

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

QIAGEN SCIENCES, LLC,
Petitioner,

v.

TECAN GENOMICS, INC.,
Patent Owner

Case No. IPR2025-00026
U.S. Patent No. 11,098,357

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

I. INTRODUCTION	1
II. TECHNOLOGY BACKGROUND	2
A. Development of Sequencing Technology	2
B. Next-Generation Technologies	3
C. Challenges With Existing Methods of NGS	5
III. THE '357 PATENT.....	7
A. Overview	7
B. Level of Ordinary Skill in the Art	7
C. Prosecution History	9
D. Claim Construction.....	9
IV. THE PETITION FAILS TO ESTABLISH A REASONABLE LIKELIHOOD OF SUCCESS ON AT LEAST ONE CLAIM.....	10
A. Ground 1: Petitioner Has Not Shown That Any Challenged Claim Is Anticipated by Porreca.....	10
1. The Petition Fails to Establish that Porreca Discloses the Claimed Adaptor 10	
2. The Petition Fails to Establish that Porreca Discloses Identifying Duplicate Sequencing Reads Based on the Identifier and at Least a Portion of the Target Sequence	14
3. The Petition Has Failed to Establish that Any Dependent Claim is Likely Invalid	18
B. Ground 2: Petitioner Has Not Shown That Any Challenged Claim Is Obvious Over the Combination of Schmitt and McCloskey.....	18
1. Schmitt Does Not Disclose All Elements of the Challenged Claims	19
2. McCloskey Similarly Does Not Disclose All Elements of the Challenged Claims	21
3. Petitioner Has Not Established That a POSA Would Have Been Motivated to Combine Schmitt and McCloskey With a Reasonable Expectation of Success.....	21
4. The Petition Has Failed to Establish that Any Dependent Claim is Likely Invalid.....	24

C. Grounds 3 and 4: Petitioner Has Not Shown That Claim 4 Is Obvious Over the Combination of Porreca, Illumina 2008, Schmitt, and/or McCloskey	24
D. Grounds 5 and 6: Petitioner Has Not Shown That Claim 7 Is Obvious Over the Combination of Porreca, Illumina 2008, Schmitt, and/or McCloskey	25
V. THE BOARD SHOULD EXERCISE ITS DISCRETION TO DENY INSTITUTION.....	26
A. Discretionary Denial Under § 325(d) Is Appropriate Because the Examiner Considered Substantially the Same Prior Art	27
1. Porreca Discloses Substantially the Same Information as McCloskey 2007 28	
2. Schmitt Discloses Substantially the Same Information as Samuels and McCloskey 2007	29
3. McCloskey Discloses Substantially the Same Information as McCloskey 2007	30
4. Illumina 2008 Was Cited by the Examiner	31
B. Petitioner Has Failed to Identify Any Material Error by the Examiner.....	31
VI. CONCLUSION	33

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH,</i> IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020).....	26, 27, 32
<i>In re Gorman,</i> 933 F.2d 982 (Fed. Cir. 1991)	21, 22
<i>InfoBionic, Inc. v. Braemar Manufacturing, LLC,</i> IPR2015-01704, Paper 11 (PTAB Feb. 16, 2016).....	23
<i>InTouch Techs., Inc. v. VGO Commc'ns, Inc.,</i> 751 F.3d 1327 (Fed. Cir. 2014)	22
<i>Microsoft Corp. v. Biscotti, Inc.,</i> 878 F.3d 1052 (Fed. Cir. 2017)	12
<i>Net MoneyIN, Inc. v. VeriSign, Inc.,</i> 545 F.3d 1359 (Fed. Cir. 2008)	10, 12
<i>Palo Alto Networks, Inc. v. Centripetal Networks, Inc.,</i> IPR2021-01520, Paper 23 (PTAB Mar. 22, 2022).....	32
<i>Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.,</i> 853 F.3d 1272 (Fed. Cir. 2017)	17
<i>Xerox Corp., et al. v. Bytemark, Inc.,</i> IPR2022-00624, Paper 12 (PTAB Feb. 10, 2023).....	15, 17
<i>Xilinx, Inc., et al v. Analog Devices, Inc.,</i> IPR2021-00294, Paper 9 (PTAB June 10, 2021)	27

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I. INTRODUCTION

Pursuant to 35 U.S.C. § 323 and 37 C.F.R. § 42.107, Patent Owner Tecan Genomics, Inc. (“Patent Owner” or “Tecan”) submits this Preliminary Response to QIAGEN Sciences, LLC’s (“Petitioner” or “Qiagen”) petition (“Petition”) challenging claims 1-10 (the “challenged claims”) of U.S. Patent No. 11,098,357 (“the ’357 Patent”). Petitioner has not met its burden of establishing that there is a reasonable likelihood it would prevail with respect to at least one challenged claim, and therefore, the Board should deny the Petition.

Both the Petition’s anticipation and obviousness arguments fail to show that the prior art taught key limitations of the challenged claims. As explained in more detail below, none of the cited prior art discloses or teaches using both an identifier site and at least a portion of the target sequence to identify duplicate reads in a DNA sequencing method, and the Petition further fails to show that the cited prior art discloses the claimed adaptor. Petitioner improperly relies on cherry-picking disclosures from different embodiments, and glosses over gaps in the prior art with conclusory expert *ipse dixit* that merely parrots the Petition verbatim. The Petition fails to articulate how a POSA would have combined the cited references to arrive at the claimed invention, offering only conclusory analyses and relying on unsupported expert testimony to carry the argument. Thus, Petitioner has failed to

show a reasonable likelihood that any challenged claim is either anticipated or rendered obvious, and institution should be denied.

Further, Petitioner relies on prior art references that are substantially the same as art that was considered and relied on by the Examiner. The Examiner raised obviousness arguments during prosecution similar to those made in the Petition, but Applicants overcame those rejections. Petitioner has failed to point to any error by the Examiner, making discretionary denial under § 325(d) appropriate here.

II. TECHNOLOGY BACKGROUND

A. Development of Sequencing Technology

Genetic sequencing, the assessment of genetic information through methods that characterize the sequence of an organism's genetic code, is essential for the understanding of biology and medicine. EX2009.0001. Several methods have been developed over the years to accurately and efficiently sequence DNA, starting with traditional sequencing methods that are now referred to as “pre-next-generation sequencing” (“Pre-NGS”) technologies. The gold standard of these Pre-NGS technologies was Sanger Sequencing, developed in 1977. *Id.*, .0002; *see also* EX2008.0001. Sanger Sequencing was the first method that allowed for a DNA sequence to be determined. In this method, the DNA was amplified in the presence of dye-labeled, chemically modified nucleotides that, when incorporated into the sequence, would prevent further strand elongation. These modified nucleotides

would be incorporated at random throughout the duplication process, yielding a variety of smaller fragments, each with a modified nucleotide at its ends. *Id.*, .0002; *see also* EX2008.0001. Each terminal nucleotide could be identified based on the dye-labeled nucleotides. By correlating the length of the fragments and the identification of the dye-labeled nucleotides, one could determine the nucleotide sequence of the original template DNA strand. *Id.* Although revolutionary, Sanger Sequencing was expensive and ill-suited for large-scale applications. EX2004.0001.

B. Next-Generation Technologies

Starting in the early 2000s, the field of genetics was revolutionized by the invention of next-generation sequencing (“NGS”). Compared to traditional, Pre-NGS sequencing methods, NGS sequencing utilized a new design that no longer relied upon disassembling and then piecing together a single original template DNA strand. Instead, NGS sequencing now allowed for hundreds of thousands of original template strands to be sequenced in the same reaction. With NGS, a user could perform massively parallel sequencing, allowing for elements of the genome to be sequenced in a fast, scalable manner. *Id.*, .0003. As compared to Sanger Sequencing, NGS was cheaper, more efficient, and capable of assessing both larger genetic samples and larger portions of the human genome in high fidelity. *Id.*

However, early NGS methods had their drawbacks. NGS was limited to shorter individual sequencing reads than Sanger Sequencing, which greatly

increased the difficulty in mapping the sequence reads to a full genome. *Id.* NGS also made it difficult to determine whether reads were duplicate, naturally occurring repetitive sections of a genome, or mutated sequences of the genome. EX2001.0001; *see also* EX2002.0001-02.

Targeted enrichment methods became one way to mitigate the issues associated with characterizing a sequence of a genomic area of interest. Rather than amplifying and sequencing the larger, full genome, targeted enrichment was a method of sample preparation in which smaller genomic areas of interest, such as individual genes, were amplified. EX2006.0001-02. However, targeted enrichment came with its own set of difficulties. The amplification of the sequence introduced PCR errors. EX2005.0005. This made it difficult to determine whether changes in nucleotides across similar sequences were due to mutations, or to PCR error, and confounded the data. There were also errors within the sequencing read, such as signal crosstalk, where signals overlap and do not accurately identify the nucleotide, leading to a sequencing read containing the wrong nucleotide. EX2010.0002-03. Lastly, errors occurred during sequencing strand synthesis, leading to sequence strands containing an incorrect insertion or deletion of a nucleotide. EX2007.0001-02.

One method of target enrichment was capture-by-circularization, which utilized linear nucleotide probes termed “Molecular Inversion Probes (“MIPs”). *See*

EX2016.0016 at 1:39-47. MIPs were designed so that both ends of the probes bound on either side of a genomic region of interest. *See id.* at 2:11-16. The genomic region of interest could then be copied into the probe while joining the two ends of the linear probe to create a circle. *Id.* By adding a copy of the sequence to the probe, thereby creating a circle, that circular probe could be amplified, allowing for selective enrichment. The genomic region of interest contained in the circularized probes could then be amplified by PCR to generate linear copies of the genomic region of interest. *See id.* at 2:16-18.

C. Challenges With Existing Methods of NGS

Because of the errors inherent in the NGS process, identifying duplicates to accurately map the sequence reads and to distinguish between mutations versus sequencing errors became an area of interest for both whole genome and targeted enrichment NGS applications. Beyond the scientific issues noted above, the problem of duplicates also had practical implications. For example, large numbers of duplicates in data led to unnecessarily large data sets, making it more difficult to parse the data and more expensive and burdensome to store. EX2015.0003-04. Removing duplicates as much as possible would not only allow for more accurate sequencing, but would also save on the time and expense of data analysis associated with sequencing.

One way to identify duplicates was to match the beginning and end of fragments to positions in the reference genome—the odds are higher that fragments with the same beginning and end sequences would be duplicates. EX2017.0009. But with this method, there was still a risk that naturally-occurring repetitive sequences would be improperly identified as duplicates. The identification of duplicates was particularly challenging with single primer target enrichment methods, where only the side of the fragment associated with the primer would vary in position across the reference genome. *Id.* The end-matching method was not usable at all in instances where the reference genome was unknown.

One potential solution involved the use of “barcodes” of nucleotides used to tag original sequences prior to sample preparation and amplification. EX2018.0099. The presence of the barcode signaled that a fragment was part of an original sequence. *Id.* It also could be used to identify mutations present in the genome versus mutations introduced via PCR, sequence read, or sequence strand synthesis errors. *Id.* The barcode method, while helpful, also had downsides. Barcodes added extra nucleotides to each fragment, which increased the total number of nucleotides that needed to be sequenced and took up space on the sequence read. EX2014.0008-09. Shorter barcodes required less space but reduced the number of unique barcodes available and had limited value for samples that contained many unique fragments. EX2003.0041. As of 2013, researchers in the field struggled to find a method of

identifying duplicates that improved on the accuracy of the original barcode method, while still allowing for longer sequence reads.

III. THE '357 PATENT

A. Overview

The '357 Patent is directed to a method of detecting, and subsequently removing, duplicate sequencing reads from a sample population. EX1002.0001. The claimed method is beneficial in overcoming issues relating to duplication that arose in previous sequencing methods, such as the problem of distinguishing between mutations and sequencing errors, as described above. *See supra* Section II. By allowing for greater ability in identifying and removing duplicates, the claimed method provides cleaner sequencing data by allowing unnecessary duplicative data to be filtered out. This is particularly beneficial for sequencing applications where a scientist seeks to understand the amount of starting material, such as in relative gene expression studies, where a scientist would need to compare the quantity of the sequenced gene in relation to another gene that might be present in the sample. In addition, as noted above, the accurate removal of duplicates can help to reduce the massive data set generated by sequencing methods, saving both time and money.

B. Level of Ordinary Skill in the Art

Petitioner proposes a level of skill in the art that does not accurately reflect the level of ordinary skill in the art as of November 2013, the priority date of the '357 Patent. Petitioner's definition of a person of ordinary skill in the art ("POSA")

requires that the POSA “would have (i) a Ph.D. in molecular biology, molecular genetics, bioinformatics, biochemistry, or a related field and at least two years of relevant applied research and/or industry experience in the field of nucleic acid library preparation and sequencing experience, including but not limited to high-throughput sequencing technologies or (ii) a Master’s degree in one of the same fields with at least four years of relevant applied research and/or industry experience in the field of nucleic acid library preparation and high-throughput sequencing technologies.” Petition, 8-9; see also EX1003.¶41. By 2008, NGS sequencing technologies were performed in laboratories according to published protocols and would have been accessible to experienced laboratory technicians and graduate students. Petitioner’s definition requiring that a POSA have both a Ph.D. or Master’s degree and several years of experience is therefore higher than ordinary.

Patent Owner proposes that the appropriate level of ordinary skill in the art requires that the POSA would have a Ph.D. in a field related to molecular biology, or a B.S. or M.S. degree with three to five years of experience working in a molecular biology lab. To the extent there are any differences between Petitioner’s definition and Patent Owner’s definition, under either definition, Petitioner has failed to establish a reasonable likelihood of success on at least one challenged claim.

C. Prosecution History

During prosecution of the '357 Patent, Applicants overcame multiple rejections based on the prior art references McCloskey 2007 (EX1015) and Samuels (EX2018). To overcome these rejections, Applicants distinguished the claimed invention by further defining the identification of a duplicate sequence by using both the identifier site *and* at least a portion of the nucleic acid fragment. Applicants further overcame rejections based on McCloskey 2007 and Samuels by distinguishing the claimed method to that disclosed in the prior art, in part because it allowed for fewer unique adapters. *See, e.g.* EX1013.0068-71; *Id.*, .0036-37. Applicants explained that because the claimed method recited the use of both the adapter and a portion of the target sequence to identify duplicates, fewer unique adaptors would be needed. *See, e.g., id.*, .0068-71.

D. Claim Construction

Petitioner argues that the term “adaptor” should be construed as “any oligonucleotide that is attached to the target sequence.” Petition, 9. For purposes of this Preliminary Response, Patent Owner does not believe any term of the '357 Patent needs to be construed beyond its plain and ordinary meaning. Patent Owner reserves the right to identify terms for construction and propose constructions in this proceeding should it be instituted.

**IV. THE PETITION FAILS TO ESTABLISH A REASONABLE
LIKELIHOOD OF SUCCESS ON AT LEAST ONE CLAIM**

**A. Ground 1: Petitioner Has Not Shown That Any Challenged Claim
Is Anticipated by Porreca**

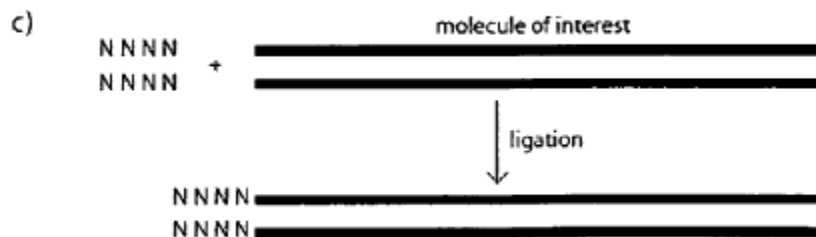
**1. The Petition Fails to Establish that Porreca Discloses the
Claimed Adaptor**

Claim 1 requires “ligating an adaptor to each of a plurality of nucleic acid fragments, wherein each adaptor comprises a unique identifier...an indexing site...and a primer binding site” followed by “amplifying the adaptor-ligated fragments...” EX1002.0024, cl.1. Petitioner has not pointed to an embodiment in Porreca that discloses the claimed adaptor. Instead, Petitioner’s anticipation arguments are improperly based on combinations of multiple, distinct teachings—none of which individually disclose all elements of claim 1—and therefore fail.

“[I]t is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008). For example, when “two separate protocols” were disclosed in a prior art reference, yet “[n]either of these protocols contain[ed] all five links arranged or combined in the same way as claimed,” the Federal Circuit has confirmed that the reference could not anticipate the claimed system. *Id.*

Petitioner points to Figures 4a and 4c of Porreca, as well as various unrelated disclosures in the specification, for alleged disclosure of the claimed adaptor. Petition at 18, 40; ; EX1006.0005, Fig 4a, 4c. However, Porreca makes clear that these figures do not describe a single embodiment; rather, they “depict various non-limiting methods for combining differentiator tag sequence and target sequences.” EX1006.0027, [0085]. These describe different alternative configurations and/or methods, not a specific adaptor structure required by the limitations of the claims. The Petition fails to establish that Porreca discloses all elements of the claimed adaptor, instead relying on an improper combination of disclosures from disparate embodiments.

For example, Petitioner relies on paragraph 150 and Figure 4c of Porreca as allegedly disclosing the “ligating an adaptor” limitation of claim 1. Figure 4c (reproduced below) discloses ligation of an adaptor, but there is no disclosure that a sample index is included as part of that adaptor:



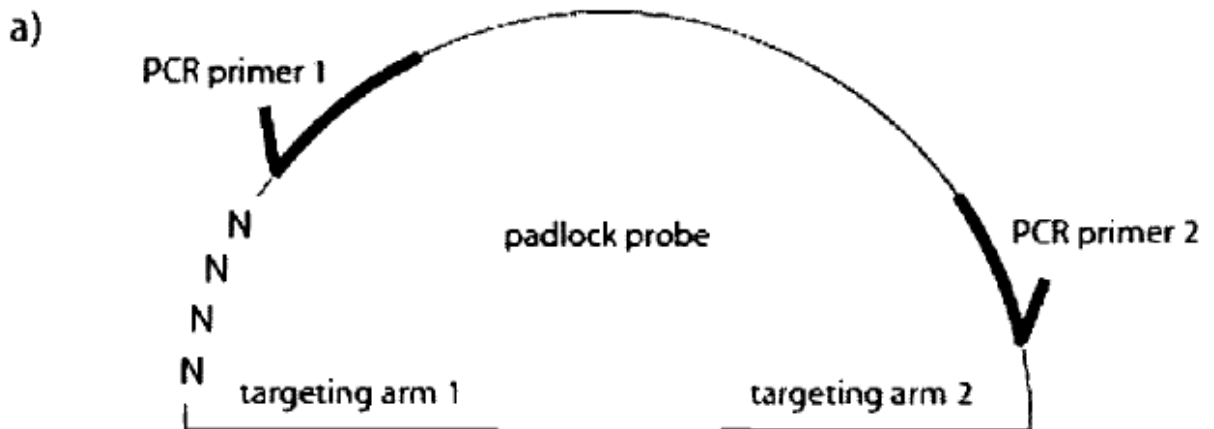
Id., .0005, Fig 4c. Likewise, Paragraph 150 discloses merely that “nucleic acids comprising differentiator tag sequences may be incorporated by ligation” and “[a]

differentiator tag sequence and adaptor sequence (which may contain the sequencing primer site) are incorporated as tags.” *Id.*, .0033, [0150]. Thus, neither Figure 4c nor Paragraph 150 discloses that the sample index is incorporated into the adaptor, as required by claim 1.

For disclosure of the “wherein each adaptor comprises a unique identifier” limitation, Petitioner relies on Porreca’s disclosure of “differentiator tags.” Petition, 19-20 (citing EX1006.0019-20, .0031-32, [23], [31], [139], [141]-[143]). The Petition does not, however, explain how the differentiator tags are incorporated into the embodiment disclosed in Figure 4c, and none of the Petition’s citations refer to Figure 4c. Indeed, the citations disclosed by Petitioner refer to different embodiments for the various aspects of the claimed adaptor. *See, e.g.*, EX1006.0020, [0023] (“In certain embodiments, the disclosure provides preparative methods for capturing target nucleic acids (e.g., genetic loci) that involve the use of differentiator tag sequences to uniquely tag individual nucleic acid molecules.”); *see also Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1072 (Fed. Cir. 2017) (affirming Board’s finding of no anticipation when the disparate disclosures “d[id] not refer back specifically to the various other disclosure cited by [Petitioner]” and were “unrelated to each other in [the] disclosure”).

To meet the indexing site limitation that is further required by claim 1, Petitioner relies on yet another embodiment. Here, Petitioner argues that paragraph

149 of Porreca discloses that an adaptor may contain a barcode. Petition, 20-21. The Petition, however, does not point to any disclosure in Porreca regarding how the barcode in paragraph 149 would work in the embodiment of Figure 4c, which Petitioner relied on for the other limitations of the claimed adaptor. Instead, paragraph 149 refers to the MIP-preparation embodiment disclosed in Figure 4a (reproduced below). EX1006.0033, [0149]. As explained in Porreca at paragraph 85, Figure 4a is a distinct embodiment from Figure 4c. *Id.*, .0027, [0085]; *see Net MoneyIN, Inc.*, 545 F.3d at 1369-71.



EX1006.0005, Fig 4a.

Petitioner's attempt to mix-and-match disparate embodiments is not only legally flawed, but also nonsensical in view of the disclosures in Porreca. Even if Petitioner could piece together separate embodiments to show anticipation of the adaptor ligation and identifier site limitations (which it cannot), it would still fail to meet the further limitation of claim 1, which requires that the adaptor containing the

unique identifier is amplified only *after* it is ligated. See EX1002.0024, cl. 1 (“amplifying the adaptor-ligated fragments into amplicons”).

Figure 4a discloses a MIP-preparation method. It is not possible to ligate an adaptor to a MIP prior to amplification because the circular shape of the MIP prevents DNA ligase from reaching the nucleotide chain backbone to add nucleotides. See EX2019.0006, .0022, .0031-32. Only once the MIP has been amplified, which yields an amplified sequence forming a linear nucleotide chain (rather than a circular chain), would it be possible for DNA ligase to reach the nucleotides and ligate an adaptor. *Id.*, .0012-13, .0046-47. In other words, Figure 4a cannot meet the limitation that requires amplification *after* ligation, as a POSA following Figure 4a would only be able to amplify the sequence *prior to* ligation. Thus, Petitioner cannot rely on the MIP-disclosure of Figure 4a to meet this limitation, and would need to combine the disclosure of Figure 4a with yet another embodiment.

Thus, the Petition fails to show that Porreca anticipates the challenged claims.

Microsoft Corp. v. Biscotti, Inc., 878 F.3d 1052, 1072 (Fed. Cir. 2017).

2. The Petition Fails to Establish that Porreca Discloses Identifying Duplicate Sequencing Reads Based on the Identifier and at Least a Portion of the Target Sequence

Claim 1 of the '357 Patent requires “identifying sequence reads with identical identifier and target sequences as duplicates.” EX1002.0024. Petitioner also does

not adequately identify where in Porreca this element is disclosed, instead pointing to only vague and ambiguous disclosures and glossing over the gaps with conclusory expert testimony.

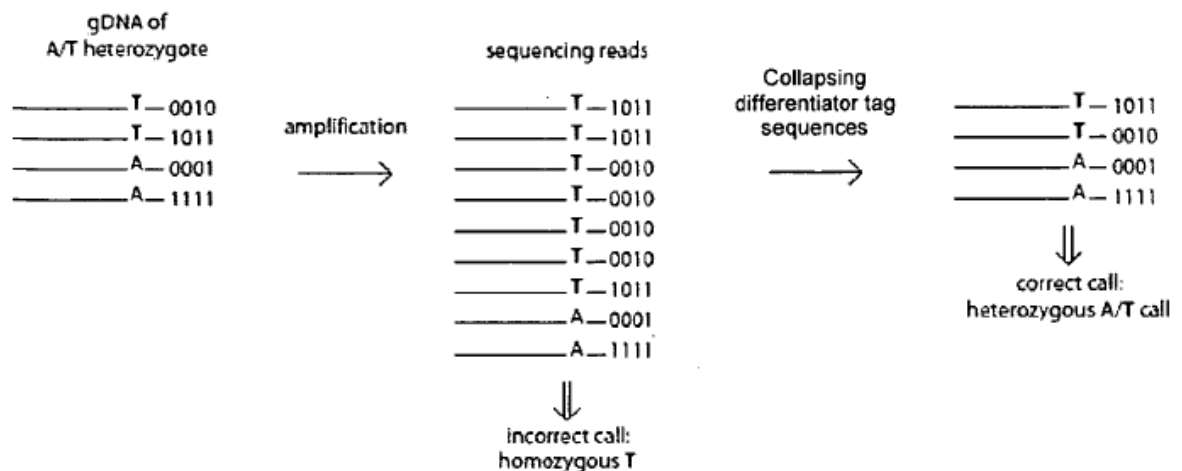
Petitioner only alleges that Porreca “teaches that differentiator tags can be used to determine whether particular nucleic acid molecules are copies from PCR amplification (i.e., duplicates). Because each nucleic acid molecule is appended to a unique differentiator tag prior to amplification, molecules having identical nucleic acid sequences and bearing the same differentiator tag are duplicates of one another.” Petition, 25. Petitioner does not point to any disclosure in Porreca for this argument. The Petition similarly provides no analysis for its position that Porreca discloses “identifying sequence reads with identical identifier and target sequences as duplicates.” Rather, it cites only to the expert declaration, which repeats verbatim the same assertions. *Xerox Corp., et al. v. Bytemark, Inc.*, IPR2022-00624, Paper 12 at 5 (PTAB Feb. 10, 2023) (“I determine that the Board was correct in giving little weight to Petitioner’s expert because the expert declaration merely offered conclusory assertions without underlying factual support and repeated, *verbatim*, Petitioner’s conclusory arguments.”).

Petitioner alleges that “[a] POSA would understand that in order to have ‘multiple copies of the same target nucleic acid molecule,’ the target nucleic acid

sequence must be identical.” Petition, 26. Here, the Petition does not provide any citation, not even to conclusory expert testimony.

Petitioner then points to Figure 5 of Porreca as allegedly disclosing the identification of duplicate sequences based on both the identifier site and portion of the target sequence. *Id.* Figure 5 (reproduced below) does not disclose the process or the level of detail that Petitioner claims, nor does it disclose the required elements of the claim 1.

FIGURE 5



EX1006.0006, Fig. 5.

Figure 5 shows a two-step process whereby sequence reads are first grouped based on the identifier site, then collapsed based on a single nucleotide. *Id.* As an initial matter, Figure 5 does not provide further explanation regarding what is included in the disclosed “differentiator tag.” Furthermore, it is not clear from this disclosure or Petitioner’s conclusory explanation how this is performed or whether

the combination of *both* the identifier site and the portion of the target sequence are used in conjunction to identify duplicates, as required by claim 1. Indeed, Figure 5 does not illustrate any portion of the target sequence being used to identify duplicates. Petitioner argues that Figure 5 shows that sequences having the same single nucleotide (e.g., all sequences with “T-1011”) must be “duplicate sequences,” but Petitioner does not explain where this is shown by Porreca. In any case, a POSA would not be able to compare versions of the target sequence based on only a single nucleotide. All a POSA can glean from Figure 5 is that after being grouped based on identifier site, sequences with the same single nucleotide—not sequences with identical portions of the target sequence—are then collapsed.

Lastly, Petitioner argues that “[a] POSA would have further understood that, while not shown, the rest of the target sequence in the collapsed reads is also identical, as collapsing a read means removing sequences having the same target and differentiator tag sequences.” Petition, 27. Again, Petitioner provides only conclusory expert testimony that repeats the Petition nearly verbatim, without any underlying reference to support the expert’s conclusory opinion. Petitioner cannot use expert testimony to import limitations into the prior art that do not exist. *Xerox Corp.*, IPR2022-00624, Paper 12 at 5.

Because Petitioner’s arguments rely on vague and ambiguous disclosures, supported merely by conclusory expert opinions, the Petition fails to meet its burden

to show that claim 1 is anticipated by Porreca. *See, e.g., Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1284 (Fed. Cir. 2017) (affirming Board's finding of no anticipation because the prior art "was at best unclear" regarding whether the claimed limitations were disclosed); *Xerox Corp.*, IPR2022-00624, Paper 12 at 5.

3. The Petition Has Failed to Establish that Any Dependent Claim is Likely Invalid

Claim 1 is the only independent claim in the '357 Patent, from which all other challenged claims depend. As explained above, the Petition fails to show that Porreca renders claim 1 anticipated because the prior art lacks disclosure of required elements of the claims. Therefore, the Petition similarly cannot establish any of the dependent claims are anticipated.

B. Ground 2: Petitioner Has Not Shown That Any Challenged Claim Is Obvious Over the Combination of Schmitt and McCloskey

Petitioner argues that the combination of Schmitt and McCloskey renders the challenged claims obvious, but neither Schmitt nor McCloskey discloses key limitations in the challenged claims. Petitioner also provides no explanation as to why a POSA would have been motivated to combine Schmitt with McCloskey to achieve the claimed method that requires use of both identifier *and* a portion of the target sequence to identify duplicate reads, let alone with a reasonable expectation of success. Petitioner has thus failed to show with a reasonable likelihood that any challenged claim is invalid under Ground 2.

1. Schmitt Does Not Disclose All Elements of the Challenged Claims

Schmitt discloses a sequencing method using an adaptor comprising a single molecule identifier (“SMI”) sequence, a ligation adaptor, a PCR primer binding site, and a sequence primer binding site. EX1007.0010, [0022]. Notably, Petitioner admits that Schmitt does *not* disclose “the claimed indexing site” as part of the adaptor. Petition, 35-36. Schmitt, therefore, fails to provide a POSA with any teaching regarding the use of “an indexing site unique to a subset of the adaptors” as required by Claim 1, let alone that there is the “ligating [of] an adaptor” with such an element.

Schmitt also fails to provide any teaching regarding the identification and removal of duplicate sequencing reads based on both the identifier and target sequence, as further required by claim 1 and by the challenged dependent claims. *See, e.g.*, EX1002.0024, cl. 1, preamble (“[a] method for detecting a duplicate sequencing read...”), cl. 1(d) (“identifying sequence reads with identical identifier and target sequences as duplicates”). Petitioner argues that Schmitt discloses “identifying sequence reads with identical identifier and target sequences as duplicates” based on Schmitt’s disclosure of SMI tags. Petition, 44-45; *see also id.* at 14. Petitioner’s analysis is flawed.

Schmitt makes clear that it is the SMI tag alone that is used to identify duplicates. Schmitt discloses a process of identifying duplicates by “grouping the

sequenced SMI-target nucleic acid products into families of paired target nucleic acid strands *based on a common set of SMI sequences.*” EX1007.0056, cl. 30 (emphasis added). Schmitt further describes “the use of SMI tags” so that “true PCR duplicates may be unambiguously identified by virtue of having a common (i.e., the same or identical) SMI sequence.” *Id.*, .0030, [0085]. Indeed, with regard to claim 2, Petitioner itself relies on paragraph 96 of Schmitt, which explicitly instructs that sequence reads are “[g]roup[ed] together” based on “identical 24 nt SMIs”:

1. Discard reads that do not have the 5 nt fixed reference (or “spacer”) sequence (CAGTA; SEQ ID NO:6) present after 12 random nucleotides.
2. Combine the 12 nt SMI tags from read 1 and read 2, and transfer the combined 24 nt SMI sequence into the read header.
3. Discard SMIs with inadequate complexity (i.e., those with > 10 consecutive identical nucleotides).
4. Remove the 5 nt fixed reference sequence.
5. Trim an additional 4 nt from the 5' ends of each read pair (sites of error prone end repair).
6. **Group together reads which have identical 24 nt SMIs.**
7. Collapse to SMI consensus reads, scoring only positions with 3 or more SMI duplicates and >90% sequence identity among the duplicates.
8. For each read in read 1 file having SMI of format AB, group with corresponding DCS partner in read 2 with SMI of format BA.
9. Only score positions with identical sequence among both DCS partners.
10. Align reads to the human genome.

Id., .0033, [0096].

Schmitt emphasizes that the identification of duplicates is accomplished via the use of the SMI tag alone, rather than via the use of a portion of the target sequence. In fact, Schmitt discourages a POSA from using anything related to the target sequence when identifying duplicates, by disclosing challenges involved with using a surrogate of a portion of the target sequence (e.g., the “sheared DNA ends”)

to match duplicates. *Id.*, .0037, [0104] (“The improved sequence coverage arose from the use of the SMI to identify PCR duplicates, because identifying PCR duplicates by consideration of uniquely sheared DNA ends is fundamentally limited by the small number of possible shear points that overlap a given position of the genome and the propensity for specific genomic regions to be more readily undergo shearing.”).

Thus, Schmitt does not teach or disclose all elements of the challenged claims.

2. McCloskey Similarly Does Not Disclose All Elements of the Challenged Claims

Petitioner relies on McCloskey *only* for the disclosure of an “indexing site unique to a subset of adaptors,” and does not assert that McCloskey discloses any other limitation of claim 1. Petition, 36-37. Thus, Petitioner has failed to meet its burden to show that all limitations of the challenged claims are disclosed by Schmitt and/or McCloskey because neither disclose the identification and removal of duplicate sequencing reads based on both the identifier and target sequence.

3. Petitioner Has Not Established That a POSA Would Have Been Motivated to Combine Schmitt and McCloskey With a Reasonable Expectation of Success

Even assuming that Petitioner adequately explained how the prior art disclosed all limitations of the challenged claims (which it has not), Petitioner fails to show that a POSA would have been motivated to combine Schmitt and McCloskey to arrive at the challenged claims with a reasonable expectation of

success. Petitioner relies on improper hindsight and the conclusory testimony of an expert witness to support its allegations, and the Board should reject these arguments. *In re Gorman*, 933 F.2d 982, 987 (Fed. Cir. 1991).

As an initial matter, Petitioner's argument is premised on hindsight. Rather than starting with the prior art, Petitioner's argument is based on a POSA being "motivated to add ***the claimed indexing site*** to *Schmitt's* adaptor." Petition., 35. This is quintessential hindsight. Petitioner improperly works backwards from the claim limitations to match the prior art to the claimed adaptor, using the claimed adaptor elements as a roadmap for its obviousness arguments. *In re Gorman*, 933 F.2d at 987 ("It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps."); *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1351 (Fed. Cir. 2014) (reversing finding of obviousness and criticizing expert for "rel[ying] on the [challenged] patent itself as her roadmap for putting what she referred to as pieces of a 'jigsaw puzzle' together.").

Finding the claimed indexing site in McCloskey, Petitioner claims that a POSA would have been motivated to start with the adaptor of Schmitt and add the indexing site of McCloskey. Petitioner makes no effort to explain why a POSA would have looked to the McCloskey adaptor specifically to modify the adaptors in

Schmitt. Instead, Petitioner argues that a “POSA would have known that it would be beneficial to append a barcode to the target sequence,” and would have thus added the barcode disclosed in McCloskey to the adaptor disclosed in Schmitt. Petition, 36. Petitioner ignores the differences between the structure of the Schmitt and McCloskey adaptors and how they might, or might not, work if combined. Petitioner’s arguments merely cherry-pick a single disclosure from McCloskey and argue that a POSA would have combined it with Schmitt to arrive at the claimed adaptor. Petition, 37-39. The only support to which Petitioner points is *ipse dixit* expert testimony without any underlying factual support. Petitioner further fails to include any of this hindsight-heavy expert analysis in the Petition itself, and therefore, should be disregarded. *InfoBionic, Inc. v. Braemar Manufacturing, LLC*, IPR2015-01704, Paper 11 at 6 (PTAB Feb. 16, 2016) (denying institution because expert testimony “offer[ed] little or no elaboration” to support Petitioner’s arguments).

As a result, the Petition lacks any prior art evidence that a POSA would have been motivated to combine the indexing site of McCloskey with Schmitt to arrive at the claimed invention with a reasonable expectation of success. The hindsight-driven combination of these two references to achieve the claimed adaptor is unsupported by any contemporaneous evidence and should be rejected. Further, the combination of the two references fails to disclose the limitation requiring

identification of duplicate sequence reads based on *both* the identifier and target sequence. Petitioner has, therefore, failed to meet its burden of showing claim 1 is likely invalid under Ground 2.

4. The Petition Has Failed to Establish that Any Dependent Claim is Likely Invalid

Claim 1 is the only independent claim, from which all other challenged claims depend. As explained above, the Petition fails to show that the prior art renders claim 1 obvious, and therefore, the Petition similarly cannot establish any of the dependent claims are obvious.

C. Grounds 3 and 4: Petitioner Has Not Shown That Claim 4 Is Obvious Over the Combination of Porreca, Illumina 2008, Schmitt, and/or McCloskey

As described above, Petitioner has not shown that Porreca, Schmitt, or McCloskey discloses all elements of the challenged claims. Petitioner also fails to show that Illumina 2008 discloses all elements of the challenged claims. Petitioner relies on Illumina 2008 to provide teachings regarding the sequencing of an adaptor sequence separately from a target sequence, which it admits is not disclosed in Porreca or Schmitt. Petition, 52-55. However Petitioner does not (and cannot) show that Illumina 2008 reference discloses a method of using both an identifier and a target sequence to identify duplicate sequencing reads, as required by claim 1. Instead, the Petition solely describes the disclosures of Illumina 2008 that relate to the “Illumina sequencing platform,” and specifically, the order in which an adaptor

and target sequence would be sequenced during sample multiplexing. *Id.*, 52-54. The Petition makes no attempt to cure the deficiencies of Porreca, Schmitt, and McCloskey regarding this limitation, and thus cannot show that—even with the addition of Illumina 2008—claim 1 would be obvious. Petitioner makes no attempt to explain why a POSA would have been motivated to combine the above references to arrive at the claimed limitation “identifying sequence reads with identical identifier and target sequences as duplicates.”

Because Petitioner has not shown that claim 1 would be obvious over Porreca, Illumina 2008, Schmitt, and McCloskey, it cannot show that claim 4 would be obvious.

D. Grounds 5 and 6: Petitioner Has Not Shown That Claim 7 Is Obvious Over the Combination of Porreca, Illumina 2008, Schmitt, and/or McCloskey

As described above, Petitioner has not shown that Porreca, Schmitt, or McCloskey disclose all elements of the challenged claims. Petitioner also fails to show that Illumina 2008 discloses all elements of the challenged claims. Petitioner relies on Illumina 2008 to provide teachings regarding the inclusion of a sequencing primer binding site in the adaptor, which Petitioner admits is not disclosed in Porreca or Schmitt. Petition, 56-57. However Petitioner does not (and cannot) show that Illumina 2008 reference discloses a method of using both an identifier and a target sequence to identify duplicate sequencing reads, as required by claim 1. Instead, the

Petition solely describes the disclosures of Illumina 2008 that relate to the “Illumina sequencing platform,” and specifically, the location of primer binding sites in the adaptors. *Id.*, 56-58. The Petition makes no attempt to cure the deficiencies of Porecca, Schmitt, and McCloskey regarding this limitation, and thus cannot show that—even with the addition of Illumina 2008—claim 1 would be obvious. Petitioner makes no attempt to explain why a POSA would have been motivated to combine the above references to arrive at the claimed limitation “identifying sequence reads with identical identifier and target sequences as duplicates.”

Because Petitioner has not shown that claim 1 would be obvious over Porreca, Illumina 2008, Schmitt, and McCloskey, it cannot show that claim 7 would be obvious.

V. THE BOARD SHOULD EXERCISE ITS DISCRETION TO DENY INSTITUTION

The Board may deny petitions where the same or substantially the same art or arguments were previously considered by the patent office during prosecution. 35 U.S.C. § 325(d); *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 10 (PTAB Feb. 13, 2020). Here, the Examiner considered prior art during prosecution that is substantially the same as the art cited in the Petition, and Petitioner has not identified any material error by the Examiner. The Board, therefore, should exercise its discretion to deny institution under Section 325(d).

A. Discretionary Denial Under § 325(d) Is Appropriate Because the Examiner Considered Substantially the Same Prior Art

The *Becton Dickinson/Advanced Bionics* factors support denying institution because the prior art cited in the Petition is substantially the same as Samuels (EX2018) and McCloskey 2007 (EX1015) addressed during prosecution. The *Becton Dickinson/Advanced Bionics* factors weigh against institution when the petitioner's asserted references are materially indistinguishable from those previously before the Examiner. See *Xilinx, Inc., et al v. Analog Devices, Inc.*, IPR2021-00294, Paper 9 at 11 (PTAB June 10, 2021) (exercising discretion to deny institution under 325(d) because petitioner's two asserted references were cumulative to those considered during prosecution). Here, there are no "material differences" between the references considered by the Examiner and the prior art asserted in the Petition.

During prosecution of the '357 Patent, the Examiner rejected the pending claims over the prior art references Samuels, McCloskey 2007, and Illumina 2008. McCloskey 2007 is directed to a method of identifying redundant sequences in a sequencing dataset, and discloses the use of 7-nucleotide-length "barcodes" and "batch-stamps" to do so. EX1015.0004. McCloskey 2007 further describes identification of sequence reads based only on reads that share the same "barcode" or "batch-stamp." *Id.*, .0006. Samuels is directed to a method of attaching barcodes to a nucleotide sequence to allow a user to differentiate PCR-caused errors from true

single nucleotide polymorphisms. EX2018.0086-87, 94, 97, 99. Samuels further discloses amplifying the barcodes and nucleotide sequence via PCR, and sequencing the amplified products. *Id.*

1. Porreca Discloses Substantially the Same Information as McCloskey 2007

During prosecution, the Examiner rejected the pending claims over McCloskey 2007, stating that the McCloskey 2007 reference taught the identification of duplicates via the use of molecular barcodes. *See, e.g.* EX1013.0080. Petitioner alleges that Porreca “teaches that differentiator tags can be used to determine whether particular nucleic acid molecules are copies from PCR amplification (i.e., duplicates).” Petition, 25. The differentiator tags disclosed in Porreca are substantially the same as those in McCloskey 2007 in both function and structure. The differentiator tags, like the McCloskey 2007 barcodes, are used by a POSA to identify duplicate sequence reads. And like the McCloskey 2007 barcodes, the differentiator tags in Porreca can be incorporated into an adaptor to allow for sequencing along with the target sequence, and can consist of 7 nucleotides. *See* EX1006.0032, [0141-42]; EX1015.0004.

Applicants overcame the rejection, arguing that “in contrast to the claimed methods, McCloskey [2007] does not use the sequence of a nucleic acid fragment to identify redundant or duplicate sequences. Thus, like Samuels, McCloskey [2007] does not teach identifying sequence reads with identical identifier and fragment

sequences as recited in the pending claims.” EX1013.0069-70. As explained above, Porreca also does not disclose the use of both the differentiator tag and the target sequence to identify and remove duplicate sequences. *See supra* Section IV.A. Thus, the Examiner considered substantially the same prior art as Porreca and allowed the claims.

2. Schmitt Discloses Substantially the Same Information as Samuels and McCloskey 2007

During prosecution the Examiner rejected the pending claims over McCloskey 2007, in particular due to the disclosures of Figure 1, stating that McCloskey 2007 teaches an adaptor comprising an identifier site (a “barcode”) and an indexing site (a “batch-stamp”). EX1013.0080. The Examiner also rejected the pending claims over Samuels, based on Samuels’ alleged disclosures of an adaptor comprising “a unique identifier.” *Id.*, .0079. Petitioner alleges that Schmitt teaches a method of identifying PCR duplicates, “through the use of a ‘single molecule identifier (SMI) adaptor molecule’.” Petition, 14. Like Schmitt, both Samuels and McCloskey 2007 disclose a sequencing method that includes an identifier site (or “barcode”). For example, Figure 5 in Samuels describes the use of an adaptor (without an identifier site), as well as a barcode, for use with sequencing. EX2018.0006. Similarly, McCloskey 2007 discloses an adaptor that includes a “batch-stamp,” a random “barcode”, a primer-binding site, and a genomic target-binding site. EX1015.0003.

Applicants overcame the Section 103 rejections based on McCloskey 2007 and Samuels. Like McCloskey 2007, Schmitt discloses detecting duplicates based on something other than the identifier site and a portion of the nucleic acid fragment, as discussed in Section IV.B. And like Samuels, Schmitt discloses only the use of an attached barcode to differentiate between sequence reads, not the use of both a barcode and an index site. *See supra* Section IV.B.

Thus, the Examiner considered substantially the same prior art as Schmitt, and Applicants overcame those rejections.

3. McCloskey Discloses Substantially the Same Information as McCloskey 2007

McCloskey is a patent application which is further described in the publication McCloskey 2007, which was considered during prosecution. As Petitioner admits, “McCloskey 2007 and McCloskey contain some overlapping disclosures.” Petition, 38. In fact, the adaptors in McCloskey 2007 include the same elements that Petitioner alleges are disclosed in McCloskey. Thus, the Examiner considered substantially the same prior art as McCloskey.

Figure 1 in McCloskey 2007 discloses an adaptor that includes a “batch-stamp” to specify the DNA source (e.g., patient v. sample), a random “barcode” to distinguish between sequences from different cell or allele copies, a primer-binding site, and a genomic target-binding site. EX1015.0003, Fig. 1. During prosecution, the Examiner explicitly rejected the pending claims over McCloskey 2007, in

particular due to the disclosures of Figure 1, stating that McCloskey 2007 teaches an adaptor comprising an identifier site (a “barcode”) and an indexing site (a “batch-stamp”). EX.1013.0080. Petitioner alleges that the adaptors disclosed in McCloskey include a barcode and a batch-stamp. Petition, 15. The adaptors in McCloskey 2007 therefore include the same elements that Petitioner alleges are disclosed in McCloskey. Thus, the Examiner considered substantially the same prior art as McCloskey.

4. Illumina 2008 Was Cited by the Examiner

Petitioners argue that the challenged claims are obvious over Illumina 2008, in part because Illumina 2008 purportedly teaches separate sequencing of index and target sequences. Petition, 53-54. During prosecution, Applicants overcame rejections based on Illumina 2008 by arguing that “Illumina publication does not teach or suggest adaptors having distinct identifiers and index sites and using the identifier and fragment sequence for deduplication.” EX1013.0071. Thus, the Examiner considered Illumina 2008—as well as substantially similar arguments based on Illumina 2008—and allowed the claims.

As a result, the first *Advanced Bionics* factor supports denial.

B. Petitioner Has Failed to Identify Any Material Error by the Examiner

The Examiner did not err in determining that the claims were allowable over the prior art, and Petitioner has not identified any material error in the Examiner’s

determination. “An example of a material error may include misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims.” *Palo Alto Networks, Inc. v. Centripetal Networks, Inc.*, IPR2021-01520, Paper 23, at 16 (PTAB Mar. 22, 2022) (citing *Advanced Bionics, LLC*, IPR2019-01469, Paper 6, at 8 n.9) (exercising discretion under 325(d) because petitioner failed to demonstrate any error, much less material error, by the examiner).

Here, Petitioner alleges merely that the Examiner materially erred because they “did not appreciate Illumina 2008’s disclosure and also did not have the benefit of analyzing Illumina 2008 in view of Porreca and Schmitt” and because the Examiner “also did not have the benefit of Dr. Metzker’s detailed expert testimony and the other evidence of record.” Petition, 61. Neither of these arguments rises to the level of material error.

As explained above, the Examiner explicitly cited Illumina 2008 during the prosecution of the ’357 Patent, and rejected the pending claims over Illumina 2008’s adaptor disclosures. Petitioner’s assertions that Porreca, Schmitt, or Dr. Metzker’s declaration would have changed the Examiner’s determination regarding Illumina 2008 is equally misplaced; as described above, both Porreca and Schmitt are substantially the same as Samuels and McCloskey 2007. Petition, 61; *see supra* Section V.B. Applicants overcame the rejection, and Petitioner does not identify

any specific teaching of Illumina 2008 that the Examiner misapprehended or overlooked. Therefore, the *Advanced Bionics* factors support denial under § 325(d).

VI. CONCLUSION

In light of the above, Petitioner has not shown that there is a reasonable likelihood that at least one challenged claim is unpatentable, and the Petition should be denied.

U.S. Patent No. 11,098,357

Dated: February 19, 2025

Respectfully submitted,

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CERTIFICATE OF WORD COUNT

The undersigned hereby certifies that the foregoing **Patent Owner's Preliminary Response** complies with the type-volume limitation of 37 C.F.R. §§ 42.24(a)(1)(i) and 42.24(b)(1). The Response contains 6,968 words, excluding the parts exempted by 37 C.F.R. § 42.24(a)(1), as measured by the word-processing system use to prepare the Response.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on February 19, 2025, a copy of the foregoing **Patent Owner's Preliminary Response** and all supporting documents were served on the counsel of record for Petitioner by filing the same through the P-TACTS System as well as delivering a copy via electronic mail to the following addresses:

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