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Paper No. 28
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2018-01675
Patent 8,603,044 B2

Before HYUN J. JUNG, BART A. GERSTENBLITH, and JAMES J. MAYBERRY, *Administrative Patent Judges*.

GERSTENBLITH, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting institution of an *inter partes* review of claims 11, 14, 15, 18, and 19 of U.S. Patent No. 8,603,044 B2 (Ex. 1002, "the '044 patent"). Sanofi-Aventis Deutschland GmbH ("Patent Owner") filed a Preliminary Response (Paper 12). With prior authorization, Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 16; "PR Reply") limited to addressing whether we should exercise our discretion under 35 U.S.C. § 314(a) to deny the Petition, and Patent Owner filed a Sur-Reply in response (Paper 19, "PR Sur-Reply"). Also with prior authorization, Petitioner filed a Motion to Correct the Petition (Paper 15) and Patent Owner filed an Opposition to the Motion (Paper 18). We granted Petitioner's Motion to Correct (Paper 21), resulting in a citation change on page 25 of the Petition, which is shown in Exhibit 1037.[1] We also granted Patent Owner's request to file an Amended Preliminary Response, which Patent Owner filed as Paper 23 ("Prelim. Resp."), to respond to the corrected citation in the Petition. Paper 21, 4. Pursuant to 35 U.S.C. § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable

[1] Because it was a very minor change, we did not require Petitioner to file a "corrected petition"; rather, we agreed that we would treat the originally filed Petition as though the correction had been made. *See* Ex. 1039, 14:17–16:4. The citation on page 25 to Exhibit 1002 was thus changed from "*cf.* EX1002, 3:42–44" to "*cf.* EX1002, 3:62–64." Ex. 1037.

likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the present record and for the reasons explained below, we determine that Petitioner has shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Accordingly, we institute an *inter partes* review of claims 11, 14, 15, 18, and 19 on all grounds raised in the Petition.

B. Related Proceedings

The parties indicate that the '044 patent has been asserted in *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105 (D.N.J.); *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812 (D. Del.); and *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, No. 1:14-cv-00113 (D. Del.). Paper 10, 2; Paper 11, 2–3.

The parties state that the '044 patent also is challenged in Case IPR2018-01676. Paper 10, 2; Paper 11, 3. The parties also state that patents related to the '044 patent are challenged in Cases IPR2018-01670, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01684, IPR2018-01696, and IPR2019-00122. Paper 10, 2–3; Paper 11, 2–3.

C. Real Parties in Interest

Petitioner identifies Mylan Pharmaceuticals Inc., Mylan Inc., Mylan GmbH, Biocon Research Ltd., Biocon Ltd., and Becton, Dickinson and Company as real parties in interest. Paper 10, 2. Patent Owner identifies Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis U.S. LLC, and Sanofi Winthrop Industrie as real parties in interest. Paper 11, 2.

D. The Asserted Ground of Unpatentability

Petitioner asserts claims 11, 14, 15, 18, and 19 of the '044 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Burroughs et al.[2] (Ex. 1013, "Burroughs"). Petitioner supports its challenge with a declaration by Karl R. Leinsing, dated September 8, 2018 (Ex. 1011, "the Leinsing Declaration").

E. The '044 Patent

The '044 patent "relates to pen-type injectors . . . . where a user may set the dose." Ex, 1002, 1:20–24. Figures 1 and 2 of the '044 patent are reproduced below.

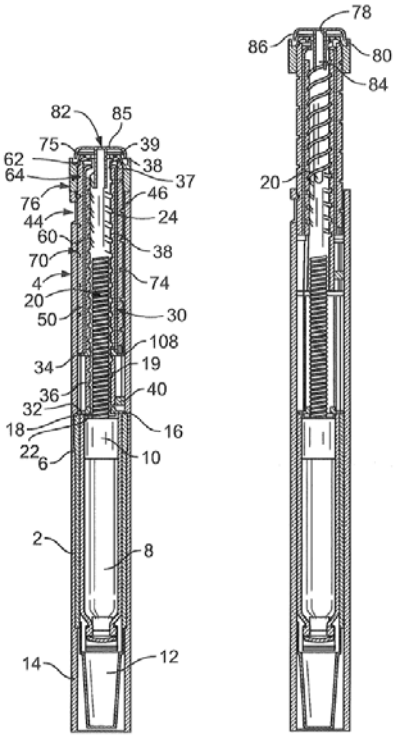

FIG. 1 FIG. 2

Figure 1 "shows a sectional view of a pen-type injector . . . in a first, cartridge full, position," and Figure 2 "shows a sectional view of the pen-

[2] US 6,221,046 B1, iss. Apr. 24, 2001.

type injector of FIG. 1 in a second, maximum first dose dialed, position." *Id.* at 2:53–57. The pen-type injector includes first cartridge retaining part 2 and second main housing part 4.[3] *Id.* at 3:27–28. Insert 16 is at a first end of housing part 4 and is fixed rotationally and axially to main housing 4. *Id.* at 3:49–51. Insert 16 includes threaded circular opening 18, through which piston rod 20 extends. *Id.* at 3:51–53, 3:57–59. Piston rod 20 includes first thread 19 that engages threaded circular opening 18. *Id.* at 3:56.

Piston rod 20 also includes pressure foot 22 that abuts piston 10 of cartridge 8. *Id.* at 3:36–37, 3:59–60. Drive sleeve 30 extends about piston rod 20, and second thread 24 of piston rod 20 engages internal helical groove 38 of drive sleeve 30. *Id.* at 3:61–62, 4:4, 4:13–14.

Clutch or clutch means 60 is disposed about drive sleeve 30 adjacent its second end. *Id.* at 4:33–35, 4:49–50. Clutch 60 is keyed to drive sleeve 30 by splines to prevent relative rotation between clutch 60 and drive sleeve 30. *Id.* at 4:60–62. Clutch 60 also has teeth 66 that engage dose-dial sleeve 70. *Id.* at 4:50–52.

Dose dial sleeve 70 is outside of clutch 60 but within main housing 4. *Id.* at 5:3–5. Dose dial sleeve 70 has helical groove 74 on its outer surface, and helical rib 46 of housing 4 is seated in helical groove 70. *Id.* at 5:5–6, 5:9–11. Dose dial grip 76 is disposed about and secured to the second end of dose dial sleeve 70. *Id.* at 5:24–25, 5:27–28.

A user rotates dose dial grip 76 to set a dose and cause dose-dial sleeve 70, clutch 60, and drive sleeve 30 to rotate together out of main

[3] The '044 patent refers to "second main housing part 4" and "main housing 4" interchangeably. *Compare* Ex. 1002, 3:28 ("second main housing part 4") *with id.* at 3:30 ("main housing 4").

housing 4. *Id.* at 5:50–53, 5:61–65, Fig. 9. The dose can be reduced by turning dose dial grip 76 in the opposite direction. *Id.* at 6:19–20, Fig. 10. The user then presses button 82, which causes clutch 60 to disengage from dose dial sleeve 70 so that clutch 60 moves axially and dose dial sleeve 70 rotates back into main housing 4. *Id.* at 6:28–35, 6:38–40, Fig. 11. Drive sleeve 30 also moves axially and causes piston rod 20 to rotate through threaded opening 18 to dispense medicine from cartridge 8. *Id.* at 6:45–47.

F. Illustrative Claim

Claim 11, the sole independent claim challenged in this proceeding, is representative of the claimed subject matter and reproduced below:

> 11. A housing part for a medication dispensing apparatus, said housing part comprising:
>
> a main housing, said main housing extending from a distal end to a proximal end;
>
> a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;
>
> a dose dial grip disposed near a proximal end of said dose dial sleeve;
>
> a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;
>
> a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and,
>
> a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,
>
> wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, and wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said

> drive sleeve has a second lead, and wherein said first lead and said second lead are different.

Id. at 8:7–36.

II. 35 U.S.C. § 314(a)

Patent Owner contends we should exercise our discretion under 35 U.S.C. §§ 314(a) and 324(a)[4] to deny the Petition, as instituting trial "would waste the Board's finite resources and is fundamentally unfair and inefficient to require Patent Owner to expend resources on an IPR trial where the final written decision will issue only after the conclusion and resolution of the identical validity challenge in the related District Court case." Prelim. Resp. 4. Patent Owner provides a procedural history leading to the related district court litigation and filing of the Petition in this proceeding. *Id.* at 6–8. Patent Owner indicates it initiated district court litigation as part of the Hatch-Waxman Act process, which was triggered by Petitioner's submission of an application to the Food and Drug Administration ("FDA") to market a follow-on insulin glargine product. *Id.* at 6. Petitioner notified Patent Owner of the application and included a "Paragraph IV" certification alleging that the claims of the '044 patent were not valid, unenforceable, and/or not infringed. *Id.* at 6–7.

Patent Owner indicates it filed a patent infringement case against Petitioner on October 24, 2017, Petitioner served its invalidity contentions on January 25, 2018 (which Petitioner amended on April 25, 2018), and Patent Owner responded with its validity contentions on August 12, 2018. *Id.* at 7. The Petition in this proceeding was filed on September 10, 2018.

[4] 35 U.S.C. § 324 applies to post-grant reviews, which this is not. Therefore, our focus is on § 314.

Paper 8, 1. Patent Owner alleges the Petition "assert[s] substantially the same invalidity grounds" alleged in the district court case. Prelim. Resp. 7–8.

Patent Owner additionally indicates the parties in the district court case jointly requested trial for October 2019, to reach resolution before the end of the FDA's 30-month stay. *Id.* at 8 (citing Ex. 2006 ¶ 8); *see also* PR Sur-Reply 1 (arguing Petitioner sought trial in advance of March 2020). Patent Owner asserts, "even if the trial date shifts to later in 2019, there is simply no basis to suggest that the District Court will not resolve all of the issues in this case, including validity, before the March 2020 transition date and expiration of the stay." PR Sur-Reply 3.[5] Thus, according to Patent Owner, the related district court litigation will be concluded before a final written decision is issued in this proceeding. Prelim. Resp. 8.

Patent Owner argues that the Board has discretion to deny under 35 U.S.C. § 314(a), pointing to statements in the August 2018 Trial Practice Guide Update regarding a purpose of the *inter partes* review system to establish a more efficient patent system and limit unnecessary litigation costs. Prelim. Resp. 9 (citing Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (Aug. 13, 2018); H.R. Rep. 112-98, pt. 1, at 48 (2011)). Patent Owner also notes that the Board has exercised its discretion to deny institution in circumstances similar to those presented

[5] Patent Owner states that "[a] *Markman* hearing is likely to occur in early February 2019." Prelim. Resp. 8. We note that the hearing is now scheduled for April 12, 2019. *See* Ex. 3001. Also, an amended scheduling order in the case indicates that Patent Owner proposed, and the court accepted, a trial date in January 2020, subject to the court's availability. *See id.*

here. *Id.* (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, Case IPR2018-00752 (PTAB Sept. 12, 2018) (Paper 8) ("*NHK Spring*")).

Patent Owner contends the facts here are similar to the facts of *NHK Spring* because the parties are at an advanced stage in district court litigation, Petitioner relies on prior art in this proceeding that is at issue in the litigation, and the district court trial will conclude before a final written decision is issued. *Id.* at 9–12. Patent Owner also argues instituting trial in this proceeding gives Petitioner a tactical advantage because Petitioner was able to review Patent Owner's response to Petitioner's invalidity contentions in the related litigation, which amounts to "two bites at the apple." *Id.* at 13. Patent Owner asserts Petitioner was aware of the timing of the district court case and engaged in gamesmanship that is highly prejudicial to Patent Owner. *Id.*; *see also* PR Sur-Reply 5 n.1 (contending Petitioner "can still tailor its District Court invalidity grounds to address weaknesses identified in the Patent Owner's Preliminary Response or the institution decision").

Patent Owner also applies the factors discussed in *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, Case IPR2016-01357 (PTAB Sept. 6, 2017) (Paper 19) ("*General Plastic*") to the facts of this case and contends that each factor favors denying the Petition. Prelim. Resp. 14–18. Patent Owner argues, although those factors were articulated in the context of denying follow-on petitions, the underlying logic applies to the present proceeding. *Id.* at 15. In its analysis of the factors, Patent Owner points to Petitioner's duplication of invalidity arguments in the related district court case and the present proceeding, the filing of the Petition after receipt of Patent Owner's response to the invalidity contentions, and the likelihood that

the district court case will be decided no later than March 18, 2020. *See id.* at 15–18.

In its Reply to the Preliminary Response, Petitioner argues its contentions in district court listed exemplary combinations, including Burroughs in combination with thirty-three additional references. PR Reply 1–2. Petitioner contends Patent Owner provides no evidence of its "detailed validity positions," other than an email that demonstrates service of the contentions. *Id.* at 2.

Petitioner also contends that the number of patents asserted by Patent Owner in the district court litigation and the word count limits in our rules necessitated Petitioner's filing of ten petitions. *Id.* at 2–3. Petitioner argues that our discretionary denial of the timely filed petitions would penalize Petitioner merely because Patent Owner asserted multiple patents in litigation. *Id.* at 3.

Petitioner also argues Patent Owner speculates that a final written decision in this case will issue after the related litigation has been resolved. *Id.* at 3–4. Petitioner asserts, contrary to Patent Owner's contentions, it did not stagger the filing of the petitions nor did it file the petitions on the eve of the one-year time limit. *Id.* at 4–5. Instead, the petitions (with one exception) were filed on the same day almost two months before the deadline. *Id.* Petitioner also contends Patent Owner's arguments run afoul of statute, case law, and the Administrative Procedure Act. *Id.* at 5–12.

Patent Owner responds, contending the district court litigation will conclude by March 2020 and asserting the District of New Jersey and Judge Chesler are known to resolve Hatch-Waxman litigation "expeditiously and in advance of stay expiration." PR Sur-Reply 2 (referring to statements

made in a related action in the Northern District of West Virginia). Patent Owner also asserts an exercise of discretion under § 314(a) in this case will not apply necessarily to all broadly Hatch-Waxman litigants. *Id.* at 3–4. Rather, Patent Owner points to the alleged duplicate grounds in the district court and this proceeding and timing issues that Patent Owner contends are "unique issues" to the facts presented here. *Id.*

In view of the arguments presented, we are not persuaded to exercise our discretion under 35 U.S.C. § 314(a) to deny the Petition. We understand that the facts in *NHK Spring* and the circumstances of this case may seem similar. The record, however, does not indicate that trial in the related district court case will occur in October 2019 or even in January 2020, in light of the latest schedule.[6] *See* Ex. 3001. Although the record indicates that the district court and the parties are working together toward resolving the litigation before the end of the FDA's 30-month stay, there are no assurances that the related litigation will in fact be resolved before then. Indeed, as indicated in the latest scheduling order in the district court litigation, the parties will not propose trial dates to the district court until October 2019. *See id.* Adding to the uncertainty of when a trial may begin, many of the district court schedule's milestones are dependent on the issuance of a claim construction order, which is not within the control of either party. *See id.*; *see also* PR Reply 4 (explaining that "most deadlines" are tied to the issuance of a *Markman* order). In this proceeding, by statute,

[6] In the district court case running parallel to *NHK Spring*, the court ultimately moved the trial date back six months, illustrating the uncertainty associated with litigation schedules. *See Intri-Plex Techs. v. NHK Int'l Corp.*, 3:17-cv-01097-EMC (N.D. Cal.) (docket entry 173 (providing new schedule), docket entry 175 (providing order granting new schedule)).

barring any good cause, review will be completed within one year of institution. For these reasons, we are not persuaded instituting review in this proceeding will be an inefficient use of Board resources.

Additionally, we are not persuaded to apply the factors enumerated in *General Plastic* to the facts of this case. As Patent Owner notes, the *General Plastic* factors were articulated in the context of follow-on petitions. Prelim. Resp. 14. Here, in contrast, Patent Owner does not complain of a follow-on petition. Rather, Patent Owner complains that Petitioner received Patent Owner's response to Petitioner's invalidity contends in related litigation before Petitioner filed the Petition. *Id.* at 14–18. We cannot discern from Exhibit 2011, however, the substance of Patent Owner's response to the invalidity contentions, so it is unclear what, if any, tactical advantage, Petitioner may have gained by receiving that response before filing the Petition in this matter. Thus, we are not persuaded that Petitioner's receipt of Patent Owner's response to the invalidity contentions amounts to a petitioner receiving the benefit of a preliminary response or decision on institution before filing a second petition challenging the same patent, the circumstances addressed by the *General Plastic* factors. For the same reasons, even if we were to apply the *General Plastic* factors, we would be unable to ascertain the same information. Also, Petitioner filed the Petition well within the timeframe allowed by statute, weighing heavily in Petitioner's favor. Accordingly, we do not exercise our discretion under 35 U.S.C. § 314(a) to deny the Petition.

III. LEVEL OF ORDINARY SKILL IN THE ART

Petitioner asserts that one of ordinary skill in the art "would have had at least a bachelor's degree in mechanical engineering, or an equivalent

degree, and approximately three years of experience in medical-device design" and "would have understood the basics of medical-device design and manufacturing, and the basic mechanical elements (e.g., gears, pistons) involved in drug-delivery devices."[7] Pet. 14 (citing Ex. 1011 ¶ 104). Patent Owner does not propose a level of ordinary skill in the Preliminary Response.

At this stage of the proceeding, we find Petitioner's proposal consistent with the level of ordinary skill in the art reflected by the prior art of record, *see Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978), and, therefore, we preliminarily adopt Petitioner's unopposed position as to the level of ordinary skill in the art.

IV. CLAIM CONSTRUCTION

In an *inter partes* review based on a petition filed prior to November 13, 2018, claim terms in an unexpired patent are construed according to their broadest reasonable interpretation in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b) (2018);[8] *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016).

[7] The articulated level of ordinary skill in the Petition differs slightly from the level of ordinary skill proposed in the petition for IPR2018-01676, which challenges the same patent. Each petition references the same paragraph of Mr. Leinsing's Declaration, which was filed in each case.

[8] A recent amendment to this rule does not apply here because the Petition was filed before November 13, 2018. *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 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective Nov. 13, 2018) (to be codified at 37 C.F.R. pt. 42).

There is a presumption that claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art in the context of the specification. *See In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Nonetheless, if the specification "reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor's lexicography governs." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Another exception to the general rule that claims are given their ordinary and customary meaning is "when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Uship Intellectual Props., LLC v. United States*, 714 F.3d 1311, 1313 (Fed. Cir. 2013) (quoting *Thorner v. Sony Computer Entm't Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). Additionally, only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

Petitioner states, "[f]or this petition, claim terms may be given their ordinary and accustomed meaning, consistent with the specification and how a [person of ordinary skill in the art] would have understood them." Pet. 15 (citing 37 C.F.R. § 42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc)). Petitioner contends "[t]he ground presented

below relies on the ordinary and customary meaning of the claim terms." *Id.* at 17.

Petitioner provides interpretations of five terms that were proffered by Patent Owner in related litigation—"drive sleeve," "main housing," "piston rod," "threading," and "tubular clutch." *Id.* at 15–16 (citing Ex. 1019, 19, 21, 23, 27, 30). Petitioner also explains it proffered means-plus-function interpretations for "tubular clutch" and "clicker" in related litigation and reiterates those interpretations here. *Id.* (citing Ex. 1028, 54–59, 62–63, 65–68; Ex. 1002, 2:16–18, 4:49–62, 4:63–65, 6:33–43). Petitioner states that the ground presented "also addresses the 'tubular clutch' and 'clicker' limitations to the extent that those terms may be construed as means-plus-function limitations." *Id.* at 17.

Patent Owner responds that Petitioner does not state what the plain and ordinary meaning is for any term. Prelim. Resp. 24. Patent Owner also contends that Petitioner fails to comply with 37 C.F.R. § 42.104(b) by not asserting clearly how the claims are construed for purposes of the Petition. *Id.* at 47–50.

By providing Patent Owner's proposed interpretations from related litigation, we understand Petitioner to contend that the broadest reasonable interpretation in view of the specification and the plain and ordinary meanings of these terms would, at a minimum, encompass Patent Owner's proposed interpretations. Also, as discussed further below, Petitioner's arguments provide sufficient indication as to how Petitioner interprets the challenged claims in its application of Burroughs to the claim limitations.

Patent Owner also disputes that "tubular clutch" and "clicker" are means-plus-function limitations. *Id.* at 28–29. Patent Owner argues that,

although Petitioner requests means-plus-function interpretations for these terms, Petitioner applies different interpretations or does not apply means-plus-function interpretations in its analysis, thereby prejudicing Patent Owner's ability to defend its patent. *Id.* at 47–50.

We do not view Petitioner's reproduction of its means-plus-function interpretations from the related litigation as alternative constructions for these terms as somehow rendering the Petition defective. To the extent Petitioner's approach results in a failure to explain how the claims are construed, it is addressed in the context of our consideration of Petitioner's challenge. The parties may address this issue further during trial.

Aside from contesting Petitioner's application of means-plus-function claim construction, as discussed above, Patent Owner proposes only one term for construction—"helical groove." *Id.* at 24–28. Patent Owner proposes "helical groove" means "a groove formed in the shape of a spiral." *Id.* at 25. Patent Owner provides citations to the specification of the '044 patent and several dictionary definitions. *Id.* at 25–28 (citing Ex. 1002, 5:5–6, Figs. 12–14; Ex. 2013, 10; Ex. 2014; Ex. 2015, 4–5).

Based on the arguments and evidence at this stage, we adopt Patent Owner's proposed construction for the purposes of this Decision. During trial, we may revisit the construction of this term and Petitioner's arguments regarding Burroughs related thereto. With respect to the other claim terms discussed above, we determine that no express interpretation is required for purposes of determining whether Petitioner demonstrates a reasonable likelihood of prevailing in its challenge based on Burroughs. *Vivid Techs.*, 200 F.3d at 803 (construing explicitly only those claim terms in controversy and only to the extent necessary to resolve the controversy).

V. ANALYSIS

A. Obviousness over Burroughs

The U.S. Supreme Court set forth the framework for applying the statutory language of 35 U.S.C. § 103 in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966):

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

As explained by the Supreme Court in *KSR International Co. v. Teleflex Inc.*:

> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.

550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")).

"Whether an ordinarily skilled artisan would have been motivated to modify the teachings of a reference is a question of fact." *WBIP, LLC v.*

Kohler Co., 829 F.3d 1317, 1327 (Fed. Cir. 2016) (citations omitted). "[W]here a party argues a skilled artisan would have been motivated to combine references, it must show the artisan 'would have had a reasonable expectation of success from doing so.'" *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017) (quoting *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)).

Petitioner asserts that Burroughs would have rendered the subject matter of claims 11, 14, 15, 18, and 19 obvious to one of ordinary skill in the art at the time of the invention. Pet. 19–48.

1. Level of Ordinary Skill in the Art

As discussed *supra*, we adopt Petitioner's unopposed position as to the level of ordinary skill in the art for purposes of this Decision. *See supra* Section III.

2. Scope and Content of the Prior Art – Burroughs

Burroughs relates to "medical dispensing devices . . . that permit selectively measured dosages of a liquid to be dispensed." Ex. 1013, 1:13–16. Figure 2 of Burroughs is reproduced below.

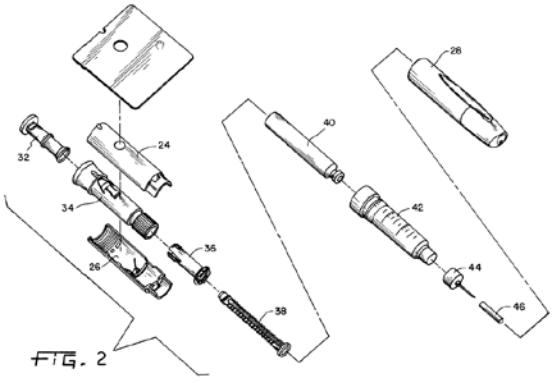

Figure 2 shows an exploded view of injection medication device 20. *Id.* at 6:42–43, 7:15–16. Medication device 20 includes mechanism housing 22

made from housing parts 24 and 26, button 32, dial mechanism 34, nut 36, and leadscrew 38 that forms a drive stem. *Id.* at 7:17–18, 7:32–34, 9:12–13.

Dial mechanism 34 engages button 32. *Id.* at 8: 9–14, Figs. 6, 8. Dial mechanism 34 also includes outwardly extending threads 110, 112 that "enter helical groove 158 during commencement of the dosing process." *Id.* at 8:33–36, 8:62–9:1, Figs. 3, 5. "As a dosage is being set, outwardly extending threads 110 and 112 of dial mechanism 34 ride in helical groove 158 of housing parts 24 and 26." *Id.* at 10:60–63.

When button 32 is depressed, dial mechanism 34 travels axially towards cartridge 40. *Id.* at 8:15–20. Splines 144 on the interior of dial mechanism 34 engage teeth 192 of nut 36 when the clutch is engaged to set a dosage. *Id.* at 8:42–48, Fig. 9. A series of numerals are printed on dial mechanism 34 to indicate a desired dosage. *Id.* at 10:5–9.

Rotating dial mechanism 34 causes nut 36 to rotate and move relative to housing 20, but rotation of leadscrew 38 is prevented. *Id.* at 10:25–27. Once a desired dosage has been set, button 32 is pushed to move dial mechanism 34, nut 36, and leadscrew 38 forward to deliver the set dosage. *Id.* at 11:13–19, 11:31–34.

3. Differences Between the Prior Art and the Claims; Motivation to Modify

Petitioner contends claims 11, 14, 15, 18, and 19 would have been obvious over Burroughs. Pet. 19–48. Petitioner provides claim charts and arguments with citations to where Burroughs allegedly teaches the limitations of the claims and citations to supporting declarant testimony. *Id.*

a. Independent Claim 11

Petitioner contends independent claim 11 recites six components: (1) a main housing; (2) a dose dial sleeve; (3) a dose dial grip; (4) a piston rod; (5) a drive sleeve; and (6) a tubular clutch. *Id.* at 6. Petitioner asserts Burroughs teaches each of the six components Petitioner's identifies as recited in claim 11. *Id.* at 19. In particular, Petitioner contends Burroughs's housing 22, dial mechanism 34, proximal portion 78, leadscrew 38, nut 36, and button 32 teach, respectively, claim 11's main housing, dose dial sleeve, dose dial grip, piston rod, drive sleeve, and tubular clutch. *See id.* at 20–35. With respect to the "dose dial sleeve," Petitioner asserts Burroughs's "dial mechanism has threads on its outer surface that form a helical rib, which engages with the main housing's helical groove, rather than an outer-surface helical groove engaging with main-housing threading as recited in independent claim 11." *Id.* at 20. Petitioner argues it would have been an obvious alternative to one of ordinary skill in the art to "swap[] these features to provide a dial mechanism with a helical groove on its outer surface . . . that engages with a thread on the main housing." *Id.*

i. "helical groove"

Claim 11 recites "a dose dial sleeve . . . comprising a helical groove configured to engage a threading provided by said main housing." Ex. 1002, 8:12–14. Petitioner argues dial mechanism 34 of Burroughs teaches the recited dose dial sleeve and that threads 110, 112 of dial mechanism 34 "are configured to releasably engage a helical spiral groove 158 provided on an inner surface of the housing 22." Pet. 25 (citing Ex. 1013, 7:31–32, 7:65–67, 8:33–36, 8:62–9:1, Figs. 1–3, 5–9; Ex. 1011 ¶¶ 162–167). Petitioner asserts "[t]hreads 110, 112 are rib-like structures that fit into and move

within helical spiral groove 158 of the housing parts 24, 26 to allow the dial mechanism to rotate and move axially away from the needle-end of the housing during the dose-setting phase." *Id.* (citing Ex. 1013, Figs. 6–9; Ex. 1011 ¶ 164). Relying upon Mr. Leinsing's testimony, Petitioner contends "in order to properly engage with the helical spiral groove 158 for rotation, the threads 110, 112 also must be positioned helically relative to one another, forming a discontinuous helical rib corresponding to the housing's helical groove." *Id.* (citing Ex. 1011 ¶ 165; *cf.* Ex. 1002, 3:62–64) (also relying on Ex. 1013, Figs. 1, 7). Thus, Petitioner argues Burroughs "discloses that the dial mechanism 34 includes a 'helical rib,' in the form of threads 110, 112, along its outer surface that engages with a threading on the housing 22." *Id.* (citing Ex. 1011 ¶ 166).

Petitioner asserts one of ordinary skill in the art "would have considered reversing the features and configuring threads 110, 112 as a 'helical groove' to be an obvious alternative." *Id.* at 40 (citing Ex. 1011 ¶ 170). Petitioner contends "[t]he use of a rib-to-groove threaded connection is a common and well-known mechanism used to provide relative rotational movement between components." *Id.* at 41 (citing Ex. 1011 ¶ 168). Petitioner argues "determining whether to place a helical rib on one component and a complementary helical groove on another engaging component . . . [would have been] a routine task, and would have been viewed . . . as no more than 'the predictable use of prior art elements according to their established functions.'" *Id.* (quoting *KSR*, 550 U.S. at 417) (citing Ex. 1011 ¶ 171). Thus, Petitioner asserts one of ordinary skill in the art "would have considered the placement of a rib-to-groove connection to be largely interchangeable between its engaging parts." *Id.* (citing

Ex. 1011 ¶ 169). Additionally, Petitioner contends one of ordinary skill in the art "would have reasonably expected that the use of the elements in that configuration would have resulted in the elements performing their same, predictable functions (*e.g.*, rotatable engagement). *Id.* at 42 (citing Ex. 1011 ¶ 170; *KSR*, 550 U.S. at 417).

Patent Owner asserts Petitioner fails to show that Burroughs teaches or would have rendered obvious a "helical groove provided along an outer surface of said dose dial sleeve," as recited by claim 11. Prelim. Resp. 36–41. Patent Owner argues "Petitioner admits that Burroughs does not disclose a helical groove on the outer surface of the dose dial sleeve," and thus, "there is no dispute that Burroughs fails to disclose this limitation." *Id.* at 36 (citing Pet. 23, 26).

Patent Owner also argues that Petitioner's "proposed modification does not result in a 'helical groove' as properly construed." *Id.* at 37. Patent Owner contends "threads 110 and 112 are discrete, tooth-like protrusions on the surface of dial mechanism 34, *not* a spiral-shaped rib or thread," and "Petitioner's assertions are both unsupported and unreliable." *Id.* Patent Owner asserts Dr. Leinsing's testimony "is unreliable because it fails to apply an appropriate construction of 'helical' . . . which requires a 'helical' structure to be a structure formed in the shape of a spiral." *Id.* at 40. Patent Owner contends Petitioner fails to establish threads 110 and 112 are in the shape of a spiral and fails to provide any evidence showing it would have been obvious to one of ordinary skill in the art to further modify threads 110 and 112 to form a spiral. *Id.* at 40–41.

On the present record, Petitioner sufficiently shows for purposes of this Decision that Burroughs teaches a helical rib and that one of ordinary

skill in the art would have been prompted to modify the helical rib/groove arrangement of Burroughs to teach a "dose dial sleeve . . . comprising a helical groove configured to engage a threading provided by said main housing," as recited by claim 11. Notably, Burroughs teaches that threads 110 and 112 "enter helical groove 158 during the commencement of the dosing process." Ex. 1013, 8:67–9:1. Mr. Leinsing and Petitioner rely upon this teaching of Burroughs in asserting Burroughs discloses a helical rib because threads 110 and 112 are positioned to enter *helical* groove 158. Pet. 25 ("in order to properly engage with the helical spiral groove 158 for rotation, the threads 110, 112 also must be positioned helically relative to one another") (citing Ex. 1011 ¶ 165; *cf.* Ex. 1002, 3:62–64).

Even under Patent Owner's proposed interpretation of "helical groove" as a "groove formed in the shape of a spiral" (Prelim. Resp. 25), which we have adopted for purposes of this Decision, Petitioner's argument is persuasive at this stage of the proceeding to show threads 110, 112 have some spiral aspect in order to engage helical groove 158. In short, the evidence presently before us demonstrates claim 11 and Burroughs each use the term "helical" consistently. Additionally, Patent Owner's argument does not appear to address Petitioner's reliance upon Burroughs's helical groove 158 and its apparent significance in determining whether threads 110 and 112 can be considered helical ribs.

Petitioner also provides argument and evidence that it would have been obvious to one of ordinary skill in the art to modify threads 110, 112 to form grooves, "reversing the features" of Burroughs. Pet. 40–42. At this stage of the proceeding, Petitioner's assertion that its proposed modification of threads 110, 112 to protruding helical grooves represents a "predictable

use of prior art elements according to their established functions" with a reasonable expectation of success is sufficient for purposes of institution. *See id.* at 41–42 (citing Ex. 1011 ¶¶ 168–171; *KSR*, 550 U.S. at 417).

ii. "wherein said first lead and said second lead are different"

Claim 11 recites "wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different." Ex. 1002, 8:33–36. As discussed *supra*, Petitioner points to Burroughs's dial mechanism 34 as teaching the recited "dose dial sleeve," and contends threads 110 and 112 have a first lead. Pet. 36. And, Petitioner points to Burroughs's nut 36 as teaching the recited "drive sleeve," contending nut 36 includes helical thread 198 with a second lead. *Id.* at 37, 39.

Petitioner provides the following argument regarding whether the identified leads are different:

> Burroughs does not specifically address the lead on threads 110 and 112, nor for helical thread 198. The [person of ordinary skill in the art] would understand that, to the extent that the lead on threads 110 and 112 is the same as the lead on helical thread 198, they would rotate at the same rate, and when the leads are different, the dose-dial sleeve and drive sleeve can be made to rotate at different rates. EX1011, ¶¶189-94, *cf.* EX1002, 5:61-65.
>
> It would have been well within the level of skill of the ordinary artisan to determine the appropriate lead on threads 110 and 112 as well as for helical thread 198 to achieve the required relative rate of rotation of the dose-dial sleeve to the drive sleeve. EX1011, ¶195. As Burroughs is silent on the leads on threads 110 and 112 and helical thread 198, and, thus, does not expressly state that they have to be the same, a [person of

> ordinary skill in the art] would understand that Burroughs may have contemplated both the same and different. EX1011, ¶194.

Pet. 39–40. Additionally, Petitioner asserts:

> Because the '044 patent does not expressly discuss making the leads of the helical groove of the dose-dial sleeve and the lead of the internal threading of the drive sleeve different, the specification of the '044 patent concedes that a [person of ordinary skill in the art] had the skill to make the leads different, as well as the same.

Id. at 40 (citing Ex. 1011 ¶¶ 196–199).

Patent Owner raises two main arguments regarding this limitation of claim 11. First, Patent Owner reiterates the argument discussed above—Burroughs fails to disclose or render obvious a dose dial sleeve with a helical groove. Prelim. Resp. 43. We addressed this argument and determined that Petitioner's position was persuasive on this record at this stage of the proceeding.

Second, Patent Owner contends Petitioner fails to show Burroughs discloses or renders obvious the recitation that the first and second leads are different. *Id.* at 44–47. With respect to disclosing this limitation of the claim, Patent Owner agrees with Petitioner that Burroughs is silent as to the identified leads. *Id.* at 44 (citing Pet. 39; Ex. 1011 ¶ 192). With respect to whether Burroughs renders obvious this limitation, Patent Owner argues Petitioner "fails to establish a credible motivation to make the lead of the dose dial sleeve threads 110 and 112 different from the lead of the helical thread 198 on the nut 36." *Id.*

At this stage of the proceeding, on the present record, Petitioner sets forth sufficient argument and evidence that it would have been obvious to create different leads. In particular, Mr. Leinsing explains "by setting the

lead of an external, helical thread of a 'dose dial sleeve' larger than the lead of an internal, helical thread of a 'drive sleeve,' usability of the device during the dose setting process may be improved." Ex. 1011 ¶ 195.

Mr. Leinsing testifies:

> [I]n cases where only small doses of medicine are needed during an injection, a person of ordinary skill would have understood that such a configuration would allow the user to retract the dose dial sleeve larger distance than the distance needed for the drive sleeve to drive the piston rod to deliver the small dose. Thus, due to the larger travel of the dose dial sleeve, the user may better perceive smaller changes in the dose during the dose setting process.

Id. (citing Ex. 1015, 1:33–57).

Patent Owner challenges Mr. Leinsing's reliance upon Exhibit 1015 and whether it, in fact, provides support for his opinion. *See* Prelim. Resp. 45 ("This portion of Moller [(Ex. 1015)], however, is inapposite as it describes difficulties in perceiving small movements of the ***injection button*** on a pen injector during the ***injection process***, not movements of a dosage dial during the process of setting a dose." (citing Ex. 1015 ¶ 5)). For the purposes of institution, we need not decide whether Exhibit 1015 supports either party's argument. We note, however, Petitioner does not rely upon Exhibit 1015 as a basis for its obviousness challenge and, therefore, the degree to which Exhibit 1015 impacts our analysis is lessened. Nonetheless, Mr. Leinsing's testimony on this point appears grounded in common sense and commensurate with the level of ordinary skill in the art, and Patent Owner will have an opportunity to explore Mr. Leinsing's opinion during trial.

b. Dependent Claims 14, 15, 18, and 19

Claims 14, 15, 18, and 19 ultimately depend from claim 11. Petitioner contends these claims are unpatentable over Burroughs with citations to the reference and declarant testimony. Pet. 42–48. We have reviewed Petitioner's arguments and evidence directed to claims 14, 15, 18, and 19. *Id.* At this time, Patent Owner does not raise an additional argument directed specifically to these dependent claims.

4. Objective Considerations

Neither party presents evidence of objective considerations at this stage of the proceeding.

5. Weighing the Graham *Factors*

"Once all relevant facts are found, the ultimate legal determination [of obviousness] involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan." *Arctic Cat*, 876 F.3d at 1361. On balance, considering the record presently before us, Petitioner demonstrates a reasonable likelihood of showing Burroughs would have rendered the subject matter of claims 11, 14, 15, 18, and 19 obvious to one of ordinary skill in the art at the time of the invention.

VI. CONCLUSION

For the foregoing reasons, Petitioner has demonstrated a reasonable likelihood that it would prevail in showing at least one claim of the '044 patent is unpatentable. Accordingly, we institute an *inter partes* review of all challenged claims. *See* Guidance on the Impact of *SAS* on AIA Trial Proceedings (Apr. 26, 2018), *available at* https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial (explaining that "the PTAB will institute as to all claims or

none" and "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition").

At this stage of the proceeding, we have not made a final determination as to the patentability of any challenged claim or any underlying factual or legal issue.

VII. ORDER

Accordingly, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 11, 14, 15, 18, and 19 of the '044 patent is instituted on the ground set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '044 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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