

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SHANGHAI HONGENE BIOTECH CORP.,
Petitioner,

v.

CHEMGENES CORP.,
Patent Owner.

IPR2023-00490
Patent 9,884,885 B2

Before JOHN G. NEW, ZHENYU YANG, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

PRELIMINARY GUIDANCE
PATENT OWNER'S MOTION TO AMEND

I. INTRODUCTION

On July 20, 2023, we instituted trial as to claims 1–5 of U.S. Patent No. 9,884,885 B2. Paper 7. After institution, Patent Owner filed a Motion to Amend. Paper 17 (“Motion” or “Mot.”). In its Motion, Patent Owner proposes to amend the ’885 patent to replace claims 1 and 5 with substitute claims 6 and 7. Mot. 1–2.¹ Petitioner timely filed an Opposition to Patent Owner’s Motion. Paper 22 (“Opposition” or “Opp.”).

In the Motion, Patent Owner requested that we provide preliminary guidance concerning the Motion in accordance with the Board’s Pilot Program concerning motion to amend practice and procedures. Mot. 1; *see also* Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board, 84 Fed. Reg. 9,497 (Mar. 15, 2019) (providing a patent owner with the option to receive preliminary guidance from the Board on its motion to amend) (“Notice”). We have duly considered Patent Owner’s Motion and Petitioner’s Opposition.

In this Preliminary Guidance, we provide information indicating our initial, preliminary, and non-binding views on whether Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend in an *inter partes* review and whether

¹ We note that Patent Owner states in the “Introduction” section of the Motion that “[t]his Motion to Amend proposes to narrow the scope of Claims 1, 4, and 5 to delete species from the recited genera and to insert inadvertently omitted language into Claim 5.” Mot. 1. However, Patent Owner does not include any proposed substitute claims for claim 4 and does not address claim 4 in the remainder of the Motion. Accordingly, Patent Owner has not presented any proposed changes to claim 4 and we do not consider any changes to claim 4 as part of our analysis.

Petitioner (or the record) establishes a reasonable likelihood that the substitute claims are unpatentable. *See* Notice, 84 Fed. Reg. at 9,497 (“The preliminary guidance . . . provides preliminary, non-binding guidance from the Board to the parties about the [motion to amend]”); *see also* 35 U.S.C. § 316(d) (statutory requirements for a motion to amend); 37 C.F.R. § 42.121 (regulatory requirements and burdens for a motion to amend); *Lectrosonics, Inc. v Zaxcom, Inc.*, IPR2018-01129, Paper 15 (PTAB Feb. 25, 2019) (precedential) (providing information and guidance regarding motions to amend).

For purposes of this Preliminary Guidance, we focus on the proposed substitute claims, and specifically on the amendments proposed in the Motion. *See* Notice, 84 Fed. Reg. at 9,497. We do not address the patentability of the originally challenged claims. *Id.* Moreover, in formulating our preliminary views on the Motion and Opposition, we have not considered the parties’ other substantive papers on the underlying merits of Petitioner’s challenges. We emphasize that the views expressed in this Preliminary Guidance are subject to change upon consideration of the complete record, including any revision to the Motion filed by Patent Owner. Thus, this Preliminary Guidance is not binding on the Board when rendering a final written decision. *See id.* at 9,500.

II. PRELIMINARY GUIDANCE

As a threshold matter, Patent Owner has not clearly articulated whether the Motion is either: (1) contingent upon a finding in a final written decision that the challenged claims are unpatentable; or (2) non-contingent. “A motion to amend claims may cancel claims and/or propose substitute claims.” *Lectrosonics* at 3 (citing 35 U.S.C. § 316(d)(1); 37 C.F.R. § 42.121(a)(3)). A request to substitute claims ordinarily will be treated as contingent. *Id.* “In other words, a proposed

substitute claim normally will be considered only if a preponderance of the evidence establishes that the original patent claim that it replaces is unpatentable.”

Id. A patent owner should adopt a claim-by-claim approach to specifying the contingency of substitution, e.g., which claim is to be substituted for which claim, and under what circumstances. *Id.*

Because Patent Owner indicates a desire to “substitute challenged Claims 1 and 5,” for purposes of this Preliminary Guidance, we treat the Motion as contingent upon a finding in a final written decision that the challenged claims are unpatentable. *Lectrosonics* at 3 (“[A] request to substitute claims ordinarily will be treated as contingent”). However, we advise Patent Owner to expressly state whether the motion is contingent or non-contingent in either a reply in support of the motion to amend or in a revised motion to amend.

A. Statutory and Regulatory Requirements

For the reasons discussed below, at this stage of the proceeding, and based on the current record, it appears that Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend.

1. Reasonable Number of Substitute Claims

Does Patent Owner propose a reasonable number of substitute claims? (35 U.S.C. § 316(d)(1)(B))
Yes. Patent Owner proposes no more than 1 substitute claim for each challenged claim. Mot. 2, 17–18 (Appx. A). Petitioner does not argue otherwise.

2. Respond to Ground of Unpatentability

Does the Motion respond to a ground of unpatentability involved in the trial? (37 C.F.R. § 42.121(a)(2)(i))

Yes. It appears that Patent Owner responds to the grounds of unpatentability. Mot. 7, 10–14. Petitioner does not argue otherwise.

3. Scope of Amended Claims

Does the amendment seek to enlarge the scope of the claims? (35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii))

No. It appears that each proposed substitute claim is narrower in scope than the corresponding original claim. Mot. 3, 17–18 (Appx. A). Petitioner does not argue otherwise.

4. New Matter

Does the amendment seek to add new subject matter? (35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii))

No. On this record, it appears that Patent Owner has set forth written description support for the proposed amendments. Mot. 3–7.

Patent Owner asserts that the proposed substitute claims are supported by the specification of the original application, No. 13/261,029 (“the ’029 application”), and International Application PCT/US2010/001494 (“PCT ’494 application”). Mot. 3–4. The ’029 application is a National Stage filing of the ’494 application under 35 U.S.C. § 371. *Id.* Patent Owner asserts that proposed substitute claim 6 is supported in claim 3 of the ’029 application and the PCT ’494 application. *Id.* Patent Owner asserts that proposed substitute claim 7 is supported in claim 7, compound 24, and page 24 (“disclosing long chain alkyl amine (lcaa) spacers”) of the ’029 application and the PCT ’494 application. *Id.* at 6–7.

Petitioner does not identify any limitations for which support is allegedly lacking.

B. Patentability

For the reasons discussed below, at this stage of the proceeding, and based upon the current record,² it appears that Petitioner has shown a reasonable likelihood that proposed substitute claims 6 and 7 are unpatentable.

Does the record establish a reasonable likelihood that the proposed substitute claims are unpatentable?

Yes. On this record, it appears that Petitioner has shown a reasonable likelihood that proposed substitute claims 6 and 7 are unpatentable as anticipated and obvious on the grounds discussed below.

We note that Patent Owner has not yet had an opportunity to respond to the arguments and evidence cited in Petitioner's Opposition or this Preliminary Guidance. Patent Owner will have the opportunity to do so in a Reply or in a Revised Motion to Amend in this proceeding.

Proposed Substitute Claim 6

In proposed substitute claim 6, Patent Owner proposes removing "cytosine-N-acetyl" from the Markush group in claim 1, such that proposed substitute claim 6 recites a limitation "where B is selected from the group consisting of Guanine-N-acetyl, adenine-N-acetyl, cytosine-N-isobutyryl, 5-methyl cytosine-N-acetyl, and 5-methyl cytosine-N-isobutyryl." Mot. 17 (App'x A). We discuss below our preliminary views regarding this limitation in the context of the prior art Petitioner raises in its Opposition.

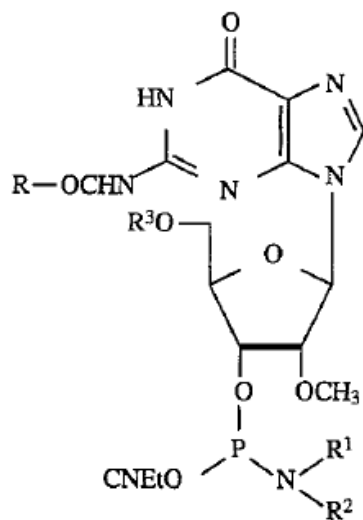
I. Anticipation

A. U.S. Patent No. 5,525,719 ("the '719 patent")³

² We express no view on the patentability of original claims 1 and 5 in this Preliminary Guidance. Instead, we focus on the proposed amendments to those claims in the Patent Owner's Motion to Amend.

³ U.S. Patent 5,525,719, issued June 11, 1996 (Ex. 1043).

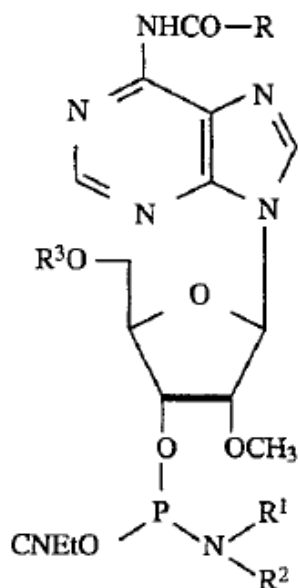
Petitioner argues the '719 patent discloses a compound of proposed substitute claim 6 where B is guanine-N-acetyl. Opp. 1–3. Petitioner maps the '719 patent's Group 5 compound, N²-protected-2'-O-methyl-5'-dimethoxytrityl-guanosine cyanoethyl N, N-dialkyl phosphoramidite ("N²-protected guanosine"), to the limitations of proposed substitute claim 6. *Id.* (citing Ex. 1043, 4:35–37, 6:48–65, 16:66–17:1; Ex. 1044, ¶¶ 18, 20–29). The '719 patent's Group 5 compound is depicted below:



(GROUP 5)

Ex. 1043, 6:48–65. More specifically, Petitioner contends the '719 patent discloses an acetyl group for protecting the N² position of guanine in the Group 5 compound, such that the Group 5 compound contains guanine-N-acetyl. Opp. 1–3 (citing Ex. 1043, 4:35–37; Ex. 1044, ¶¶ 25–27). The '719 patent states that "N²-Protection of guanosine is meant to include isobutyryl, acetyl, substituted acetyls, phenoxyacetyl, and related compounds." Ex. 1043, 4:35–37.

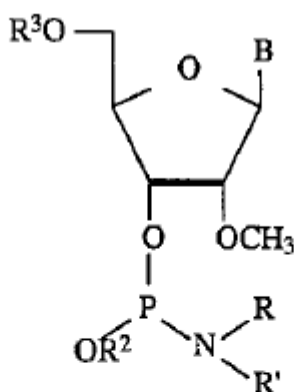
Petitioner also argues the '719 patent discloses a compound of proposed substitute claim 6 where B is adenine-N-acetyl. Opp. 1, 3–5. Petitioner maps the '719 patent's Group 4 compound, N⁶-protected-2'-O-methyl-5'-dimethoxytrityl-adenosine cyanoethyl N, N-dialkylphosphoramidite ("N⁶-protected adenosine"), to the limitations of proposed substitute claim 6. *Id.* (citing Ex. 1043, 4:29–31, 6:32–45, 16:63–65; Ex. 1044, ¶¶ 18, 31–40). The '719 patent's Group 4 compound is depicted below:



(GROUP 4)

Ex. 1043, 6:32–45. More specifically, Petitioner contends the '719 patent discloses an acetyl group for protecting the N⁶ position of adenine in the Group 4 compound, such that the Group 4 compound contains adenine-N-acetyl. Opp. 1, 3–5 (citing Ex. 1043, 4:29–31; Ex. 1044, ¶¶ 36–38). The '719 patent states that “‘N⁶-Protection of adenosine’ is meant to include benzoyl, substituted benzoyl, other aroyls (such as naphthoyl), acetyl, substituted acetyl, phenoxyacetyl, and related compounds.” Ex. 1043, 4:29–31.

Petitioner argues the '719 patent discloses a compound of proposed substitute claim 6 where B is cytosine-N-isobutyryl. Opp. 1, 6–7. Petitioner maps the '719 patent's Group 1, Structure IIb compound to the limitations of proposed substitute claim 6. *Id.* (citing Ex. 1043, 5:50–65; Ex. 1044, ¶¶ 18, 42–48). The '719 patent's Group 1, Structure IIb compound is depicted below:



Structures:

- I; B; A^{bz}; R&R; Isopropyl, R²; CH₃; R³; DMT
- II; B; C^{bz}; R&R; Isopropyl, R²; CH₃; DMT
- IIb; B; C^{ibu}; R&R; Isopropyl, R²; CH₂CH₂CN; R³; DMT
- III; B; G^{ibu}; R&R; Isopropyl, R²; CH₃; R³; DMT
- IVa; B; U; R&R; Isopropyl, R²; CH₃; R³; DMT
- IVb; B; U; R&R; Isopropyl, R²; CH₂CH₂CN; R³; DMT

Ex. 1043, 5:50–65. More specifically, Petitioner contends the '719 patent discloses that the Group 1, Structure IIb compound contains cytosine-N-isobutyryl in the same position as in proposed substitute claim 6. Opp. 1, 6–7. (citing Ex. 1043, 5:50–65; Ex. 1044, ¶44).

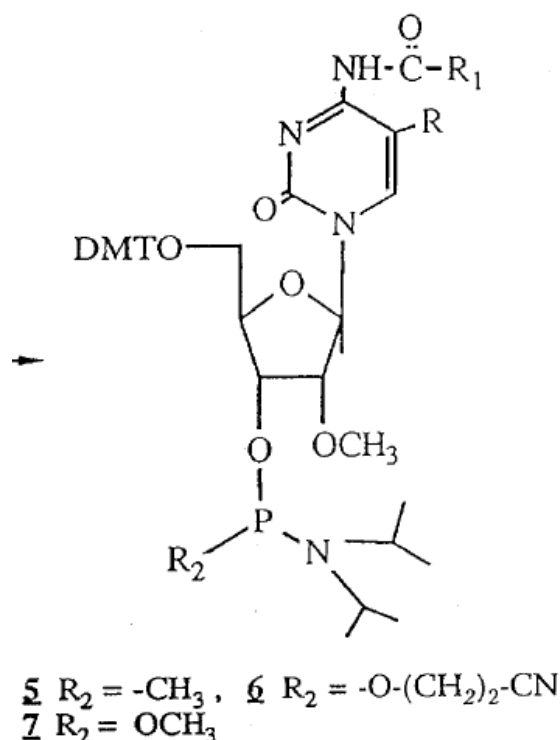
Petitioner's contentions appear to show that proposed substitute claim 6 includes subject matter disclosed in the cited art. Thus, it is our preliminary, non-binding opinion that Petitioner has established a reasonable likelihood that the '719 patent discloses the limitations of proposed substitute claim 6.

B. *U.S. Patent No. 5,606,049* ("the '049 patent")⁴

Petitioner argues the '049 patent discloses a compound of proposed substitute claim 6 where B is cytosine-N-isobutyryl. Opp. 9–10.

Petitioner maps the '049 patent's Figure 2 compound to the limitations of proposed substitute claim 6. *Id.* (citing Ex. 1045, Fig. 2, 1:48–65, 2:39–42, 2:50–53, 5:13–14, claims 1, 2; Ex. 1044, ¶¶ 61–68). The '049 patent's Figure 2 compound is depicted below:

⁴ U.S. Patent 5,606,049, issued February 25, 1997 (Ex. 1045).



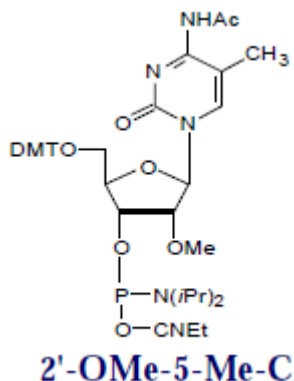
Ex. 1045, Fig. 2 (excerpt). More specifically, Petitioner contends the '049 patent discloses an isobutyryl protecting group on the cytosine group in the Figure 2 compound, such that the Group 5 compound contains cytosine-N-isobutyryl. Opp. 9–10 (citing Ex. 1045, 1:64, 2:50–53, 5:13–14; Ex. 1044, ¶ 64). The '049 patent states that the R_1 protecting group “is alkyl of about 1 to 6 carbon atoms.” Ex. 1043, 1:64.

Petitioner argues the '049 patent discloses a compound of proposed substitute claim 6 where B is 5-methyl cytosine-N-isobutyryl. Opp. 9, 11–12. Petitioner maps the '049 patent's Figure 2 compound to the limitations of proposed substitute claim 6. *Id.* (citing Ex. 1045, Fig. 2, 1:48–65; Ex. 1044, ¶¶ 70–75). More specifically, Petitioner contends the '049 patent discloses an isobutyryl protecting group on the cytosine group in the Figure 2 compound, such that the Group 5 compound contains 5-methyl cytosine-N-isobutyryl. *Id.* (citing Ex. 1045, 1:48–65; Ex. 1044, ¶¶ 71–72).

Petitioner's contentions appear to show that proposed substitute claim 6 includes subject matter disclosed in the cited art. Thus, it is our preliminary, non-binding opinion that Petitioner has established a reasonable likelihood that the '049 patent discloses the limitations of proposed substitute claim 6.

*C. The Glen Report*⁵

Petitioner argues the Glen Report was published and discloses a commercial offer for sale of a compound of proposed substitute claim 6 where B is 5-methylcytosine-N-acetyl. Opp. 13–15. Petitioner maps the Glen Report’s Figure 1 compound, 2’-OMe-5-Me-C, to the limitations of proposed substitute claim 6. *Id.* (citing Ex. 1046, 1, 6; Ex. 1044, ¶¶ 83–99). The Glen Report’s Figure 1 compound is depicted below:



Ex. 1046, 6 (excerpt of Fig. 1). More specifically, Petitioner contends the Glen Report states that 2’-OMe-5-Me-C is “the 5-methyl analogue of protected 2’-OMe-Cytidine which also has acetyl protection and is compatible with UltraFAST deprotection.” *Id.* at 13 (citing Ex. 1046, 6).

Petitioner’s contentions appear to show that proposed substitute claim 6 includes subject matter disclosed in the cited art. Thus, it is our preliminary, non-binding opinion that Petitioner has established a reasonable likelihood that the Glen Report discloses the limitations of proposed substitute claim 6.

⁵ *New universal and degenerate bases*, 8(1) THE GLEN REPORT 1–8 (June 1995) (Ex. 1046).

II. Obviousness

Proposed Substitute Claim 6

A. The '719 Patent Alone or with Pitsch⁶

Petitioner argues that the '719 patent discloses compounds of proposed substitute claim 6 where B is guanine-N-acetyl and adenine-N-acetyl as discussed above. Petitioner argues that a person of ordinary skill in the art would have also been motivated to make such compounds with a reasonable expectation of success because the '719 patent lists acetyl as a suitable protecting group for both N-protected guanine and N-protected adenine. Opp. 15–16 (citing Ex. 1043, 4:29–37; Ex. 1044, ¶ 104). Petitioner states that a person of ordinary skill in the art would have had a reasonable expectation of success in making the compounds because the synthesis of protected phosphoramidites was a routine procedure and the '719 patent includes an enabling disclosure. *Id.* (citing Ex. 1044, ¶¶ 104–105).

Petitioner also argues that Pitsch would have motivated a person of ordinary skill in the art to make compounds of proposed substitute claim 6 where B is guanine-N-acetyl and adenine-N-acetyl using the teachings of the '719 patent with a reasonable expectation of success because “Pitsch discloses acetyl-protecting groups on both adenosine and guanosine phosphoramidites.” Opp. 16–17 (citing Ex. 1018, 3775, 3778; Ex. 1044, ¶¶ 110–11; Ex. 1003, ¶ 119). According to Petitioner, “Pitsch explains that the acetyl protecting group was chosen for its fast deprotection speed, concluding that ‘the Ac [acetyl] group, in combination with MeNH₂, is indeed suited for a labile universal nucleobase protection.’” *Id.* (citing Ex. 1018, 3778). Therefore, Pitsch “not only discloses acetyl protection of both guanine and adenine but also concludes that acetyl in combination with MeNH₂ is suitable for ‘universal nucleobase protection.’” *Id.* (citing Ex. 1018, 3778; Ex. 1044, ¶ 111).

Petitioner’s contentions appear to show that proposed substitute claim 6 includes subject matter that that would have been obvious over the cited art. Thus, it is our preliminary, non-binding opinion that Petitioner has established a reasonable likelihood that the '719 patent alone or with Pitsch would have rendered proposed substitute claim 6 obvious.

B. The '049 Patent Alone or with Pitsch

Petitioner argues that the '049 patent discloses compounds of proposed substitute claim 6 where B is cytosine-N-isobutyryl and 5-methyl cytosine-N-isobutyryl as discussed above. Petitioner argues that a person of ordinary skill in the art would have also been motivated to make such compounds with a reasonable expectation of success because Figure 2 of the '049 patent discloses isobutyryl-protected compounds in which both hydrogen and methyl are suitable options for an R group at the 5-position of cytosine. Opp. 17–18 (citing Ex. 1045, 1:48–65; Ex. 1044, ¶¶ 115–16). Petitioner states that a person of ordinary skill in the art would have had a reasonable expectation of success in making the compounds because the '049 patent includes an enabling disclosure. *Id.* (citing Ex. 1044, ¶ 116).

Petitioner also argues that Pitsch would have motivated a person of ordinary skill in the art to make a compound of proposed substitute claim 6 where B is 5-methylcytosine-N-acetyl using the teachings of the '049 patent with a reasonable expectation of success because Pitsch discloses acetyl-protected cytosine and “that an acetyl protecting group was chosen for its fast deprotection speed, concluding that acetyl in combination with MeNH₂ is suitable for ‘universal nucleobase protection.’” Opp. 18–19 (citing Ex. 1018, 3775, 3778; Ex. 1044, ¶¶ 120–22).

Petitioner’s contentions appear to show that proposed substitute claim 6 includes subject matter that would have been obvious over the cited art. Thus, it is our preliminary, non-binding opinion that Petitioner has established a reasonable likelihood that the '049 patent alone or with Pitsch would have rendered proposed substitute claim 6 obvious.

Proposed Substitute Claim 7

In proposed substitute claim 7, Patent Owner proposes removing “cytosine-N-acetyl” and “cytosine-N-isobutyryl” from the Markush group in claim 5, such that proposed substitute claim 7 recites a limitation “wherein B is selected from the group consisting of Guanine-N-acetyl,

⁶ Pitsch et al., *Reliable chemical synthesis of oligoribonucleotides (RNA) with 2'-O-[(triisopropylsilyl)oxy]methyl(2'-O-tom)-protected phosphoramidites*, 84 HELVETICA CHIMICA ACTA 3773–95 (2001) (Ex. 1018).

adenine-N-acetyl, 5-methyl cytosine-N-acetyl, and 5-methyl cytosine-N-isobutyryl.” Mot. 17–18 (Appx. A). Patent Owner also proposes specifying that the “supports of general formula 2” are solid, such that proposed claim 7 recites “Derivatized nucleosides, succinates and solid supports of general formula 2.” *Id.* Patent Owner also proposes adding a limitation to specify that “NH is capable of being attached to a solid support with a spacer selected from the group consisting of C1–C20 alkyl, ethyloxyglycol, and a combination of alkyl and ethyleneglycoxy.” *Id.* We discuss our preliminary views regarding these limitations in the context of the prior art Petitioner raises in its Opposition below.

A. The '719 Patent and Scaringe⁷, or the '719 Patent, Pitsch, and Scaringe

According to Petitioner, the moiety bound to the 3'-O position of the sugar ring in the compound of proposed substitute claim 7 differs from the compound of proposed substitute claim 6. Opp. 19 (citing Ex. 1044, ¶ 131). Petitioner explains that the moiety bound to the 3'-O position of the sugar ring in proposed substitute claim 6 is cyanoethyl dialkyl phosphoramidite, whereas the moiety bound to the 3'-O position of the sugar ring in proposed substitute claim 7 can be a succinyl-NH group. *Id.* Given this difference, Petitioner argues that it was well-known that the side group bound to the O at the 3' position of a nucleoside could be a phosphoramidite or a succinate, and a person of ordinary skill in the art “would have known how to switch between a phosphoramidite group and a succinate group based on the prior art.” *Id.* at 20–22 (citing Ex. 1022, 5434, 5440; Ex. 1044, ¶¶ 137, 141). For example, Scaringe teaches that each of the four canonical RNA nucleosides can be converted to its corresponding phosphoramidite or succinylated derivative. *Id.*

According to Petitioner, a person of ordinary skill in the art would have been motivated to substitute the phosphoramidite in the Group 4 and Group 5 compounds disclosed in the '719 patent for a succinyl group to reach a compound of proposed substitute claim 7 where B is guanine-N-acetyl or adenine-N-acetyl with a reasonable expectation of success

⁷ Scaringe et al., *Chemical synthesis of biologically active oligoribonucleotides using β -cyanoethyl protected ribonucleoside phosphoramidites*, 18(18) NUCLEIC ACIDS RES. 5433–41 (1990) (Ex. 1022).

because “succinate was ‘very popular because of low cost and ease of incorporation.’” Opp. 20–21 (citing Ex. 2031, 11; Ex. 1044, ¶¶ 136–40). Petitioner explains that a succinyl group “is capable of being attached to a solid support with a spacer selected from the group in Substitute Claim 7.” Opp. 20 (citing Ex. 1044, ¶¶ 136–39). According to Petitioner, Scaringe teaches that its succinylated derivatives are coupled to long chain alkylamine controlled pore glass to prepare the solid supports for solid phase oligonucleotide synthesis. *Id.* at 21–22 (citing Ex. 1022, 5434, 5440; Ex. 1044, ¶¶ 141–43). Petitioner explains that “the ‘long chain alkyl’ functions as a spacer attaching the ‘amine’ group (i.e., -NH-) to the ‘controlled pore glass,’ i.e., the solid support.” *Id.*

Petitioner argues that for the same reasons discussed above, claim 7 would have been obvious in view of the ’719 patent, Pitsch, and Scaringe. Opp. 22–23 (citing Ex. 1044, ¶ 147).

Petitioner’s contentions appear to show that proposed substitute claim 7 includes subject matter that would have been obvious over the cited art. Thus, it is our preliminary, non-binding opinion that Petitioner has established a reasonable likelihood that the ’719 patent in combination with Scaringe or Scaringe and Pitsch would have rendered proposed substitute claim 7 obvious.

B. The ’049 Patent and Scaringe, or the ’049 Patent, Pitsch, and Scaringe

Petitioner argues that a person of ordinary skill in the art would have been motivated to substitute the phosphoramidite in the Figure 2 compound disclosed in the ’049 patent for a succinyl group to reach a compound of proposed substitute claim 7 where B is 5-methyl cytosine-N-isobutyryl with a reasonable expectation of success for the same reasons discussed above. Opp. 23–24 (citing Ex. 1044, ¶¶ 151–52, 155).

Petitioner’s contentions appear to show that proposed substitute claim 7 includes subject matter that would have been obvious over the cited art. Thus, it is our preliminary, non-binding opinion that Petitioner has established a reasonable likelihood that the ’049 patent in combination with Scaringe or Scaringe and Pitsch would have rendered proposed substitute claim 7 obvious.

C. The Glen Report and Scaringe

Petitioner argues that a person of ordinary skill in the art would have been motivated to substitute the phosphoramidite in the Glen Report's Figure 1 compound, 2'-OMe-5-Me-C, for a succinyl group to reach a compound of proposed substitute claim 7 where B is 5-methyl cytosine-N-acetyl with a reasonable expectation of success for the same reasons discussed above. Opp. 25 (citing Ex. 1044, ¶¶ 159–60).

Petitioner's contentions appear to show that proposed substitute claim 7 includes subject matter that would have been obvious over the cited art. Thus, it is our preliminary, non-binding opinion that Petitioner has established a reasonable likelihood that the Glen Report in combination with Scaringe would have rendered proposed substitute claim 7 obvious.

III. CONCLUSION

This concludes the Preliminary Guidance, which is Patent Owner's first option under the Board's Pilot Program. Notice, 84 Fed. Reg. at 9,497. Patent Owner has the additional option under the Board's Pilot Program to file a revised motion to amend by February 27, 2024 (Due Date 3). Paper 18, 2. These two options are in addition to Patent Owner's original option to file a reply brief in response to Petitioner's opposition to the motion to amend.

In addition to those two options under the Board's Pilot Program and the option to file a reply brief, Patent Owner is reminded that amendments of the challenged claims may also be pursued in a separate reissue or reexamination proceeding before, during, or after an AIA trial proceeding, including subsequent to the issuance of the Final Written Decision. We draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind

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Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

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FOR PETITIONER:

Jeremy Edwards
Raymond Chan
Xiaofan Yang
Jack Shaw
PROCOPIO, CORY, HARGREAVES & SAVITCH, LLP
jeremy.edwards@procopio.com
raymond.chan@procopio.com
frank.yang@procopio.com
jack.shaw@procopio.com

FOR PATENT OWNER:

Daniel Shores
Joseph Hynds
Aydin Harston
Xiaoban Xin
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
dshores@rfem.com
jhynds@rfem.com
aharston@rfem.com
xxin@rfem.com