

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 IPR2018-01684  
Patent 9,604,008 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, 3, 7, 8, 11, and 17 of U.S. Patent No. 9,604,008 B2 (Ex. 1005, “the ’008 patent”). Sanofi-Aventis Deutschland GmbH (“Patent Owner”) filed a Preliminary Response (Paper 13, “Prelim. Resp.”). Although authorized by our Order (Paper 10), Petitioner did not file a reply, and Patent Owner did not file a sur-reply in this proceeding. 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 Petition and Preliminary Response 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 the one presented challenge, and thus, institute an *inter partes* review of claims 1, 3, 7, 8, 11, and 17 of the ’008 patent.

## II. BACKGROUND

### A. *Related Proceedings*

The parties indicate that the ’008 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. 1–2; Paper 5, 2; Paper 7, 2; Paper 12, 2; Exs. 1029, 1030.



Figure 1 shows a sectional view of a drug delivery device. *Id.* at 6:7–8. The drug delivery device comprises a housing having first cartridge retaining part 2 and second main housing part 4.<sup>1</sup> *Id.* at 7:11–13. Main housing 4 includes helical rib 46. *Id.* at 8:61–62. The '008 patent indicates that helical rib 46 can be a thread. *See id.*

Dose dial sleeve 70 is radially inward of main housing 4. *Id.* at 8:55–56. Dose dial sleeve 70 has helical groove 74 provided about its outer surface. *Id.* at 8:56–58. Helical rib 46 of main housing 4 is adapted to be seated in helical groove 74. *Id.* at 8:61–64. The '008 patent indicates that helical groove 74 can be a thread. *See id.*

Clutch 60 is disposed between dose dial sleeve 70 and drive sleeve 30 at the second end of drive sleeve 30. *Id.* at 8:18–20, 8:34–35. Drive sleeve 30 has helical groove 38 extending along its internal surface. *Id.* at 7:62–63. The '008 patent indicates that helical groove 38 can be a thread. *See id.* Drive sleeve 30 extends about piston rod 20. *Id.* at 7:55.

Piston rod 20 has first thread 19 extending from an end and second thread 24 extending from another end of piston rod 20. *Id.* at 7:40–41, 7:45–47. Second thread 24 of piston rod 20 works within helical groove 38. *Id.* at 7:63–65. Insert 16 is provided at an end of main housing part 4 near cartridge retaining part 2, and insert 16 has threaded circular opening 18. *Id.* at 7:33–36.

---

<sup>1</sup> The '008 patent refers to “second main housing part 4” and “main housing 4” interchangeably. *Compare* Ex. 1003, 7:12–13 (“second main housing part 4”) *with id.* at 7:15 (“main housing 4”).

*C. Illustrative Claim*

The '008 patent has 19 claims, of which Petitioner challenges claims 1, 3, 7, 8, 11, and 17. Of those, claim 1, reproduced below, is the only independent claim.

1. A drive mechanism for use in a drug delivery device comprising:
  - a housing comprising a helical thread;
  - a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing,
  - an insert provided in the housing, where the insert has a threaded circular opening;
  - a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread;
  - a piston rod having a first thread and a second thread, wherein the first thread is engaged with the threaded circular opening of the insert and the second thread is engaged with the internal helical thread of the drive sleeve; and
  - a clutch located between the dose dial sleeve and the drive sleeve, wherein the clutch is located (i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve.

Ex. 1005, 17:28–45.

*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 2002/0052578 A1,<sup>2</sup> published May 2, 2002 (Ex. 1015, “Moller”).

---

<sup>2</sup> Petitioner identifies Exhibit 1015 as U.S. Patent No. 6,663,602 to Moller (Pet. 3); however, Exhibit 1015 is a patent application publication to Moller.

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

*E. Asserted Ground*

Petitioner challenges, under 35 U.S.C. § 103, claims 1, 3, 7, 8, 11, and 17 as unpatentable over Moller and Steinfeldt-Jensen. Pet. 3–4, 18–56.

III. CHALLENGE 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).<sup>3</sup>

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]” and the “ground presented below relies on the ordinary and customary meaning of the claim terms as they would be understood by a [person of ordinary skill].” Pet. 10, 12 (citing Ex. 1011 ¶¶ 108-1). Petitioner also provides interpretations of “insert,” “drive sleeve,” “thread,” “piston rod,” and

---

<sup>3</sup> 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, 1 (according filing date of September 10, 2018 to the Petition).

“clutch” that were proffered by Patent Owner in related litigation. *Id.* at 10–11 (citing Ex. 1019, 19–21, 24–25, 27–28, 32–33).

Patent Owner does not propose an interpretation for any claim term but “reserves the right to address the construction of all other terms should the Petition be instituted.” Prelim. Resp. 13–14 n.2. Patent Owner also responds that Petitioner does not state what the plain and ordinary meaning is for any term. *Id.* at 2, 13. Patent Owner additionally 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 2, 32–33.

By providing Patent Owner’s proposed interpretations from related litigation, we understand Petitioner to be contending 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 is interpreting the challenged claims in its application of the asserted references to the claim limitations.

Petitioner also notes that it proposed means-plus-function interpretations for “clutch” and “insert” in related litigation. Pet. 11 (citing Ex. 1028, 141–144, 150–152). Petitioner additionally proposes means-plus-function interpretations for these terms in this proceeding. *Id.* at 12 (citing Ex. 1005, 1:63–65, 2:16–18, 3:58–64, 8:48–50, 10:23–31, Figs. 1, 5–11; Ex. 1028, 135, 141–144, 152). Patent Owner disputes that “clutch” and “insert” are means-plus-function limitations. Prelim. Resp. (citing Pet. 11–12).

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 of these terms in view of the specification would be a means-plus-function interpretation. We also 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 during trial.

For the purposes of determining whether Petitioner demonstrates a reasonable likelihood of prevailing in its challenges, we determine that no express interpretation is required for any claim term. *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, through education or practical experience, at least the equivalent of a bachelor’s degree in mechanical engineering, or a related field” 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. 10 (citing Ex. 1011 ¶¶ 104–107). Patent Owner does not propose a level of ordinary skill at this stage of the proceeding.

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 one of the claims challenged in the Petition.



*C. Steinfeldt-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 Steinfeldt-Jensen are reproduced below.

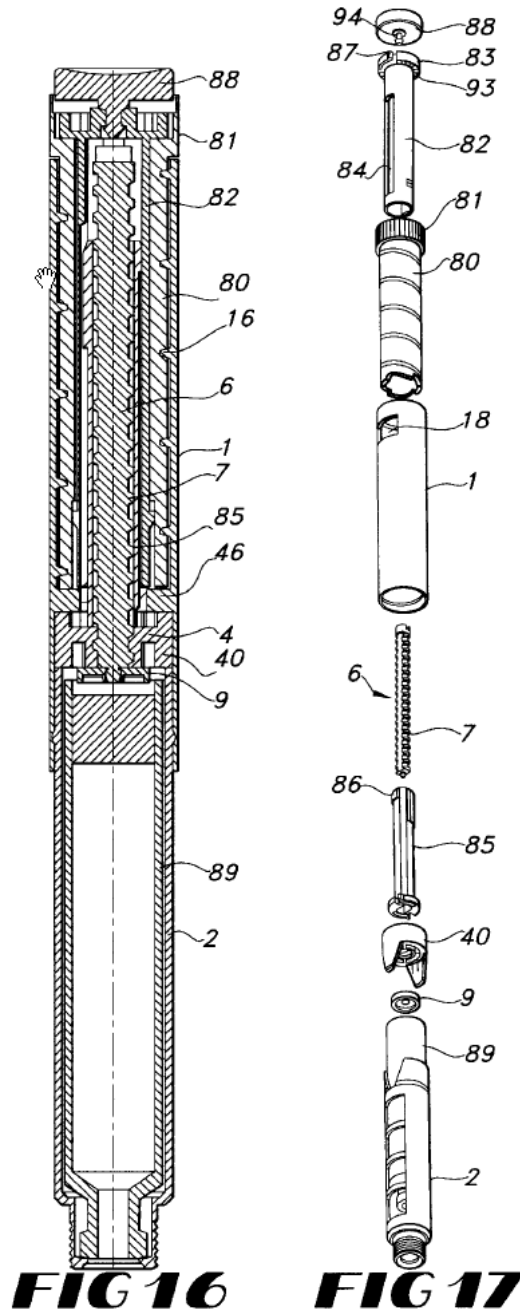


Figure 16 shows a side sectional view of a syringe, and Figure 17 shows an exploded view of that same syringe. *Id.* at 5:25–28. The syringe of Steinfeldt-Jensen includes tubular housing 1 that is partitioned so that a first division has ampoule holder 2. *Id.* at 5:38–40. Ampoule holder 2 has a central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

*D. 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.

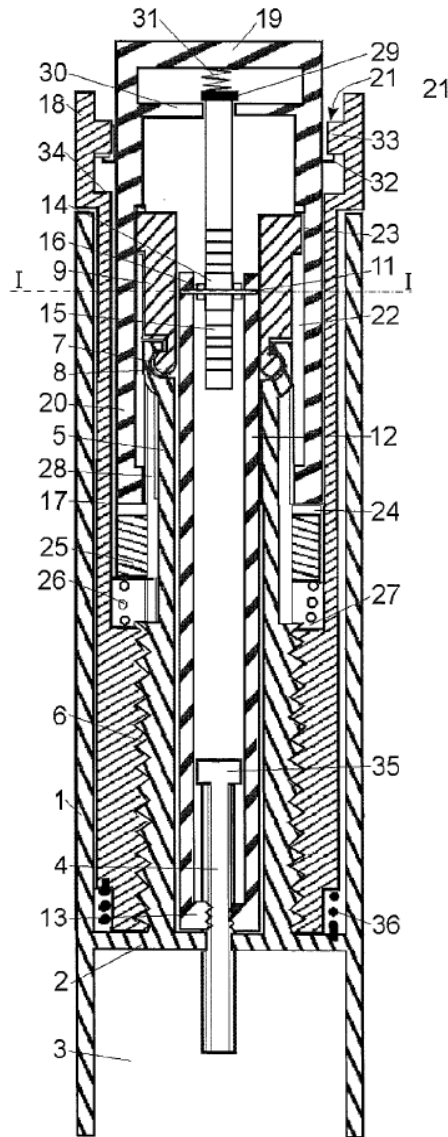


Fig. 1

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.

*E. Claims 1, 3, 7, 8, 11, and 17*

Petitioner contends that claims 1, 3, 7, 8, 11, and 17 are unpatentable over Moller and Steinfeldt-Jensen. Pet. 3, 18–56. In particular, Petitioner argues that the claims of the '008 patent were allowed after amending the claims to require a clutch that is “radially outward of the drive sleeve” and

“radially inward of the dose dial sleeve.” *Id.* at 18 (citing Ex. 1010, 231–233). Petitioner argues that these features were known as evidenced by Moller. *Id.* at 19 (citing Ex. 1011 ¶¶ 792–795; Ex. 1014, 7:84–8:24, Fig. 8; Ex. 1015 ¶¶ 30–31, Figs. 1, 5).

Petitioner provides claim charts and arguments with citations to where Moller and Steinfeldt-Jensen teach or suggest the elements of the claims and citations to supporting declarant testimony. *Id.* at 19–41, 44–56. To the extent “insert” or “clutch” is construed as means-plus-function limitations, Petitioner contends that Steinfeldt-Jensen teaches the “insert” and that Moller and Steinfeldt-Jensen would have rendered obvious the “clutch” with citations to the references and declarant testimony. *Id.* at 26–27, 39–41.

Petitioner also argues that one of ordinary skill in the art would have had a reason to combine Moller’s and Steinfeldt-Jensen’s dose-setting approaches. *Id.* at 19, 41. In particular, Petitioner starts with Moller, wherein rotating a knob on a dose indicator rotates a drive sleeve to set a dose and pressing an injection button decouples rotationally the dose indicator and the drive sleeve so that the drive sleeve moves axially without rotating. *Id.* at 41. Petitioner proposes modifying Moller so that its drive sleeve’s dose dispensing operates as taught by Steinfeldt-Jensen, wherein the drive sleeve engages a dual-threaded piston rod to drive the piston rod through a threaded piston rod holder. *Id.* (citing Ex. 1011 ¶¶ 832–833).

Petitioner contends that its proposed combination would be a simplification, a reduction of internal components, and an increase in durability that would have outweighed any concerns about an increase in friction and would have had a reasonable expectation of success. *Id.* at 18, 26 (citing Ex. 1011 ¶¶ 804–807, 832–837, Ex. 1014, 5:55–57, 7:41–43,

Fig. 7), 41–44 (citing Ex. 1011 ¶¶ 114–115, 120–122, 124, 832–833, 835–854; Ex. 1014, 6:42–7:29, 11:6–19, 12:4–12, Fig. 7; Ex. 1015 ¶¶ 6–11, 24–25, 30–31).

Patent Owner responds that one of ordinary skill in the art would not have been motivated to combine Moller and Steinfeldt-Jensen in the manner Petitioner asserts. Prelim. Resp. 1, 21–29. Patent Owner first contends that Moller expressly teaches away from Petitioner’s proposed modification because an objective of Moller is to provide an injection device without the disadvantages of the prior art. *Id.* at 21–22 (citing Ex. 1015 ¶ 11). According to Patent Owner, Moller criticizes mating threads because of undesirable friction losses and does not use threads. *Id.* at 22–23 (citing Ex. 1015 ¶¶ 8, 11, 33). Patent Owner also asserts that Petitioner mischaracterizes Moller and does not acknowledge that Moller disparages threaded gearing. *Id.* at 23 (citing Pet. 43; Ex. 1011 ¶ 836).

Whether Moller teaches 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.

Patent Owner also contends that Moller and Steinfeldt-Jensen are not similar, as asserted by Petitioner. Prelim. Resp. 23–24 (citing Pet. 41–42). Patent Owner argues that (1) Moller’s and Steinfeldt-Jensen’s gearing mechanisms are different; (2) Moller has a cup-shaped clutch mechanism that Steinfeldt-Jensen lacks and does not need; and (3) Moller’s piston rod is driven axially for dose injection, but Steinfeldt-Jensen’s piston rod is

screwed through a threaded opening for dose injection. *Id.* at 24–25 (citing Ex. 1014, 8:25–33, Fig. 7; Ex. 1015 ¶ 26, Fig. 1).

Petitioner, however, argues that the drive sleeves of Moller and Steinfeldt-Jensen “have similar piston-rod engagements and similar movement principles” and “provide the same benefits” with citations to these references and supporting declarant testimony. Pet. 42 (citing Ex. 1011 ¶¶ 832, 835; Ex. 1014, 6:42–7:29; Ex. 1015 ¶¶ 30–31). The asserted similarities provide sufficient support for Petitioner’s proposed combination for purposes of institution. After the record is fully developed, we will reanalyze whether one of ordinary skill in the art would have found enough similarities between Moller and Steinfeldt-Jensen so as to combine the references in the manner asserted by Petitioner.

Patent Owner also argues that Moller and Steinfeldt-Jensen have “different, conflicting objectives.” Prelim. Resp. 25. According to Patent Owner, “a principle objective of Moller is to provide a gearing between the injection button and piston rod that reduces reliance on threads due to their inherent frictional losses,” and “Steenfeldt-Jensen, by contrast, uses threads for gearing and focuses on . . . *e.g.*, minimizing the number of parts.” *Id.* at 25–26 (citing Ex. 1014, 1:27–30; Ex. 1015 ¶¶ 8, 11). Patent Owner further argues that the drive mechanism of Moller and Steinfeldt-Jensen “do not provide the same benefit.” *Id.* at 26. Patent Owner contends that the drive mechanism of Moller minimizes frictional losses and the force on its injection button but the pen of Steinfeldt-Jensen cannot. *Id.* at 26–27 (citing Ex. 1015 ¶¶ 6, 8, 11). Patent Owner also contends that Moller disparages Steinfeldt-Jensen and takes a different approach. *Id.* at 27 (citing Ex. 1015 ¶¶ 8, 11).

Petitioner characterizes the drive mechanisms for Moller and Steinfeldt-Jensen as “[e]ach involv[ing] a gearing mechanism that produces a mechanical advantage.” Pet. 42 (citing Ex. 1011 ¶ 835). Although the characterization may be broad, for institution purposes, it sufficiently supports Petitioner’s proposed combination of the references. Also, similar to the issues of teaching away and the asserted similarities between the asserted references, Patent Owner raises an issue that would benefit from a fully developed record, in particular, whether one of ordinary skill in the art considering the structural differences of the asserted references would have still combined the references as argued by Petitioner.

Patent Owner also responds that the purported benefits of Petitioner’s proposed modification (more durable pen with fewer parts that is less prone to malfunction and easier to use) are unsupported and entitled to little weight. Prelim. Resp. 23, 27 (citing Pet. 42–43). Patent Owner argues that the Petition cites no evidence that Moller is prone to malfunction or not durable and does not substantiate that one of ordinary skill in the art would have reduced the number of parts and eliminated advantageous features. *Id.* Patent Owner also contends that the cited portions of Petitioner’s declarant testimony are “conclusory statements about injection pens generally . . . without any supporting evidence.” *Id.* (citing Pet. 42–43; Ex. 1011 ¶¶ 835, 836). Patent Owner additionally contends that Petitioner fails to provide evidence that its proposed modification would be easier to use and argues that the proposed combination would result in higher friction and be harder to use. *Id.* at 28 (citing Pet. 43). Patent Owner further responds that “Petitioner has not shown that the proposed combination would be more advantageous than either pen alone” and that one of ordinary skill in the art



“would have just used Steinfeldt-Jensen’s pen instead of making Petitioner’s contrived combination.” *Id.* at 28. Patent Owner contends that Petitioner’s proposed combination “eliminates the unique advantage possessed by Moller’s pen” and “stems . . . from hindsight aimed solely at challenging the validity of the claim.” *Id.*

Petitioner, however, provides supporting declarant testimony that its proposed combination would reduce the number of components, thereby providing easier assembly and reducing the likelihood of mechanical malfunction. Pet. 43 (citing Ex. 1011 ¶¶ 835–854). Petitioner proposes combining the advantages of the individual references and, therefore, contends that the proposed combination would have the asserted benefits over the individual references. *See id.* at 42–43. Also, those benefits of Petitioner’s proposed combination sufficiently show that Petitioner is not relying on hindsight. At this stage, Petitioner’s asserted benefits are sufficient for institution. Instituting trial would provide Patent Owner the opportunity to depose Petitioner’s declarant and submit evidence disputing the benefits of Petitioner’s proposed combination.

Patent Owner also responds that Petitioner’s proposed combination fails to teach or suggest a housing having a helical thread engaged with a dose dial sleeve. Prelim. Resp. 1–2, 29–32. According to Patent Owner, Petitioner points to Moller’s housing 1, wall 2, and tubular element 5 and argues that these components together teach the housing of claim 1. *Id.* at 29 (citing Pet. 22), 30 (citing Pet. 21). Patent Owner argues that Moller treats its housing 1, wall 2, and tubular element 5 as separate components and “repeatedly references these discrete parts separately throughout the specification without once treating them collectively as a housing.” *Id.* at

29–31 (citing Ex. 1015 ¶¶ 22–25, 27, 29–34). Patent Owner also argues that Moller distinguishes itself from prior art devices that included a housing with a helical thread. *Id.* at 31 (quoting Ex. 1015 ¶¶ 8, 11).

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”). 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 Figs. 1 and 2 show one embodiment and Figs. 3–5 show another embodiment).

Patent Owner also disputes Petitioner’s argument that wall 2 of Moller teaches “an insert provided in the housing,” as recited by claim 1. Prelim. Resp. 31 (citing Pet. 25). Patent Owner contends that “[i]f wall 2 is part of the housing, then wall 2 cannot be the insert” and “[i]f wall 2 is the insert, it cannot be part of the housing.” *Id.* at 32.

We agree with Patent Owner that, if Moller’s wall 2 is part of Petitioner’s asserted housing, then Petitioner does not explain sufficiently how it is also the recited “insert provided in the housing” in view of its arguments regarding “a housing comprising a helical thread.” For the “insert provided in the housing,” Petitioner asserts that “Moller teaches the

use of wall 2” without further explanation. Pet. 25 (citing Ex. 1015 ¶ 22, Fig. 1). Petitioner relies on paragraph 22 and Figure 1 of Moller. *Id.* Paragraph 22 states that “an elongated cylindrical housing 1 has a partitioning wall 2 which divides the housing . . .” and goes on to describe how piston rod 4 fits through wall 2. Figure 1 shows wall 2 as part of housing 1. *See* Pet. 22 (providing annotated Fig. 1 of Moller that indicates wall 2 is part of housing 1); Ex. 1011 ¶ 799 (showing the same annotated Fig. 1 that includes wall 2 as part of housing 1). Petitioner’s declarant testimony regarding “an insert provided in the housing” does not explain any further how Moller’s wall 2 teaches the limitation in view of previous arguments regarding the housing. *See* Ex. 1011 ¶¶ 804–809. Thus, we agree with Patent Owner that Petitioner does not explain sufficiently how Moller’s wall 2 teaches “an insert provided in the housing” in view of its previous arguments regarding “a housing comprising a helical thread.”

Petitioner, however, provides argument and evidence that wall 4 of Steinfeldt-Jensen is the required insert of claim 1. *See* Pet. 25–28. At this stage of the proceeding, Petitioner shows enough for purposes of institution that Steinfeldt-Jensen teaches “an insert provided in the housing, where the insert has a threaded circular opening.” *See id.*

For the reasons above, we determine that Petitioner demonstrates a reasonable likelihood of prevailing in its challenge of claim 1 of the ’008 patent as unpatentable Moller and Steinfeldt-Jensen. 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 the one presented ground. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

Regarding claims 3, 7, 8, 11, and 17, which depend from claim 1, we provide the following guidance for the parties. Claim 3 recites “wherein the insert is secured in the housing against rotational and longitudinal motion.” Ex. 1005, 17:53–55. Petitioner contends that Moller’s wall 2 and Steinfeldt-Jensen’s wall 4 each teach the limitations of claim 3. Pet. 44–46. As discussed above regarding Petitioner’s arguments for the insert of claim 1 and Moller’s wall 2, Petitioner does not explain adequately how Moller’s wall 2 teaches claim 1’s insert in view of arguments regarding the housing of claim 1. Petitioner’s argument for claim 3 likewise does not explain how Moller’s wall 2 is the insert of the challenged claims in view of the arguments regarding the housing. *See id.* at 44–46 (citing Ex. 1015 ¶ 22, Fig. 1).

Turning to Steinfeldt-Jensen’s wall 4 at the end of ampoule holder 2, Petitioner points us to where Steinfeldt-Jensen describes wall 4 and to supporting declarant testimony. Pet. 45–46 (citing Ex. 1011 ¶¶ 839–841; Ex. 1014, 5:55–57, 7:41–47, Fig. 7); *see also* Ex. 1014, 5:55–56 (stating that the “end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 . . .”). Steinfeldt-Jensen, however, does not describe wall 4 as being rotationally fixed. Steinfeldt-Jensen’s column 5, lines 55 to 57 merely states that ampoule holder 2 is closed by wall 4, which is consistent with Petitioner’s contention. Steinfeldt-Jensen’s column 7, lines 41 to 43 states that end wall 4 forms a nut member relative to which the piston rod is rotated. The Petition does not explain how this disclosure would have demonstrated to a person having ordinary skill in the art that wall 4 cannot rotate relative to housing 1.

Petitioner also points to Figure 7, which shows another embodiment, but the description related to wall 4 of Figure 1 applies to the embodiment of Figure 7. *See* Ex. 1014, 7:48–50 (stating that “[a]nother embodiment is described with reference to the FIGS. 6–10” and that “[e]lements corresponding to elements in the embodiment described with references to the FIGS. 1–5 are provided with the same reference numbers”). In connection with the embodiment shown in Figure 1, Steinfeldt-Jensen states that “[b]y this snap connection the ampoule holder 2 is secured in the housing 1 so that it *can be rotated* but not axially displaced relative to this housing.” Ex. 1014 5:44–46 (emphasis added). Both Figures 1 and 7 show ampoule holder 2 with wall 4 and ring shaped bead 3 that forms a snap lock. *See id.* at 5:40–42 (“[A]mpoule holder 2 is snapped by a snap lock comprising a ring shaped bead 3 on the ampoule holder 2 . . .”).

Paragraphs 839–841 of declarant testimony further explain that member 40 of yet another embodiment is interchangeable with the asserted insert of Figures 6–10. Petitioner’s declarant, however, does not explain why separate member 40 would be interchangeable with ampoule holder 2 of Figures 6–10. *See* Ex. 1011 ¶¶ 839–841; Ex. 1014, 8:42–44 (describing ampoule holder 2 of Figs. 11–13). Further, neither the Petition nor declarant testimony explain adequately how the different embodiments of Steinfeldt-Jensen affect how wall 4 rotates relative to housing 1 or on which embodiment Petitioner relies.

As for the remaining challenged dependent claims, we are satisfied at this stage that Petitioner provides enough argument and evidence to show a reasonable likelihood of prevailing in its challenge of claims 7, 8, 11, and 17. Patent Owner also has not yet presented arguments and evidence

specific to any of the challenged dependent claims. Thus, we determine that any further analysis of Petitioner's challenge of claims 3, 7, 8, 11, and 17 is best left for trial after full development of the record.

#### IV. CONCLUSION

After considering the evidence and arguments in the present record, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one of claims 1, 3, 7, 8, 11, and 17 of the '008 patent is unpatentable.

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.

#### V. 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, 3, 7, 8, 11, and 17 of U.S. Patent No. 9,604,008 B2 is instituted with respect to the one ground set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 9,604,008 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2018-01684  
Patent 9,604,008 B2

**PETITIONER:**

Richard Torczon  
Douglas Carsten  
Wesley Derryberry  
Tasha Thomas  
Lorelei Westin  
Nicole Stafford

**WILSON SONSINI GOODRICH & ROSATI**

rtorczon@wsgr.com  
dcarsten@wsgr.com  
wderryberry@wsgr.com  
tthomas@wsgr.com  
lwestin@wsgr.com  
nstafford@wsgr.com

**PATENT OWNER:**

Elizabeth Stotland Weiswasser  
Anish R. Desai  
William S. Ansley  
**WEIL, GOTSHAL & MANGES LLP**  
elizabeth.weiswasser@weil.com  
anish.desai@weil.com  
sutton.ansley@weil.com