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Paper 19
Entered: April 3, 2019

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 IPR2018-01670
Patent 8,679,069 B2

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

JUNG, *Administrative Patent Judge.*

DECISION TO INSTITUTE
35 U.S.C. § 314

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting institution of an *inter partes* review of only claim 1 of U.S. Patent No. 8,679,069 B2 (Ex. 1001, "the '069 patent"). Sanofi-Aventis Deutschland GmbH ("Patent Owner") filed a Preliminary Response (Paper 13, "Prelim. Resp."). As authorized in our Order (Paper 10), Petitioner filed a Reply to the Preliminary Response (Paper 14), and Patent Owner filed a Sur-Reply (Paper 16). Under 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 that there is a reasonable likelihood that it would prevail with respect to claim 1. As such, we institute an *inter partes* review of claim 1 of the '069 patent, the only challenged claim, on all presented challenges.

II. BACKGROUND

A. Related Proceedings

The parties indicate that the '069 patent has been asserted in *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105-SRC-CLW (D.N.J.); *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812-RGA-MPT (D. Del.); and *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, No. 1:14-cv-00113-RGA-MPT (D. Del.). Pet. 1; Paper 5, 2; Paper 7, 2; Exs. 1029, 1030.

The parties also state that related patents are being challenged in Cases IPR2018-01675, IPR2018-01676, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01684, IPR2018-01696, and IPR2019-00122. Pet. 1–2; Paper 5, 3; Paper 7, 3.

B. The '069 Patent (Ex. 1001)

The '069 patent issued March 25, 2014, from an application filed November 11, 2010, which is a continuation of an application filed on July 11, 2006, which, in turn, is a continuation of an application filed on March 2, 2004. Ex. 1001, [22], [45], [63], 1:6–12. The '069 patent also claims priority to a foreign application filed on March 3, 2003. *Id.* at [30], 1:10–11.

The '069 patent "relates to pen-type injectors . . . where a user may set the dose." *Id.* at 1:13–17. Figures 1 and 2 of the '069 patent are reproduced below.

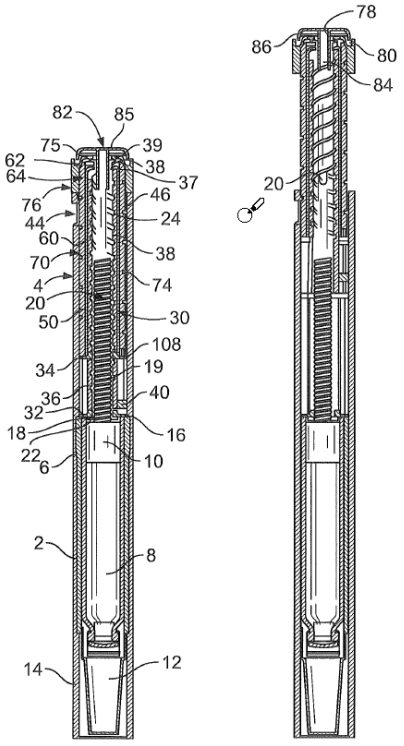

FIG. 1 FIG. 2

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-type injector . . . in a second, maximum first dose dialed, position." *Id.* at 2:38–42. The injector includes first cartridge retaining part 2 and second main housing part 4.[1] *Id.* at 3:8–9. Insert 16 is at a first end of main housing 4 and is fixed rotationally and longitudinally to main housing 4. *Id.* at 3:29–30. Insert 16 includes threaded circular opening 18, through which piston rod 20 extends. *Id.* at 3:31–33, 3:37–39. Piston rod 20 includes first thread 19. *Id.* at 3:36. Piston rod 20 also includes pressure foot 22 that abuts piston 10 of cartridge 8. *Id.* at 3:39–41.

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 3:41–42, 3:51, 3:58–60. Clutch 60 is disposed about drive sleeve 30 adjacent its second end. *Id.* at 4:12–14, 4:28–29. Clutch 60 is keyed to drive sleeve 30 by splines to prevent relative rotation between clutch 60 and drive sleeve 30. *Id.* at 4:39–41.

Dose-dial sleeve 70 is outside of clutch 60 but within main housing 4. *Id.* at 4:49–51. Dose-dial sleeve 70 has helical groove 74 on its outer surface. *Id.* at 4:51–52. Dose-dial grip 76 is disposed about the second end of dose-dial sleeve 70 and secured to dose-dial sleeve 70 to prevent relative motion. *Id.* at 5:3–4, 5:6–8.

A user rotates dose-dial grip 76 to set a dose and to cause dose-dial sleeve 70 and drive sleeve 30 to rotate together out of main housing 4. *Id.* at

[1] The '069 patent refers to "second main housing part 4" and "main housing 4" interchangeably. *Compare* Ex. 1003, 3:9 ("second main housing part 4") *with id.* at 3:30 ("main housing 4").

5:29–32, 5:42–44, Fig. 9. The dose can be reduced by turning dose-dial grip 76 in the opposite direction. *Id.* at 5:65–66, 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 housing part 4. *Id.* at 6:6–9, 6:11–13, 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 6:23–25.

C. Sole Challenged Claim

The ’069 patent has three claims, of which Petitioner challenges only claim 1, reproduced below:

> 1. 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.

Ex. 1003, 6:37–60.

D. Evidence Relied Upon

Petitioner identifies the following references as prior art in the asserted grounds of unpatentability:

(1) U.S. Patent No. 6,221,046 B1, issued April 24, 2001 (Ex. 1013, "Burroughs");

(2) U.S. Patent No. 6,235,004 B1, issued May 22, 2001 (Ex. 1014, "Steenfeldt-Jensen"); and

(3) U.S. Patent Application Publication No. US 2002/0053578 A1, published May 2, 2002 (Ex. 1015, "Moller").

Petitioner also provides a Declaration of Karl R. Leinsing (Ex. 1011).

E. Asserted Grounds

Petitioner challenges, under 35 U.S.C. § 103, claim 1 as unpatentable over (1) Burroughs alone, (2) Steenfeldt-Jensen alone, and (3) Moller in combination with Steenfeldt-Jensen. Pet. 3–4, 25–88.

III. 35 U.S.C. § 314(a)

Patent Owner urges us to exercise our discretion under 35 U.S.C. §§ 314(a) and 324(a)[2] to deny the Petition because instituting trial "would waste the Board's finite resources and it is fundamentally unfair and inefficient to require [Patent Owner] to defend an IPR where the final written decision will issue after the District Court has already resolved the same validity challenges." Prelim. Resp. 3. Patent Owner provides a procedural history leading to the related district court litigation and filing of the Petition in this proceeding. *Id.* at 4–7. Patent Owner indicates that it

[2] 35 U.S.C. § 324(a) applies to post-grant review proceedings, not *inter partes* review proceedings.

filed a patent infringement case against Petitioner on October 24, 2017, and Petitioner served its invalidity contentions on Patent Owner on January 25, 2018. *Id.* at 5–6.

According to Patent Owner, the invalidity contentions included the same prior art grounds presented in the Petition. *Id.* at 1, 6, 9–10 (arguing that "Petitioner relies on the same prior art in the Petition as in the District Court case") (citing portions of Exs. 2007–2010), 26–28 (arguing that Petitioner asserts that same prior art grounds in this proceeding and related litigation). Patent Owner also notes that Petitioner received Patent Owner's response to those contentions on August 12, 2018, approximately one month before the present Petition was filed. *Id.* at 6; Paper 16, 3 (arguing that "Mylan continues its quest for its 'second bite' by seeking to preserve its ability to assert invalidity positions in the District Court that Mylan contends are not 'specific[ally]' identical to those in the IPR").

Patent Owner additionally indicates that the parties in the case have jointly requested trial in the District Court for October 2019, to reach resolution before the end of the FDA's 30-month stay of regulatory approval of Petitioner's FDA application of its insulin glargine product on March 18, 2020. Prelim. Resp. 6–7 (citing Ex. 2005 ¶ 8); Paper 16, 1–2 (citing Ex. 2017, 6:17–24; Ex. 2029 (amended scheduling order proposing trial for "January 2020, subject to the [District] Court's availability")). Thus, according to Patent Owner, the related district court litigation will be decided before a final written decision is issued in this proceeding. Prelim. Resp. 1, 7; *see also id.* at 23–24 (arguing that related litigation will be tried by March 2020); Paper 16, 1–2.

Patent Owner argues that the Board has discretion to deny under 35 U.S.C. §§ 314(a) and 324(a) to establish a more efficient patent system and limit unnecessary litigation costs. Prelim. Resp. 7–8 (citing H.R. Rep. 112-98, pt. 1, at 40 (2001); Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (Aug. 13, 2018) ("Trial Practice Guide Update")). Patent Owner also notes that the Board has done so in circumstances similar to the ones of this proceeding. *Id.* at 8 (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, Case IPR2018-00752 (PTAB Sept. 12, 2018) (Paper 8) ("*NHK Spring*")). Patent Owner further argues that exercising discretion in this proceeding will not impact broadly Hatch-Waxman litigants. *Id.* at 25–26 (citing Ex. 2020, 19); Paper 16, 3–4 (arguing that Petitioner admits that this case would not affect broadly Hatch-Waxman cases).

Patent Owner contends that the facts here are similar to the facts of *NHK Spring*, because the parties are at an advanced stage in district court litigation, Petitioner is relying on prior art that is at issue in that litigation, and the district court trial will conclude before a final written decision is issued. Prelim. Resp. 9–12 (citing Pet. 3; Exs. 2006–2010, 2017, 2018); *see also* Paper 16, 8 (arguing that this proceeding can be distinguished from other Board cases where *NHK Spring* was not applied). Patent Owner also argues that 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." Prelim. Resp. 12. Patent Owner asserts that Petitioner was aware of the timing of the district court case and engaged in gamesmanship that is highly prejudicial to Patent Owner. *Id.* at 12, 28 (arguing that "each petition seeks a second bite at duplicative invalidity

grounds and provides a tactical advantage to Petitioner resulting from being filed after Petitioner had received Sanofi's validity contentions in the District Court case").

Patent Owner also provides its application of 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 all of those factors favor denying the petition. *Id.* at 13–17; *see also* Paper 16, 9 (arguing that *General Plastic* apply to this proceeding). Patent Owner argues that, although those factors were articulated in the context of denying follow-on petitions, the underlying logic applies to the present proceeding. Prelim. Resp. 13. In its analysis of the factors, Patent Owner points to Petitioner's duplication of invalidity arguments in the related court case and the present proceeding, the filing of the Petition after Petitioner received Patent Owner's response to the invalidity contentions in related litigation, and the likelihood that the invalidity contentions pending in district court will be decided no later than March 18, 2020. *See id.* at 14–16.

In an attempt to address preemptively Petitioner's arguments in a reply filed in a related case with similar challenges, Patent Owner contends that Petitioner misstates and misapplies the law regarding discretionary denial under § 314(a). *Id.* at 17–22 (addressing the Administrative Procedures Act; *Click-to-Call Tech., LP v. Ingenio, Inc*, 899 F.3d 1321 (Fed. Cir. 2018); 157 Cong. Rec. S1360, 1377 (Mar. 11, 2018)). Patent Owner argues that the Board has discretion to deny a petition in circumstances similar to the ones in this case. *Id.* at 18–19; Paper 16, 5–8 (replying to Petitioner's arguments based on Administrative Procedures Act; *Click-to-*

Call; Trial Practice Guide Update), 10 (reply to Petitioner's arguments based on legislative history).

In its Reply to the Preliminary Response, Petitioner provides arguments that the challenges in this proceeding have not been shown to be the same as, and are not the same as, the invalidity contentions in related litigation. Paper 14, 1–3 (citing Ex. 2009, 348; Ex. 2010, 16–17; Ex. 2011). Petitioner contends that Patent Owner's "evidence of *its* allegedly detailed validity positions is just an email demonstrating service." *Id.* at 2 (citing Ex. 2011). Petitioner also contends that it filed multiple petitions to address five patents and to meet rules regarding word limits (*id.* at 3–4) and that it filed all related petitions on the same day (*id.* at 6–7). According to Petitioner, Patent Owner speculates as to when the related district court case will be tried. *Id.* at 4–6, 14. Petitioner also provides arguments regarding the scope of the discretion under § 314(a) (*id.* at 7–9, 21) and argues that Patent Owner's arguments regarding that discretion run afoul of statute, case law, the Administrative Procedures Act, certain Board decisions, and the legislative history of the America Invents Act (*id.* at 9–24).

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 January 2020.[3] *See* Ex. 2026 (scheduling

[3] 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)).

trial "subject to Court's availability"). Although the record indicates that the district court and the parties are working together towards resolving the related litigation before March 18, 2020, the end of the FDA's 30-month stay, the record does not provide enough indications that the related litigation will in fact be resolved before the end of the 30-month stay. Indeed, as indicated in the latest scheduling order in the district court litigation, the parties will not propose trial dates to the court until October 2019. *See id.* Adding to the uncertainty of when a trial may begin, many of the schedule's milestones are dependent on the district court issuing its claim construction order, something completely out of the parties' hands. *See id.*; Paper 14, 5 (explaining that "most deadlines are tied to the issuance of a Markman order"). In this proceeding, by statute, barring good cause for extending pendency, review will be completed within one year of institution. For these reasons, we are not persuaded that instituting review in this proceeding will be an inefficient use of Board resources.

We are also 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. 13. 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 6. The excerpts of Petitioner's invalidity contentions provided by Patent Owner, however, show that, in that related litigation, the references asserted in this proceeding are also combined with other references not asserted in this proceeding for teaching limitations of claim 1. *See* Ex. 2007 (asserting Burroughs, Steenfeldt-

Jensen, and Moller, alone, in combination with each other, and in combination with other references not asserted in this proceeding); Ex. 2008 (asserting the references alone and in combination with other references not asserted in this proceeding); Ex. 2009 (asserting references in this proceeding in combination with other references not asserted in this proceeding). Also, we cannot discern from the exhibits 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 in the related district court litigation 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. Therefore, we are not persuaded those factors apply. Moreover, even if we did apply *General Plastic* to this case, the differences between Petitioner's invalidity contentions in related litigation and the grounds at issue in this case do not indicate clearly what benefit, if any, Petitioner could have had in drafting its petition for this proceeding. Also, Petitioner filed its Petition well within the timeframe allowed by statute, weighing heavily in its favor.

Thus, for the foregoing reasons, we do not exercise our discretion under 35 U.S.C. § 314(a) to deny institution.

IV. CHALLENGES UNDER 35 U.S.C. § 103

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2018); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard).[4]

Petitioner states that "claim terms should be given their ordinary and customary meaning, consistent with the specification and how they would have been understood by [a person of ordinary skill in the art]." Pet. 15. Petitioner notes that Patent Owner proffered interpretations of "drive sleeve," "main housing," "piston rod," "thread/threaded/threading," and "tubular clutch" in related litigation. *Id.* at 15–16 (citing Ex. 1019, 19−24, 27–28, 30–31). Petitioner also notes that it proffered a means-plus-function interpretation for "tubular clutch" in related litigation and proffers the same interpretation in this proceeding if the broadest reasonable interpretation of "tubular clutch" is a means-plus-function interpretation. *Id.* at 16–17 (citing Ex. 1001, 2:5–7, 4:42–44, 6:14–22, 11:58–12:4, Figs. 1, 5–11; Ex. 1028, 80–85).

[4] On October 11, 2018, the Office revised its rules to harmonize the Board's claim construction standard with that used in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42). This rule change, however, applies to petitions filed on or after November 13, 2018, so the revised claim construction standard does not apply to this proceeding. *Id.*; *see* Paper 8 (according a filing date of September 10, 2018 to the Petition).

Patent Owner responds that Petitioner does not state what the plain and ordinary meaning is for any term. Prelim. Resp. 31. 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 encompass at least Patent Owner's proposed interpretations. Also, Petitioner's arguments provide sufficient indication as to how Petitioner interprets the challenged claim in its application of the asserted references to the claim limitations.

Patent Owner also disputes that "clutch" is a means-plus-function limitation. Prelim. Resp. 32, 35–36. At this stage of the proceeding, the mere fact that Petitioner proposed means-plus-function interpretations in related litigation does not, by itself, demonstrate that the broadest reasonable interpretation in view of the specification would be a means-plus-function interpretation. The parties, however, may address this issue further during trial.

Patent Owner proposes to interpret "helical groove" to mean "a groove formed in the shape of a spiral." *Id.* at 32–35. Patent Owner provides citations to the specification of the '069 patent and dictionary definitions. *Id.* at 32–34 (citing Ex. 1001, 4:51–52, Figs. 12–14; Ex. 2013, 10; Ex. 2014; Ex. 2015, 4, 5). Patent Owner also "reserves the right to address the construction of all other terms." *Id.* at 32 n.7.

Based on the arguments and evidence at this stage, we adopt Patent Owner's proposed interpretation of "helical groove" for the purposes of this Decision. After the record has been developed at trial, we may revisit the

interpretation 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 any claim term for the purposes of determining whether Petitioner demonstrates a reasonable likelihood of prevailing in its challenges. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (construing explicitly only those claim terms in controversy and only to the extent necessary to resolve the controversy); *see also 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).

B. Level of Ordinary Skill

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 "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." Pet. 15 (citing Ex. 1011 ¶ 106). Patent Owner does not propose a level of ordinary skill at this stage of the proceeding.

We preliminarily adopt Petitioner's, not yet challenged, asserted level of ordinary skill solely to determine whether there is a reasonable likelihood that Petitioner would prevail with respect to claim 1, the only claim challenged in the Petition.

C. Challenge Based on Burroughs

1. Burroughs (Ex. 1013)

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.

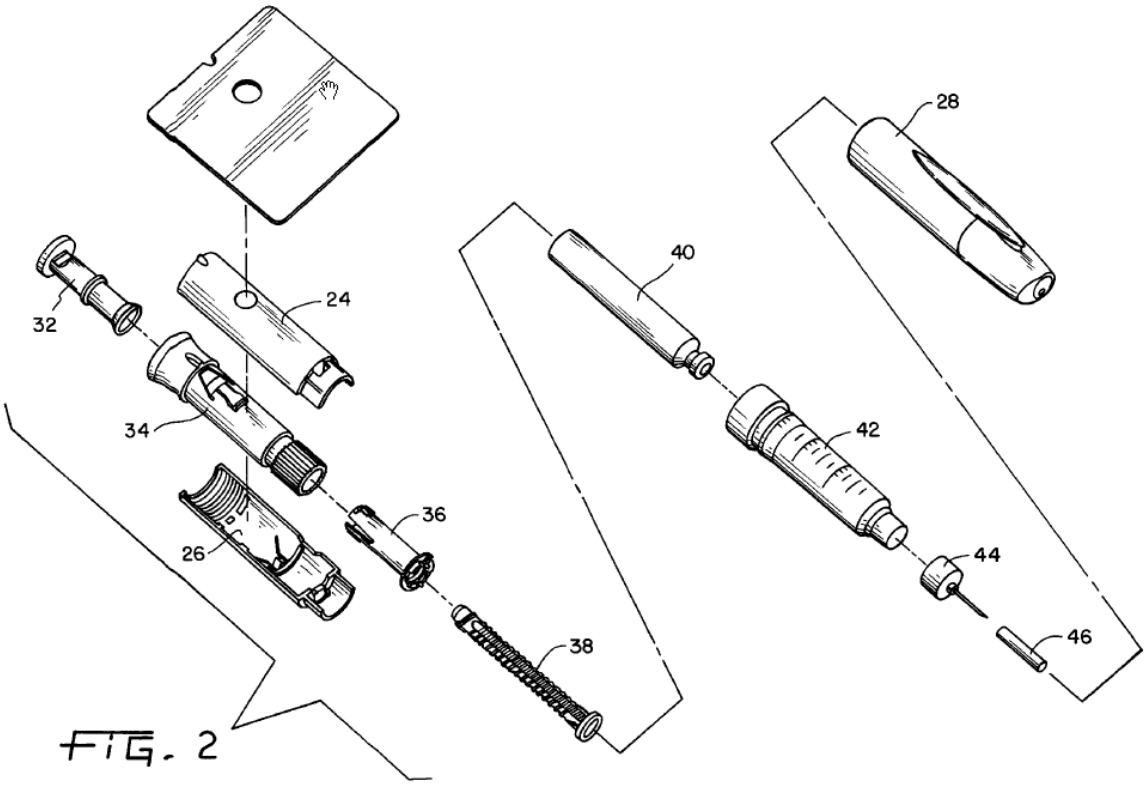

Figure 2 shows an exploded view of injection medication device 20. *Id.* at 6:42–43, 7:15–16. Medication device 20 includes mechanism housing 22 made from housing parts 24 and 26, button 32, dial mechanism 34, nut 36, and leadscrew 38 that forms a drive stem. *Id.* at 7:17–18, 7:32–34, 9:12–13.

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.

2. Claim 1

Petitioner contends that Burroughs teaches all the components recited by claim 1 but that the dial mechanism of Burroughs has threads on its outer surface that engage a helical groove of a main housing. Pet. 25. Petitioner asserts that it would have been obvious to modify Burroughs so that the dial mechanism has a helical groove that engages with a thread on the main housing. *Id.*

Petitioner provides a chart that explains where Burroughs teaches or suggests the limitations of claim 1. Pet. 25–40 (citing Ex. 1011 ¶¶ 126, 158, 161–167, 173–188; Ex. 1013, Abstract, 7:9–20, 7:31–32, 7:46–55, 7:65–67, 8:2–6, 8:11–20, 8:24–29, 8:33–36, 8:42–48, 8:62–9:1, 9:8–11, 9:12–34, 10:26–42, 11:5–20, 11:27–30, 11:52–56, Figs. 1, 2, 3, 5–15). Petitioner asserts that (1) one of ordinary skill in the art would have known of the alternative configuration of a helical groove, (2) the use of rib-to-groove

threaded engagement was known and interchangeable on parts to be engaged, and (3) its proposed modification would have been the predictable use of prior art elements according to their established functions. *Id.* at 40–42 (citing Ex. 1011 ¶¶ 166–171; Ex. 1013, 10:34–38, 10:60–63).

Patent Owner responds that Burroughs does not teach and would not have rendered obvious a "helical groove provided along an outer surface of said dose dial sleeve." Prelim. Resp. 46. Patent Owner argues that "Petitioner admits that Burroughs does not disclose a helical groove on the outer surface of the dose dial sleeve." *Id.* (citing Pet. 30). Patent Owner also argues that Petitioner's "proposed modification does not result in a 'helical groove' as properly construed" and "does not create a helical groove" because Burroughs's "threads 110 and 112 are *discrete, tooth-like protrusions* on the surface of dial mechanism 34, and *not* a spiral-shaped." *Id.* at 46–47 (citing Pet. 40–42; Ex. 1013, Figs. 7, 9).

Patent Owner further argues that Petitioner's declarant opines without support that threads 110, 112 "constitute a 'discontinuous "helical rib."'" *Id.* at 47 (citing Ex. 1011 ¶ 165). Patent Owner contends that Petitioner's declarant "fails to apply an appropriate construction of 'helical,' . . . which requires a structure formed in the shape of a spiral" and the testimony "is based on his contention that one could trace an imaginary, spiral-shaped path between the threads, rather than the threads themselves being formed in the shape of a spiral." *Id.* at 49 (citing Ex. 1011 ¶ 165). According to Patent Owner, Petitioner provides no evidence "showing that it would have been obvious . . . to further modify threads 110 and 112 such that the threads, and not some imaginary line, are formed in the shape of a spiral." *Id.* at 49–50. Patent Owner additionally argues that Petitioner's citations to the

’069 patent do not support Petitioner’s assertion that Burroughs’s threads 110, 112 are helical because the ’069 patent describes helical thread 24 with discrete interruptions. *Id.* at 47–49 (discussing Ex. 1001, 3:42–44, Figs. 1, 2).

On the present record, Petitioner sufficiently shows for purposes of institution that Burroughs would have rendered obvious a “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,” as recited by claim 1. Ex. 1001, 6:41–45. Petitioner relies on portions of Burroughs that teach “outwardly extending thread 110, 112” that “enter helical groove 158 during commencement of the dosing process.” *See* Pet. 29–30 (citing Ex. 1011 ¶¶ 161–167; Ex. 1013, 7:31–32, 7:65–67, 8:24–29, 8:33–36, 8:62–9:1, 10:34–37, Figs. 1–3, 5–9). Burroughs also teaches “[a]s 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.” Ex. 1013, 10:60–63. These portions of Burroughs adequately support Petitioner’s contention that “[t]hreads 110, 112 are configured to releasably engage with helical spiral groove 158 on an inner surface of housing 22” and that “dial mechanism 34 includes a ‘helical rib,’ in the form of threads 110, 112, along its outer surface that engages with threading on housing 22.” *See* Pet. 29–30 (citing Ex. 1011 ¶¶ 164, 165; Ex. 1013, 8:62–9:1, Figs. 1, 3, 5–9).

Even under Patent Owner’s proposed interpretation of “helical groove” as a “groove formed in the shape of a spiral” (Prelim. Resp. 32), which we have adopted for purposes of this Decision, based on the same teachings of Burroughs discussed above, Petitioner at this stage sufficiently

argues that threads 110, 112 must have some spiral aspect to be able to engage helical spiral groove 158. *See* Pet. 29–30. Petitioner also provides argument and evidence that threads 110, 112 would have been modified to be a helical groove. *See id.* at 40–42. Thus, in view of all the arguments and evidence at this stage, Petitioner adequately shows for institution that Burroughs would have rendered obvious a "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," as recited by claim 1.

Patent Owner also responds that Petitioner fails to provide a motivation for its proposed modification of Burroughs because Petitioner only asserts that its proposed modification "would have been 'interchangeable' with the structure disclosed in Burroughs and that the modified elements would have still performed the same functions." Prelim. Resp. 50–51 (citing Pet. 40–42). Patent Owner argues that Petitioner's mere assertion is insufficient for obviousness and does not show why the modification would have been made, does not identify any problem solved by the proposed modification, and does not identify any improvement to Burroughs from the proposed modification. *Id.* at 51. Patent Owner also argues that Petitioner's proposed modification increases the complexity of Burroughs and "would simply perform the same function as the structure already disclosed in Burroughs." *Id.* (citing Pet. 42).

At this stage, Petitioner's assertion that its proposed modification of threads 110, 112 to be protruding helical grooves as 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* Pet. 40–

42 (citing Ex. 1011 ¶¶ 166–171). After the record has been developed at trial, Petitioner's reasons for modifying Burroughs will be further analyzed in view of all evidence presented.

For the reasons above and on the present record, Petitioner demonstrates a reasonable likelihood of success in proving that claim 1 of the '069 patent, the only claim challenged, is unpatentable over Burroughs. Thus, we institute on all presented challenges. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); Guidance on the Impact of *SAS* on AIA Trial Proceedings (Apr. 26, 2018), 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").

To provide guidance to the parties for the trial, we turn to Petitioner's other challenges to claim 1 based on Steenfeldt-Jensen alone and based on the combination of Moller and Steenfeldt-Jensen.

D. Challenge Based on Steenfeldt-Jensen

1. Steenfeldt-Jensen (Ex. 1014)

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

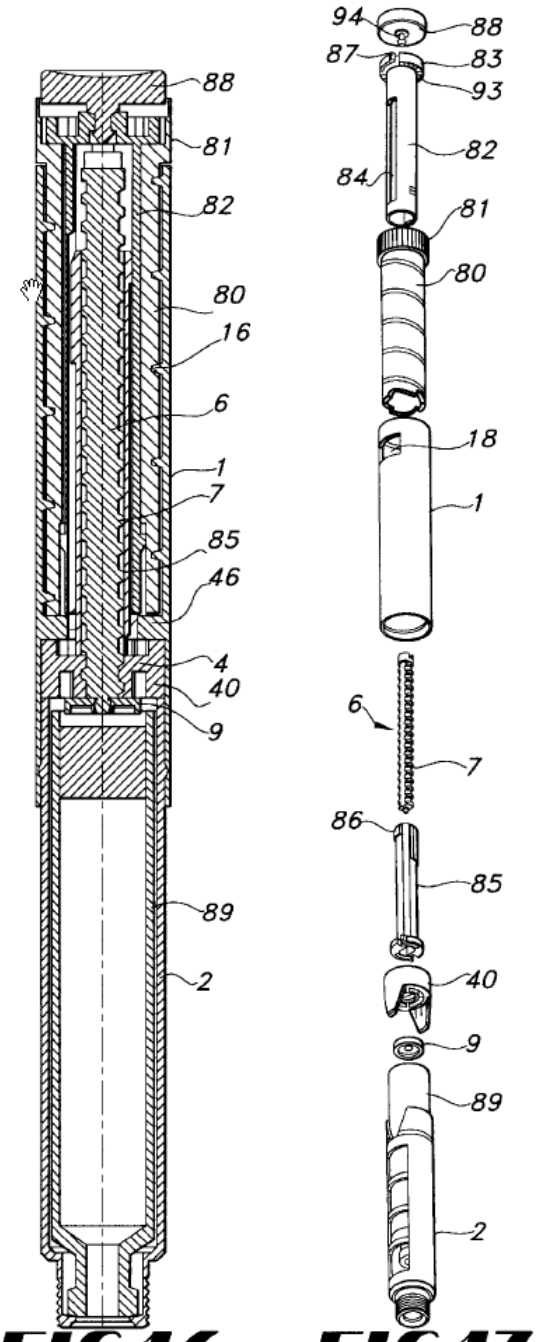

FIG 16 FIG 17

Figures 16 and 17 show side sectional views of a syringe. *Id.* at 5:25–28. The syringe of Steenfeldt-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 is engaged with 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 82 and over driver tube 85. *Id.* at 11:26–29. Bushing 82 is coupled to driver tube 85 so that both 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. *Id.* at 12:4–5. Scale drum 80 is pressed back into housing 1. *Id.* at 12:9–10. Dose setting button 81 rotates because of the engagement between the helical track of scale drum 80 and the helical rib of housing 1. *Id.* at 12:6–9. Piston rod 6 is screwed into ampoule 89 in ampoule holder 2. *Id.* at 12:12–13.

2. Claim 1

Petitioner contends that Steenfeldt-Jensen teaches all the structural limitations of claim 1. Pet. 42. Petitioner also contends that, to the extent

that Steenfeldt-Jensen does not teach or suggest a drive sleeve, it would have been obvious to include such a drive sleeve. *Id.*

Petitioner provides a chart that explains where Steenfeldt-Jensen teaches or suggests the limitations of claim 1. Pet. 43–59 (citing Ex. 1011 ¶¶ 131, 261, 263–268, 270, 271, 273, 274, 280–283, 285; Ex. 1014, 1:12–15, 5:38–44, 5:55–58, 7:49–51, 8:35–38, 11:6–42, 11:52–62, 12:1–13, Figs. 15–17, claim 11). Petitioner asserts a reason to modify Steenfeldt-Jensen so that driver tube 85 would have internal threading near its distal end and that one of ordinary skill in the art would have had a reasonable expectation of success. *Id.* at 55 (citing Ex. 1011 ¶¶ 275–279), 60–62 (citing Ex. 1011 ¶¶ 274–278; Ex. 1014, 2:46–53, 3:15–20, 3:44–47, 7:44–47).

Patent Owner responds that Steenfeldt-Jensen does not teach and would not have rendered obvious "a drive sleeve . . . comprising an internal threading . . . adapted to engage an external thread of said piston rod," as recited by claim 1. Prelim. Resp. 52. Patent Owner notes that Petitioner and its declarant concede that the relied-upon fifth embodiment of Steenfeldt-Jensen does not teach the limitation. *Id.* (citing Pet. 55; Ex. 1011 ¶ 274).

Patent Owner also argues that it would not have been obvious to use the internal threading of member 40 in Steenfeldt-Jensen's first embodiment in Steenfeldt-Jensen's fifth embodiment, as argued by Petitioner. *Id.* (citing Pet. 55, 60–62; Ex. 1011 ¶¶ 274–278). Patent Owner asserts that the internal threading is strictly for the first embodiment, the asserted motivation does not apply to the relied-upon fifth embodiment, and the proposed modification "creates a substantial risk that the resulting device would not work for its intended purpose." *Id.* at 52–53.

In particular, Patent Owner argues that Petitioner's cited passage from Steenfeldt-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 53–54 (citing Ex. 1014, 5:33–7:47, 11:6–12:16, Figs. 1–5, 15–17) (quoting Ex. 1014, 7:41–47). According to Patent Owner, however, the relied upon portion of Steenfeldt-Jensen does not teach replacing the internal threading of member 40 in the fifth embodiment with the non-circular bore of its driver tube 85 because the fifth embodiment does not have driver tube 26 or a rotatable ampoule holder with a threaded opening. *Id.* at 54 (citing Ex. 1014, 11:6–12:16). Patent Owner also argues that Petitioner's other citations teach either the piston rod rotating or the nut member rotating but do not teach or suggest a threaded driver tube with a new nut member. *Id.* at 54–55 (citing Pet. 60; 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 make Petitioner's proposed modification to Steenfeldt-Jensen's fifth embodiment because the modification removes a high-friction interface for dialing a dose in the first embodiment and the fifth embodiment does not have or need a high-friction interface, and thus, such teachings are not applicable to the fifth embodiment. *Id.* at 55–60 (citing Ex. 1014, 6:42–43, 6:54–59, 7:17–40, 11:52–12:3, Figs. 2, 16).

Patent Owner also responds that Petitioner's proposed modification results in an inferior pen injector. *Id.* at 60. Patent Owner contends that making the proposed modification to Steenfeldt-Jensen's fifth embodiment would introduce a source of friction that would make it harder to use. *Id.* at 60–63 (citing Ex. 1003, 1:31–35; Ex. 1014, 12:10–13, Fig. 16; Ex. 1015 ¶¶ 4–6).

In view of the arguments and evidence at this stage of the proceeding, we are satisfied that Petitioner sufficiently demonstrates that Steenfeldt-Jensen would have rendered obvious claim 1. *See* Pet. 43–59. We are also 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 Steenfeldt-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 55, 60–62. In support of its proposed modification, Petitioner quotes column 7, lines 44–47 of Steenfeldt-Jensen, which states 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 embodiments will not be beyond the scope of the invention." *Id.* at 60. At this stage, Petitioner shows sufficiently that Steenfeldt-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.

We note, however, that whether this sentence in Steenfeldt-Jensen which Petitioner cites in support of its proposed modification provides adequate reason for one of ordinary skill in the art to modify the fifth embodiment in the manner asserted by Petitioner will be reanalyzed after fully developing the record. A fully developed record would aid in determining whether the teaching applies only to Steenfeldt-Jensen's first embodiment as contended by Patent Owner (*see* Prelim. Resp. 52–59) or whether the same teaching would have been applied to the fifth embodiment with its alternative arrangement of structures, as argued by Petitioner (*see* Pet. 55, 60–62).

Also, the present record does not indicate that moving the internal threads of Steenfeldt-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. 60–63. Patent Owner's argument presents another factual issue regarding friction in Petitioner's proposed modification that would also benefit from further developing the record at trial.

E. Challenge Based on Moller and Steenfeldt-Jensen

1. Moller (Ex. 1015)

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.

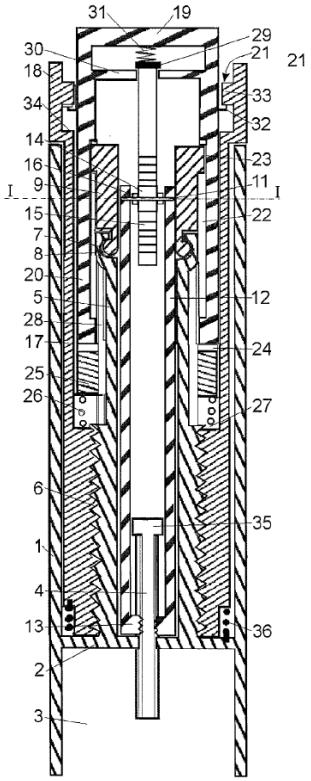

Fig. 1

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.

2. Claim 1

Petitioner argues that Moller teaches the same structural limitations of claim 1. Pet. 62. Petitioner asserts that it would have been obvious to

modify drum 17 of Moller to have a helical groove on its outer surface instead of its inner surface. *Id.* at 62–63. Petitioner additionally notes that its analysis primarily relies on the embodiment of Moller shown in Figures 1 and 2, but that the challenged claim is unpatentable over the embodiment shown in Figures 3–5. *Id.* at 63 (citing Ex. 1011 ¶ 139 n.16; Ex. 1015 ¶¶ 22–40, Figs. 1–5).

Petitioner provides a chart that explains where Moller or Moller and Steenfeldt-Jensen teach or suggest the limitations of claim 1. Pet. 63–85 (citing Ex. 1011 ¶¶ 343–350, 352–362, 364–367, 370–376, 378–381; Ex. 1014, 6:7–17, 11:52–54, 12:4–9, Figs. 3, 8, 13, 17; Ex. 1015, Abstract, ¶¶ 22–27, 29, 30, 32, 33, 36, 38–40, Figs. 1, 3–5). Petitioner asserts a reason to modify Moller to have the outer helical groove of Steenfeldt-Jensen that engages a housing for rotational movement and that one of ordinary skill in the art would have had a reasonable expectation of success. *Id.* at 85–87 (citing Ex. 1011 ¶¶ 354–361; Ex. 1014, 6:7–17, Figs. 3, 8, 13, 17; Ex. 1015 ¶¶ 8, 11, 12, 14, 33).

Patent Owner responds that Moller's connection bars 12 with nut 13 do not teach and would not have rendered obvious the "drive sleeve" of claim 1. Prelim. Resp. 64 (citing Pet. 74–77). Patent Owner notes that the parties agreed that "'drive sleeve' is at least 'an essentially tubular component'" in related district court litigation. *Id.* at 65 n.10 (citing Ex. 2016). According to Patent Owner, connection bars 12 are parallel bars and not a tubular component. *Id.* at 64. Patent Owner contends that Petitioner tacitly admits connection bars 12 with nut 13 are not a sleeve because "Petitioner also points to tubular connection element 112 and nut 113." *Id.* at 65 (citing Pet. 77). Patent Owner argues that, 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 . . . could be formed as a tubular structure without affecting the device's operation." *Id.* at 65. Patent Owner also argues that connection bars 12 and connection element 112 are not functionally and structurally equivalent, that Petitioner provides no meaningful analysis of its asserted equivalency, and that Petitioner's obviousness argument fails because it is predicated on a purported equivalency. *Id.* at 66–67 (citing Ex. 1015 ¶ 24, Figs. 1, 5; Ex. 2027; Ex. 2028), 69. Patent Owner also responds that 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 68, 69–70.

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 Burroughs. 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.

Patent Owner further responds that 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. 70 (citing Pet. 70–71, 85–87). In particular, Patent Owner contends that Moller teaches away from Petitioner's proposed modification of a helical groove engaging a helical rib. *Id.* at 71–72 (citing Ex. 1015 ¶¶ 8, 11; Ex. 2026). Patent Owner also contends that Moller rejected Petitioner's proposed modification (*id.* at 73 (citing Ex. 1015 ¶¶ 8, 11, Fig. 1)), that Petitioner's modification would impair precisely dialing a dosage (*id.* at 73–76 (citing Ex. 1014, Fig. 16; Ex. 1015 ¶ 24, Fig. 1)), and that Moller has a different solution to the purported problem (*id.* at 76–77 (citing Ex. 1015 ¶ 33)).

Whether, at least, paragraphs 8 and 11 of Moller teach away from Petitioner's proposed modification is an issue that would benefit from a fully developed record. We note that 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 of Moller.

V. CONCLUSION

The Supreme Court held that a final written decision under 35 U.S.C. § 318(a) must decide the patentability of all claims challenged in the petition. *SAS Inst.*, 138 S. Ct. at 1359–60. After considering the evidence and arguments presented in the record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in proving that claim 1, the only challenged claim, of the '069 patent is unpatentable.

Because Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to claim 1, we institute an *inter partes* review of the only challenged claim on all presented challenges.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or any underlying factual and legal issues.

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claim 1 of U.S. Patent No. 8,679,069 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 8,679,069 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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