

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,  
Patent Owner.

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Case IPR2018-01676  
Patent 8,603,044 B2

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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 10). With prior authorization, Petitioner filed a Reply to Patent Owner’s Preliminary Response (Paper 13; “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 15, “PR Sur-Reply”). Pursuant to 35 U.S.C. § 314, an *inter partes* review may not be instituted “unless . . . there is a reasonable 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 8, 2; Paper 9, 1–2.

The parties state that the '044 patent also is challenged in Case IPR2018-01675. Paper 8, 2; Paper 9, 2. 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 8, 2–3; Paper 9, 1–2.

*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 8, 2. Patent Owner identifies Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis U.S. LLC, and Sanofi Winthrop Industrie as real parties in interest. Paper 9, 1.

*D. The Asserted Grounds 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 (1) Steinfeldt-Jensen et al.<sup>1</sup> (Ex. 1014, “Steenfeldt-Jensen”) and (2) Moller<sup>2</sup> (Ex. 1015) in combination with Steinfeldt-Jensen. Petitioner supports its challenge with a declaration by Karl R. Leinsing, dated September 9, 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.

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<sup>1</sup> U.S. Patent No. 6,235,004 B1, iss. May 22, 2001.

<sup>2</sup> U.S. Patent Application Pub. No. 2002/0052578 A1.

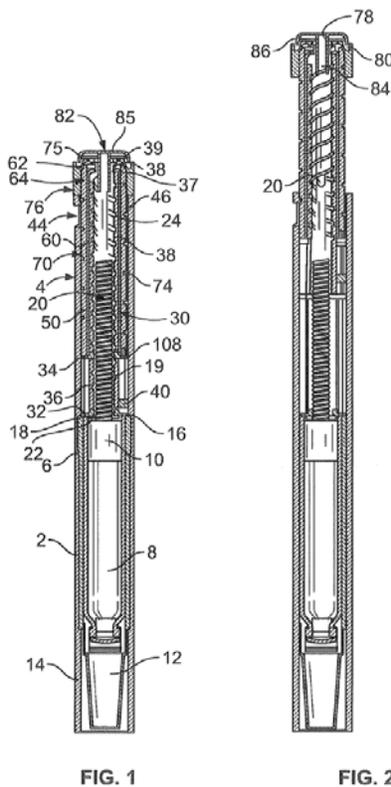


Figure 1 “shows a sectional view of a pen-type injector . . . in a first, cartridge full, position,” and Figure 2 “shows a sectional view of the pen-type injector of FIG. 1 in a second, maximum first dose dialed, position.” *Id.* at 2:53–57. The pen-type injector includes first cartridge retaining part 2 and second main housing part 4.<sup>3</sup> *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.

<sup>3</sup> 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”).

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 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)<sup>4</sup> 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. Paper 6, 1. Patent Owner alleges the Petition “assert[s] substantially the same invalidity grounds” alleged in the district court case. Prelim. Resp. 7.

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

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.<sup>5</sup> 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. 8–9 (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 here. *Id.* at 9 (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, Case IPR2018-00752 (PTAB Sept. 12, 2018) (Paper 8) (“*NHK Spring*”)).

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<sup>5</sup> 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.*

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 9–13. 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. 13–18. 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 14. 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 14–18.

In its Reply to the Preliminary Response, Petitioner argues its contentions in district court listed exemplary combinations, including Steinfeldt-Jensen or Moller 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 Sanofi’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 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.<sup>6</sup> *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 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, barring any good cause, review will be completed within one year of institution. For

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<sup>6</sup> 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)).

these reasons, we are not persuaded instituting review in this proceeding will be an inefficient use of Board resources.

Additionally, we are not persuaded the circumstances of this case warrant review according to the factors enumerated in *General Plastic*. 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 contentions 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-year's experience"<sup>7</sup> and would have "understood the basics of medical-device design and manufacturing, and the basic mechanical elements (e.g., gears, pistons) in drug-delivery devices."<sup>8</sup> Pet. 14 (citing Ex. 1011 ¶ 104–06). 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)

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<sup>7</sup> Mr. Leinsing testifies the three years of practical experience would have been "with medical device design and manufacturing." Ex. 1011 ¶ 106.

<sup>8</sup> The articulated level of ordinary skill in the Petition differs slightly from the level of ordinary skill proposed in the petition for IPR2018-01675, which challenges the same patent. Each petition references the same paragraph of Mr. Leinsing's Declaration, which was filed in each case.

(2018);<sup>9</sup> *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). 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).

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<sup>9</sup> 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).

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] understood them.” Pet. 14 (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 “the grounds rely on the ordinary and customary meaning of the claim terms.” *Id.* at 16.

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 (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.* at 15–16 (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 grounds presented “also address the ‘tubular clutch’ and ‘clicker’ limitations as means-plus-function limitations.” *Id.* at 16.

Patent Owner responds that Petitioner does not state what the plain and ordinary meaning is for any term. Prelim. Resp. 23. 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 67–70.

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 the asserted references to the claim limitations.

Patent Owner also disputes that “tubular clutch” and “clicker” are means-plus-function limitations. *Id.* at 26–27. 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 69–70.

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—“main housing.” *Id.* at 23–26. Patent Owner proposes “main housing” means “an exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components.” *Id.* at 24. Patent Owner contends its proposed interpretation is derived from lexicography in a related patent (Ex. 1005, 2:66–3:12). *Id.* at 24–25. Patent Owner also cites to a decision in a prior district court case. *Id.* at 25–26 (citing Ex. 2013, 7–9). Patent Owner asserts Petitioner’s plain and ordinary meaning is so broad that it includes an interior housing. *Id.* at 26 (citing Pet. 52–54).

Based on the arguments and evidence at this stage and for the reasons discussed below, Petitioner sufficiently shows for purposes of institution that the asserted references teach the claimed “main housing,” even under Patent Owner’s proposed interpretation. After the record has been developed at trial, we may further analyze Patent Owner’s proposed interpretation of “main housing” and, as discussed *infra*, whether Moller teaches this limitation of the claims. At this stage, for the reasons given above, we determine that no express interpretation is required for any claim term for the purposes of determining whether Petitioner demonstrates a reasonable likelihood of prevailing in its challenges. *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. *Law of Obviousness*

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)).

*B. Obviousness over Steinfeldt-Jensen*

Petitioner asserts that Steinfeldt-Jensen 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. 21–49.

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 – Steinfeldt-Jensen*

Steenfeldt-Jensen “relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge.” Ex. 1014, 1:12–13. Figures 16 and 17 of Steinfeldt-Jensen are reproduced below.

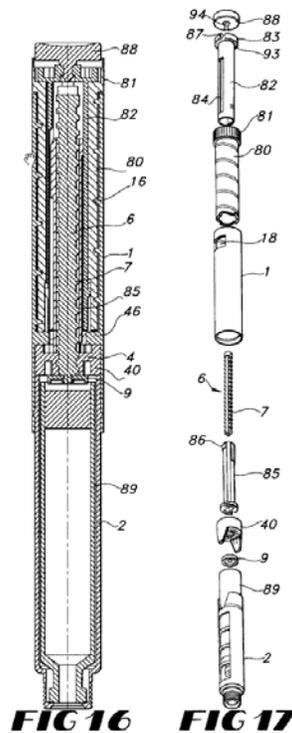


Figure 16 shows a side sectional view of a syringe, and Figure 17 shows an exploded view of that same syringe. *Id.* at 5:25–28. The syringe of Steinfeldt-Jensen includes tubular housing 1 that is partitioned so that a first division has ampoule holder 2. *Id.* at 5:38–40. Ampoule holder 2 has a central bore with thread 5 that engages external thread 7 of piston rod 6. *Id.* at 5:55–58. Driver tube 85 is disposed about piston rod 6. *See id.* at

Figs. 15–17. “The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section” so that “rotation is transmitted” and “the piston rod is allowed to move longitudinally through the driver tube.” *Id.* at 11:15–19.

Within housing 1 is scale drum 80, and scale drum 80 has on its outer wall a helical track that engages a helical rib on the inner wall of housing 1. *Id.* at 11:20–22. One end of scale drum 80 has a larger diameter so as to form dose setting button 81. *Id.* at 11:22–24. Bushing 82 fits within scale drum 80 and over driver tube 85. *Id.* at 11:26–29. Bushing 82 is coupled to driver tube 85 so that both bushing 82 and driver tube 85 can rotate but not longitudinally move. *Id.* at 11:30–33. Injection button 88 is rotatably mounted at an end of bushing 82. *Id.* at 49–51.

A dose is set by rotating dose setting button 81, which causes scale drum 80 to rotate out of housing 1. *Id.* at 11:52–55. Injection button 88 is pressed to inject the set dose, and bushing 82 rotates with dose setting button 81 because of the engagement of the helical track of scale drum 80 with the rib of housing 1 when scale drum 80 is pressed into housing 1. *Id.* at 12:4–10. The rotation of bushing 82 rotates driver tube 85, which causes piston rod 6 to rotate and screw into ampoule 89 in ampoule holder 2. *Id.* at 12:10–13.

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

a. *Independent Claim 11*

Petitioner argues Steinfeldt-Jensen teaches all the structural limitations of claim 11. Pet. 21. Petitioner alternatively argues “[i]f Steinfeldt-Jensen does not disclose a ‘drive sleeve,’ it would have been routine to modify the Steinfeldt-Jensen device to include one.” *Id.*

Petitioner provides a claim chart in which it asserts Steinfeldt-Jensen teaches or suggests all the limitations of claim 11. *Id.* at 21–39. Petitioner points to Steinfeldt-Jensen’s housing 1, scale drum 80, dose setting button 81, piston rod 6, driver tube 85, and bushing 82 for teaching, respectively, claim 11’s main housing, dose dial sleeve, dose dial grip, piston rod, drive sleeve, and tubular clutch. *See id.*

Petitioner notes Steinfeldt-Jensen teaches driver tube 85 “rotationally engages with the [piston] rod [6] through [a] non-circular bore, rather than ‘an internal threading near a distal portion.’” *Id.* at 31 (citing Ex. 1011 ¶ 274). Petitioner argues one of ordinary skill in the art would have considered it obvious to modify driver tube 85 to provide a “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,” as recited by claim 11. *Id.* at 32. In particular, Petitioner contends that it would have been obvious to modify driver tube 85 to have internal threading near its distal portion because Steinfeldt-Jensen contemplates a driver tube with internal threading that engages external threading of a piston rod. *Id.* at 40 (citing Ex. 1011 ¶¶ 274–275).

Petitioner also contends one of ordinary skill in the art would have understood that driver tube 85 includes a piston rod guide, that member 40 includes a nut element because of its internal threading on wall 4, and that Steinfeldt-Jensen suggests providing the nut element on driver tube 85 and providing the piston rod guide on member 40. *Id.* at 41 (citing Ex. 1011 ¶ 276; Ex. 1014, 2:46–53, 3:15–20). Petitioner, thus, asserts Steinfeldt-Jensen suggests modifying driver tube 85 to have internal threading that engages external threading on the piston rod and modifying member 40 to

include a non-circular cross-section for axially guiding the piston rod with a reasonable expectation of success, thereby meeting the requirements of claim 11. *Id.* at 41 (citing Ex. 1011 ¶¶ 277–278). Petitioner asserts that one of ordinary skill in the art would have expected the modified parts to perform the same function they would had been known to perform. *Id.* at 42 (citing *KSR*, 550 U.S. at 417; Ex. 1011 ¶ 278).

Patent Owner responds that Petitioner relies on the fifth embodiment of Steinfeldt-Jensen but concedes it does not teach “*said drive sleeve comprising an internal threading . . . adapted to engage an external thread of said piston rod,*” as required by claim 11. Prelim. Resp. 32 (citing Pet. 31; Ex. 1011 ¶ 274). Patent Owner argues Petitioner’s evidence does not show one of ordinary skill in the art would have modified the fifth embodiment to have such threading because (1) Petitioner relies on teachings only relevant to Steinfeldt-Jensen’s first embodiment, (2) motivations to modify the first embodiment are not applicable to the fifth embodiment, and (3) Petitioner’s proposed modification would result in a device that would be inoperable for its intended purpose. *Id.* at 33.

In particular, Patent Owner argues that Petitioner’s cited passage from Steinfeldt-Jensen suggests replacing the non-circular opening of driver tube 26 in the first embodiment with a threaded opening in its ampoule holder. *Id.* at 34 (citing Ex. 1014, 5:33–7:47). According to Patent Owner, however, the relied-upon portion of Steinfeldt-Jensen does not teach replacing the internal threading of member 40 in the fifth embodiment with the non-circular bore of driver tube 85 of the same embodiment because the fifth embodiment does not have the features interchanged in the cited portion of Steinfeldt-Jensen—driver tube 26 or rotatable ampoule holder 2 with

threaded [opening in] end wall 4. *Id.* at 34–35. Patent Owner also argues Petitioner’s other citations teach either the piston rod rotating or the nut member rotating but do not teach or suggest modifying a device component to create a new nut member. *Id.* at 35 (citing Ex. 1014, 3:15–20, 3:44–47).

Patent Owner additionally responds that one of ordinary skill in the art would not have been motivated to modify Steinfeldt-Jensen’s fifth embodiment, based on the disclosed modification to the first embodiment, because that modification would remove a high-friction interface for dialing a dose in the first embodiment, but the fifth embodiment does not have or need a high-friction interface. *Id.* at 36–37. Thus, Patent Owner asserts the teachings are not applicable to the fifth embodiment. *Id.* at 36–42.

Patent Owner also asserts Petitioner’s proposed modification would result in an inferior pen injector. *Id.* at 42–45. Patent Owner contends making the proposed modification to Steinfeldt-Jensen’s fifth embodiment would introduce a source of friction that would make it harder to use. *Id.*

In view of the arguments and evidence at this stage of the proceeding, we are satisfied that Petitioner sufficiently demonstrates for purposes of institution that Steinfeldt-Jensen would have rendered claim 11 obvious. *See* Pet. 21–42. We also are satisfied at this early stage that Petitioner sufficiently argues with citations to evidence of record that one of ordinary skill in the art would have modified the fifth embodiment of Steinfeldt-Jensen so that the internal threading of its member 40 is in driver tube 85 and the non-circular opening of driver tube 85 is in member 40. *See id.* at 40–42. In support of its proposed modification, Petitioner quotes Steinfeldt-Jensen’s statement that “[e]mbodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver

tube and such embodiment[s] will not be beyond the scope of the invention.” *Id.* at 40 (quoting Ex. 1014, 7:44–47). For purposes of institution, Petitioner shows sufficiently that Steinfeldt-Jensen includes “[e]mbodiments . . . wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube.” Ex. 1014, 7:44–47.

For purposes of deciding whether to institute, we determine this sentence in Steinfeldt-Jensen, which Petitioner cites in support of its proposed modification, provides an adequate reason for one of ordinary skill in the art to modify the fifth embodiment in the manner asserted by Petitioner. This is not a final determination, however, and the matter will be reanalyzed after the record is fully developed. A fully developed record would aid in determining whether the teaching only applies to Steinfeldt-Jensen’s first embodiment as contended by Patent Owner or whether one of ordinary skill in the art would have understood the same teaching to apply to the fifth embodiment with its alternative arrangement of structures as argued by Petitioner.

Also, the present record does not indicate that moving the internal threads of Steinfeldt-Jensen’s fifth embodiment from one component to another nearby component would result in new or additional friction, as asserted by Patent Owner. *See* Prelim. Resp. 42–45. Patent Owner’s argument presents another factual issue regarding friction in Petitioner’s proposed modification that would also benefit from further development of the record at trial.

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

Claims 14, 15, 18, and 19 ultimately depend from claim 11. Petitioner argues these claims are unpatentable over Steinfeldt-Jensen with citations to

the reference and declarant testimony. Pet. 42–49. We have reviewed Petitioner’s arguments and evidence directed to these dependent claims. *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 Steinfeldt-Jensen 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.

C. *Obviousness over Moller and Steinfeldt-Jensen*

Petitioner asserts the combination of Moller and Steinfeldt-Jensen 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. 49–90.

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*

a. *Moller*

Moller “relates to syringes by which a dose can be set by rotating a dose setting member and by which an injection button elevates from an end of the syringe a distance proportional to the set dose.” Ex. 1015 ¶ 1.

Figure 1 of Moller is reproduced below.

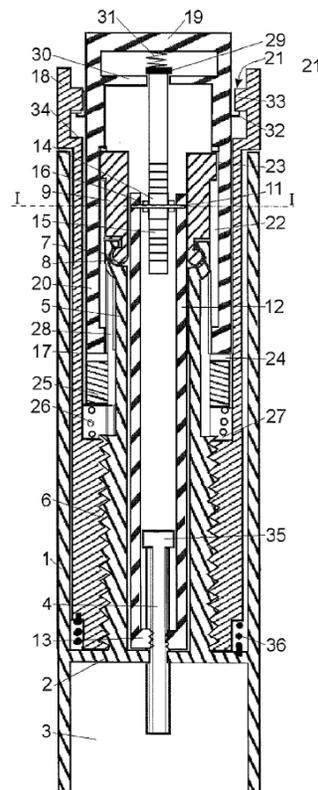


Fig. 1

Figure 1 shows a sectional view of an injection device. *Id.* ¶ 17. The device includes housing 1 with partitioning wall 2 that divides housing 1 into two compartments, one with a dose setting mechanism and the other for accommodating an ampoule. *Id.* ¶ 22. Threaded piston rod 4 extends through an opening in wall 2 so that it can move longitudinally but not rotationally because threaded piston rod 4 has a non-circular cross section. *Id.* Tubular element 5 extends from the opening around threaded piston

rod 4 and engages gearbox 9 so that gearbox 9 can rotate within housing 1. *Id.* ¶ 23.

Nut 13 engages the threads of the threaded piston rod 4 and connects to gearbox 9 via connection bars 12. *Id.* ¶ 24. Dose setting drum 17 engages thread 6 of tubular element 5 at one end and at the opposite end has an enlarged diameter forming dose setting button 18. *Id.* ¶ 25. Dose setting drum 17 can be screwed into or out of housing 1 and includes a scale on its outer surface. *Id.*

A cup shaped element that fits over gearbox 9 and into dose setting drum 17 forms an injection button. *Id.* ¶ 26. The cup shaped element is coupled to dose setting drum 17 so that the cup shaped element, dose setting drum 17, and gearbox 9 rotate together. *Id.*

Dose setting button 18 is rotated to set a dose, which causes dose setting drum 17 to screw out with the cup shaped element. *Id.* ¶ 29. Bottom 19 of the cup shaped element is pressed to inject the set dose. *Id.* ¶ 32.

*b. Steinfeldt-Jensen*

Steenfeldt-Jensen is discussed in the context of Petitioner's first obviousness challenge. *See supra* Section V.B.2.

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

*a. Independent Claim 11*

Petitioner argues one of ordinary skill in the art would have understood that Moller teaches the same components and structural elements of claim 11, with the exception that Moller "discloses dose-setting drum 17 with threading on its internal surface adapted to engage with the housing,

instead of a ‘helical groove’ on its outer surface.” Pet. 49. Petitioner asserts Steinfeldt-Jensen teaches “using a ‘dose dial sleeve,’ scale drum 80, including a ‘helical groove’ on its outer surface for engaging the housing,” and it would have been “obvious to modify Moller’s drum 17 to include a ‘helical groove’ on its outer surface, rather than its inner surface.” *Id.*

Petitioner provides a claim chart detailing where Moller and Steinfeldt-Jensen teach the limitations of claim 11. *Id.* at 49–75. Petitioner contends that Moller’s housing 1 with partitioning wall 2 and tubular element 5, dose setting drum 17, dose setting button 18, piston rod 4, connection bars 12 with nut 13, and cup-shaped element with bottom 19 and tubular part 20 teach, respectively, claim 11’s main housing, dose dial sleeve, dose dial grip, piston rod, drive sleeve, and tubular clutch. *See id.* Petitioner further contends Steinfeldt-Jensen teaches a dose dial sleeve including a helical groove on its outer surface. *Id.* at 57 (citing Ex. 1011 ¶ 353). Petitioner also provides alternative arguments in which “tubular clutch” is construed as a means-plus-function limitation. *Id.* at 66–69.

*i. “drive sleeve”*

Petitioner contends Moller teaches a “‘drive sleeve’ in the form of connection bars 12 having a nut 13 at its needle-end.” *Id.* at 63 (citing Ex. 1011 ¶ 366). Petitioner explains nut 13 is internally-threaded and engages with the thread of piston rod 4 to drive the piston rod during injection. *Id.* (citing Ex. 1015 ¶¶ 24, 32, Fig. 1; Ex. 1011 ¶ 367). Petitioner asserts “[t]o the extent connection bars 12 with nut 13 are not a ‘sleeve,’ Moller taught a sleeve in the form of a tubular connection element 112 with nut 113.” *Id.* (citing Ex. 1015 ¶ 40, Figs. 3–5; Ex. 1011 ¶ 370). Petitioner relies upon Moller’s teaching—that (1) connection bars 12 correspond to

tubular connection element 112 and (2) nut 13 corresponds to nut 113—to argue one of ordinary skill in the art “would have understood the components to be structurally and functionally equivalent.” *Id.* (citing Ex. 1011 ¶¶ 370–371). Petitioner argues one of ordinary skill would have expected “connection bars 12 with nut 13 could readily be formed as a tubular structure that encompasses piston rod 4, without affecting the device’s operation.” *Id.* (citing Ex. 1011 ¶¶ 370–371).

Patent Owner responds, arguing Moller’s connection bars 12 with nut 13 do not teach and would not have rendered obvious the “drive sleeve” of claim 11. Prelim. Resp. 48–56. Patent Owner notes the parties agreed the claimed “‘drive sleeve’ is at least ‘an essentially tubular component’” in related district court litigation. *Id.* at 50 n.13 (citing Ex. 2016). According to Patent Owner, connection bars 12 are parallel bars and not a tubular component. *Id.* at 49–50. Patent Owner contends Petitioner “[t]acitly admit[s]” connection bars 12 with nut 13 are not a sleeve because “Petitioner also points to tubular connection element 112 and nut 113” from a different embodiment of Moller. *Id.* at 50 (citing Pet. 63).

Patent Owner argues, although Petitioner contends that connection bars 12 with nut 13 and connection element 112 with nut 113 are structurally and functionally equivalent, one of ordinary skill in the art would not have expected “connection bars 12 and nut 13 in Moller’s first embodiment could be formed as a tubular structure without affecting the device’s operation.” *Id.* In particular, Patent Owner asserts connection bars 12 and connection element 112 are “differently shaped, engage with components in different ways, and operate in different manners.” *Id.* at 52 (citing Exs. 2017, 2018). Patent Owner contends Petitioner provides no meaningful analysis of its

asserted equivalency, and Petitioner's obviousness argument fails because it is predicated on that equivalency. *Id.* at 54–55.

Additionally, Patent Owner asserts Petitioner's proposed modification would require significant reconstruction and redesign because (1) gear and rack components would have to be within a tubular element and (2) connection bars 12 have a non-tubular, open shape to allow the engagement of rack 10 and gear wheel 16. *Id.* at 55–56.

Patent Owner raises issues that would benefit from developing the record at trial, which we are instituting for the reasons discussed above in connection with Petitioner's challenge based on Steinfeldt-Jensen. A fully developed record would address issues, such as, whether connection bars 12 and nut 13 would have been understood as forming a tubular component, whether connection bars 12 and nut 13 are sufficiently equivalent to a tubular component to support Petitioner's proposed modification, and whether connection bars 12 and nut 13 could have been modified into a tubular component without substantial redesign.

- ii. *“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”*

Petitioner asserts one of ordinary skill in the art “would have considered it obvious to place the drum's thread, Steinfeldt-Jensen's outer helical groove, to engage the housing for rotational movement.” Pet. 76 (citing Ex. 1011 ¶¶ 354–361). Specifically, Petitioner contends one of ordinary skill “would have recognized the benefit to placing a threaded engagement, like that in Steinfeldt-Jensen, on a drum and housing like that

of Moller.” *Id.* at 78 (citing Ex. 1011 ¶ 360). Petitioner asserts modifying Moller as proposed would “reduce the force needed to rotate the drum back into the housing during injection.” *Id.* (citing Ex. 1011 ¶ 360). Thus, Petitioner argues reducing the force needed to rotate the drum relative to the housing provides a reason to “incorporate a high-pitch helical groove as taught by Steinfeldt-Jensen on the outer surface of Moller’s drum” and one of ordinary skill in the art “would have reasonably expected that such a configuration would perform in the same manner as the inner threading of Moller’s drum by allowing relative rotational movement between the drum and housing.” *Id.* at 78–79 (citing Ex. 1011 ¶ 361).

In response to Petitioner’s proposed modification, Patent Owner asserts one of ordinary skill in the art would not have been motivated to modify Moller’s dose setting drum 17 to have a helical groove that engages a helical rib on tubular element 5. Prelim. Resp. 56. In particular, Patent Owner contends Moller teaches away from Petitioner’s proposed modification of a helical groove engaging a helical rib. *Id.* at 57–58. Patent Owner also contends Moller rejected Petitioner’s proposed modification (*id.* at 58 (citing Ex. 1015 ¶¶ 8, 11)), Petitioner’s modification would impair precisely dialing a dosage (*id.* at 59–62 (citing Ex. 1014, Fig. 16; Ex. 1015 ¶ 24, Fig. 1)), and Moller has a different solution to the purported problem (*id.* at 63 (citing Ex. 1015 ¶ 33)). As discussed with respect to Patent Owner’s arguments regarding the recited drive sleeve of claim 11, Patent Owner raises issues that would benefit from developing the record at trial,

which we are instituting for the reasons discussed above in connection with Petitioner's challenge based on Steinfeldt-Jensen.<sup>10</sup>

With respect to this limitation of claim 11, Patent Owner raises an additional argument directed to Moller's disclosure, contending Moller does not teach or suggest "dose-setting drum 17 is configured to engage a threading provided by said *main housing*"; instead, Patent Owner asserts the threads of dose setting drum 17 engage threads of tubular element 5, which is not a "main housing" under Patent Owner's proposed interpretation. Prelim. Resp. 63–67. Patent Owner contends tubular element 5 is "an interior, not an exterior, component" and Moller describes tubular element 5 as separate and distinct from housing 1. *Id.* at 64 (citing Ex. 1015 ¶ 23, Fig. 1). Patent Owner asserts tubular element 5 is "insubstantially different from the 'insert' described in the [']044 Patent," which insert "is described as a separate interior component." *Id.* at 65.

On the present record, Figure 1 of Moller shows, via cross-hatching, that housing 1, wall 2, and tubular element 5 are one piece. Ex. 1015, Fig. 1; *see also* 37 C.F.R. § 1.84(h)(3) (requiring for sectional views that "various parts of a cross section of the same item should be hatched in the same manner . . ." and the "hatching of juxtaposed different elements must be angled in a different way"). Thus, even under Patent Owner's proposed interpretation of "main housing" (Prelim. Resp. 24), we are persuaded sufficiently at this stage of the proceeding that Moller depicts "an *exterior*

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<sup>10</sup> We note that Moller's paragraph 8 states that "traditional gearing using mutual engaging gear wheels and racks is *preferred*" (Ex. 1015 ¶ 8 (emphasis added)), which may indicate sliding surfaces may not be one of the disadvantages discussed in paragraph 11.

*unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components*” (emphases added). Moreover, even if Moller’s housing 1, wall 2, and tubular element 5 were distinct structural components, we are persuaded sufficiently on the present record that they appear to form “an exterior . . . multipart component configured to . . . engage with one or more inner components,” because the proposed interpretation does not exclude a multipart component that resides on both the exterior and interior.

Also, Moller states for another embodiment that “partitioning wall 102 and the tubular element 105 are made as two parts which are by the assembling of the device connected to each other to make the assembled parts act as one integral part.” Ex. 1015 ¶ 36. Moller, thus, indicates, at least, wall 2 and tubular element 5 of the previous embodiment shown in Figures 1 and 2 are one piece. *See also id.* ¶¶ 17–21 (stating that Figures 1 and 2 show one embodiment and Figures 3–5 show another embodiment).

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

Claims 14, 15, 18, and 19 ultimately depend from claim 11. Petitioner argues these claims are unpatentable over Moller and Steinfeldt-Jensen with citations to the references and declarant testimony. Pet. 79–90. We have reviewed Petitioner’s arguments and evidence directed to these dependent claims. *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 the combination of Moller and Steinfeldt-Jensen 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 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(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.

IPR2018-01676  
Patent 8,603,044 B2

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