

Moreover, “[i]n an IPR, 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)); *see also Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (“It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify ‘with particularity’ the ‘evidence that supports the grounds for the challenge to each claim.’” (quoting 35 U.S.C. § 312(a)(3))).

Here, Petitioner fails to show with particularity for any of its grounds that the claims of the ’962 Patent are obvious.

A. *Petitioner Fails To Show That The Combination of Divi, Moody, and Enzymicals Renders Obvious Claims 1–14 (Ground 1)*

1. Independent Claim 1

- a. *Petitioner fails to show that a POSITA would be motivated to start with Divi’s non-enantioselective synthesis of racemic nicotine to develop an enantioselective synthesis of (S)-nicotine.*

Divi discloses a non-enantioselective route of synthesis for racemic nicotine,² which is followed by a resolution and racemization step to separate (S)-nicotine from the “unwanted” (R)-nicotine. *See* Divi at 2:21–25; *see also* Petition at 13, 21. Petitioner asserts that “[a] POSITA would have looked at the reaction disclosed in Divi as a logical starting point, while recognizing that avoiding a resolution step would further improve the reaction.” Petition at 21. Yet, Petitioner provides no support for this assertion beyond an identical conclusory statement by Dr. Winkler, which should be afforded no weight. *See* 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”).

Petitioner also fails to identify any reason why the *non-enantioselective* reaction of Divi would be a logical starting point for the claimed *enantioselective*

² Notably, Divi discloses the same non-enantioselective synthesis of racemic nicotine found in Arnold (U.S. Patent Publication No. 2016/0115150), which was considered by the Examiner during prosecution. *See* Ex. 1019 at pg. 6–8. Divi, like Arnold, discloses reducing myosmine to (R,S)-nornicotine (i.e., not (S)-nornicotine in an enantioselective reaction) and reducing (R,S)-nornicotine to (R,S)-nicotine. *Compare* Divi at 3:60–4:12, Scheme 3, *with* Arnold at 1:65–67, Scheme 1.

synthesis of (S)-nicotine. Specifically, neither Petitioner nor Dr. Winkler presents any evidence or reasoning showing that Divi's non-enantioselective reduction of myosmine to (R,S)-nornicotine would be the logical starting point for any enantioselective synthesis, let alone the enantioselective synthesis of (S)-nicotine. Simply put, Petitioner's selection of the non-enantioselective reaction of Divi as a "logical starting point" for the claimed enantioselective reaction is an unsupported conclusory statement based on improper hindsight knowledge of the '962 Patent.

Moreover, not only does Divi not disclose an enantioselective reaction, but Divi expressly teaches away from the use of enantioselective syntheses. A reference teaches away "when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009). Teaching away can include criticizing, discrediting, or otherwise discouraging investigation into the claimed invention. *Id.*

Here, Divi expressly states it explored "[the] synthesis of (R,S)-nicotine followed by resolution and racemization of unwanted (R)-nicotine" because "enantioselective synthesis is *too expensive* on an industrial scale." Divi at 2:8–11. As an alternative to an enantioselective synthesis, Divi states that "[t]ogether with the known methods for its resolution and racemization of the unwanted isomer, this

[non-enantioselective] process provides *an attractive and economical method* for the production of synthetic (S)-nicotine.” Divi at 2:22–25. Neither Petitioner nor Dr. Winkler explains why a POSITA would be motivated to avoid the “attractive and economical method” that includes the resolution and racemization of the unwanted (R)-nicotine from a racemic mixture of nicotine and instead pursue the disparaged enantioselective approach that was identified in Divi as “too expensive.”

Again, this failure to acknowledge the principle teachings of Divi is further evidence of Petitioner’s improper selective culling of components from the prior art to fit the parameters of the patent invention. *See Cheese Sys., Inc.*, 725 F.3d at 1352. In other words, Petitioner is simply using improper hindsight knowledge of the ’962 Patent to support its motivation to use Divi’s non-enantioselective synthesis as a starting point for an enantioselective synthesis.

b. Petitioner fails to show that a POSITA would be motivated to modify Divi with Moody and Enzymicals.

Petitioner states that its obviousness challenge for Ground 1 relies on the combination of Divi, Moody, *and* Enzymicals. Petition at 10. Yet, Petitioner does not provide any alleged motivation to combine Moody or Enzymicals individually with Divi, the primary reference. Instead, Petitioner presents Moody and Enzymicals as an already combined package without explanation and attempts to combine that package with Divi. *See, e.g.*, Petition at 27 (“[A] POSITA would have been motivated by the disclosures of Enzymicals and Moody to use an imine

reductase to reduce myosmine to (S)-nornicotine.”). Similarly, Petitioner does not explain why there is a motivation to combine Enzymicals if the teachings of Moody already disclose the commercial availability of imine reductases and commercially available enzyme screens—or vice versa. *See* Petition at 27. As a result, Petitioner fails to demonstrate that a POSITA would be motivated to combine all three prior art references as proposed in Ground 1. *See Intelligent Bio-Sys.*, 821 F.3d at 1367–68.

Second, Petitioner continues its improper use of hindsight knowledge of the ’962 Patent to support its motivation to combine or modify Divi with Moody and Enzymicals. Petitioner asserts that “[a] POSITA would have been motivated to apply the teachings of Enzymicals and/or Moody to use Enzymicals or Almac to identify an imine reductase capable of reducing myosmine to (S)-nornicotine asymmetrically and use that imine reductase to catalyze the reduction of myosmine to (S)-nornicotine.” Petition at 27. Notably, Petitioner must rely on its multi-pronged motivation to combine argument because Divi does not disclose the use of enzymes in its non-enantioselective reactions and neither Moody nor Enzymicals discloses myosmine, nornicotine, or nicotine, let alone the use of imine reductases to stereoselectively reduce myosmine to (S)-nornicotine, as claimed in the ’962 Patent. Nonetheless, Petitioner’s strained argument fails to articulate any rationale why a POSITA would have been motivated to modify Divi with the teachings of

both Enzymicals and Moody.

In support of its assertion of a motivation to combine, Petitioner states that “[a] POSITA would have recognized that the Divi reaction provided an opportunity for a stereoselective reaction where myosmine is reduced to nornicotine.” Petition at 26. However, as explained above, this is an unsupported and conclusory statement based on improper hindsight knowledge of the ’962 Patent. *See* Section V.A.1.a. Petitioner does not articulate or explain this “opportunity for a stereoselective reaction.” On its own, this vague “opportunity” to use an enantioselective reaction is not an actual motivation to modify Divi’s non-enantioselective reaction. Furthermore, as explained above, Divi is directed towards a process that utilizes a non-enantioselective synthesis of racemic nicotine followed by resolution and racemization that is “an attractive and economical method for the production of synthetic (S)-nicotine” because enantioselective syntheses (i.e., stereoselective reactions) are “too expensive on an industrial scale.” *See* Section V.A.1.a; *see also* Divi at 2:8–11, 22–25. Petitioner conspicuously fails to provide any rationale to depart from and modify Divi’s “attractive and economical” process.

Petitioner also alleges that “[a] POSITA would have understood from [*sic*] reaction pathway disclosed in Divi that the conversion of myosmine, an imine, to nornicotine, the corresponding amine, requires reducing the imine bond of myosmine” and that “[a] POSITA, familiar with imine reductases, would have

known that imine reductases reduce imines to their corresponding amines asymmetrically.” Petition at 26 (citing Winkler at ¶¶ 133–134, which includes identical, unsupported statements). Petitioner also states that “[a] POSITA would have known from Enzymicals and Moody that imine reductases were widely available commercially.” Petition at 27. These statements simply address the purported knowledge of a POSITA—they are not motivations to modify Divi’s non-enantioselective process of producing (S)-nicotine. In fact, Petitioner does not provide any rationale describing *why* a POSITA would be motivated to modify Divi with Moody and Enzymicals.

Finally, Petitioner states that “a POSITA would have understood from Moody and Enzymicals that commercial services could analyze a ‘customer substrate’ imine (such as myosmine), build a custom enzyme screen of imine reductases targeting the reduction of myosmine, and identify an imine reductase ‘for the enantioselective reduction of the imine.’” Petition at 27.³ As stated above, this is merely a statement of a POSITA’s purported knowledge of what is available, not an actual motivation to modify Divi with Moody and Enzymicals. Moreover, stating that “commercial services *could analyze* a ‘customer substrate’ imine” does not provide the alleged motivation for a POSITA to modify Divi with Moody and Enzymicals. *See Hulu,*

³ Neither Moody nor Enzymicals disclose or mention myosmine, nornicotine, or nicotine.

LLC v. Sound View Innovations, LLC, IPR2018-00582, Paper 34, at 21 (PTAB Aug. 5, 2019) (informative decision) (“We are also mindful that obviousness concerns whether a skilled artisan not only ***could have made*** but ***would have been motivated to make*** the combinations or modifications of prior art to arrive at the claimed invention.”). Petitioner does not present any evidence that a POSITA ***would have been motivated*** to engage these additional commercial services to try to identify an imine reductase to reduce myosmine to (S)-nornicotine.

Accordingly, Petitioner fails to present any evidence or reasoned explanation demonstrating that a POSITA would have been motivated to modify Divi with the teachings of Moody and Enzymicals. *See In re NuVasive*, 842 F.3d 1376, 1384–85 (Fed. Cir. 2016).

c. *Petitioner fails to show a reasonable expectation of success for the modification of Divi with Moody and Enzymicals.*

In addition to its failure to show a motivation to modify Divi with Moody and Enzymicals, Petitioner also fails to show that a POSITA “would have had a reasonable expectation of success in doing so.” *Procter & Gamble*, 566 F.3d at 994. A reasonable expectation of success analysis focuses on the highly desired goals of the challenged patent. *See Institut Pasteur v. Focarino*, 738 F.3d 1337, 1346 (Fed. Cir. 2013) (“Importantly, without a sound explanation for doing otherwise, ... the expectation-of-success analysis must match the highly desired goal, not switch to a

different goal that may be a less challenging but also less worth-while pursuit.”). Here, success would include reducing myosmine with an imine reductase to (S)-nornicotine with high activity (including near full conversion of myosmine to nornicotine)⁴ and high enantiomeric selectivity (the production of at least 90% enantiomeric excess of (S)-nornicotine)). *See* ’962 Patent at 2:23–26, 3:42–46, 7:15–17.

However, Petitioner’s proposed modification of Divi with Moody and Enzymicals relies on conclusory and unsupported statements regarding the purely hypothetical success of vaguely described commercial services disclosed in Moody and Enzymicals to identify an imine reductase capable of asymmetrically reducing myosmine to (S)-nornicotine. *See* Petition at 28 (“A POSITA would have had a reasonable expectation of success that Enzymicals, through its screening kit or in-house screening service, would identify an imine reductase to reduce myosmine to (S)-nornicotine asymmetrically.”); *id.* at 28–29 (“A POSITA would have had a reasonable expectation of success that Almac’s enzyme screen would yield an imine reductase that reduced myosmine to (S)-nornicotine asymmetrically”). However, Petitioner’s evidence is nothing more than a process of trial and error,

⁴ Divi discloses that myosmine is an impurity that should not exceed 0.5% under the current U.S. Pharmacopeia. *See* Divi at 1:40–51; *see also* ’962 Patent at 1:53–56. Myosmine, along with other alkaloid impurities, are difficult to remove due to their close relationship to nicotine. *See* Divi at 1:54–55; ’962 Patent at 2:2–4.

which cannot establish a reasonable expectation of success. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1365 (Fed. Cir. 2007) (“To have a reasonable expectation of success, one must be motivated to do more than merely to vary all parameters or try each of the numerous possible choices until one possibly arrived at a successful result, where the prior art gave no indication of which parameters were critical or no direction as to which of the many possible choices is likely to be successful.”).

To be clear, neither Moody nor Enzymicals discloses reducing *myosmine* (as claimed in the '962 Patent) with imine reductases to (S)-nornicotine. Instead, as support for its reasonable expectation of success, Petitioner asserts that “Enzymicals sold a screening kit of four imine reductases and disclosed that it would screen a given substrate *such as myosmine* ‘to find out the most suitable enzyme for your desired reaction.’” Petition at 28. Contrary to Petitioner’s implication, Enzymicals does not identify myosmine as a substrate. Petitioner also asserts that “Enzymicals further disclosed that it offered mutant enzymes with ‘enhanced substrate specificity and/or increased stereoselectivity towards appropriate substrates’ that were ‘available on request’ and that ‘an in-house screening with suitable enzyme classes about all available enzymes from public or private panel’ was available.” *Id.* First, The mere existence of commercially-available imine reductases does not support a reasonable expectation of success of reducing *myosmine* with imine reductase to

(S)-nornicotine with high activity and enantiomeric selectivity. Second, Petitioner presents no evidence a POSITA would expect that Enzymical's screening kit of four enzymes—two of which are selective against the opposite stereoisomer as the other two—would lead to the successful reduction of myosmine to (S)-nornicotine. Third, Enzymicals does not disclose any specific details of its enzyme screening service or mutant enzymes that would inform a POSITA of the critical parameters necessary to determine whether there is a reasonable expectation of success when used with undisclosed substrates, such as myosmine. *See Pfizer, Inc.*, 480 F.3d at 1365.

For Moody, Petitioner asserts that “Almac could analyze a ‘customer substrate’ imine, build a custom enzyme screen of imine reductases specifically targeting the reduction of the imine, and identify an imine reductase ‘for the enantioselective reduction of the imine.’” Petition at 28. As evidence, Petitioner relies on Moody's disclosure of a single screen of 50 *in-silico* designed imine reductases against a customer imine. Petition at 28–29; *see also* Moody at 12–13, Fig. 3. First, Moody does not identify the imine used, and Petitioner does not present any articulable reason why the screen of imine reductases against an undisclosed imine is evidence of a reasonable expectation of success for the reduction of *myosmine* with imine reductases to (S)-nornicotine with high activity and enantiomeric selectivity. Second, like Enzymicals, Moody does not disclose the details of how it designs its enzyme screen such that it would inform a POSITA of

the critical parameters necessary to determine whether there would be a reasonable expectation of success when used with undisclosed substrates. *See Pfizer, Inc.*, 480 F.3d at 1365. Third, out of the 50 imine reductases that were designed to target the specific, unidentified imine, only one imine reductase showed the reduction of the imine to the (S)-isomer with high activity and selectivity. Moody at 13, Fig. 3. These facts indicate that Almac's *in silico* enzyme design had not identified the critical parameters for success and was simply varying all the parameters to hopefully identify a hit, which does not establish a reasonable expectation of success absent impermissible hindsight. *See Pfizer, Inc.*, 480 F.3d at 1365.

Perhaps the most telling evidence that there was no reasonable expectation of success arises from the fact that Petitioner's modification of Divi with both Moody and Enzymicals presents four different approaches for identifying an imine reductase capable of reducing myosmine to (S)-nornicotine—the screening kit, the in-house screening service, the mutant enzymes disclosed in Enzymicals, and the *in silico* enzyme design and screening service disclosed in Moody. This reliance on four distinct and separate approaches illustrates that Petitioner is proposing the use of trial and error without any discernable direction or guidance disclosed in the references themselves and is, instead, using hindsight to cull selective disclosures to arrive at the asserted combination. Accordingly, Petitioner fails to establish a reasonable expectation of success upon the modification of Divi with the disclosures

of Moody and Enzymicals.

For at least the reasons stated above, Petitioner fails to show with particularity that claim 1 of the '962 Patent is obvious.

2. Dependent Claims 2–14

As described above, Petitioner fails to show that claim 1 is obvious under the combination of Divi, Moody, and Enzymicals. *See* Section V.A.1. Petitioner also fails to show that claims 2–14, as dependents ultimately of claim 1, are obvious under the combination of Divi, Moody, and Enzymicals for at least the same reasons.

B. Petitioner Fails To Show That The Combination of Divi, Moody, Enzymicals, and Arnold Renders Obvious Claims 6 and 12 (Ground 2)

As described above, Petitioner fails to show that claim 1 is obvious under the combination of Divi, Moody, and Enzymicals. *See* Section V.A.1. Petitioner also fails to show that claims 6 and 12, as dependents of claim 1, are obvious under the combination of Divi, Moody, Enzymicals, and Arnold as suggested in Ground 2 for at least the same reasons.

C. Petitioner Fails To Show That The Combination of Divi, Moody, Enzymicals, and Sheldon Renders Obvious Claims 7 and 8 (Ground 3)

As described above, claim 1 not obvious under the combination of Divi, Moody, and Enzymicals. *See* Section V.A.1. As dependents from claim 1, both claims 7 and 8 are not obvious under the combination of Divi, Moody, Enzymicals, and Sheldon as suggested in Ground 3 for at least the same reasons that claim 1 is

not obvious.

D. Petitioner Fails To Show That The Combination of Divi, Moody, Velikogne, and Wetzl Renders Obvious Claims 1–14 (Ground 4)

1. Independent Claim 1

- a. *Petitioner fails to show that a POSITA would be motivated to start with Divi’s non-enantioselective synthesis of racemic nicotine to develop an enantioselective synthesis of (S)-nicotine.*

Petitioner asserts that “[a] POSITA would have looked at the reaction disclosed in Divi as a logical starting point, while recognizing that avoiding a resolution step would further improve the reaction.” Petition at 47. Yet, Petitioner provides no support for this assertion beyond an identical conclusory statement by Dr. Winkler, which should be afforded no weight. Winkler at ¶ 221; *see also* 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”).

As discussed above, Petitioner does not provide any non-conclusory evidence of any improvement by avoiding the resolution step or any evidence that Divi’s non-enantioselective reaction would be a “logical starting point.” *See* Section V.A.1.a. Moreover, Petitioner ignores Divi’s core teaching and express discouragement of the use of enantioselective synthesis. *See* Section V.A.1.a; *see also* Divi at 2:8–11. Petitioner’s failure to acknowledge the principle teachings of Divi is further evidence of Petitioner’s improper selective culling of components from the prior art to fit the parameters of the ’962 Patent’s invention. *See Cheese Sys., Inc.*, 725 F.3d

at 1352. In other words, Petitioner is simply using improper hindsight knowledge of the '962 Patent to support its motivation to use Divi's non-enantioselective synthesis as a starting point for an enantioselective synthesis.

b. Petitioner fails to show that a POSITA would be motivated to modify Divi with Moody, Velikogne, and Wetzl.

To support its motivation to combine or modify the prior art as suggested in Ground 4, Petitioner continues to improperly use hindsight knowledge of the '962 Patent. Petitioner makes many of the same arguments for the alleged combination of prior art as it made in Ground 1, which fail for the same reasons discussed above. For example, in support of its assertion of a motivation to combine, Petitioner states that “[a] POSITA would have recognized that the Divi reaction provided an opportunity for a stereoselective reaction where myosmine is reduced to nornicotine.” Petition at 52. However, as explained above, this bald assertion is unsupported by the prior art and is based on improper hindsight knowledge of the '962 Patent. *See* Sections V.A.1.a, V.D.1.a. Petitioner does not articulate or explain this “opportunity for a stereoselective reaction.” On its own, this vague “opportunity” to use an enantioselective reaction is not an actual motivation to modify Divi's non-enantioselective reaction. Furthermore, as explained above, Divi is directed towards a process that utilizes a non-enantioselective synthesis of racemic nicotine followed by resolution and racemization that is “an attractive and

economical method for the production of synthetic (S)-nicotine” because enantioselective syntheses (i.e., stereoselective reactions) are “too expensive on an industrial scale.” *See* Sections V.A.1.a, V.D.1.a; *see also* Divi at 2:8–11, 22–25. Petitioner conspicuously fails to provide any rationale to modify Divi’s “attractive and economical” process.

Petitioner also alleges that “[a] POSITA would have understood from the nicotine reaction pathway in Divi that the conversion of myosmine, an imine, to nornicotine, the corresponding amine, requires reducing the imine bond of myosmine” and that “[a] POSITA, familiar with imine reductases, would have known that imine reductases reduce imines to their corresponding amines asymmetrically.” Petition at 52. Petitioner also states that “[a] POSITA would have known from Moody that imine reductases were widely available commercially.” Petition at 52–53. As discussed above in connection with Ground 1, these statements simply address the purported knowledge of a POSITA—they are not motivations to modify Divi’s process of producing (S)-nicotine. In fact, Petitioner does not provide any articulable rationale describing why a POSITA would be motivated to modify Divi with Moody.

For Moody, Petitioner states that “a POSITA would have understood from Moody that Almac could analyze a ‘customer substrate’ imine (such as myosmine), build a custom enzyme screen of imine reductases targeting the reduction of

myosmine, and identify an imine reductase ‘for the enantioselective reduction of the imine.’” Petition at 53.⁵ As above, this is merely a statement of a POSITA’s purported knowledge of what is available, not an actual motivation to modify Divi with Moody. Moreover, stating that “Almac *could analyze* a ‘customer substrate’ imine” does not, on its own, provide the necessary motivation for a POSITA to modify Divi with Moody. *See Hulu, LLC*, IPR2018-00582, Paper 34, at 21. Petitioner does not present any evidence that a POSITA *would have been motivated* to engage Almac to try to identify an imine reductase to reduce myosmine to (S)-nornicotine. Accordingly, Petitioner fails to present any evidence or reasoned explanation demonstrating that a POSITA would have had a reason to combine the teachings of Moody with Divi. *See In re NuVasive*, 842 F.3d at 1384–85.

For Velikogne and Wetzl, Petitioner asserts that “Velikogne and Wetzl would have further motivated a POSITA to catalyze the reduction of myosmine to (S)-nornicotine using an imine reductase.” Petition at 53. However, Petitioner fails to articulate how the teachings of Velikogne and Wetzl would have allegedly been incorporated into the teachings of either Moody or Divi or why a POSITA would be motivated to incorporate those teachings.

First, Petitioner does not explain why a POSITA would have been “further motivated” by Velikogne and Wetzl, when, according to Petitioner, “a POSITA

⁵ Moody does not disclose or mention myosmine, nornicotine, or nicotine.

would have been motivated to use an imine reductase to catalyze the reduction of myosmine to (S)-nornicotine asymmetrically” based on a POSITA’s purported familiarity with imine reductases and their ability to “reduce imines to their corresponding amines asymmetrically.” *See* Petition at 52. Similarly, Petitioner does not explain why there would have been a motivation to also combine Velikogne if the teachings of Wetzl purportedly already disclose that “imine reductases reduced imines to chiral amines ‘across a broad range of substrates,’” or vice versa. *See* Petition at 49.

Second, Petitioner does not provide any non-conclusory evidence of a purported motivation to combine Velikogne with the other references. Instead, Petitioner provides the conclusory statement that “[d]isclosures from Velikogne and Wetzl would have further motivated a POSITA to catalyze the reduction of myosmine to (S)-nornicotine using an imine reductase.” Petition at 53. Neither the Petition nor Dr. Winkler’s declaration supports that assertion with any evidence or citations to Velikogne of a motivation to combine for Velikogne. *See* Petition at 53; *see also* Winkler at ¶ 239.

Third, Petitioner states that “Wetzl recognized the motivation to use a biocatalyst to synthesize chiral amines asymmetrically to improve yield and reduce the need for an enantiomeric resolution—one of the issues the ’962 Patent recognized.” Petition at 53. Notwithstanding Petitioner’s strained characterizations

of Wetzl’s generalized statements, Petitioner does not explain why such statements would have motivated a POSITA to modify Divi, which discloses “an attractive and economical method for the production of synthetic (S)-nicotine” that includes the resolution *and racemization* of the unwanted (R)-isomer. *See* Divi at 2:21–25.

Accordingly, Petitioner fails to demonstrate that a POSITA would have been motivated to combine all four prior art references as suggested in Ground 4. *See Intelligent Bio-Sys.*, 821 F.3d at 1367–68.

c. Petitioner fails to show a reasonable expectation of success for the modification of Divi with Moody, Velikogne, and Wetzl.

In addition to its failure to show a motivation to modify Divi with Moody, Velikogne, and Wetzl, Petitioner also fails to show that a POSITA “would have had a reasonable expectation of success in doing so.” *Procter & Gamble*, 566 F.3d at 994. A reasonable expectation of success analysis focuses on the highly desired goals of the challenged patent. *See Institut Pasteur v. Focarino*, 738 F.3d 1337, 1346 (Fed. Cir. 2013) (“Importantly, without a sound explanation for doing otherwise, ... the expectation-of-success analysis must match the highly desired goal, not switch to a different goal that may be a less challenging but also less worthwhile pursuit.”). Here, success would include reducing myosmine with an imine reductase to (S)-nornicotine with high activity (including near full conversion of

myosmine to nornicotine)⁶ and high enantiomeric selectivity (the production of at least 90% enantiomeric excess of (S)-nornicotine)). *See* '962 Patent at 2:23–26, 3:42–46, 7:15–17.

Petitioner's proposed modification of Divi with Moody, Velikogne, and Wetzl relies on conclusory and unsupported statements regarding the hypothetical success of a vaguely described imine reductase screen disclosed in Moody and Velikogne to identify an imine reductase capable of asymmetrically reducing myosmine to (S)-nornicotine. *See* Petition at 54 ("A POSITA would have had a reasonable expectation of success that Almac's enzyme screen would identify an imine reductase that reduced myosmine to (S)-nornicotine asymmetrically"); *id.* at 57 ("A POSITA following Velikogne's teachings would have had a reasonable expectation of success of finding at least one enzyme reducing myosmine to (S)-nornicotine selectively."). However, Petitioner's evidence is nothing more than a process of trial and error, which is insufficient to show a reasonable expectation of success. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1365 (Fed. Cir. 2007) ("To have a reasonable expectation of success, one must be motivated to do more than merely to vary all parameters or try each of the numerous possible choices until one

⁶ Divi discloses that myosmine is an impurity that should not exceed 0.5% under the current U.S. Pharmacopeia. *See* Divi at 1:40–51; *see also* '962 Patent at 1:53–56. Myosmine, along with other alkaloid impurities, are difficult to remove due to their close relationship to nicotine. *See* Divi at 1:54–55; '962 Patent at 2:2–4.

possibly arrived at a successful result, where the prior art gave no indication of which parameters were critical or no direction as to which of the many possible choices is likely to be successful.”).

To be clear, Moody does not disclose reducing myosmine with imine reductases to form (S)-nornicotine. Instead, as support for its purported reasonable expectation of success, Petitioner asserts that “Almac could analyze a ‘customer substrate’ imine, build a custom enzyme screen of imine reductases specifically targeting the reduction of the imine, and discover an imine reductase ‘for the enantioselective reduction of the imine.’” Petition at 54. As evidence, Petitioner relies on Moody’s disclosure of a single screen of 50 *in-silico* designed imine reductases against a customer imine. Petition at 54–55; *see also* Moody at 12–13, Fig. 3. First, the identity of the imine is not disclosed, and Petitioner does not present any articulable reason why the screen of imine reductases against an undisclosed imine is evidence of a reasonable expectation of success for the specific reduction of *myosmine* with imine reductases to (S)-nornicotine with high activity and enantiomeric selectivity. Second, Moody does not disclose the details of how it designs its enzyme screen such that it would inform a POSITA of the critical parameters necessary to determine whether there would be a reasonable expectation of success. *See Pfizer, Inc.*, 480 F.3d at 1365. Third, out of the 50 imine reductases that were designed to target the specific, unidentified imine, only one imine

reductase showed the reduction of the imine to the (S)-isomer with high activity and selectivity. Moody at 13, Fig. 3. These facts indicate that Almac's *in silico* enzyme design had not identified the critical parameters for success and was simply varying all the parameters to hopefully identify a hit, which does not indicate a reasonable expectation of success. *See Pfizer, Inc.*, 480 F.3d at 1365.

For Velikogne, which also does not disclose reducing myosmine with imine reductases to (S)-nornicotine, Petitioner states that “[a] POSITA following Velikogne’s teachings would have had a reasonable expectation of success of finding at least one enzyme reducing myosmine to (S)-nornicotine selectively.” As support, Petitioner states that “Velikogne’s screen resulted in every single screened imine substrate being selectively reduced to the corresponding (S)-amine by multiple imine reductases with at least 99% enantiomeric excess.” Petition at 57. Velikogne screened a total of 14 imine reductases against 11 imines. Velikogne at Table 1, Fig. 2. There are far more imines (thousands if not millions) that were not evaluated by Velikogne, such as myosmine. Petitioner does not present any evidence to explain why Velikogne’s results for those 11 imines would lead a POSITA to have a reasonable expectation of success that the Moody’s *in silico* enzyme design and screen would identify a imine reductase that reduces myosmine—a completely different compound—to (S)-nornicotine with high activity and enantiomeric

selectivity.⁷ Furthermore, Petitioner does not point to any evidence that Velikogne informs a POSITA of the critical parameters necessary to determine whether there would be a reasonable expectation of success for the reduction of myosmine to (S)-nornicotine with high activity and enantiomeric selectivity. *See Pfizer, Inc.*, 480 F.3d at 1365.

For Wetzl, Petitioner states that “Wetzl disclosed that ‘[t]he vast majority of the tested IRED candidates displayed good conversions (>90%) against nearly all of the tested substrates as well as good to excellent enantioselectivities, often yielding the corresponding product with an enantiomeric excess >90%.’” Petition at 56. Notably, Wetzl discloses that, in its screen of 15 imine reductases with 9 imines (none of which is myosmine), one third of the imines tested did not produce any asymmetric conversion with any of the tested imine reductases. *See Wetzl* at Table 2 (substrates 7, 9, and 11). Like with Velikogne, Petitioner does not present any evidence to explain why Wetzl’s results for only two-thirds of the tested imines would lead a POSITA to have a reasonable expectation of success that Moody’s *in silico* enzyme design and screen would identify a imine reductase that reduces myosmine—a completely different compound—to (S)-nornicotine with high

⁷ Petitioner does not assert that Velikogne’s 14 imine reductases would be combined with Moody’s screen. Nonetheless, even if such a combination had been proposed, Petitioner still does not present any evidence to explain why the results for Velikogne’s 11 imines, which do not include myosmine, is relevant to determine a reasonable expectation of success for reducing myosmine to (S)-nornicotine.

activity and enantiomeric selectivity.

Finally, as a conspicuous display of Petitioner's improper use of hindsight knowledge of the '962 Patent, Petitioner asserts, without support, that one of the imine reductases in Wetzl was also used in the '962 Patent as example of an imine reductase capable of reducing myosmine to (S)-nornicotine. Petition at 56. Petitioner then claims that "[a] POSITA replicating Wetzl's exact panel of imine reductases would have discovered a working imine reductase. This use of the '962 Patent's teachings to combine the prior art as suggested illustrates Petitioner's improper selective culling of components from the prior art to fit the parameters of the patent invention. *See Cheese Sys., Inc.*, 725 F.3d at 1352.

For at least the reasons stated above, Petitioner fails to show with particularity that claim 1 of the '962 Patent is obvious.

2. Dependent Claims 2–14

As described above, Petitioner fails to show that claim 1 is obvious under the combination of Divi, Moody, Velikogne, and Wetzl. *See* Section V.D.1. Petitioner also fails to show that claims 2–14, as dependents ultimately of claim 1, are obvious under the combination of Divi, Moody, Velikogne, and Wetzl for at least the same reasons.

E. Petitioner Fails To Show That The Combination of Divi, Moody, Velikogne, Wetzl, and Arnold Renders Obvious Claims 6 and 12 (Ground 5)

As described above, Petitioner fails to show that claim 1 is obvious under the combination of Divi, Moody, Velikogne, and Wetzl. *See* Section V.D.1. Petitioner also fails to show that claims 6 and 12, as dependents of claim 1, are obvious under the combination of Divi, Moody, Velikogne, Wetzl, and Arnold for at least the same reasons.

F. Petitioner Fails To Show That The Combination of Divi, Moody, Velikogne, Wetzl, and Sheldon Renders Obvious Claims 7 and 8 (Ground 6)

As described above, Petitioner fails to show that claim 1 is obvious under the combination of Divi, Moody, Velikogne, and Wetzl. *See* Section V.D.1. Petitioner also fails to show that claims 7 and 8, as dependents of claim 1, are obvious under the combination of Divi, Moody, Enzymicals, Velikogne, Wetzl, and Sheldon for at least the same reasons.

VI. THE *FINTIV* FACTORS WEIGH IN FAVOR OF DENYING INSTITUTION

As explained in detail above, the Board should exercise its discretion to deny institution because Petitioner fails to set forth evidence establishing a reasonable likelihood that it will establish the unpatentability of any of the claims of the '962 Patent. However, even if the Board finds that Petitioner has established a reasonable likelihood that it will be able to show that at least one claim is unpatentable, the

Board should nonetheless deny institution because the *Fintiv* factors strongly favor denial of institution and Petitioner has not presented compelling evidence of unpatentability.

A holistic analysis of the *Fintiv* factors 1–5 establishes the advanced stage of the parallel district court proceedings, which is scheduled for trial nearly 6 months before the Board will likely issue its final written decision, and the duplication of the invalidity grounds asserted in the Petition and the district court proceedings. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) at 2–3; *see also Cisco Sys., Inc. v. Oyster Optics, LLC*, IPR2021-00238, Paper 10 (PTAB June 1, 2021) (exercising discretion to deny institution after a holistic analysis of the *Fintiv* factors).

Given that an “analysis of *Fintiv* factors 1–5 favors denial of institution, the Board shall then assess compelling merits.” *Commscope Technologies LLC, v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23, at 5 (PTAB Feb. 27, 2023). “Compelling, meritorious challenges are those in which the evidence, if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence.” Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation, PTO Director’s Memorandum (June 21, 2022) (“Interim Guidance”) at 4. Indeed, the Interim Guidance cautions that “a compelling-merits challenge is a higher standard than the

reasonable likelihood required for the institution of an IPR under 35 U.S.C. § 314(a).” *Id.* As described in detail below, the Petition fails to meet the “compelling” merits required to institute *inter partes* review.

A. Whether The Court Granted A Stay or Evidence Exists That One May Be Granted If A Proceeding Is Instituted

The first *Fintiv* factor addresses the likelihood of a stay if this proceeding is instituted. Here, the District Court of the Western District of Texas has not stayed the district court proceedings, Petitioner has not filed a motion to stay the district court proceedings, and Petitioner presents no evidence that a stay may be granted. As such, this factor weighs in favor of discretionary denial.

B. Proximity of the Court’s Trial Date To The Board’s Projected Deadline For A Final Written Decision

For the second *Fintiv* factor, the Interim Guidance notes that “the PTAB will consider the median time from filing to disposition of the civil trial for the district in which the parallel litigation resides.” Interim Guidance at 3. Given that the deadline for the Board to issue an institution decision is no later than August 8, 2023, the expected deadline for the Board to issue a final written decision would be no later than August 8, 2024. *See* 37 C.F.R. § 42.108; 35 U.S.C. § 314(b); 37 C.F.R. § 42.100(c). The second *Fintiv* factor weighs in favor of discretionary denial. The median time to trial for civil trials in the Western District of Texas is 28.3 months.⁸

⁸ *See* Ex. 1020 at 37.

28.3 months after the filing of Patent Owner’s complaint⁹ is roughly late July 2024, which means the district court trial would be expected to occur before the expected final written decision in August 2024.

Furthermore, in the Amended Scheduling Order, the District Court has set a trial date for the week of January 29, 2024, which is over six months before the expected final written decision from the Board. *See* Ex. 2002 (Scheduling Order). Petitioner asserts that this is not the “final” trial date because the schedule mentions the trial date may be scheduled “at the Court’s convenience.” Petition at 77. However, Petitioner presents no evidence showing that the Court may delay trial for 6 months. In fact, the trial date in the Amended Scheduling Order is consistent with the median time to trial for patent cases in the Western District of Texas and Judge Albright’s court—24.3 and 24.0 months, respectively. *See* Ex. 2003 (Western District of Texas patent case statistics), Ex. 2004 (Judge Albright patent case statistics). Thus, by the time the final oral hearing occurs or the final written decision is likely to be issued, the district court trial will likely have already commenced and concluded, addressing both infringement and the same invalidity arguments presented in the Petition. Accordingly, this factor weighs heavily in favor of denial.

⁹ Patent Owner’s complaint was filed in the Western District of Texas on March 12, 2022. *See* Ex. 1015.

C. Investment In The Parallel Proceeding By The Court and The Parties

The third *Fintiv* factor, which addresses the district court's and parties' investments into the parallel proceeding, also weighs in favor of denying institution because the parallel litigation has progressed significantly and will continue to do so by the time the Board issues an institution decision in this proceeding.

Petitioner misleadingly states that “[t]he District Court Litigation is in its infancy.” Petition at 77. Prior to the filing of the Petition, the parties had already shared preliminary invalidity and infringement contentions, and the Court held claim construction proceedings,¹⁰ where it rejected the same claim constructions presented in the Petition. *See* Ex. 2001 (Claim Construction Order). Since the filing of the Petition, the parties have also shared final invalidity and infringement contentions and have been heavily engaged in fact discovery for months, including multiple responses to discovery requests, the production of thousands of pages of documents by the parties, and the service of subpoenas to third parties. Furthermore, the deadline for the close of fact discovery is August 22, 2023. *See* Ex. 2002 (Scheduling Order). Thus, by the time the Board issues an institution decision in this proceeding, the parties will have substantially completed fact discovery in the District Court proceeding.

¹⁰ The District Court held the *Markman* hearing on January 20, 2023, four days before the Petition was filed on January 24, 2023.

Given the investment by the District Court and the parties to date, as well as the deadlines in the corresponding litigation and the progress that will accrue in that litigation before any institution decision by the Board, this factor also weighs in favor of discretionary denial.

D. Overlap Between The Issues Raised In The Petition and The Parallel Proceeding

The fourth *Fintiv* factor, which addresses the overlap between the issues raised in the Petition and the parallel proceeding, also weighs in favor of denial. In the parallel litigation, Patent Owner has asserted that Petitioner infringes all 14 claims of the '962 Patent. Petitioner has asserted the same invalidity arguments in the District Court litigation that it sets forth in the Petition. *See* Ex. 2005 (Hangsen's Final Invalidity Contentions) at 4–7 (asserting invalidity arguments based on Divi, Moody, Enzymicals, Velikogne, Wetzl, Arnold, and Sheldon).

Moreover, Petitioner has not presented a stipulation not to pursue in the district court litigation the same grounds or any grounds that could have been reasonably raised before the PTAB. *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, at 18–19 (PTAB Dec. 1, 2020) (precedential as to § II.A). This violates the fundamental tenet of *inter partes* reviews, which is that a litigant cannot simply hedge its bets on the forum in which to pursue invalidity, but instead should make a concerted decision regarding where it wishes to litigate its invalidity challenges, and then honor that decision—as opposed to proposing to

simultaneously assert those same references in two district court litigations. *See* 77 Fed. Reg. 48680-01 (Aug. 14, 2012) (IPRs are intended “to create a timely, cost-effective *alternative* to litigation”). This factor also weighs in favor of discretionary denial.

E. Whether The Petitioner and The Defendant In The Parallel Proceeding Are The Same Party

Petitioner admits that it is the defendant in the co-pending litigation. Petition at 2. As a result, this fifth *Fintiv* factor also weighs in favor of discretionary denial. *Cisco*, IPR2021-00238, Paper 10 at 16–17.

F. Other Circumstances That Impact The Board’s Exercise of Discretion, Including The Merits

Finally, the sixth *Fintiv* factor addresses other circumstances that impact the Board’s exercise of discretion. As explained in detail above, Patent Owner raises substantive reasons why the Petition should be denied on the merits and has demonstrated that those merits are far from “compelling.” *See* Interim Guidance at 4.

VII. CONCLUSION

Petitioner has failed to meet its burden of showing that there is a reasonable likelihood that any of the claims of the ’962 Patent are unpatentable. Additionally, a holistic analysis of *Fintiv* factors 1–5 heavily favors denial, and Petitioner has not presented compelling merits for institution. As such, Patent Owner respectfully requests that the Board exercise its discretion and deny institution.

Dated: May 8, 2023

Respectfully submitted,
/s/ Daniel Prati
Daniel Prati (Reg. No. 65,869)
Lead Counsel for Patent Owner

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(a)(i), the undersigned certifies that this Paper—exclusive of the table of contents, exhibit list, certificate of service, and this certificate of word count—includes 8200 words. The undersigned has relied upon the word count feature provided by Microsoft Word.

Dated: May 8, 2023

Respectfully submitted,

/s/ Daniel Prati

Daniel Prati

Reg. No. 65,869

Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on May 8, 2023, copies of Patent Owner's Preliminary Response and Exhibits 2001–2005 were served on Lead and Backup Counsel for Petitioner via email (by consent) to:

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