

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 IPR2018-01678
Patent 8,992,486 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 2, “Pet.”) requesting institution of an *inter partes* review of claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of U.S. Patent No. 8,992,486 B2 (Ex. 1003, “the ’486 patent”). Sanofi-Aventis Deutschland GmbH (“Patent Owner”) filed a Preliminary Response (Paper 10, “Prelim. Resp.”). As authorized in our Orders (Papers 12, 14), Petitioner filed a Reply to the Preliminary Response (Paper 13), and Patent Owner filed a Sur-Reply (Paper 15). 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 at least one of the challenged claims. As such, we institute an *inter partes* review of all challenged claims on all presented challenges, and thus, institute an *inter partes* review of claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of the ’486 patent.

II. BACKGROUND

A. *Related Proceedings*

The parties indicate that the ’486 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*

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Co., No. 1:14-cv-00113-RGA-MPT (D. Del.). Pet. 1; Paper 5, 2; Paper 8, 2; Exs. 1029, 1030.

The parties state that the '486 patent is also challenged in Cases IPR2018-01677, IPR2018-01679, and IPR2018-00122. Pet. 2; Paper 5, 3; Paper 8, 2. Petitioner's motion to dismiss its petition in IPR2018-01677 was granted.

The parties also state that related patents are challenged in Cases IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01680, IPR2018-01682, IPR2018-01684, and IPR2018-01696. Pet. 2; Paper 5, 2–3; Paper 8, 2–3.

B. The '486 Patent (Ex. 1003)

The '486 patent issued March 31, 2015, from an application filed June 4, 2013, which is the latest application in a series of continuation applications, the first of which was filed on March 2, 2004. Ex. 1003, [22], [45], [63], 1:6–12. The '486 patent also claims priority to a foreign application filed on March 3, 2003. *Id.* at [30], 1:12–14.

The '486 patent “relates to pen-type injectors . . . where a user may set the dose.” *Id.* at 1:20–24. Figures 1 and 2 of the '486 patent are reproduced below.

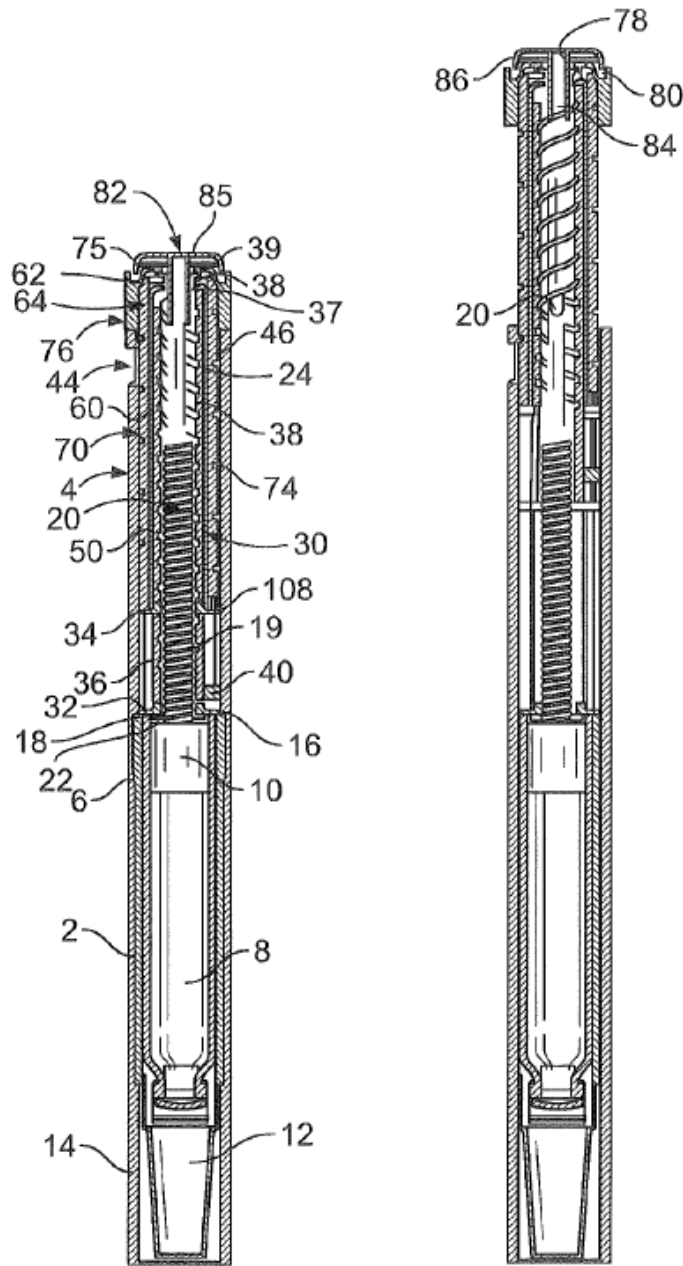


FIG. 1

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 2:53–57. The injector includes first cartridge retaining part 2 and main housing

part 4.¹ *Id.* at 3:27–28. Insert 16 is at a first end of housing part 4 and is fixed rotationally and axially to main housing 4. *Id.* at 3:49–51. Insert 16 includes threaded circular opening 18, through which piston rod 20 extends. *Id.* at 3:51–53, 3:57–59. Piston rod 20 includes first thread 19 that engages threaded circular opening 18. *Id.* at 3:56.

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

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

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

A user rotates dose-dial grip 76 to set a dose and to 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.

¹ The '486 patent refers to “second main housing part 4” and “main housing 4” interchangeably. *Compare* Ex. 1003, 3:28 (“second main housing part 4”) *with id.* at 3:30 (“main housing 4”).

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.

C. Illustrative Claim

The '486 patent has 57 claims, of which Petitioner challenges claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 in this proceeding. Of those, claim 1, reproduced below, is the only independent claim.

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;
 - a dose knob 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 driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, 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 knob, said tubular clutch operatively coupled to said dose knob, wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

Ex. 1003, 6:59–7:12.

D. Evidence Relied Upon

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

- (1) U.S. Patent No. 6,235,004 B1, issued May 22, 2001 (Ex. 1014, “Steenfeldt-Jensen”); and
- (2) U.S. Patent Application Publication No. US 2002/0053578 A1, published May 2, 2002 (Ex. 1015, “Moller”).

In support of its challenges, Petitioner provides a Declaration of Karl R. Leinsing (Ex. 1011).

E. Asserted Grounds

Petitioner challenges, under 35 U.S.C. § 103, claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 as unpatentable over (1) Steenfeldt-Jensen alone and (2) Moller and Steenfeldt-Jensen. Pet. 3, 21–98.

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 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 the filing of the Petition in this proceeding. *Id.* at 5–8. Patent Owner indicates that it filed a patent

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

infringement case against Petitioner on October 24, 2017, and Petitioner served its invalidity contentions on Patent Owner on January 25, 2018. *Id.* at 6–7.

According to Patent Owner, the invalidity contentions included the same prior art grounds presented in the Petition. *Id.* at 7; *see also* Paper 15, 4–5 (arguing that “Petitioner asserts the same invalidity grounds in the Petition and the District Court”) (citing Paper 10, 10–11; Ex. 2024, 13:10–14:3). 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. Prelim. Resp. 7.

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. *Id.* at 7–8 (citing Ex. 2005 ¶ 8); *see also* Paper 15, 1–3 (arguing that Petitioner has sought trial in advance of March 2020) (citing Ex. 2006 ¶ 8; Ex. 2016, 1; Ex. 2017, 19; Ex. 2018, 1; Ex. 2019, 1; Ex. 2020, 7–8; Ex. 2021, 31:15–32:3; Ex. 2022, 6:17–24; Ex. 2023, 1, 2). Patent Owner believes that “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.” Paper 15, 3. 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, 4.

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. 1–2 (citing H.R. Rep. 112-98, pt. 1, at 48 (2011)), 8–9 (citing Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (Aug. 13, 2018)). Patent Owner also notes that the Board has done so in circumstances similar to the ones of this proceeding. *Id.* at 9 (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, Case IPR2018-00752 (PTAB Sept. 12, 2018) (Paper 8) (“*NHK Spring*”).

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. *Id.* at 9–12 (citing Pet. 3; Exs. 2006–2009). Patent Owner also argues that 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 12–13. 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 13; *see also* Paper 15, 5 n.1 (contending that “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 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. Prelim. Resp. 13–18. 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. *Id.* at 14. 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 15–17.

In its Reply to the Preliminary Response, Petitioner argues that it identified in related litigation potential combinations of the references asserted in the Petition (Paper 13, 1–2), that the arguments in related litigation and the Petition differ (*id.* at 2), that Patent Owner provides no evidence of its “detailed validity positions” (*id.*), that it filed all related Petitions on the same day (*id.* at 4–5), and that Patent Owner speculates that a final written decision in this case will issue after related litigation has been resolved (*id.* at 3–4). Petitioner also provides arguments regarding the scope of our discretion under 35 U.S.C. § 314(a) (*id.* at 3–4), particularly in view of workload and resources considerations (*id.* at 10, 12). Petitioner further argues how Patent Owner’s arguments affect that scope and run afoul of statute, case law, and the Administrative Procedure Act. *Id.* at 5–8, 10–11.

In its Sur-Reply in support of its Preliminary Response, Patent Owner further contends that the related district court case will conclude by March 2020 and that Petitioner is asserting duplicative grounds in this case and the related court case. Paper 5, 1–3, 4–5. Patent Owner additionally responds that an exercise of discretion under § 314(a) in this case will not impact broadly Hatch-Waxman litigants. *Id.* at 3–4.

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 is scheduled for, and will occur, in October 2019, or even in January 2020 in accordance with the latest schedule.³ *See* Ex. 3001. 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 even propose trial dates to the court until October 2019. *See* Ex. 3001. 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 13, 4 (explaining that “most deadlines” are tied to the issuing 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.

³ In the district court case running parallel to *NKH 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)).

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. 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 15–17. The excerpts of Petitioner's invalidity contentions provided by Patent Owner, however, show that, in that related litigation, other references are relied upon for teaching limitations of the claims challenged in this proceeding, and the references asserted in this proceeding are cited only for some, not all, of the limitations of the challenged claims. *See* Ex. 2007 (asserting Steinfeldt-Jensen and/or Moller teach most, but not all, limitations of challenged claims); Ex. 2008 (relying on Steinfeldt-Jensen or Moller for teaching some, not all, limitations); Ex. 2009 (asserting Steinfeldt-Jensen or Moller in combination with other references not asserted in this proceeding). We cannot discern whether the identical combinations are asserted. 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 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 Petitioner’s 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 “[c]laims should be given their ordinary and customary meaning, consistent with the specification, as a [person of ordinary skill in the art] understood them” and that the “grounds rely on the

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 6, 1 (according a filing date of September 10, 2018, to the Petition).

ordinary and customary meaning.” Pet. 14, 16. Petitioner provides Patent Owner’s proposed interpretations of “driver,” “main housing,” “piston rod,” “thread/threaded/threading,” “tubular clutch,” “clicker,” and “insert” that were proffered in related litigation. *Id.* at 14–15 (citing Ex. 1019, 21, 23, 25, 27, 30–32). Petitioner also notes that it proffered means-plus-function interpretations for “clutch,” “clicker,” and “insert” in related litigation. *Id.* at 15 (citing Ex. 1028, 101–106, 112–116). Petitioner proposes the same interpretations in this proceeding, if they are applicable. *Id.* at 15–16 (citing Ex. 1003, Abstract, 2:1–3, 2:16–35, 4:33–67, 5:1–6, 5:44–60, 6:16–43, Figs. 1, 3–11; Ex. 1028, 104, 106, 112–116). Petitioner states that the “grounds . . . also address the ‘clutch,’ ‘clicker,’ and ‘insert’ 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 54–55.

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, 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 “clutch,” “clicker,” and “insert” are means-plus-function limitations. Prelim. Resp. 23, 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 55–57.

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. We need not determine, at this stage of the proceeding, if these terms are means-plus-function terms, as Petitioner provides alternative analyses with respect to claims reciting these terms. The parties, however, may address this issue further during trial if necessary. Also, we note that Petitioner does apply its asserted means-plus-function interpretations in some of its challenges. *See* Pet. 45–46 (providing arguments if “clicker” is construed to be a means-plus-function limitation), 73–75 (providing arguments if “clutch” is construed to be a means-plus-function limitation), 87 (providing arguments if “clicker” is construed to be a means-plus-function limitation).

Patent Owner proposes to interpret “main housing” to mean “an exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components.” Prelim. Resp. 23–24. Patent Owner contends that 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 also contends that Petitioner's plain and ordinary meaning is so broad that it includes an interior housing. *Id.* at 26 (citing Pet. 60–66). 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 Petitioner’s argument that Moller teaches this limitation.

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., 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 “had at least a bachelor’s degree in mechanical engineering, or an equivalent degree, plus three-years’ experience” and “understood the basics of medical-device design and manufacturing, and mechanical elements (*e.g.*, gears, pistons) involved in drug-delivery devices.” Pet. 13–14 (citing Ex. 1011 ¶ 106). Patent Owner does not propose a level of ordinary skill at this stage of the proceeding.

We note that the articulation of the asserted level of ordinary skill in the Petition of this proceeding differs from the articulation in the Petition for IPR2018-01679, which challenges the same patent. We also note that both

Petitions reference the same paragraph of declarant testimony, which is the same testimony filed for each case. We preliminarily adopt Petitioner's as-yet unchallenged, asserted level of ordinary skill solely to determine whether there is a reasonable likelihood that Petitioner would prevail with respect to at least 1 of the claims challenged in the Petition.

C. Challenge Based on Steinfeldt-Jensen

Petitioner contends that claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 are unpatentable over Steinfeldt-Jensen. Pet. 3, 21–56. Patent Owner responds that Petitioner's proposed modification would result in an inferior or inoperable device without any beneficial tradeoff. Prelim. Resp. 2, 32–44.

1. Steinfeldt-Jensen (Ex. 1014)

Steinfeldt-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 Steinfeldt-Jensen are reproduced below.

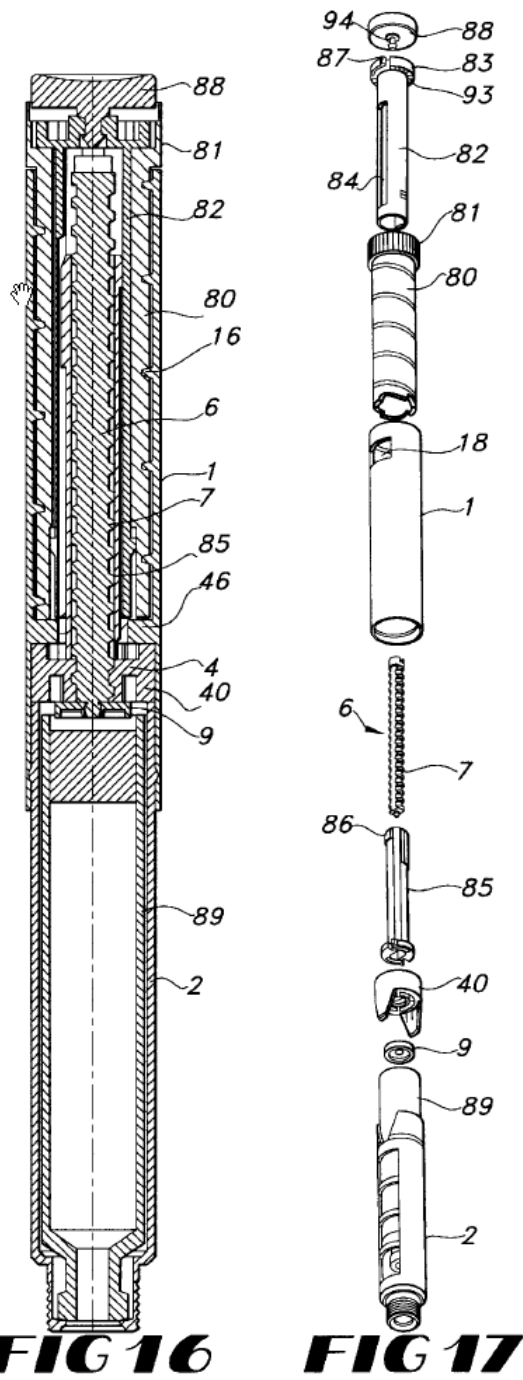


Figure 16 shows a side sectional view of a syringe, and Figure 17 shows an exploded view of that same syringe. *Id.* at 5:25–28. The syringe of Steinfeldt-Jensen includes tubular housing 1 that is partitioned so that a first division has ampoule holder 2. *Id.* at 5:38–40. Ampoule holder 2 has a

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.

2. *Independent Claim 1*

For claim 1, Petitioner argues that Steinfeldt-Jensen teaches all the limitations of claim 1 except a driver with internal threading but contends that Steinfeldt-Jensen suggests such a driver. Pet. 21–22. Petitioner

provides a claim chart that asserts Steinfeldt-Jensen teaches or suggests all the limitations of claim 1. *Id.* at 22–34 (citing Ex. 1011 ¶¶ 261–271, 273–276, 280–283, 285; Ex. 1014, Abstract, 1:12–15, 5:38–44, 5:55–58, 11:6–42, 11:52–62, 12:1–13, claim 11, Figs. 15–17). 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 1’s main housing, dose dial sleeve, dose knob, piston rod, driver, and clutch. *See* Pet. 22–34.

Petitioner notes that Steinfeldt-Jensen teaches that driver tube 85 rotationally engages piston rod 6 via a non-circular bore instead of internal threading. *Id.* at 35 (citing Ex. 1011 ¶ 274). Petitioner argues that one of ordinary skill in the art would have considered it obvious to modify driver tube 85 to provide “a driver . . . comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod,” as recited by claim 1. *Id.* at 30 (citing Ex. 1011 ¶¶ 275–279). 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 35–36 (citing Ex. 1011 ¶¶ 274, 275; Ex. 1014, 3:15–20, 3:44–47, 7:44–47).

According to Petitioner, one of ordinary skill in the art would have understood that driver tube 85 includes a piston rod guide, that member 40 includes the 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 36 (citing Ex. 1011 ¶ 276; Ex. 1014, 2:46–53, 3:15–20). Petitioner, thus, contends that

Steenfeldt-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 1. *Id.* at 36–37 (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 have been known to perform. *Id.* at 37 (citing Ex. 1011 ¶ 278).

Patent Owner responds that Petitioner relies on the fifth embodiment of Steenfeldt-Jensen but concedes it does not teach “*said driver comprising an internal threading . . . adapted to engage an external thread of said piston rod,*” as required by claim 1. Prelim. Resp. 32 (citing Pet. 30, 35; Ex. 1011 ¶ 274). Patent Owner argues that Petitioner’s evidence does not show that 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 Steenfeldt-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 (citing Pet. 30, 35–37; Ex. 1011 ¶¶ 274–278).

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 33–34 (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 34–35 (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 drive tube with 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 make Petitioner’s proposed modification to Steinfeldt-Jensen’s fifth 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, and thus, such teachings are not applicable to the fifth embodiment. *Id.* at 36–41 (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 would result in an inferior pen injector. *Id.* at 41. Patent Owner contends that making the proposed modification to Steinfeldt-Jensen’s fifth embodiment would introduce a source of friction that would make it harder to use. *Id.* at 41–44 (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 for purposes of institution that Steinfeldt-Jensen would have rendered obvious claim 1. *See* Pet. 22–34. 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 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 36–37. In support of its proposed modification, Petitioner quotes column 7, lines 44–47 of Steinfeldt-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 35. At this stage, 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 that this sentence in Steinfeldt-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. However, this is not a final determination, and the matter will be reanalyzed after the record is fully developed. A fully developed record would aid in determining whether the teaching applies only to Steinfeldt-Jensen’s first embodiment as contended by Patent Owner (*see* Prelim. Resp. 33–41) or whether the same teaching would have been applied to the fifth embodiment with its alternative arrangement of structures as argued by Petitioner (Pet. 30, 35–37).

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. 41–44. 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.

For the reasons above, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to at least independent claim 1 of the '486 patent. Therefore, we institute *inter partes* review of all challenged claims 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”).

3. *Challenged Dependent Claims*

Petitioner argues that claims 2–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40, which depend from claim 1, are unpatentable over Steinfeldt-Jensen with citations to the reference and declarant testimony. Pet. 37–56.

For the reasons discussed above for claim 1, we determine that Petitioner demonstrates a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition, and thus, we institute review of all challenged claims on all presented challenges. We have also reviewed Petitioner’s arguments and evidence directed to the challenged dependent claims and determine that Petitioner provides sufficient argument and evidence for purposes of institution. *See* Pet. 37–56. At this stage, Patent Owner does not provide arguments specifically for the challenged dependent claims. *See* Prelim. Resp. 32–44. Therefore, we determine that further analysis of Petitioner’s challenge of claims 2–6, 12–18, 20, 23, 26–

30, 32, 33, 36, and 38–40 is best left for trial after full development of the record.

D. Challenge Based on Moller and Steinfeldt-Jensen

Petitioner contends that claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 are unpatentable over Moller and Steinfeldt-Jensen. Pet. 3, 57–98. Patent Owner responds that one of ordinary skill in the art would not have been motivated to make the proposed modification because Moller disparages the modification and that, under Patent Owner’s proposed interpretation of “main housing,” Moller does not teach or suggest a “dose dial sleeve . . . configured to engage a threading provided by said main housing.” Prelim. Resp. 2–3, 47–53.

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.

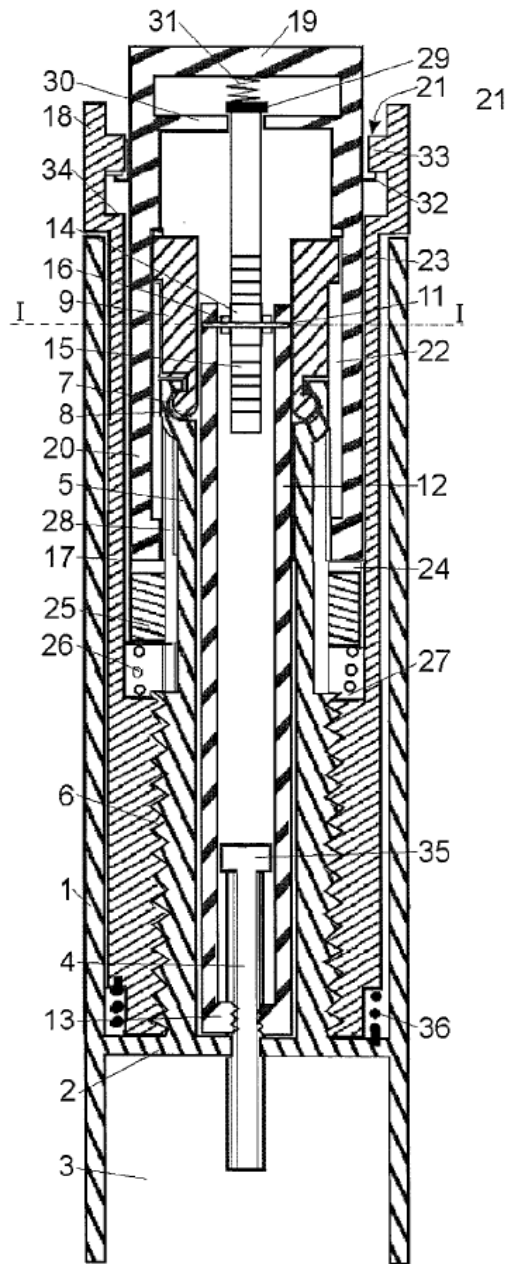


Fig. 1

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. *Independent Claim 1*

For the reasons given above regarding Petitioner's challenge based on Steinfeldt-Jensen, Petitioner shows a reasonable likelihood of prevailing in showing that, at least, claim 1 is unpatentable. We, therefore, institute review of all claims on all challenges. Nonetheless, we address below the parties' dispute at this stage regarding Petitioner's challenge based on Moller to provide guidance for trial.

Petitioner argues that one of ordinary skill in the art would have understood that Moller teaches the same components and structural elements of claim 1. Pet. 57. Petitioner also argues that, even if the asserted “dose dial sleeve” of Moller does not contain a “helical groove,” Moller and Steinfeldt-Jensen would have rendered obvious such a dose dial sleeve. *Id.* Petitioner notes that its analysis primarily focuses on a first embodiment of Moller shown in Figures 1 and 2 but references are made to a second embodiment shown in Figures 3–5. *Id.* Petitioner additionally contends that the challenged claims are unpatentable over the second embodiment. *Id.*

Petitioner provides a claim chart that asserts Moller teaches the limitations of claim 1 but does not explicitly teach a helical groove. *Id.* at 58–73 (citing Ex. 1011 ¶¶ 343–351, 362–369, 372–377; Ex. 1015, Abstract, ¶¶ 22–26, 29–33, Figs. 1, 3–5), 75–76 (citing Ex. 1011 ¶ 381; Ex. 1015 ¶ 26, Fig. 1). Petitioner contends that Moller’s housing 1 with partitioning wall 2 and tubular element 5, dose setting drum 17, 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 1’s main housing, dose dial sleeve, dose knob, piston rod, driver, and clutch. *See id.* Petitioner further contends that Steinfeldt-Jensen teaches a dose dial sleeve. *Id.* at 64 (citing Ex. 1014, 11:20–25; 11:52–12:9, Fig. 17). Petitioner also provides alternative arguments in which “tubular clutch” is construed as a means-plus-function limitation. *Id.* at 73–75 (citing Ex. 1003, 2:17–19, 4:50–52, 5:1–2; Ex. 1011 ¶¶ 378, 380; Ex. 1015 ¶¶ 27, 29, 30, 36, 38–40, Figs. 1, 3–5).

Petitioner asserts that one of ordinary skill in the art “would have understood the thread to contain [a helical ‘groove’]” and “would have recognized that, even if the threading were configured as a rib, multiple

passes of the rib would create a groove running therebetween.” *Id.* at 65 (citing Ex. 1011 ¶¶ 349–351). Petitioner also argues that, if thread 6 lacks a helical groove, one of ordinary skill in the art “would have known to implement thread 6 as a groove from Steinfeldt-Jensen’s teaching of a similar dose-dial sleeve having a ‘helical track.’” *Id.* (citing Ex. 1014, 11:20–25, Fig. 17). Petitioner contends that “groove-to-rib and rib-to-groove threaded engagements were functionally equivalent and largely interchangeable.” *Id.* (citing Ex. 1011 ¶¶ 352–353). Petitioner also contends that “implementing such threading was a routine task,” “would have been viewed as no more than ‘the predictable use of prior art elements according to their established functions,’” and “would have had a reasonable expectation of success implementing thread 6 as a helical groove.” *Id.* at 65–66 (citing Ex. 1011 ¶ 353).

Patent Owner responds that Moller does not teach or suggest that “dose-setting drum 17 is configured to engage threading provided by said *main housing*” and instead, 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. 47–48. According to Patent Owner, tubular element 5 is “an interior, not exterior, component” and Moller describes tubular element 5 as separate and distinct from housing 1. *Id.* at 48–49 (citing Ex. 1015 ¶ 23, Fig. 1). Patent Owner contends that tubular element 5 is like the insert of the ’486 patent, which can be separate from the main housing. *Id.* at 49–50 (quoting Ex. 1003, 3:49–55; Ex. 1005, 2:66–3:2 (related patent)).

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,” we are persuaded sufficiently at this stage of the proceeding that Moller depicts “an *exterior 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 that, 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).

Patent Owner also responds that one of ordinary skill in the art would not have been motivated to modify Moller with the teachings of Steinfeldt-Jensen, as asserted by Petitioner. Prelim. Resp. 50–51. Patent Owner argues that Moller teaches away from Petitioner’s proposed modification because Moller identifies Steinfeldt-Jensen’s grooved features as a disadvantage that

is not adopted in its injection device. *Id.* at 51–52 (quoting Ex. 1015 ¶¶ 8, 11).

Patent Owner also argues that Moller considered the externally grooved dose scale drum 80 of Steinfeldt-Jensen and rejected it. *Id.* at 52–53 (citing Ex. 1015 ¶¶ 8, 11, Fig. 1). Patent Owner additionally argues that Petitioner and its declarant testimony do not explain, nor point to any evidence beyond Moller, as to why one of ordinary skill in the art would have modified Moller as proposed by Petitioner. *Id.* at 53. Patent Owner contends that one of ordinary skill in the art would not have modified Moller as proposed in view of Moller’s teaching away. *Id.*

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.

3. *Challenged Dependent Claims*

Petitioner argues that claims 2–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40, which depend from claim 1, are unpatentable over Moller and Steinfeldt-Jensen with citations to the reference and declarant testimony. Pet. 76–98.

For the reasons stated above, we determine that Petitioner adequately shows a reasonable likelihood of prevailing in its challenge of claim 1 as unpatentable over Steinfeldt-Jensen alone, and thus, we institute on all challenged claims on all presented challenges. We have also reviewed Petitioner’s arguments and evidence directed to the challenged dependent

claims and determine that Petitioner provides sufficient argument and evidence for purposes of institution. *See* Pet. 79–98. Because, at the present stage, Patent Owner does not make arguments specifically for the challenged dependent claims (*see* Prelim. Resp. 47–53), we determine that further analysis of Petitioner’s challenge of claims 2–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 is best left for trial after full development of the record.

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*, 138 S. Ct. at 1359–60. After considering the evidence and arguments presented in the Petition and the Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in proving that at least one of claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of the ’486 patent is unpatentable.

Because Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims, we institute an *inter partes* review of all challenged claims 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 claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of U.S. Patent No. 8,992,486 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. 8,922,486 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2018-01678
Patent 8,992,486 B2

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