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Paper 12
Entered: November 13, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFENEX INC.,
Petitioner,

v.

GLAXOSMITHKLINE BIOLOGICALS SA,
Patent Owner.

IPR2019-01028
Patent No. 9,422,345 B2

Before SHERIDAN K. SNEDDEN, JO-ANNE M. KOKOSKI, and RICHARD J. SMITH, *Administrative Patent Judges.*

SMITH, *Administrative Patent Judge*.

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

I. INTRODUCTION

Pfenex Inc. ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1, 2, 4, 6, 8, 12–14, 17–19, and 21 ("the challenged claims") of U.S. Patent No. 9,422,345 B2 (the "'345 patent") on May 6, 2019. Paper 2 ("Pet." or "'028 Petition"). Petitioner relies on the Declaration of George Georgiou, Ph.D. ("Georgiou Declaration") in support of the Petition. Ex. 1002.

GlaxoSmithKline Biologicals SA ("Patent Owner") filed a Preliminary Response to the Petition on August 16, 2019. Paper 8 ("Prelim. Resp."). Patent Owner relies on the Declaration of Dr. James E. Galen ("Galen Declaration") in support of the Preliminary Response. Ex. 2001.

On May 6, 2019, Petitioner concurrently filed another petition for *inter partes* review of the challenged claims of the '345 patent on other grounds. *Pfenex Inc. v. GlaxoSmithKline Biologicals SA*, IPR2019-01027, Paper 2 (PTAB May 6, 2019) ("'027 Petition").[1] On August 9, 2019, Petitioner filed another petition for *inter partes* review of claims 1, 2, 4–14, and 16–21 of the '345 patent on other grounds. *Pfenex Inc. v. GlaxoSmithKline Biologicals SA*, IPR2019-01478, Paper 3 (PTAB August 9, 2019) ("'478 Petition").

In connection with the '478 Petition, Petitioner also filed a paper titled "Petitioner's Explanation of Multiple Petitions Challenging Patent No. 9,422,345 and Ranking of Petitions" ("'478 Multiple Petitions Paper"). *Pfenex*, IPR2019-01478, Paper 2. The '478 Multiple Petitions Paper was filed pursuant to the Office Patent Trial Practice Guide, July 2019 Update

[1] The present Petition and '027 Petition, both filed on May 6, 2019, are referred to herein as the "Concurrent Petitions."

("TPG July 2019 Update").[2] TPG July 2019 Update, 26–28. The '478 Multiple Petitions Paper addressed the present Petition, the '027 Petition, and the '478 Petition, and included a table listing the preferred ranking of those three petitions, but was not filed in either the present case or IPR2019-01027.

On September 27, 2019, we requested a conference call with the parties to discuss the filing of a "multiple petitions" paper in both IPR2019-01027 and the present case, pursuant to the TPG July 2019 Update. Ex. 3001.[3] In that e-mail, we also indicated that "[i]n lieu of a teleconference, Petitioner may file the ['478 Multiple Petitions Paper] in each of IPR2019-01027 and IPR2019-01028." *Id.* Petitioner responded via e-mail on September 30, 2019, indicating that (1) Petitioner proposed filing the '478 Multiple Petitions Paper in both IPR2019-01027 and IPR2019-01028, revised to update the caption for the corresponding case and adding the case number for IPR2019-01478 in the table ranking the three petitions, and (2) Patent Owner requested to file a three page response to Petitioner's filings, which Petitioner did not oppose in the interest of expediting the matter. *Id.* On October 2, 2019, we notified the parties via e-mail that Petitioner's proposal, as outlined in its e-mail of September 30, 2019, was acceptable. *Id.*

Thereafter, Petitioner filed a paper titled "Petitioner's Explanation of Multiple Petitions Challenging Patent No. 9,422,345 and Ranking of Petitions" in both IPR2019-01027 (Paper 10, "'027 Multiple Petitions

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[2] 84 Fed. Reg. 33,925 (July 16, 2019), available at https://www.uspto.gov/TrialPracticeGuide3.
[3] Exhibit 3001 includes three separate e-mails, two from the Board and one from Petitioner.

Paper") and the present case (Paper 10, "'028 Multiple Petitions Paper").[4] In those filings, Petitioner ranked the present Petition first, the '027 Petition second, and the '478 Petition third. Paper 10, 3. Patent Owner then filed a paper titled "Patent Owner's Response to Petitioner's Explanation of Multiple Petitions Challenging Patent No. 9,422,345 and Ranking of Petitions" in both IPR2019-01027 (Paper 11, "Response to '027 Multiple Petitions Paper") and the present case (Paper 11, "Response to '028 Multiple Petitions Paper").[5]

We have jurisdiction under 35 U.S.C. § 314, which authorizes the Director of the U.S. Patent and Trademark Office to decide whether to institute an *inter partes* review. To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). A decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

Upon considering the arguments and evidence presented in the Petition, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims in the Petition. Accordingly, we institute an *inter partes* review of all claims and all grounds asserted in the Petition.

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[4] The '027 Multiple Petitions Paper and the '028 Multiple Petitions Paper are identical except for the different case numbers in the caption.
[5] The Response to '027 Multiple Petitions Paper and Response to '028 Multiple Petitions Paper are substantially identical.

A. Real Parties in Interest

Petitioner identifies itself as the real party-in-interest. Pet. 3.

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

B. Related Proceedings

Petitioner identifies the concurrently filed '027 Petition, and two petitions for *inter partes* review of the '345 patent (IPR2019-00230 and IPR2019-00241) filed by Merck Sharp & Dohme Corp. ("Merck") on November 7, 2018 ("Merck Petitions"). Pet. 1.

Patent Owner identifies the following additional matters:

IPR2018-01229 and IPR2018-01236, involving U.S. Patent No. 8,753,645, and IPR2018-01234 and IPR2018-01237, involving U.S. Patent No. 9,265,839. Paper 4, 1.

C. The '345 Patent (Ex. 1001)

The '345 patent "relates to the field of the expression of bacterial toxins, in particular diphtheria toxins (including mutant forms of diphtheria toxin, such as CRM197)," and states that it "provides novel polynucleotides and polypeptides which can be used or produced during the processes of the invention." Ex. 1001, 1:9–15.

The '345 patent states that "CRM197 is a non-toxic form of the diphtheria toxin but is immunologically indistinguishable from the diphtheria toxin," and that CRM197 "differs from [diphtheria toxin] by a single base change in the structural gene . . . [leading] to a glycine to glutamine change of amino acid at position 52." *Id.* at 1:39–40, 1:44–48. CRM197 is a component in vaccines providing immunity against *Corynebacterium diphtheriae*, and has been used in vaccines as safe and effective T-cell dependent carriers for saccharides. *Id.* at 1:52–54, 1:59–61.

SEQ ID NO:32 in the '345 patent is the amino acid sequence of mature[6] CRM197. *Id.* at Fig. 9E.

The '345 patent also states that the disclosed polynucleotides comprise a 5' signal sequence portion and a 3' toxin portion wherein "(a) the 5' signal sequence portion encodes a polypeptide having an amino acid sequence capable of directing transport of a heterologous protein to the bacterial periplasm and wherein the 5' signal sequence is not derived from *C. diphtheriae*;" and "(b) the 3' toxin portion encodes a polypeptide having an amino acid sequence at least 90% identical to SEQ ID NO: 32 or fragments thereof encoding at least 15 amino acids and/or at least one B or T cell epitope." *Id.* at 2:60–3:4. The '345 patent also describes various amino acid sequences of a signal peptide encoded by the 5' signal portion. *Id.* at 3:7–19.

D. Illustrative Claims

Claims 1 and 6 are the only independent claims, and are reproduced below:

> 1. A polynucleotide comprising a 5' signal sequence portion and a 3' toxin portion wherein:
>
> (a) the 3' toxin portion encodes a mature bacterial toxin polypeptide having an amino acid sequence at least 90% identical to SEQ ID NO: 32; and
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> (b) the 5' signal sequence portion encodes a polypeptide having an amino acid sequence capable of directing transport of said bacterial toxin polypeptide to the bacterial periplasm when expressed in a ba[c]terial host cell, and wherein the 5' signal sequence is not derived from *C. diphtheriae*.

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[6] The '345 patent indicates that a "mature" bacterial toxin is one in which the signal peptide has been removed. Ex. 1001, 2:37–38; 16:10–13; *see also* Ex. 1004, 570 ("'Mature' refers to a diphtheria toxin polypeptide lacking the signal sequence, see e.g. paragraphs 0153 and 0204 of the present specification.").

Ex. 1001, 49:54–64.

> 6. A polynucleotide comprising a 5' signal sequence portion and a 3' toxin portion, wherein:
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> (i) the 3' toxin portion encodes a mature bacterial toxin polypeptide having an amino acid sequence at least 90% identical to SEQ ID NO:32; and
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> (ii) the 5' signal sequence portion encodes a polypeptide having an acid sequence capable of directing transport of said bacterial toxin polypeptide to the bacterial periplasm when expressed in a bacterial host cell, and wherein the 5' signal sequence is not derived from *C. diphtheria*, and wherein the encoded polypeptide has an amino acid sequence selected from:
>
> (a) SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, and 26;
>
> (b) variants of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, or 26, varying from the corresponding sequences by 1, 2 or 3 point mutations, amino acid insertions or amino acid deletions, which variants are capable of directing transport of said bacterial toxin polypeptide to the periplasm of said bacterial host cell; and
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> (c) fragments of at least 10 amino acids of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, or 26, which fragments are capable of directing transport of said bacterial toxin polypeptide to the periplasm of said bacterial host cell.

Id. at 51:13–37.

Claims 2, 4, 18, 19 and 21 depend directly from claim 1, and claims 8, 12–14, and 17 depend directly from claim 6. *See id.* at 49:65–52:42.

E. The Asserted Grounds of Unpatentability

Petitioner asserts that the challenged claims would have been unpatentable on the following grounds. Pet. 5.

Claims Challenged	35 U.S.C. §	Reference(s)
1, 2, 4, 6, 8, 12–14, 17–19, 21	103(a)	Davis[7] and Inouye[8]
1, 2, 4, 6, 8, 12–14, 17–19, 21	103(a)	Zhou[9] and Ikemura[10]

II. ANALYSIS

A. Discretionary Denial of Petition

Institution of *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a); *SAS*, 138 S. Ct. at 1356 (explaining that section "314(a) invests the Director with discretion on the question *whether* to institute review"). When determining whether to exercise the Director's discretion under § 314(a), we consider, among other factors, whether the same patent has previously been challenged by the same or another petitioner ("follow-on" petitions), and whether the petitioner filed other petitions at or about the same time challenging the same patent.

In this case, we consider whether to exercise our discretion to deny the present Petition based on the prior filing of the Merck Petitions or the concurrent filing of the '027 Petition.

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[7] Davis et al., U.S. Patent Application Publication No. 2009/0010966 A1, published Jan. 8, 2009 ("Davis"). Ex. 1005.
[8] S. Inouye et al., *Up promoter mutations in the lpp gene of Escherichia coli*, 13 NUCLEIC ACIDS RESEARCH 9, 3101–10 (1985) ("Inouye"). Ex. 1006.
[9] J. Zhou, *Secretory Expression of Recombinant Diphtheria Toxin Mutants in B. Subtilis*, 19 J. TONGJI MED. UNIV. 4, 253–56 (1999) ("Zhou"). Ex. 1007.
[10] H. Ikemura et al., *Requirement of Pro-sequence for the Production of Active Subtilisin E in Escherichia coli*, 262 J. BIOL. CHEM. 16, 7859–64 (1987) ("Ikemura"). Ex. 1008.

1. Merck Petitions

Petitioner argues that "[d]iscretionary denial of institution of the present petition in view of the Merck Petitions is not appropriate." Pet. 1–3. Patent Owner does not advance any substantive arguments that the present Petition should be denied based on the Merck Petitions. *See generally* Prelim. Resp. However, because the Merck Petitions were directed to the same '345 patent and previously before the Board, we consider whether to exercise our discretion to deny the present Petition based on the Merck Petitions.

General Plastic Industrial Co., v. Canon Kabushiki Kaisha, IPR2016-01357, Paper 19 at 15–16 (PTAB Sept. 6, 2017) (Section II.B.4.i precedential) articulated a non-exhaustive list of factors[11] to be considered in determining whether to exercise discretion under § 314(a) to deny a follow-on petition by the same petitioner against the same patent. *Valve Corp. v. Electronic Scripting Products, Inc.*, IPR2019-00062, Paper 11 at 2 (PTAB Apr. 2, 2019) (precedential) held that application of the *General Plastic* factors is not limited solely to instances when multiple petitions are filed by the same petitioner. *Id.* When different petitioners challenge the same patent, "we consider any relationship between those petitioners when weighing the *General Plastic* factors." *Id.*

The Merck Petitions resulted in *inter partes* reviews that were instituted on May 9, 2019, after the present Petition was filed. *See* Pet. 3 ("The Board has not issued a Decision on Institution for either of the Merck petitions."); *see also Merck Sharp & Dohme Corp. v. GlaxoSmithKline*

[11] Petitioner lists those factors at Pet. 1 n.1.

Biologicals SA, IPR2019-00230 (PTAB May 9, 2019) ("'230 IPR"), and *Merck Sharp & Dohme Corp. v. GlaxoSmithKline Biologicals SA*, IPR2019-00241 (PTAB May 9, 2019)("'241 IPR"). The '230 IPR and the '241 IPR were terminated on June 12, 2019, due to a settlement before a Final Written Decision was issued in either case. '230 IPR and '241 IPR, Paper 14 (both cases).

We find that two of the *General Plastic* factors are particularly pertinent to our analysis. The first factor is "whether the same petitioner previously filed a petition directed to the same claims of the same patent." *General Plastic*, Paper 19 at 16. Here, Petitioner has not previously filed a petition challenging claims of the '345 patent. Pet. 2–3. Petitioner was not a party to the Merck Petitions, or identified as a real party-in-interest. *Id.* There is no evidence in the record before us of any relationship between Merck and Petitioner related to the '345 patent.[12] *Id.*; *see Valve Corp.*, Paper 11 at 2.

Another *General Plastic* factor is "whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition." *General Plastic*, Paper 19 at 16. Here, based on the filing date of the Petition, Petitioner had access to Patent Owner's preliminary responses to the Merck Petitions in the '230 IPR and the '241 IPR, but those preliminary responses addressed claim

[12] Patent Owner unsuccessfully argued in other cases directed to other patents that Petitioner should have been named as a real party-in-interest. *See, e.g., Merck Sharp & Dohme Corp. v. GlaxoSmithKline Biologicals SA*, IPR2018-01236, Paper 13 at 6–13 (PTAB Dec. 18, 2018).

construction and priority date issues. *See Merck*, IPR2019-00230, Paper 6; *Merck*, IPR2019-00241, Paper 6. Although a claim construction issue is raised in this case with respect to a term that was at issue in the '230 IPR and '241 IPR, Patent Owner does not raise a priority date issue in this case. *See generally* Prelim. Resp. Furthermore, the present Petition was filed prior to the institution decisions for the Merck Petitions, the art cited in the present Petition is different than the art cited in the Merck Petitions, and there is no evidence of "gamesmanship" or that Petitioner had any advantage in having access to Patent Owner's preliminary responses to the Merck Petitions prior to filing the present Petition.

Accordingly, based on our consideration of the pertinent *General Plastic* factors, and the lack of any relevant relationship of record between Merck and Petitioner, we exercise our discretion and do not deny institution on the basis of the previously-filed Merck Petitions.

2. Concurrent Petitions

As explained above, Petitioner concurrently filed both the present Petition and the '027 Petition, both of which challenge the same claims of the '345 patent. As further explained above, Petitioner filed the '028 Multiple Petitions Paper describing the basis for its filing of the Concurrent Petitions,[13] arguing that there are differences between the Concurrent Petitions and that we should institute on both the present Petition and '027 Petition. Paper 10, 3–4. Petitioner also ranked the present Petition as its first choice, ahead of the '027 Petition. *Id.* at 3. Petitioner argues that it

[13] Although the '028 Multiple Petitions Paper also addresses the '478 Petition, we do not address the '478 Petition in this Decision, and limit our discussion to the Concurrent Petitions.

filed the Concurrent Petitions "in good faith [following] the guidance at the time, filing two petitions to obtain additional word count as well as to avoid potential issues presented by *SAS*." *Id.* at 4–5.

Patent Owner advances arguments that we should exercise our discretion to deny institution of the present Petition under 35 U.S.C. § 314(a) based on (1) Petitioner's filing of multiple petitions, and (2) its contention that "the obviousness grounds raised in the ['028 Petition] are duplicative and cumulative of those raised in the ['027 Petition]." Prelim. Resp. 15–21; Paper 11, 3. Patent Owner further argues that "thus, the ['028 Petition] should be denied institution." Prelim. Resp. 20.

In the exercise of the Director's discretion, we concurrently deny institution of the '027 Petition. *See Pfenex*, IPR2019-01027. In doing so, we institute *inter partes* review based on the present Petition, Petitioner's designated first choice as between the two Concurrent Petitions. Furthermore, in view of Petitioner's filing of the '028 Multiple Petitions Paper and denial of institution based on the '027 Petition, we deem Patent Owner's arguments moot.

B. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art ("POSA") before October 8, 2009, the earliest priority date asserted in the '345 patent,

(1) "would have held an M.S or Ph.D. in microbiology, microbial genetics, or molecular biology, and would have had working knowledge of microbial genetics, including genetic engineering and recombinant DNA to manipulate microbial DNA and induce bacterial host production of exogenous proteins and polypeptides;"

(2) "would have had at least 3 years of experience with an M.S., or less with a Ph.D. . . . [that] may have come from the POSA's own

experience, or through research or work collaborations with other individual(s) with experience in the biotechnology industry or in academia," for example, "as members of a research team or group;" and

(3) would have known (a) "about the variety of research kits and recombinant tools, including commercially available products that could be used to improve protein expression in microbial systems," and (b) "how to apply these available tools in order to, for example, optimize bacterial cell culture growth and purify a target protein." Pet. 10 (citing Ex. 1002 ¶¶ 27–29).

Petitioner provides a further example of the experience identified in (2) above, stating that "the POSA may have worked as part of a team or collaboration to develop or utilize genetic engineering and microbial process techniques, or research potential therapeutic or diagnostic molecules for expression in bacterial systems." *Id.* (citing Ex. 1002 ¶ 27).

Patent Owner argues that it "disagrees with Petitioner's definition to the extent it includes individuals who had no experience with bacterial host production of exogenous ***diphtheria toxin*** proteins and polypeptides." Prelim. Resp. 8. According to Patent Owner, an individual who lacked appreciation of certain difficulties associated with bacterial host production of exogenous diphtheria toxin proteins and polypeptides "would not be considered a person of ordinary skill in the art of designing polynucleotides that 'encode[] a polypeptide having an amino acid sequence capable of directing transport of said bacterial toxin polypeptide to the bacterial periplasm,' as claimed." *Id.* at 8–9.

We are not persuaded by Patent Owner's argument because the level of ordinary skill in the art is determined as of "the time the invention was made," (i.e., October 8, 2009, the earliest asserted filing date of the '345

patent), and "the pertinent knowledge is that possessed at the time of the invention." *See Bristol-Meyers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967 (Fed. Cir. 2014), *reh'g denied and en banc reh'g denied*, *Bristol-Meyers Squibb Co. v. Teva Pharms. USA, Inc.*, 769 F.3d 1339, 1341 (Fed. Cir. 2014) (J. Dyk, concurring) ("[A]n invention is not patentable if it 'would have been obvious *before the effective filing date* of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.' 35 U.S.C. § 103 (emphasis added)."). Here, Patent Owner's argument relies on prior art dated twenty years before October 8, 2009, and is thus not persuasive regarding a person of ordinary skill in the art as of October 8, 2009.

Patent Owner supports its argument with statements from the '345 patent, which cites Bishai[14] and O'Keefe,[15] and by Exhibit 2008[16] and citation to paragraphs 46 and 47 of the Galen Declaration. Prelim. Resp. 8–9.

The statements in the background section of the '345 patent, referred to by Patent Owner, are (1) "[p]roduction of significant quantities of diphtheria toxins such as CRM197 for use in vaccines has been hindered due to low protein abundance," a problem that the '345 patent states is described

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[14] W.R. Bishai et al., *High-level Expression of a Proteolytically Sensitive Diphtheria Toxin Fragment in Escherichia coli*, 169 J. BACTERIOLOGY 11, 5140–51 (1987) ("Bishai"). Ex. 2018.
[15] D.O. O'Keefe et al., *Cloned Diphtheria toxin within the periplasm of Escherichia coli causes lethal membrane damage at low pH*, PROC. NATL. ACAD. SCI. USA (Microbiology) 86, 343–46 (1989) ("O'Keefe"). Ex. 1019.
[16] J.P. Perentesis et al., *Expression of diphtheria toxin fragment A and hormone-toxin fusion proteins in toxin-resistant yeast mutants*, PROC. NATL. ACAD. SCI. USA (Biochemistry) 85, 8386–90 (1988). Ex. 2008.

in Bishai as leading to the production of degraded protein from "the expression of a recombinant fusion protein containing diphtheria toxin (including the tox signal sequence)," and (2) "[c]loning of Dip[h]theria fragments containing the tox signal sequence and expression of these sequences in *Escherichia coli* involves certain difficulties," which the '345 patent discusses in connection with Bishai and O'Keefe. Prelim. Resp. 8–9 (citing Ex. 1001, 2:7–25).

Bishai and O'Keefe are dated twenty years or more prior to October 8, 2009. Ex. 2018; Ex. 1019. The same is true of Exhibit 2008 relied on by Patent Owner. The cited testimony from the Galen Declaration also relies on those exhibits, as well as Ex. 2019,[17] which is also dated 1988. Ex. 2001 ¶¶ 46–47; Ex. 2019. Exhibit 2013,[18] dated 2008, is the only exhibit identified in the cited testimony from the Galen Declaration that is dated close to October 8, 2009, but that exhibit is a general discussion of pathways for secreting proteins across the cytoplasmic membrane and does not appear to address diphtheria toxin. Ex. 2013; *see, e.g., id.* at 1735 (Abstract); Ex. 2001 ¶ 46. Accordingly, Patent Owner's argument, based on difficulties associated with bacterial host production of exogenous diphtheria toxin proteins and polypeptides that may have existed at least twenty years prior to October 8, 2009, does not persuade us that the definition of a person of ordinary skill in the art as of October 8, 2009, must not include individuals

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[17] V. Cabiaux et al., *Expression of a biologically active diphtheria toxin fragment B in Escherichia coli*, 2 MOLECULAR MICROBIOLOGY 3, 339–46 (1988). Ex. 2019.

[18] P. Natale et al., *Sec- and Tat-mediated protein secretion across the bacterial cytoplasmic membrane—Distinct translocases and mechanisms*, BIOCHIMICA ET BIOPHYSICA ACTA 1778, 1735–56 (2008). Ex. 2013.

who lacked experience with bacterial host production of exogenous diphtheria toxin proteins and polypeptides. *See* Prelim. Resp. 8.

For purposes of this Decision, and based on the current record, we apply Petitioner's assessment of a person of ordinary skill in the art. We also note that the level of ordinary skill in the art at the time of the invention may be reflected in the prior art in this proceeding. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

C. Claim Construction

In this *inter partes* review, filed May 6, 2019,[19] we construe the claims of the '345 patent by applying "the standard used in federal courts, in other words, the claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b), which is articulated in *Phillips*."[20] Under that standard, "the words of a claim 'are generally given their ordinary and customary meaning' . . . [which] is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1312–13 (citations omitted). Any special definitions for claim terms must be set forth with reasonable clarity,

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[19] *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,343 (amending 37 C.F.R. § 42.100(b) effective November 13, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)).
[20] *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner argues that the phrase "*capable of directing transport of said bacterial toxin polypeptide to the bacterial periplasm"* should be given its ordinary and customary meaning. Pet. 11–13. According to Petitioner, the '345 patent "does not provide a definition for this phrase," and the "plain meaning of 'capable of' is 'having ability, capacity, or power to do something.'" *Id.* at 12 (citing Ex. 1009, 75).

Petitioner further contends that "the phrase is used in the context of a composition; therefore, the signal peptide merely has the ability to direct the bacterial toxin to the periplasm regardless of whether or not it actually does so, and regardless of the particular amount to be secreted to the periplasm." *Id.* Petitioner thus argues that the phrase should be construed as meaning "an amino acid sequence having the ability to direct transport of the bacterial toxin polypeptide to the bacterial periplasm when expressed in a bacterial host cell." *Id.* at 12–13.

Patent Owner argues that Petitioner's alleged construction "vitiates certain claim limitations and prevents the claimed invention from achieving its intended purpose." Prelim. Resp. 10. According to Patent Owner, a POSA "would understand that the disputed term should be construed as requiring a signal sequence that ***directs*** the bacterial toxin polypeptide to the periplasmic space, not one that ***may or may not*** be able to direct periplasmic transport." *Id.* (citing Ex. 2001 ¶ 54). Patent Owner argues further that the claimed invention will be unable to achieve its intended purpose if a signal sequence cannot direct transport to the periplasmic space, and that "in order to accomplish the goal of the claimed invention, the sequence must be

capable of directing transport such that, at the appropriate time, transport actually occurs." *Id.* (citing Ex. 2001 ¶ 55).

Patent Owner supports its argument by reference to the statement in the '345 patent that

> [a] signal sequence ***is capable of directing an expressed protein to the periplasm*** **if**, when it is attached to a polypeptide of interest, during translation of the polypeptide in a gram negative bacteria, **more of said polypeptide is found in the periplasm of a gram negative bacteria than in the absence of the signal sequence**.

Id. at 11 (citing Ex. 1001, 7:33–39 (emphasis added by Patent Owner)). Patent Owner contends that the '345 patent states "what the inventors meant by" the disputed phrase; namely, that "when more of the mature bacterial toxin polypeptide expressed by the claimed polynucleotide ***is found in the periplasm*** of a gram-negative bacteria than in the absence of a signal sequence, the claimed signal sequence is 'capable of directing transport of said bacterial toxin polypeptide to the bacterial periplasm.'" *Id.* (citing Ex. 1001, 49:60–62) (emphasis added by Patent Owner).

We begin our claim construction analysis by considering the challenged claims and the context in which the disputed term or phrase is used in the claims. *See Phillips*, 415 F.3d at 1314 ("the claims themselves provide substantial guidance as to the meaning of particular claim terms . . . the context in which a term is used in the asserted claim can be highly instructive"). Here, the '345 patent claims an apparatus or product (i.e., a polynucleotide), not a process or method. Thus, the claims of the '345 patent cover what the polynucleotide is, not what the polynucleotide does. *See ParkerVision, Inc. v. Qualcomm Inc.*, 903 F.3d 1354, 1361 (Fed. Cir. 2018) ("We explained long ago that '[a]pparatus claims cover what a device

is, not what a device *does*.") (quoting *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990)). Moreover, "an apparatus that is 'capable of' performing certain functions may be anticipated by or obvious in view of a prior art apparatus that can likewise perform these functions." *Id.*

Here, for example, claim 1 recites a polynucleotide that includes a 5' signal sequence portion having a structure that encodes a polypeptide having an amino acid sequence that is *capable of* directing transport of said bacterial toxin polypeptide to the bacterial periplasm *when* expressed in a bacterial host cell. *See* Ex. 1001, 49:54–64 (emphases added). Patent Owner disputes Petitioner's assertion that "the signal peptide merely has the ability to direct the bacterial toxin to the periplasm ***regardless of whether or not it actually does so***," by arguing that the signal sequence is "not one that ***may or may not*** be able to direct periplasmic transport." Prelim. Resp. 10 (citing Pet. 12; Ex. 2001 ¶ 54) (emphasis added by Patent Owner). But Petitioner does not argue that the signal sequence *may or may not* be able to direct periplasmic transport; rather, Petitioner argues that the signal sequence has the ability, capacity, or power (plain meaning of "capable of") to direct periplasmic transport, i.e., that it *is* able to direct "transport of said bacterial toxin polypeptide to the bacterial periplasm when expressed in a bacterial host cell." *See* Pet. 12. Thus, the claimed polynucleotide has a structure that encodes a polypeptide that *has the ability to* direct periplasmic transport *when* expressed in a bacterial host cell, but the polynucleotide, as claimed, *does not require* expression of the polypeptide in a bacterial host cell. *See ParkerVision*, 903 F.3d at 1361.

Accordingly, giving the claim term its plain and ordinary meaning, we determine that the term "capable of directing transport of said bacterial toxin

polypeptide to the bacterial periplasm" means that the structure of the 5' signal sequence portion of the polynucleotide encodes a polypeptide having an amino acid sequence (claim 1) or acid sequence (claim 6) that is capable of directing transport of said bacterial toxin polypeptide to the bacterial periplasm when expressed in a bacterial host cell.

We determine, for purposes of this Decision, that we need not expressly construe any undisputed terms. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'") (*quoting Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

D. Principles of Law

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

An obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418.

E. Obviousness over Davis and Inouye

Petitioner asserts that claims 1, 2, 4, 6, 8, 12–14, 17–19, and 21 of the '345 patent are unpatentable as obvious, under pre-AIA 35 U.S.C. § 103, over the combined teachings of Davis and Inouye, and relies on the Georgiou Declaration in support of those assertions. Pet. 23–39 (citing Ex. 1002 ¶¶ 52, 59, 60, 62, 72, 142, 145–149, 150–160, 165, 166, 168–172).

Patent Owner does not substantively argue against Petitioner's obviousness challenge based on Davis and Inouye, other than to argue that we should deny institution because Petitioner's alleged grounds of unpatentability rely on its erroneous claim construction that seeks to remove the limitation "capable of directing transport of said bacterial toxin polypeptide to the bacterial periplasm" from the claims. Prelim. Resp. 1, 9–15. At this stage of the proceeding, we are not persuaded by Patent Owner's claim construction arguments because, as discussed above, Petitioner does not rely on an "erroneous" claim construction that seeks to remove the "capable of" limitation from the claims. *See supra* § II.C. Moreover, as discussed below, Petitioner has established a reasonable likelihood of showing that the cited prior art teaches and suggests transport of CRM197 (SEQ ID NO: 32) to the bacterial periplasm when expressed in a bacterial host cell.

1. Davis (Ex. 1005)

Davis discloses "compositions of modified diphtheria toxin and fusion proteins containing modified diphtheria toxin that reduce binding to vascular endothelium or vascular endothelial cells." Ex. 1005, code (57) (Abstract). Davis describes the experimental use of diphtheria toxin (DT) variant DT-Glu52 which is CRM-197. *Id.* ¶¶ 38, 41, Fig. 2, Fig. 3, Fig. 5; Ex. 1002 ¶ 79.

Davis also describes the expression of modified diphtheria toxins in *Escherichia coli*, and further describes means for expressing protein that include using pIN vectors, such as those disclosed in Inouye (Ex. 1006). Ex. 1005 ¶¶ 149, 324; Ex. 1002 ¶ 80. Davis also teaches that "DT . . . [is] synthesized at the start of stage 2 using codons optimized for expression in *E. coli* using conventional techniques known in the art. . . . vector systems are used which include secretory leader sequences for export of DT into the periplasmic space of *E. coli*. . . . [t]he method developed in stage 2 provides for reliable production of multiple DT variants." Ex. 1005 ¶ 324; Ex. 1002 ¶ 81.

2. Inouye (Ex. 1006)

Inouye describes a high expression secretion vector, pIN-III-ompA that encodes the ompA signal sequence, which "facilitated the secretion of the [staphylococcal nuclease A] across the cytoplasmic membrane, and its accumulation in the periplasmic space." Ex. 1006, 3107; Ex. 1002 ¶ 84.

3. Analysis

a. Claim 1

Petitioner argues that "Davis, which concerns diphtheria toxin mutants and discloses expression of such proteins in *E. coli* expression systems, taught or suggested each element of independent claim 1." Pet. 23. Petitioner argues further that Davis disclosed that "useful vectors include pIN vectors," citing to Inouye. *Id.* (citing Ex. 1002 ¶ 148). Petitioner also argues that "Inouye disclosed the generation of pIN vectors, specifically pIN-III-ompA, which encodes the *E. coli*-derived OmpA signal sequence for expressing and secreting protein into the periplasmic space of *E. coli*." *Id.* (citing Ex. 1002 ¶ 149).

Petitioner argues that Davis disclosed "polynucleotide and polypeptide compositions of modified diphtheria toxin," and studies of diphtheria toxin mutants, including the utilization of CRM197 (termed "DT-Glu52"), i.e., SEQ ID NO:32. Pet. 24–25 (citing Ex. 1005, Abstract, Fig. 2, and Fig. 5; Ex. 1002 ¶¶ 146–147). Petitioner argues further that "Davis taught and encouraged the expression of modified diphtheria toxin, including CRM197, using secretory leader sequences and secreting the expressed protein into the *E. coli* periplasmic space." *Id.* at 25–26 (citing Ex. 1005 ¶ 324; Ex. 1002 ¶ 148); *see* Ex. 1005 ¶ 324 ("DT . . . [is] synthesized . . . using codons optimized for expression in *E. coli* . . . vector systems are used which include secretory leader sequences for export of DT into the periplasmic space of *E. coli*.").

Petitioner also argues that "Davis referred to the use of pIN vectors to synthesize the disclosed constructs and specifically cited to the work of Inouye." Pet. 26 (citing Ex. 1005 ¶ 149; Ex. 1002 ¶ 148). Petitioner further argues that "Inouye disclosed an *E. coli* high expression vector, pIN-III-ompA, and demonstrated that this vector facilitated the secretion of a cloned bacterial protein . . . across the cytoplasmic membrane, and its accumulation in the periplasmic space of *E. coli*." *Id.* (citing Ex. 1006, 3107; Ex. 1002 ¶ 149). Petitioner thus asserts that "Inouye . . . referred to in Davis as a source for secretion vector constructs, disclosed the use of a 5' signal sequence (*i.e.*, *E. coli*-derived OmpA), which is not derived from *C. diphtheria*, fused to a heterologous polypeptide specifically for expressing and secreting protein into the periplasmic space of the *E. coli*." *Id.* at 27 (citing Ex. 1002 ¶ 150).

Petitioner provides a number of reasons that a person of ordinary skill in the art would have combined the teachings of Davis and Inouye to arrive

at claim 1, including the multiple advantages of periplasmic secretion compared to expression in the cytoplasm. Pet. 28–32 (citing Ex. 1002 ¶¶ 52, 59–60, 62, 72, 148, 149, 151, 152). For example, Petitioner asserts the "ample direction and motivation" provided by Davis to "use the secretion vector constructs comprising CRM197 as the 3' bacterial toxin polypeptide fused to a 5' signal peptide from the secretion vector," including a vector having a secretory leader sequence such as "disclosed in Davis through referencing the pIN vectors of Inouye." *Id.* at 31 (citing Ex. 1002 ¶¶ 148–149, 151).

Petitioner further argues that a person of ordinary skill in the art "would have had a reasonable expectation of success in achieving the claimed polynucleotide constructs." Pet. 32 (citing Ex. 1002 ¶ 151). According to Petitioner, "[b]y October 8, 2009, a POSA was well-versed and trained in the use of the multitude of commercial products that were widely available to assist in constructing secretion vectors for expressing and secreting heterologous proteins into the periplasmic space of *E. coli*." *Id.* (citing Ex. 1002 ¶ 142).

Based on our review of the current record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing that the combined teachings of Davis and Inouye would have rendered obvious claim 1 of the '345 patent.

b. Claim 6

Claim 6 differs from claim 1 in limiting the signal peptide (encoded by the 5' signal sequence portion) to an amino acid sequence selected from a specified group of SEQ ID NOs, or variants or fragments thereof. Ex. 1001, 51:13–37. Petitioner relies on the same arguments advanced in connection with claim 1, and further asserts that SEQ ID NO:6 recited in claim 6 is the

OmpA signal sequence taught and exemplified in Davis and Inouye. Pet. 33–36 (citing Ex. 1002 ¶¶ 153–160).

Based on our review of the current record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing that the combined teachings of Davis and Inouye would have rendered obvious claim 6 of the '345 patent.

c. Dependent Claims

Petitioner argues that dependent claims 2, 12–14, 17–19, and 21 would have been obvious over the combined teachings of Davis and Inouye for the same reasons that it provides for the obviousness of claims 1 and 6. Pet. 37 (citing Ex. 1002 ¶¶ 165, 166). Petitioner also argues that dependent claim 4 would have been obvious for the same reasons as argued for claim 6, and that dependent claim 8 would have been obvious for the same reasons as argued for claims 4 and 6. *Id.* at 38–39 (citing Ex. 1002 ¶¶ 168–172).

4. Summary

For the reasons articulated by Petitioner, and in view of the record as a whole at this stage of the proceeding, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail in showing that at least one of the challenged claims would have been obvious in view of the combined teachings of Davis and Inouye.

F. Obviousness over Zhou and Ikemura

Petitioner asserts that claims 1, 2, 4, 6, 8, 12–14, 17–19, and 21 of the '345 patent are unpatentable as obvious, under pre-AIA 35 U.S.C. § 103, over the combined teachings of Zhou and Ikemura, and relies on the Georgiou Declaration in support of those assertions. Pet. 40–50 (citing Ex. 1002 ¶¶ 181–186, 188, 189, 191–200, 202–206).

Patent Owner does not substantively argue against Petitioner's obviousness challenge based on Zhou and Ikemura, other than to argue that we should deny institution because Petitioner's alleged grounds of unpatentability rely on its erroneous claim construction that seeks to remove the limitation "capable of directing transport of said bacterial toxin polypeptide to the bacterial periplasm" from the claims. Prelim. Resp. 1, 9–15. As discussed above, we are not persuaded by Patent Owner's claim construction arguments at this stage of the proceeding. *See supra* § II.C. Moreover, as discussed below, Petitioner has established a reasonable likelihood of showing that the cited prior art teaches and suggests transport of CRM197 (SEQ ID NO: 32) to the bacterial periplasm when expressed in a bacterial host cell.

1. Zhou (Ex. 1007)

Zhou describes the cloning of diphtheria toxin mutant CRM-197 in *B. [s]ubtilis* plasmid PSM604 under the subtilisin signal sequence, and the secretion of the recombinant protein. Ex. 1007, 253 (Abstract); Ex. 1002 ¶ 87. Zhou states that "[t]he nontoxic DT mutants were also believed to be the candidates for next generation recombinant vaccine and therefore [are] now drawing attention in [their] engineering and production." Ex. 1007, 253 (left column).

2. Ikemura (Ex. 1008)

Ikemura describes subtilisin E (protease) "produced as a precursor, pre-pro-subtilisin, which consists of a signal peptide for protein secretion (pre-sequence) and a peptide extension of 77 amino acid residues (pro-sequence) between the signal peptide and the mature subtilisin." Ex. 1008, 7859 (Abstract); Ex. 1002 ¶ 90. Ikemura also teaches that "[w]hen the entire coding region for pre-pro-subtilisin E was cloned into an *Escherichia coli*

expression vector, active mature subtilisin E was secreted into the periplasmic space," and that "[w]hen the pre-sequence was replaced with the *E. coli* OmpA signal peptide, active subtilisin E was also produced." *Id.*

3. Analysis

a. Claim 1

Petitioner argues that Zhou discloses "polynucleotide and polypeptide compositions of modified diphtheria toxins, including CRM197 (*i.e.,* SEQ ID NO:32." Pet. 40 (citing Ex. 1007, Abstract; Ex. 1002 ¶ 181). Petitioner further argues that "Zhou utilized a gram positive *Bacillus subtilis* bacterial expression system using a *B. subtilis* plasmid 'PSM604 under the subtilisin signal sequence.'" *Id.* at 41 (citing Ex. 1007, 253; Ex. 1002 ¶ 182). Petitioner acknowledges that "[g]ram positive bacteria have only a small periplasmic space,"[21] and that "POSAs would have known that '*B. subtilis* expression systems possessed issues of protein degradation due to the high amounts of proteases secreted by the *B. subtilis* bacterial cells into the culture medium,'" as illustrated in Figure 1 of Zhou. *Id.* at 41–42 (citing Ex. 1002 ¶ 183).

Based on the foregoing, Petitioner argues that "instead of using the *B. subtilis* expression system to make heterologous protein, a POSA would have been motivated to express heterologous protein in *E. coli* using a subtilisin leader peptide as was done in Ikemura." Pet. 42–43 (citing Ex. 1008, 7859 (Abstract); Ex. 1002 ¶ 184). Petitioner states that, in

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[21] Petitioner nevertheless argues that "gram positive signal peptide sequences would also be 'capable of directing transport of said bacterial toxin polypeptide to the bacterial periplasm when expressed in a baterial [sic] host cell' as claimed in claim 1." Pet. 41–42 (citing Ex. 1001, claim 1; Ex. 1002 ¶¶ 182–186).

Ikemura, "the subtilisin signal peptide is used in expression vector constructs to express heterologous protein in an *E. coli* system and secrete into the periplasmic space." Pet. 43 (citing Ex. 1008, 7859 (Abstract); Ex. 1002 ¶ 184).

Petitioner cites Ikemura's statement that "[w]hen the entire coding region for pre-pro-subtilisin E was cloned into an *Escherichia coli* expression vector, active mature subtilisin E was secreted into the periplasmic space." Pet. 43 (citing Ex. 1008, 7859 (Abstract) (emphasis added by Petitioner); Ex. 1002 ¶ 184). Petitioner also argues that Ikemura demonstrated "that the subtilisin signal sequence could be successfully substituted with the OmpA signal peptide from *E. coli* to express and secrete pro-subtilisin E into the periplasmic space of *E. coli*," and that "*E. coli*-derived OmpA could express and secrete a heterologous protein . . . into the periplasmic space of *E. coli*." *Id.* (citing Ex. 1008, 7859 (Abstract); Ex. 1002 ¶ 184).

Petitioner further argues that a POSA would have been motivated to "use the vector constructs of Zhou comprising a 5' signal sequence (*B. subtilis*-derived subtilisin signal peptide), which is not derived from *C. diphtheria*, fused to CRM197 (*i.e.*, SEQ ID NO:32) and express the vector construct in an *E. coli* expression system as taught and disclosed in Ikemura." Pet. 44 (citing EX1002 ¶¶ 185–186). Petitioner also argues that, combined with the POSA's knowledge of the many advantages of expressing and secreting heterologous proteins into the periplasmic space, "Zhou and Ikemura provided the direction and motivation to use the secretion vector constructs comprising CRM197 as the 3' bacterial toxin polypeptide fused to a *B. subtilis* subtilisin signal peptide for expression and secretion into the periplasmic space of *E. coli*," and a POSA "would have

had a reasonable expectation of success in doing so." *Id.* (citing Ex. 1002 ¶¶ 185, 186).

Based on our review of the current record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing that the combined teachings of Zhou and Ikemura would have rendered obvious claim 1 of the '345 patent.

b. Claim 6

Claim 6 differs from claim 1 in limiting the signal peptide (encoded by the 5' signal sequence portion) to an amino acid sequence selected from a specified group of SEQ ID NOs, or variants or fragments thereof. Ex. 1001, 51:13–37. Petitioner relies on the same arguments advanced in connection with claim 1, and further asserts that SEQ ID NO:6 recited in claim 6 is the OmpA signal sequence taught by Ikemura. Pet. 45–48 (citing Ex. 1002 ¶¶ 188, 189, 191–194).

Based on our review of the current record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing that the combined teachings of Zhou and Ikemura would have rendered obvious claim 6 of the '345 patent.

c. Dependent Claims

Petitioner argues that dependent claims 2, 12–14, 17–19, and 21 would have been obvious over the combined teachings of Zhou and Ikemura for the same reasons that it provides for the obviousness of claims 1 and 6. Pet. 49 (citing Ex. 1007, 253; Ex. 1002 ¶¶ 195–200). Petitioner also argues that dependent claims 4 and 8 would have been obvious over Zhou and Ikemura for the same reasons as argued for claim 6. *Id.* at 49–50 (citing Ex. 1002 ¶¶ 202–206).

4. Summary

For the reasons articulated by Petitioner, and in view of the record as a whole at this stage of the proceeding, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail in showing that at least one of the challenged claims would have been obvious in view of the combined teachings of Zhou and Ikemura.

III. CONCLUSION

Based on the record as a whole at this stage of the proceeding, and for the foregoing reasons, we conclude that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims of the '345 patent.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1, 2, 4, 6, 8, 12–14, 17–19, and 21 of U.S. Patent No. 9,422,345 B2 is instituted with respect to all grounds set forth in the Petition; and

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

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