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Paper No. 13
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME CORP.,
Petitioner,

v.

GLAXOSMITHKLINE BIOLOGICALS SA,
Patent Owner.

Case IPR2018-01234
Patent No. 9,265,839 B2

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

SNEDDEN, *Administrative Patent Judge.*

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

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner"), filed a Petition requesting an *inter partes* review of claims 1–10 of U.S. Patent No. 9,265,839 B2 (Ex. 1001, "the '839 patent"). Paper 1 ("Pet."). GlaxoSmithKline Biologicals SA ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp."). In its Preliminary Response, Patent Owner raised the issue of whether Petitioner identified all of the real parties-in-interest. Prelim. Resp. 17–24. Petitioner thereafter requested permission to file a reply to the Preliminary Response to address the real parties-in-interest issue. We granted Petitioner's request, allowing Petitioner to file a reply, and also allowing Patent Owner to file a sur-reply. Paper 9. Petitioner filed its reply (Paper 10, "Reply") accompanied by a Declaration of John T. Haines ("Haines Declaration," Ex. 1061) and Patent Owner filed its sur-reply (Paper 12, "Sur-Reply").

To institute an inter partes review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). After considering the evidence and arguments presented in the Petition, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least claim 1 of the '839 patent is unpatentable. Accordingly, an *inter partes* review of all of the claims and all of the grounds presented in the Petition is hereby instituted.

In this Decision, we address all issues raised by the parties in the pre-trial briefing. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This is not a final decision as to the patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record as fully developed during trial

A. Related Matters

The parties represent that they are not aware of litigations involving the '839 patent. Pet. xii; Paper 4, 1–3.

The '839 patent is concurrently challenged in IPR2018-01237 by Petitioner on different grounds.

The '839 patent is a continuation of U.S. Patent Application No. 13/581,824, which issued as Patent No. 8,753,645. The '645 patent is concurrently challenged in IPR2018-01229 and IPR2018-01236 by Petitioner.

B. The '839 patent

The '839 patent describes a "[p]rocess for conjugation of bacterial saccharides including *Streptococcus pneumoniae and Haemophilus influenzae* saccharides by reductive amination." Ex. 1001, Abst. "Reductive amination involves two steps, (1) oxidation of the antigen, (2) reduction of the antigen and a carrier protein to form a conjugate." *Id.* at 1:43–45.

The oxidation step may involve reaction with periodate, which "may lead to size reduction." *Id.* at 46–47. However, according to the '839

patent, "using lower concentrations of periodate in the presence of low phosphate may lead to retention of size and/or the retention of epitopes." *Id.* at 51–53. In this regard, the claims of the '839 patent require "reacting the bacterial saccharide with 0.001–0.7 molar equivalents of periodate to form an activated bacterial saccharide." *Id.* at 26:31–44 (claim 1). The '839 patent discloses that the buffer used in this reaction step should not contain an amine group. *Id.* at 4:41–42. Suitable buffers include the "phosphate buffer, borate buffer, acetate buffer, carbonate buffer, maleate buffer and citrate buffer." *Id.* at *Id.* at 4:42–48.

The bacterial saccharide may be an *S. pneumoniae* capsular saccharide 6B. *Id.* at 5:1–33, 8:16–10:60.

The carrier protein used to form the conjugate may be "any peptide or protein." *Id.* at 6:28–30. Suitable carrier proteins include tetanus toxoid, fragment C of tetanus toxoid, diphtheria toxoid, CRM197, Pneumolysin, protein D, PhtD, PhtDE and N19. *Id.* at 7:4–9.

"Reducing agents which are suitable for use in the process of the invention include the cyanoborohydrides, such as sodium cyanoborohydride, borane-pyridine, or borohydride exchange resin." *Id.* at 12:7–10.

The '839 patent states that the inventors "have surprisingly found that using lower concentrations of periodate in the presence of low phosphate may lead to retention of size and/or the retention of epitopes." *Id.* at 1:51–53. The '839 patent further describes that "[t]reatment with periodate may lead to a reduction in the size of the bacterial saccharide (sizing effect)." *Id.* at 6:14–15. Additionally, the '839 patent states: "When low concentrations

of buffer . . . and low amounts of periodate are used, this may reduce the sizing effect described above." *Id*. at 8:11–13.

C. Illustrative Claims

Independent claim 1, reproduced below, is illustrative of the challenged claims:

> 1. A process for conjugating a bacterial saccharide and reducing the sizing effect on bacterial saccharide comprising the steps of
>
> a) reacting the bacterial saccharide with 0.001–0.7 molar equivalents of periodate to form an activated bacterial saccharide;
>
> b) mixing the activated bacterial saccharide with a carrier protein;
>
> c) reacting the activated bacterial saccharide and the carrier protein with a reducing agent to form a conjugate;
>
> wherein step a) occurs in a buffer which does not contain an amine group, and the buffer has a concentration between 1–100 mM and wherein the bacterial saccharide is *S. pneumoniae* capsular saccharide 6B.

Ex. 1001, 26:32–44.

D. Evidence Relied Upon

Petitioner relies upon the following prior art references:

Ex. 1004, Chen et al., PCT Patent Application Publication No. WO 2004/043376A2, published May 27, 2004 ("WO'376" or "Chen").

Ex. 1005, Frasch, "Preparation of Bacterial Polysaccharide-Protein Conjugates: Analytical and Manufacturing Challenges," 27 VACCINE 6468–70 (2009) ("Frasch").

Ex. 1006, Lees et al., *Conjugation Chemistry*, Chap. 11 *Pneumococcal Vaccines: The Impact of Conjugate Vaccine*, 163–74 (2008) ("Lees").

Ex. 1007, Biemans et al., WO 2009/000825 A2, published Dec. 31, ("GSK 2009 PCT" or "Biemans").

Ex. 1008, Prevnar®, *2009 Physicians' Desk Reference*, *63rd ed.*, (2008) ("Prevnar").

Petitioner also relies upon the Declaration of Fikri Avci, Ph.D. (Ex. 1009) to support its contentions.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 5–6):

Ground	Claims	Basis	References
1	1–10	§ 102(b)	WO'376
2	1–10	§ 103(a)	WO'376, Frasch, and Lees
3	4	§ 103(a)	WO'376, Frasch, Lees, and GSK 2009 PCT
4	5	§ 103(a)	WO'376, Frasch, Lees, and Prevnar
5	9	§ 103(a)	WO'376, Frasch, Lees, and GSK 2009 PCT

II. ANALYSIS

A. Real Parties-in-Interest

The statute governing *inter partes* review proceedings sets forth certain requirements for a petition, including that "the petition identif[y] all real parties in interest." 35 U.S.C. § 312(a)(2); *see also* 37 C.F.R. § 42.8(b)(1) (requirement to identify real parties-in-interest in mandatory notices). Pursuant to 35 U.S.C. § 312(a)(2) and 37 C.F.R. § 42.8(b)(1), Petitioner states that "[t]he real parties-in-interest are Petitioner Merck Sharp & Dohme Corp., and Merck & Co., Inc. (collectively, "Merck"). Pet. xii.

In its Preliminary Response, Patent Owner argues that Pfenex Inc. ("Pfenex") also qualifies as a real party-in-interest ("RPI") "due at least in part to its exclusive license to assist in developing a vaccine related to the claimed invention," and that Petitioner's failure to identify Pfenex as an RPI requires that we deny the Petition. Prelim. Resp. 17–24. Patent Owner relies on the recent decisions of our reviewing court in *Applications in Internet Time, LLC v. RPX Corp*., 897 F.3d 1336 (Fed. Cir. 2018) ("*AIT*") and *Worlds Inc. v. Bungie, Inc*., 903 F.3d 1237 (Fed. Cir. 2018) ("*Worlds*"). *Id*. Patent Owner also cites to "publicly available information"[1] as showing that "Pfenex granted Merck an exclusive worldwide license to Pfenex Expression Technology™ *Pseudomonas*-based recombinant protein expression technology for the production of specific proteins to be used in the development of Merck's vaccine product." *Id.* at 20–21.

Petitioner bears the burden of persuasion regarding the real party-in-interest contention advanced by Patent Owner. *See Worlds*, 903 F.3d at 1241–42. .

1. Petitioner's Arguments

Petitioner's reply challenges the factual and legal bases for Patent Owner's contention that Pfenex should have been named as an RPI. Reply 1–5. Petitioner[2] states that, even if one were to accept Patent Owner's

[1] Patent Owner submits several web pages (Exs. 2003, 2004, 2007, 2008 and 2010), a journal article (Ex. 2005), a Statement of Claim from a Canadian legal proceeding (Ex. 2006), and a Pfenex Corporate Presentation (Ex. 2009).

[2] Both the reply and Haines Declaration also refer to Petitioner as "Merck."

characterization of Pfenex's press releases and other evidence as true, they "show nothing more than that Pfenex has licensed certain technology to Merck for Merck to use in Merck's proposed V114 product." *Id.* at 1–2 (citing Patent Owner's Exhibits 2003, 2005, and 2007–2010). According to Petitioner:

> The RPI requirement should not be (and never has been before) expanded to capture all third parties who license technology to a petitioner, or who otherwise might indirectly derive revenue from the sale of a petitioner's proposed product. Such an impractical, overreaching rule would have the effect of ensnaring suppliers and contract research organizations with no connection to the Petition. It would also create unnecessary and unreasonable uncertainty as to which entities should be named as RPI.

Id. at 2. Petitioner further argues that the "heart" of an RPI inquiry involves two questions: whether a petition "has been filed at a nonparty's 'behest'" and whether a non-party "desires review of the patent." *Id.* (quoting *Applications in Internet Time*, 897 F.3d at 1351). Petitioner also explains that it did not file the Petition at the behest of Pfenex and that Pfenex has no reason to desire review of the '839 patent. *Id.* at 3–5.

According to the Haines Declaration, Petitioner has a proposed vaccine product (V114) for preventing pneumococcal disease, which is currently undergoing clinical trials, and contains a protein called CRM197. Ex. 1061 ¶ 3. The Haines Declaration indicates that Petitioner and Pfenex "have entered into a license to Pfenex Expression Technology™ that relates to a production strain capable of producing the CRM197 protein in Merck's

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Paper 10, 1; Decl. ¶ 2.

proposed vaccine product." *Id.* ¶ 5. The Haines Declaration further states that "Pfenex's only role in Merck's proposed vaccine product is the licensing of this technology and related intellectual property to Merck. Pfenex has not been, and will not be, involved in making, using, offering to sell, selling or importing Merck's proposed vaccine product or any portion of that product," including the protein known as CRM197. *Id*. ¶ 6. Moreover, assuming FDA approval, Petitioner's proposed vaccine product and "the materials used to make it, including CRM197, will be manufactured and sold by Merck or other entities that do not include Pfenex." *Id*. ¶ 7.

Petitioner thus denies Patent Owner's contentions that "Petitioner and Pfenex are involved in making the clinical candidate V114 that contains 23F-CRM197" and are "similarly at risk of infringing" the '839 patent." Reply 1. Petitioner also submits a journal article[3] showing that carrier protein CRM197 was first disclosed 45 years ago. *Id.* at 5, n.4. Petitioner also argues, contrary to Patent Owner's allegation, that CRM197 is not covered by the claims of the challenged patent. *Id*. Petitioner further argues that "Merck and Pfenex have no similar common ownership, management overlap, or history of coordinating legal matters suggesting that Merck filed this Petition at Pfenex's behest." *Id.* at 4.

2. Patent Owner's Arguments

Patent Owner argues that, according to Petitioner's press release in 2009, "Pfenex granted Merck an exclusive worldwide license to Pfenex

[3] Uchida et al., *Diphtheria Toxin and Related Proteins,* 248 J. BIOLOGICAL CHEMISTRY 11, 3838–44 (1973). Ex. 1062.

Expression Technology™ *Pseudomonas*-based recombinant protein expression technology for the production of specific proteins to be used in the development of Merck's vaccine product." Prelim. Resp. 21(citing Ex. 2003, 1). Patent Owner also argues that Merck has paid Pfenex upfront licensing fees and milestone payments, and that Pfenex is entitled to royalty payments "on any product sales derived from the agreement." Prelim. Resp. 22 (citing Ex. 2003, 1; Ex. 2010, 1). Patent Owner also contends that these facts satisfy the statement in *AIT* that the RPI inquiry involves "determining whether the non-party is a clear beneficiary that has a preexisting, established relationship with the petitioner." Prelim. Resp. 19 (quoting *Applications in Internet Time*, 897 F.3d at 1351 (Patent Owner's emphasis omitted)).

Patent Owner further argues that the carrier protein CRM197 is covered by dependent claim 5 of the '839 patent. Prelim. Resp. 21–22. Petitioner also points to Canadian litigation involving Petitioner, and Petitioner's allegation that it "has a reasonable basis to believe that the manufacture, use, and/or sale of V114 in Canada will be impugned by [Patent Owner] as an infringement of" the Canadian counterpart of the '839 patent, and further argues that both Petitioner and Pfenex "are involved in making the clinical candidate V114 that contains 6B-CRM197" and are "similarly at risk of infringing" the '839 patent. Prelim. Resp. 23 (citing Ex. 2006 ¶ 18 and Ex. 2004, 1).

In its Sur-Reply, Patent Owner argues that the RPI inquiry "is not limited to entities that are subject to potential infringement liability with respect to a challenged patent," and that Petitioner "fails to establish why

Pfenex should not be named as an RPI in view of its relationship with Petitioner and Pfenex's potential to benefit from these IPR proceedings." Sur-Reply 1–2. Patent Owner reasserts that Pfenex has an established relationship with Petitioner, that Pfenex stands to benefit from Petitioner's IPRs, and that this satisfies "[t]he proper test for RPI." *Id.* at 3–5.

3. Analysis

On the record before us and for the reasons set forth below, we are persuaded that Petitioner has satisfied its burden of establishing that Pfenex is not a real party-in-interest under 35 U.S.C. § 312(a)(2).[4]

"Determining whether a non-party is a 'real party in interest' demands a flexible approach that takes into account both equitable and practical considerations, with an eye toward determining whether the non-party is a clear beneficiary that has a preexisting, established relationship with the petitioner." *Applications in Internet Time*, 897 F.3d at 1351. Whether a particular entity is a real party-in-interest is a "highly fact-dependent question" that is assessed "on a case-by-case basis." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012) (citing *Taylor v. Sturgell*, 553 U.S. 880, 893–95 (2008)). Although multiple factors may be relevant to the inquiry, "[a] common consideration is whether the non-party exercised or could have exercised control over a party's participation

[4] Unlike *AIT* or *Worlds*, the RPI considerations in this case arise under 35 U.S.C. § 312(a)(2) rather than 35 U.S.C. § 315(b). The Director can allow the petitioner to add a real party in interest if a petition fails to identify all real parties in interest under Section 312(a)(2). *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364, 1374 n.9 (Fed. Cir. 2018) (*en banc*).

in a proceeding." *Id.* The two questions lying at the heart of the RPI inquiry are "whether a non-party 'desires review of the patent' and whether a petition has been filed at a non-party's 'behest.'" *Applications in Internet Time*, 897 F.3d at 1351 (quoting Trial Practice Guide, 77 Fed. Reg. at 48,759).

The present Petition relates to the question of whether claims directed to a "process for conjugating a bacterial saccharide and reducing the sizing effect on bacterial saccharide" are invalid under Sections 102 and/or 103. Paper 1. Although claim 5 refers to CRM197 as one of several carrier proteins that may be used in the process of claim 1, we agree with Petitioner that none of the claims at issue "cover" the protein identified as CRM197.

The evidence submitted by Petitioner establishes that Petitioner has a proposed vaccine product (V114) for preventing pneumococcal disease, which is currently undergoing clinical trials, and contains a protein called CRM197. Ex. 1061 ¶ 3. The evidence presented by Petitioner further establishes that, although Pfenex granted Merck a license to technology and intellectual property related to "a production strain capable of producing the CRM197 protein in Merck's proposed vaccine product," . . . "Pfenex has not been, and will not be, involved in making, using, offering to sell, selling or importing Merck's proposed vaccine product or any portion of that product," including the protein known as CRM197. *Id*. at ¶¶ 5–6. The information submitted by Patent Owner indicates that this license agreement was entered into prior to the filing of the application giving rise to the '839 patent, and included the payment of upfront licensing fees, milestone payment(s), and "royalty payments on any product sales derived from the agreement."

Prelim. Resp. 21–22. Petitioner does not indicate any disagreement with those contentions.

Patent Owner's contention that Pfenex is an RPI solely because Pfenex has a preexisting, established relationship with Petitioner and is a clear beneficiary of the Petition, is an incomplete reading of *AIT* and unavailing. *See Unified Patents, Inc. v. Realtime Adaptive Streaming, LLC*, IPR2018-00883 (PTAB Nov. 27, 2018 (Public Version)) (Paper 36, 14–15) ("We agree with Petitioner that Patent Owner is overextending the reasoning of *AIT*. The RPI analysis set out in *AIT* and the common law require more than simply confining the analysis to determining whether a party benefits generally from the filing of this Petition and also has a relationship with the Petitioner.").

Here, we agree with Petitioner that if the sole requirement for being named an RPI was as argued by Patent Owner, it would ensnare third parties, such as suppliers and contract research organizations, with no connection to the Petition.[5] Reply 2. Moreover, given the nature of the relationship with Pfenex, as established by Petitioner, Patent Owner's contention that Pfenex is a clear beneficiary of the Petition is seemingly based on assumptions and speculation that a negative outcome for Petitioner in challenging the validity of the '839 patent will result in depriving Pfenex

[5] If the RPI test were simply a preexisting relationship and benefit from a successful Petition, it might also ensnare shareholders of Petitioner. Such a result would not meet the practicality or equity considerations stated in *AIT*.

of the benefit of its license agreement with Petitioner. The record before us does not support such assumptions or speculation.

Petitioner has persuaded us that the nature of its relationship with Pfenex is such that Pfenex is not exercising, or could have exercised, control over Petitioner's participation in the present *inter partes* review, that the Petition has not been filed at the behest of Pfenex, or that Pfenex desires review of the '839 patent. Accordingly, based on the entirety of the record before us at this stage of the proceeding, we find that Petitioner has persuasively established that Pfenex need not be named as an RPI in connection with the Petition.

B. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art at the time of the invention would have would have had a Ph.D. degree in Biochemistry, Chemistry, or a comparable discipline, and at least 2–3 years of research experience focused on carbohydrate chemistry. Pet. 6 (citing Ex. 1009 ¶ 21).

At this stage of the proceeding, and absent opposition from Patent Owner, we adopt Petitioner's definition of the level of ordinary skill in the art. Moreover, the prior art itself is sufficient to demonstrate the level of skill in the art at the time of the invention. *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

For petitions filed before November 13, 2018, we interpret the claims of an unexpired patent that will not expire before issuance of a final written decision using the broadest reasonable interpretation in light of the specification. *See* 37 C.F.R. § 42.100(b) (2016); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable construction standard, claim terms are presumed to have their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc*., 504 F.3d 1249, 1257 (Fed. Cir. 2007). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999).

Petitioner proposes constructions for the terms "reducing the sizing effect," "molar equivalents," and "average molecular weight." Pet. 21–29. At this stage of the proceeding, Patent Owner disputes only Petitioner's construction of "reducing the sizing effect" and "average molecular weight." Prelim. Resp. 5–17. We address the parties proposed claim constructions below. Based on the record before us, we determine that no other claim terms require an explicit construction at this time.

We emphasize that the following constructions are preliminary and invite the parties to address them as necessary during trial.

1. "reducing the sizing effect"

Preamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim. *See*

Boehringer Ingelheim Vetmedica, Inc. v. Schering–Plough Corp., 320 F.3d 1339, 1345 (Fed.Cir.2003); *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). "In considering whether a preamble limits a claim, the preamble is analyzed to ascertain whether it states a necessary and defining aspect of the invention, or is simply an introduction to the general field of the claim." *On Demand Mach. Corp. v. Ingram Indus., Inc*., 442 F.3d 1331, 1343 (Fed. Cir. 2006), *cert. denied*, 549 U.S. 1054 (2006). For example, "preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc*., 289 F.3d 801, 809 (Fed. Cir. 2002) (citations omitted).

A preamble may be limiting, however, if: "it recites essential structure or steps"; claims "depend[ ] on a particular disputed preamble phrase for antecedent basis"; the preamble "is essential to understand limitations or terms in the claim body"; the preamble "recit[es] additional structure or steps underscored as important by the specification"; or there was "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art." *Catalina Mktg*., 289 F.3d at 808.

Petitioner contends that the preamble phrase "reducing the sizing effect on bacterial saccharide" in claim 1 is not limiting. Pet. 3, 23–25. Petitioner argues that the body of claim 1 itself sets forth the steps required to practice the claimed process, and that those steps in and of themselves would lead to a reduction in the sizing effect. *Id*. at 23.

Patent Owner contends that "[t]he prosecution histories of both the '839 patent and the [related] '645 patent[6] illustrate that 'reducing the sizing effect' is not merely an intended purpose but an important characteristic of the claimed process." Prelim. Resp. 13. Patent Owner notes that during prosecution of the '839 patent, "Applicant argued that the claimed range of 0.001–0.7 molar equivalents of periodate was not obvious over the cited prior art because the claimed range 'has previously ***unexpected properties***' for the 23F saccharide, i.e., 'the saccharide[] [is] ***not reduced in size*** by the activation process.'" *Id.* at 10–11 (citing Ex. 2002, 508 (Response datedNovember 20, 2013) (emphases added)). Patent Owner further contends that the "reducing the sizing effect" language was added by Examiner Amendment, which accompanied the statement that, "***[i]n view of amendment to the claim 1*** and arguments of record, the rejection of claims 1, 2, 6, 14-6, 33, 46, 51, 62 and 67 . . . under 35 USC § 103 . . . is withdrawn.'" *Id.* at 12 (citing Ex. 2002, 519 (Notice of Allowance) (emphasis added)). Patent Owner also directs our attention to the Examiner's statement in the Notice of Allowance under the heading "Reasons for Allowance," which provides as follows:

> None of the prior art teaches or suggests the claimed process. The current process is drawn for ***not only conjugating*** *S. pneumoniae* capsular saccharide 23F or 6B by using 0.001–0.7 molar equivalents of periodate but also ***for reducing the [sizing effect]***[7] of the capsular saccharide by using low 0.001–0.7 molar equivalents of periodate.

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[6] U.S. Patent No. 8,753,645.

[7] The parties agree that the original language "reducing the size" was a

Id. at 11–12 (citing Ex. 2002, 520 (emphases added)).

Anticipating Patent Owner's reliance on the Examiner's Reasons for Allowance, Petitioner contends that "[t]he Examiner's statement clearly demonstrates that 'reducing the sizing effect' is not an additional limitation because the Examiner recognized that the step needed to achieve such reduction, i.e., step a), was already recited in the claim body." Pet. 25. That is, "'reducing the sizing effect' is a result of using the 0.001–0.7 MEq of periodate of step a), which was already recited in the body of claim 1 before the addition of this claim term." *Id.* "Thus, 'reducing the sizing effect' was included in the preamble for the same reasons that 'conjugating a bacterial saccharide' was—to state the purpose of the process." *Id.*

Upon consideration of the parties' positions and a review of the current record, we are persuaded by Petitioner that the preamble of claim 1 is non-limiting. Patent Owner relies on *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc*., 868 F.2d 1251 (Fed. Cir. 1989), where the Federal Circuit found that the preamble "optical waveguides" was limiting. Prelim. Resp. 8–9. The present case is distinguishable from *Corning*, however, because in concluding that the preamble was limiting, the court determined that "[t]he claim requires . . . the particular structural relationship defined in the specification for the core and cladding to function as an optical waveguide." *Corning*, 868 F.2d at 1257. That structural relationship was relevant when

typographical error made by the Examiner. Pet. 25, n.12; Prelim. Resp. 12, n.5.

distinguishing the claimed optical waveguides from "all types of optical fibers." *Id.*

In contrast to the preamble phrase in *Corning*, the preamble phrase "reducing the sizing effect" in this case is not defined structurally by the specification, but merely identifies the particular problem solved by the inventors of the '839 patent. While the '839 patent discloses that the inventors "surprisingly found" a way to achieve the "retention of size and/or the retention of epitopes," the '839 patent discloses also that this size reduction effect is accomplished by "using lower concentrations of periodate in the presence of low phosphate." Ex. 1001, 1:51–53. In this regard, the steps recited in the method of claim 1 set forth limitations for concentrations of both periodate and buffer. That is, "'reducing the sizing effect' is a result of using the 0.001–0.7 MEq of periodate of step a), which was already recited in the body of claim 1 before the addition of this claim term." Pet. 25.

Clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention. *See generally Bristol–Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375, 58 USPQ2d 1508, 1513 (Fed.Cir.2001) (A preamble may limit when employed to distinguish a new use of a prior art apparatus or process.). In this regard, we acknowledge that the preamble phrase was added by Examiner's Amendment, but we are not persuaded that the language was added clearly for the purpose of distinguishing the claimed invention from the prior art. First, that

amendment was not limited to adding language to the preamble, but also deleted text from the body of the claim. Ex. 2002, 518. Second, the Examiner's Reasons for Allowance acknowledges that the purpose of the claims process is "for reducing the [sizing effect] of the capsular saccharide," which is achieved "by using low 0.001–0.7 molar equivalents of periodate." *Id.* at 519. On the current record, we are persuaded by Petitioner's argument that the Examiner's Reasons for Allowance suggests that "'reducing the sizing effect' was included in the preamble for the same reasons that 'conjugating a bacterial saccharide' was—to state the purpose of the process." *Id.* at 25. The language adds context and purpose, but does not otherwise limit the claim.

2. "average molecular weight"

A clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited. *Tex. Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1172 (Fed.Cir.1993). However, when a "clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329 (Fed. Cir. 2005).

Claim 4 recites "[t]he process of claim 1 wherein the average molecular weight of the bacterial saccharide is between 1–1100 kDa after step a)." Ex. 1001, 26:50-52. Petitioner contends that the term "molecular weight" is non-limiting and merely reflects the "intended result that follow from practicing the claimed method." Pet. 28.

Patent Owner contends that "the only difference between claim 1 and claim 4 is that claim 4 further recites a range of post-activation and pre-conjugation 'average molecular weight' of 6B" and that "[t]his indicates that the recited molecular weight limitation represents a meaningful manipulative difference in the recited steps compared to claim 1." Prelim. Resp. 16 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) ("the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.")). Additionally, Patent Owner contends that "[t]he average molecular weight recited in claim 4 further limits the claim scope to cover certain activation conditions and certain levels of reduction of the sizing effect." Prelim. Resp. 17.

We are persuaded by Patent Owner's rationale, which we adopt as our own, that the wherein clause of claim 4 further limits independent claim 1. *Id.* at 16–17. We construe the term "average molecular weight," for the purposes of this decision, to have the express definition set forth in the '839 patent, i.e., "the weight-average molecular weight (Mw) of the bacterial saccharide measured prior to conjugation and is measured by MALLS." Ex. 1001, 5:61-64;[8] *see Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511

[8] We note that the terms "average molecular weight" and "weight-average molecular weight" are used synonymously in the '839 patent. *See* Ex. 1001, 5:61–64 ("The molecular weight or average molecular weight of a saccharide herein refers to the weight-average molecular weight (Mw) of the bacterial saccharide measured prior to conjugation and is measured by MALLS.").

F.3d 1132, 1138 (Fed. Cir. 2007) ("We have frequently found that a definition set forth in the specification governs the meaning of the claims.").

3. "molar equivalents"

Petitioner contends that the term "molar equivalents of periodate" should be construed to mean "the ratio of moles of periodate to the moles of saccharide [repeating unit]." Pet. 26–27. At this stage of the proceeding, for purposes of this decision, we adopt Petitioner's unopposed constructions.

D. Petitioner's Ground I: Anticipation of Claims 1–10 By WO'376

Petitioner asserts that claims 1–10 of the '839 patent are unpatentable as anticipated by WO'376. Pet. 29–43. Patent Owner does not substantively address Petitioner's unpatentability contentions.

1. WO '376 (Ex. 1004)

WO'376 describes polysaccharide-polypeptide conjugates for treating or preventing pneumococcal infection. Ex. 1004, Abstract. WO'376 describes an Example 4 titled "Preparation of Polysaccharide-Protein Conjugates." *Id*. at 23:22–27:25. Section A of Example 4 is titled "Oxidation of Polysaccharide" and Section D of Example 4 is titled "Preparation of Polysaccharide-Protein Conjugates." *Id.* at 23:25–33 and 27:13–25.

Example 4 discloses a method for conjugating bacterial saccharides, including serotype 6B (*id*. at 23:26), by (a) reacting the bacterial saccharide with 0.27 MEq of periodate (*id*. at 23:27–30; see below), in 100 mM phosphate buffer solution (pH 7.2) (*id*. at 23:27–29), (b) mixing the activated bacterial saccharide with a pneumolysin carrier protein (*id*. at

27:18–20), and (c) reacting the activated bacterial saccharide and the carrier protein with the reducing agent sodium cyanoborohydride to form a conjugate (*id*.).

Section A of Example 4 describes the addition of 1 mL of 0.2 M phosphate buffered saline (PBS) to pneumococcal capsular polysaccharides, such as 6B and 23F, dissolved in distilled water. *Id.* at 23:26–29. Section A further describes the oxidation of the polysaccharide with 2 mM sodium periodate. *Id*. at 23:29–30.

Section D of Example 4 describes the conjugation of *S. pneumoniae* polysaccharide to pseudopneumolysin protein by direct conjugation using a reductive animation assay. *Id.* at 27:14–18. Section D further describes that sodium cyanoborohydride was added to the oxidized polysaccharide and pseudopneumolysin mixture. *Id*. at 27:18–20. WO'376 further describes that polysaccharide-pseudopneumolysin protein conjugates, such as 23F and 6B, were prepared as described in Example 4 and tested for their ability to raise antibodies against polysaccharide and pneumolysin in mice. *Id.* at 27:28–30.

2. Analysis

In support of its assertion that WO'376 anticipates claims 1–10, Petitioner sets forth the foregoing teachings of WO'376 and provides a detailed discussion explaining how each claim limitation is disclosed in the reference, including citations to the Avci Declaration as support. Pet. 29–43. In particular, Petitioner argues that Example 4 of WO'376 discloses a conjugation process to prepare bacterial saccharide-protein conjugates, and that the preamble of claim 1 is non-limiting. *Id.* at 29–30. Petitioner further

argues that, even if limiting, WO'376 inherently discloses "reducing the sizing effect" because it is the natural result of practicing step a) of claim 1, which Example 4 explicitly discloses. *Id.* at 30–33. As discussed above, we do not find, at this stage of the proceeding, that the phrase "reducing the sizing effect" is a limitation of claim 1.

Regarding claim step a), Petitioner contends that WO'376 discloses "that bacterial saccharide 6B was 'oxidized by reaction' with 0.27 MEq of periodate,[9] which is within the claimed range." *Id.* at 34. In particular, Petitioner shows how the disclosure in Example 4 allows for the calculation of MEq, and specifically the calculation that Example 4 discloses use 0.27 MEq of periodate. *Id.* at 34–35. Moreover, in addition to disclosing step a) of the process of claim 1, Petitioner explains that Example 4 discloses "wherein step a) occurs in a buffer which does not contain an amine group, and the buffer has a concentration between 1–100 mM." *Id.* at 35. In particular, Petitioner explains that PBS does not contain an amine group and that the amount of buffer used in Example 4 is calculated to be 0.1 M (100 mM). *Id.* at 36.

Regarding claim step b), Petitioner refers to section D of Example 4 as disclosing that pseudopneumolysin was added to the oxidized (activated) polysaccharide reaction mix, and the teaching of WO'376 that

[9] Petitioner construes the term "molar equivalents of periodate" as meaning "the ratio of moles of periodate to the moles of saccharide repeating unit." Pet. 26–27. Patent Owner does not contest this construction in its Preliminary Response.

pseudopneumolysin is useful as a carrier of polysaccharides. *Id.* at 36 (citing Ex. 1004, 10:18).

Regarding claim step c), Petitioner points to the disclosure in Example 4 of the addition of sodium cyanoborohydride (a reducing agent as indicated in Ex. 1006, 168) to the oxidized polysaccharide (i.e. the activated bacterial saccharide) and pseudopneumolysin (i.e. carrier protein) mixture. *Id.* at 37–38. Petitioner also explains that the limitation "and wherein the bacterial saccharide is *S. pneumoniae* capsular saccharide 6B" is disclosed by WO'376 because it specifically discloses a method of conjugating *S. pneumoniae* capsular saccharide 6B. *Id.*

With regard to dependent claims 2–10, Petitioner provides a detailed discussion explaining how each claim limitation set forth in dependent claims 2–10 are disclosed WO'376, including citations to the Avci Declaration as support. Pet. 38–43. Patent Owner does not substantively address Petitioner's citations and arguments regarding dependent claims 2–10 beyond its claim construction arguments. For purposes of this Decision, we agree with Petitioner's analyses of claims 2–10 and adopt them as our own.

In view of the above, based on our review of the parties' positions, the evidence of record, and our discussion of claim 1 above, we determine that at this stage of the proceeding the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail in showing that one or more of claims 1–10 are anticipated by WO'376.

E. Petitioner's Ground 2: Obviousness of Claim 1–10 over the Combination of WO'376, Frasch, and Lees

Petitioner asserts that claims 1–10 are unpatentable under § 103 as obvious over the combination of WO'376, Frasch, and Lees, including citations to the Avci Declaration as support. Pet. 43–53. For the reasons discussed below, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing claims 1–10 are unpatentable over the combination of WO'376, Frasch, and Lees.

1. Frasch

Frasch provides a review of the "[a]nalytical and manufacturing challenges" associated with the preparation of bacterial saccharide-protein conjugates. Ex. 1005, 6468 (title). Frasch discloses that "[o]ne important potential problem with use of periodate to activate the [polysaccharides ("PS")] is altering the physical structure of the PS, with loss of important epitopes." *Id.* at 6468–69). Frasch teaches the chemical mechanism for how this structural alteration occurs:

> Sodium periodate oxidizes diols (two adjacent carbons with hydroxyl groups) into aldehydes (C=O) and in the process breaks C-C bonds. Thus, depending upon the PS structure, periodate activation can fragment a PS and open the ring structure of sugars. When the diol is within a ring, the ring sugar is opened possibly altering the PS confirmation. When the diol is in a glycerol or ribitol side chain, the side chain disappears.

Id. at 6469.

Frasch further cautions that "[t]he chemistry to be used for PS activation must be carefully considered, because some activation methods can degrade the PS in addition to causing a size reduction." *Id.* at 6469.

Frasch further explains that "[t]he size of the purified PS or oligosaccharide should be known, both before and after activation, because the activation chemistry may significantly reduce the size of the [polysaccharide.]" *Id.*

2. Lees

Lees discloses that

> The capsular [polysaccharides ("PSs")], in their native forms, are known to be high-molecular-weight polymers, containing well over 1,000 repeat units. While the reduction of size prior to conjugation offers several advantages during conjugate manufacture (e.g., a marked reduction in viscosity and ease of separation of the conjugate from the free carbohydrate), it also entails extra steps and losses and can affect important epitopes.

Ex. 1006, 164. Lees discloses that, in order to form conjugates, "[t]he carbohydrate is first oxidized using sodium periodate to create aldehydes." *Id.* at 167. "[D]epending on where these hydroxyl groups are located on the sugar, oxidation can open up the ring and possibly cleave the polymer," thereby reducing the size reduction of the saccharide. *Id.* at 168. According to Lees, "[v]icinal [cis] hydroxyls are usually cleaved first, and at higher concentrations of periodate, trans hydroxyls are also cleaved." *Id.*

3. Analysis

In support of its assertion that the combination of WO'376, Frasch, and Lees renders claims 1–10 obvious, Petitioner sets forth the foregoing teachings of WO'376, Frasch, and Lees and provides a detailed discussion explaining how each claim limitation is disclosed in the combination of references. Pet. 43–53. Petitioner largely repeats its argument that WO'376

discloses every limitation of claim 1. Pet. 44–45. We incorporate here our earlier findings and discussion regarding the disclosures of WO'376.

Petitioner further asserts that "[t]he only recited language of claim 1 that WO'376 does not explicitly discuss is 'reducing the sizing effect' of the saccharide, which is not even a limitation, but that is the natural result of practicing the claimed process." *Id.* at 44. Petitioner further argues that "given a POSA's knowledge that periodate oxidation can decrease the size of the saccharide . . . 'reducing the sizing effect' would have been obvious." *Id.* Petitioner asserts that Frasch and Lees teach persons of skill in the art to expect a reduction in sizing effect when following the steps of Example 4 of WO'376, that based on Frasch and Lees "it would have been obvious to POSAs that using lower concentrations of periodate . . . would reduce the sizing effect," and that Frasch and Lees "motivate[s] POSAs to reduce the sizing effect in order to preserve important epitopes for immunogenicity." *Id.* at 44–45; Ex. 1009 ¶¶ 144, 146, 154. Petitioner further argues that persons of skill in the art would have been motivated to combine WO'376 with Frasch and Lees with a reasonable expectation of success in reducing the sizing effect by following the steps of WO'376 Example 4. *Id.* at 51–52.

Additionally, Petitioner argues that the limitations of claims 2–10 are disclosed by WO'376, and that "POSAs would have combined the teaching of WO'376 with Frasch and Lees with a reasonable expectation of success for the same reasons set forth above with respect to claim 1." *Id.* at 53. For purposes of this Decision, we agree with Petitioner's analyses of claims 2–10 and adopt them as our own.

Having considered the arguments and evidence set forth in the Petition, we are persuaded that Petitioner has shown sufficiently that each limitation of claims 1–10 is taught or suggested by the combination of WO'376, Frasch, and Lees. Accordingly, we determine Petitioner has shown a reasonable likelihood of prevailing on its assertion that claims 1–10 are unpatentable as obvious over WO'376, Frasch, and Lees.

F. Petitioner's Ground 3: Obviousness of Claim 4 over the Combination of WO '376, Frasch, Lees, and GSK 2009 PCT

Petitioner asserts that claim 4 is unpatentable under § 103 as obvious over the combination of WO '376, Frasch, Lees, and GSK 2009 PCT. Pet. 53–56. Patent Owner does not substantively address Petitioner's unpatentability contentions. For the reasons discussed below, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing claim 4 is unpatentable over the combination of WO '376, Frasch, Lees, and GSK 2009 PCT.

We incorporate here our earlier findings and discussion regarding the disclosures of WO '376, Frasch, and Lees.

1. GSK 2009 PCT

GSK 2009 PCT discloses methods of preparing pneumococcal capsular saccharide-conjugate vaccines, including with periodate activation and reductive amination. Ex. 1007, 17:1–35. GSK 2009 PCT teaches that a carrier protein, such as diphtheria toxoid, is conjugated to pneumococcal saccharides, including 6B. *Id.* at 9:13–14, 10:12–17, 11:34–12:12, 21:28–22:12, 23:15–24:2, 54:28–55:1 (Table 1)).

GSK 2009 PCT discloses that the "present inventors have found that saccharide conjugate vaccines retaining a larger size of saccharide can provide a good immune response against pneumococcal disease . . . In one embodiment, one or more saccharide conjugates of the invention should have an average size of saccharide pre-conjugation of 50–1600, 80–1400, 100–1000, 150–500 or 200–400 kDa." *Id.* at 14:23–33. GSK 2009 PCT discloses that the weight-average molecular weight of the saccharides are measured by MALLS. *Id.* at 15:32–16:6.

2. Analysis

Ground 3 is substantially similar to Ground 2. For this ground, Petitioner additionally relies on the disclosures of GSK 2009 PCT, summarized above. Pet. 53–56. In particular, Petitioner cites to the statement in GSK 2009 PCT that "[i]n one embodiment, one or more saccharide conjugates of the invention should have an average size of saccharide pre-conjugation of 50–1600, 80–1400, 100–1000, 150–500, or 200–400 kDA." *Id.* at 54 (citing Ex 1007, 14:30–32 (Petitioner's emphasis omitted)). Based on that statement, Petitioner contends that GSK 2009 PCT discloses that the saccharide that is to be conjugated should have a molecular weight within the ranges recited in claims 4 and 5. *Id.* Moreover, Petitioner contends that "the prior art, including GSK 2009 PCT, taught POSAs ways to obtain the pre-conjugation saccharide sizes recited in the claims," and that "based on the prior art, such as GSK 2009 PCT, POSAs knew of and would have been motivated to use routine ways to obtain the pre-conjugation saccharide sizes recited in the claims with a reasonable expectation of success." *Id.* at 55 (citing Ex. 1009 ¶ 168).

For purposes of this Decision, we agree with Petitioner's analysis of claim 4 and adopt it as our own. Accordingly, at this stage of the proceeding, we are persuaded that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail with respect to claim 4.

G. Petitioner's Ground 4: Obviousness of Claim 5 over the Combination of WO '376, Frasch, Lees, and Prevnar

Petitioner asserts that claim 5 is unpatentable under § 103 as obvious over the combination of WO '376, Frasch, Lees, and Prevnar. Pet. 56–57. Patent Owner does not substantively address Petitioner's unpatentability contentions.

Petitioner's Ground 4 is substantially similar to Ground 2. For this ground, Petitioner additionally relies on the disclosures of Prevnar. Pet. 56–57. In particular, Petitioner asserts that "Prevnar discloses an FDA-licensed, commercially available vaccine that includes pneumococcal conjugates prepared by reductive amination (like those of WO'376)," and that Prevnar disclosed "CRM197" as recited in claim 5 because "Prevnar teaches that a carrier protein, *e.g.*, CRM_{197}, is conjugated to its saccharides, including serotype 6B." *Id.* (citing Ex. 1008, 3241). Petitioner also argues that a person of ordinary skill in the art would have been motivated "to use CRM_{197} as the carrier protein for the pneumolysin in WO'376's example to make the conjugates," and that "POSAs would have had a reasonable expectation of success in using CRM_{197} as the carrier protein in WO'376's method for making the 6B-protein conjugates." *Id.* at 57.

For purposes of this Decision, we agree with Petitioner's analysis of claim 5 and adopt it as our own. Accordingly, at this stage of the proceeding, we are persuaded that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail with respect to claim 5.

H. Petitioner's Ground 5: Obviousness of Claim 9 over the Combination of WO '376, Frasch, Lees, and GSK 2009 PCT

Petitioner asserts that claim 9 is unpatentable under § 103 as obvious over the combination of WO '376, Frasch, Lees, and GSK 2009 PCT. Pet. 57–59. Patent Owner does not substantively address Petitioner's unpatentability contentions.

Petitioner's Ground 5 is substantially similar to Ground 2. For this ground, Petitioner additionally relies on the disclosures of GSK 2009 PCT. In particular, Petitioner asserts that GSK 2009 PCT states "that its compositions containing the conjugates may also contain *S. pneumoniae* proteins as free or unconjugated proteins, and that "[t]hese proteins can be the ones recited in claim 9, *e.g.*, pneumolysin." *Id.* at 58 (citing Ex. 1007, 21:28–31 and 22:8–12). Petitioner further asserts that "POSAs would have been motivated to combine GSK 2009 PCT's *S. pneumoniae* proteins with the conjugates prepared by WO'376's method to arrive at claim 9 of the '839 patent, with a reasonable expectation of success in doing so." *Id*.

For purposes of this Decision, we agree with Petitioner's analysis of claim 9 and adopt it as our own. Accordingly, at this stage of the proceeding, we are persuaded that the information presented in the Petition

establishes that there is a reasonable likelihood that Petitioner would prevail with respect to claim 9.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood that it will succeed on at least one of its challenges to patentability. Under the Office's Guidance implementing *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018): "[a]t this time, if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." Guidance on the Impact of *SAS* on AIA Trial Proceedings ("Guidance"), available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial (April 26, 2018). Accordingly, we institute trial as to all claims and all grounds presented in the Petition.

IV. ORDER

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–10 of U.S. Patent No. 9,265,839 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, *inter partes* review of the '839 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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