

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 IPR2018-01696  
Patent 9,526,844 B2

---

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

MAYBERRY, *Administrative Patent Judge*.

DECISION DENYING INSTITUTION  
*35 U.S.C. § 314*

## I. INTRODUCTION

Petitioner, Mylan Pharmaceuticals Inc. (“Mylan”), filed a Petition (Paper 2, “Pet.”) requesting *inter partes* review of claims 21–30 (the “Challenged Claims”) of U.S. Patent No. 9,526,844 B2 (Ex. 1004, the “’844 patent”). Pet. 1. Patent Owner, Sanofi-Aventis Deutschland GmbH (“Sanofi”), filed a Preliminary Response (“Prelim. Resp.”) to the Petition. Paper 13. With our authorization, Mylan filed a Reply and Sanofi a Sur-Reply to the Preliminary Response. Papers 14, 16. We have jurisdiction under 35 U.S.C. § 314. *See also* 37 C.F.R. § 42.4(a) (permitting the Board to render institution decisions on behalf of the Director).

To institute an *inter partes* review, we must determine whether the information presented in the Petition shows “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). For the reasons set forth below, upon considering the present record, we determine that Mylan has not established a reasonable likelihood that it would prevail with respect to at least one of the Challenged Claims. So, we do not institute an *inter partes* review.

### A. Related Matters

The parties indicate that the ’844 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.

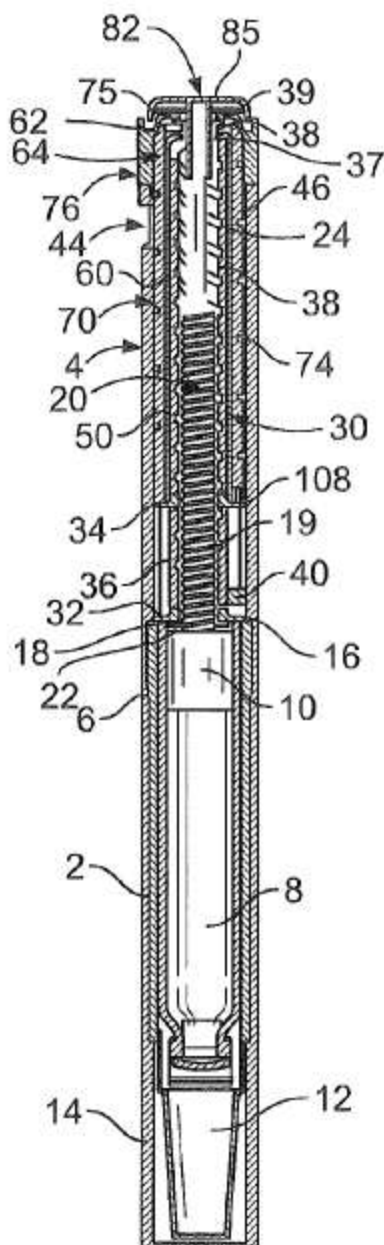
The parties state that the ’844 patent is also challenged in Cases IPR2018-01680 and IPR2018-01682. Pet. 2; Paper 5, 3; Paper 7, 3.

IPR2018-01696  
Patent 9,526,844 B2

The parties also state that related patents are challenged in Cases IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01677, IPR2018-01678, IPR2018-01679, and IPR2018-01684. Pet. 1–2; Paper 5, 2–3; Paper 7, 2–3.

*B. The '844 Patent*

The '844 patent, titled “Pen-Type Injector,” issued December 27, 2016 from an application filed May 17, 2016. Ex. 1004, [54], [45], [22]. The application that matured into the '844 patent claims priority to a foreign application filed March 3, 2003. *Id.* at [30]. The '844 patent “relates to pen-type injectors . . . where a user may set the dose.” *Id.* at 1:25–29. Figure 1 of the '844 patent is reproduced below.



**FIG. 1**

Figure 1 “shows a sectional view of a pen-type injector . . . in a first, cartridge full position.” *Id.* at 2:60–62. The injector includes first cartridge retaining part 2 and main housing part 4. *Id.* at 3:37–38. Insert 16 is at a first end of housing part 4 and is fixed rotationally and axially to housing part 4. *Id.* at 3:58–59. Insert 16 includes threaded circular opening 18,

through which piston rod 20 extends. *Id.* at 3:59–62. Piston rod 20 includes first thread 19 that engages threaded circular opening 18. *Id.* at 3:65–4:1.

Piston rod 20 also includes pressure foot 22 that abuts piston 10 of cartridge 8. Ex. 1004, 4:1–3. 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 4:13–23.

Clicker 50 and clutch 60 are disposed between drive sleeve 30 and dose dial sleeve 70. Ex. 1004, 4:42–44. Clicker 50 is generally cylindrical and includes, at one end, extending arm 52 and, at the other end, saw teeth 56. *Id.* at 4:46–53. Clutch or clutch means 60 includes, at one end, saw teeth 66, which interface with saw teeth 56. *Id.* at 4:59–61, Fig. 7.

Clutch 60 is generally cylindrical and includes a radially inwardly directed flange 62 and dog teeth 65 at the end opposite of saw teeth 66. *Id.* at 4:63–67. Clutch 60 is keyed to drive sleeve 30 by splines to prevent relative rotation between clutch 60 and drive sleeve 30. *Id.* at 5:2–4.

Dose-dial sleeve 70 is outside of clutch 60 but within housing 4. Ex. 1004, 5:12–14. 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 to allow relative motion. *Id.* at 5:14–20. 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 5:34–39.

In operation, 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 housing part 4. Ex. 1004, 5:60–64, Fig. 9. The dose can be reduced by turning dose-dial grip 76 in the opposite direction. *Id.* at 6:28–30, Fig. 10. Clicker 50 and clutch 60 provide audible and tactile feedback of the dose

being dialed, as torque is transmitted through the saw teeth 56, 66. *Id.* at 5:64–66. Flexible arm 52 deforms and drags toothed member 54 over splines 42 to produce a click. *Id.* at 5:67–6:2. Splines 42 may be configured such that each click corresponds to a unit dose. *Id.* at 6:2–2. Once the proper dose is set, 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 6:38–45, 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 6:55–57. Drive sleeve 30 is prevented from rotating by the deformation of flexible arm 52, such that saw teeth 56, 66 are not overhauled. *Id.* at 6:46–48.

### *C. Challenged Claims*

Of the Challenged Claims, claim 21 is the sole independent claim and is reproduced below.

21. A drug delivery device comprising:
  - a housing comprising a dose dispensing end and a first thread;
  - a dose indicator comprising a second thread that engages with the first thread;
  - a driving member comprising a third thread;
  - a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;
  - a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;
  - a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing;

wherein:

the housing is disposed at an outermost position of the drug delivery device;

the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing;

the driving member is configured to rotate relative to the piston rod;

the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and

the piston rod and the driving member are configured to rotate relative to one another during dose dispensing; and

the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

Ex. 1004, 8:16–49.

#### *D. The Applied References*

Mylan's asserted grounds of unpatentability for the Challenged Claims rely on the following three references:

Steenfeldt-Jensen	US 6,235,004 B1	May 22, 2001	Ex. 1014
Moller	US 2002/0052578 A1	May 2, 2002	Ex. 1015
Klitgaard	US 6,582,404 B1	June 24, 2003	Ex. 1017

Mylan also relies on the declaration testimony of Mr. Karl R. Leinsing. *See* Ex. 1011.

#### *E. Asserted Grounds of Unpatentability*

Mylan asserts two grounds of unpatentability (1) claims 21–29 are unpatentable under 35 U.S.C. § 103 over Moller and Steenfeldt-Jensen; and

(2) claim 30 is unpatentable under 35 U.S.C. § 103 over Moller, Steinfeldt-Jensen, and Klitgaard. Pet. 3.

*F. Overview of the Applied References*

We provide a brief summary of the applied references below.

*1. Moller*

Moller, titled “Injection Device,” published May 2, 2002. Ex. 1015, [54], [43]. 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.” *Id.* ¶ 1. Figure 1 of Moller is reproduced below.

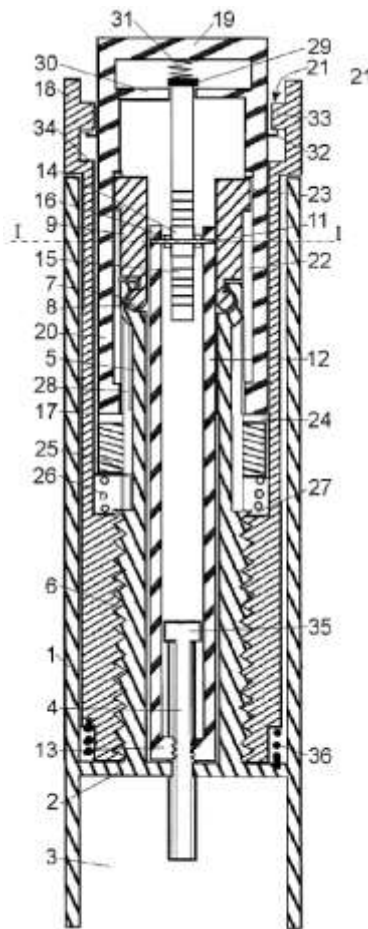


Fig. 1



Figure 1 depicts “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. Ex. 1015 ¶ 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. Ex. 1015 ¶ 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. Ex. 1015 ¶ 29. Bottom 19 of the cup shaped element is pressed to inject the set dose. *Id.* ¶ 32.

## 2. *Steenfeldt-Jensen*

*Steenfeldt-Jensen*, titled “Injection Syringe,” issued May 22, 2001, from an application filed October 28, 1999. Ex. 1014, [54], [45], [22].

Steenfeldt-Jensen relates to “injection syringes of the kind apportioning set doses of a medicine from a cartridge . . . [and] are mainly made for users who have to inject themselves frequently, e.g. diabetics.” *Id.* at 1:12–17.

We reproduce Steenfeldt-Jensen’s Figures 15–17, depicting an exemplary embodiment, below.

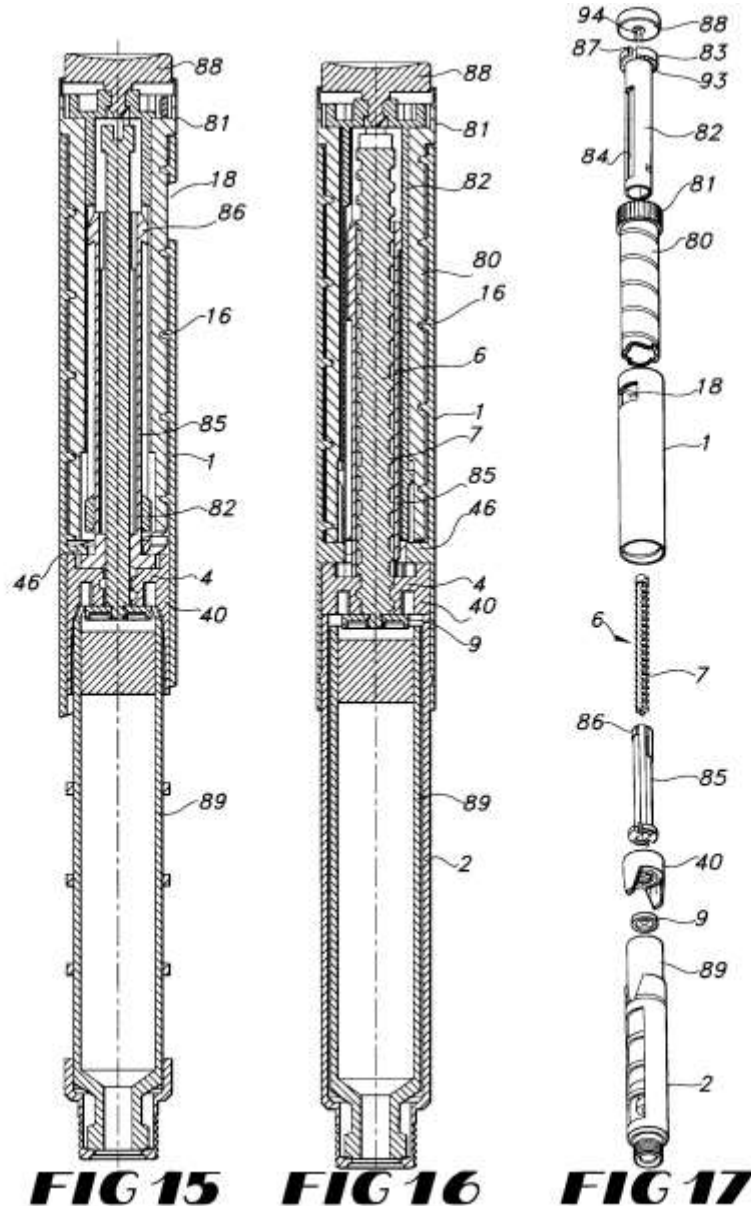


Figure 15 depicts “a sectional side view of” Steenfeldt-Jensen’s injection syringe and Figure 16 depicts a “sectional side view perpendicular to the

view in [Figure] 15.” Ex. 1014, 5:23–26. Figure 17 depicts “an exploded view of the syringe in [Figures] 15 and 16.” *Id.* at 5:27–28. Steinfeldt-Jensen’s injection syringe 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.* 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.

Steenfeldt-Jensen also discloses:

To set a dose the ampoule holder 2 is rotated anticlockwise in the first division of the housing 1. This rotation is performed against a resistance presented due to the fact that a protrusion 30 on the outer wall of the ampoule holder rests in one of a number of depressions 31 circumferentially provided in the inner wall of said first division of the housing as shown in the cross-sectional view in FIG. 3. The angular spacing of the depressions are appropriately made so that a dose of one unit is set when the protrusion is moved from one depression to the [neighboring] depression so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose.

*Id.* at 6:42–53. That is, the audible and tactile clicks formed when setting the dose for Steenfeldt-Jensen’s pen represent one unit of dose.

## 2. Klitgaard

Klitgaard, titled “Dose Setting Limiter,” issued June 24, 2003 from an application filed September 6, 2000. Ex. 1017, (54), (45), (22). Klitgaard is directed to “injection devices where[] the contents of a cartridge are injected as a number of individually set doses.” *Id.* at 1:13–15. We reproduce Klitgaard’s Figure 3, below.

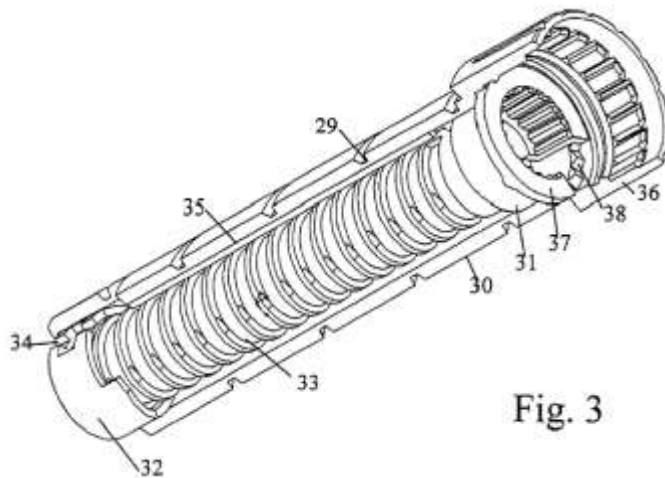


Fig. 3

Figure 3 depicts “the dose setting member, the driver, and the track follower of an[] embodiment of an injection syringe.” *Id.* at 2:60–63. Relevant to our decision, Klitgaard discloses nut member 32, which is disposed between dose setting-member 30 and driver 31. *Id.* at 4:26–29. During dose setting, nut member 32 rotates with dose-setting element 30 relative to driver 31 because of the engagement between ridge 35 and recess 34, such that the position of nut member 32 on driver 31 depends on the set dose. *Id.* at 4:33–37. When the medicine is injected, dose-setting member 30 is forced to rotate relative to the housing and transmits rotational force to driver 31, but nut member 32 maintains its position on driver 31, such that the position indicates the total injected dose. *Id.* at 4:37–58.

## II. ANALYSIS

### *A. Our Discretion under § 314(a)*

Sanofi contends that we should exercise our discretion under 35 U.S.C. §§ 314(a) to deny the Petition. Prelim. Resp. 4. Because we deny institution on the merits, we need not address this argument.

### *B. Level of Ordinary Skill in the Art*

The level of skill in the art is “a prism or lens” through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Mylan 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 basic mechanical elements (*e.g.*, gears, pistons) involved in drug-delivery devices.” Pet. 19 (citing Ex. 1011 ¶ 106). Sanofi does not

dispute this characterization nor does it provide its own characterization of the level of ordinary skill in the art.

We preliminarily adopt Mylan's asserted level of ordinary skill solely to determine whether there is a reasonable likelihood that Mylan would prevail with respect to at least one of the claims challenged in the Petition.

### *C. Claim Construction*

The claim construction standard to be employed in an *inter partes* review recently has changed. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. § 42). That new standard, however, applies only to proceedings in which the petition is filed on or after November 13, 2018. The Petition in this proceeding was accorded a filing date of September 10, 2018, and we apply the broadest reasonable interpretation standard that was in effect at that time. *See* Paper 8; 37 C.F.R. § 42.100(b) (2016). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Also, we are careful not to read a particular embodiment appearing in the written description into the claim. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) (“[L]imitations are not to be read into the claims from the specification.”).

Mylan asserts that “[f]or this [P]etition, claim terms should be given their ordinary and accustomed meaning, consistent with the specification and how they would have been understood by” a person having ordinary skill in the art. Pet. 19. Mylan also asserts that, in the parallel District Court

litigation, Sanofi has taken claim construction positions for certain claim terms<sup>1</sup>, and that the broadest reasonable interpretation of those term should at least encompass Sanofi’s proposed constructions. *Id.* at 19–20.

Mylan also asserts that, in the parallel District Court litigation, Mylan proposed means-plus-function constructions for the terms “clutch,” “clicker,” and “holder.” Pet. 21. Mylan identifies the functions and structures related to these three terms. *See id.* at 21–22.

Sanofi contends that Mylan fails to satisfy its obligations under our rules to “clearly identify[] how the claims are to be construed.” Prelim. Resp. 64. Sanofi argues that the Petition (1) indicates that the ordinary and customary meaning of the claim terms apply; (2) provides express constructions based on Sanofi’s positions in the parallel District Court litigation; and (3) identifies certain terms as means-plus-function terms. *Id.* at 65. Sanofi argues that the Petition “puts the onus on [Sanofi] to guess what constructions were applied. This unfairly prejudices [Sanofi’s] ability to defend its patent, and independently warrants denying the Petition.” *Id.*

We do not agree. We determine that, at this stage of the proceeding, Mylan has adequately identified how the claim terms of the Challenged Claims should be construed—the ordinary and customary meaning of the terms. In reviewing Mylan’s application of the prior art to the claim terms, we determine that Sanofi and the Board are able to determine how Mylan

---

<sup>1</sup> Mylan presents Sanofi’s proposed district court litigation constructions for the terms: “driving member,” “main housing,” “piston rod,” “the piston rod and the driving member are configured to rotate relative to one another during dose dispensing,” “thread,” “clutch,” “clicker,” and “holder.” Pet. 19–20.

interprets the claim terms based on how Mylan applies the prior art to the claims, allowing us to reach the merits of the Petition.

For the purposes of determining whether Mylan 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 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). With respect to the terms “clutch,” “clicker,” and “holder,” we need not determine, at this stage of the proceeding, if these terms are means-plus-function terms, as Mylan provides alternative analyses with respect to claims reciting these terms.

#### *D. Asserted Grounds of Unpatentability*

Mylan’s grounds of unpatentability are based on obviousness. *See* Pet. 3. A patent claim is unpatentable as obvious when “the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. § 103 (2012).<sup>2</sup> The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any

---

<sup>2</sup> We quote the AIA version of 35 U.S.C. § 103, which applies to applications with an effective filing date after March 16, 2013, however, the pre-AIA version of § 103 is nearly identical and any differences do not affect our analysis here.



differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art;<sup>3</sup> and (4) when available, secondary considerations, such as commercial success, long felt but unsolved needs, and failure of others.<sup>4</sup> *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We address these factual determinations below.

*1. Claims 21–29 as allegedly unpatentable over Moller and Steinfeldt-Jensen*

a. Effective filing date of the '844 patent.

Mylan asserts that the '844 patent is entitled to a priority date of May 17, 2016, making Moller and Steinfeldt-Jensen prior art under AIA 35 U.S.C. § 102(a). *See* Pet. 15–18. Sanofi disputes this position, contending that the '844 patent is entitled to the priority date of March 3, 2003, the filing date of Great Britain patent application 0304822.0. *See* Prelim. Resp. 39; Ex. 1004, [30]. Sanofi argues, however, that we need not reach this issue here, given that the issue dates of Steinfeldt-Jensen and Klitgaard and the publication date of Moller are before March 3, 2003. *Id.*

We agree with Sanofi that we need not reach this issue.

b. Independent claim 21.

Relevant to our analysis, claim 21 recites “a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing.” Ex. 1004, 8:27–31 (the “piston rod holder” limitation). Mylan contends that “[b]oth Møller and Steinfeldt-Jensen teach the use of a piston rod holder that is

---

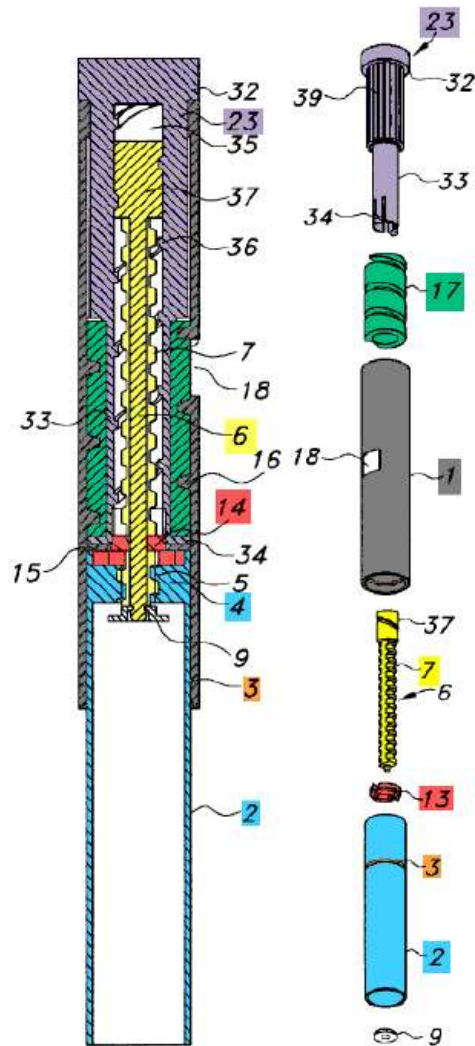
<sup>3</sup> We addressed the level of ordinary skill in the art in Section II.B., *supra*.

<sup>4</sup> Sanofi does not present any evidence concerning secondary considerations at this stage of the proceeding.

rotat[a]bly fixed in the housing,” identifying Moller’s wall 2 and Steinfeldt-Jensen’s wall 4. Pet. 43 (referencing Ex. 1014, 5:55–57; Ex. 1015 ¶ 22, Fig. 1). Mylan, however, discusses only Steinfeldt-Jensen’s wall 4 in asserting that the combination of Moller and Steinfeldt-Jensen discloses the subject matter of the “piston holder” limitation. *See id.* at 43–47. In discussing wall 4, Mylan states “[b]ased on the disclosure of Steinfeldt-Jensen, a [person having ordinary skill in the art] would understand that the wall 4 is rotatably fixed relative to the housing.” *Id.* at 45 (referencing Ex. 1011 ¶ 725; Ex. 1014, 5:55–57; 7:41–43, 8:35–42). Mr. Leinsing declares that “[i]n my opinion, a person of ordinary skill in the art would have understood end wall 4 is ‘rotatably fixed relative to the housing’ since it is an integral part of the housing.” Ex. 1011 ¶ 725 (referencing Ex. 1014, 5:66–6:41).

Sanofi argues that “[t]he Petition does not explain how Møller’s wall 2 satisfies any of the other elements of this limitation, and instead attempts to explain how only Steinfeldt-Jensen’s wall 4 meets all elements of [the ‘piston rod holder’] limitation.” Prelim. Resp. 60. Sanofi adds that Steinfeldt-Jensen’s wall 4 fails to satisfy the limitation, as it is not rotatably fixed to the housing. *Id.*

Sanofi explains that wall 4 is an integral part of ampoule holder 2. Prelim. Resp. 60–61. We reproduce Sanofi’s annotated version of Steinfeldt-Jensen’s Figures 7 and 8, below.



Ex. 1014, Figs. 7, 8.

*Id.* at 61. These annotated figures colorize certain components of the figures and depict ampoule holder 2 with wall 4 in blue. *See id.* at 60–61. Sanofi argues that Steinfeldt-Jensen expressly discloses that ampoule holder 2 can rotate relative to housing 1. *Id.* at 62. Sanofi continues that, because wall 4 is an integral part of ampoule holder 2, it also rotates relative to housing 1.

We determine that the Petition fails to explain adequately how Moller’s wall 2 satisfies the “piston rod holder” limitation or how Steinfeldt-Jensen’s wall 4 is rotatably fixed relative to the housing as

required by the “piston rod holder” limitation. With respect to Moller’s wall 2, Mylan contends that Moller’s housing 1 and threads 6 teach the “housing comprising a dose dispensing end and a first thread” recited by claim 21. *See* Pet. 31–33. Wall 2, which is between housing 1 and thread 6, appears to be a part of Mylan’s asserted housing (*see id.* at 32 (annotated Fig. 1)), but Mylan does not expressly contend that wall 2 is part of the asserted housing (*see id.* at 33). For the “piston rod holder” limitation, Mylan expressly asserts that wall 2 teaches the limitation. *See id.* at 43. If wall 2 is not a part of the asserted housing, Mylan does not explain adequately how housing 1 can comprise thread 6, and if wall 2 is a part of the asserted housing, Petitioner does not argue sufficiently why one of ordinary skill in the art would have understood wall 2 as teaching both a part of the housing and the required piston rod holder. In particular, Mylan does not address sufficiently why one of ordinary skill in the art would have understood that Moller teaches wall 2 as simultaneously forming the housing and a structure fixed to the housing. *See id.* at 31–33, 43–47. Mylan’s reason for combining the references also does not address Moller’s wall 2. *See id.* at 55–58.

With respect to Steinfeldt-Jensen’s wall 4, Mylan relies on Exhibit 1011, paragraph 725 and Exhibit 1014, column 5, lines 55 to 57; column 7, lines 41 to 43; and column 8, lines 35 to 42 in support of its contention with respect to the “piston rod holder” limitation. Pet. 45. Mr. Leising’s testimony at paragraph 725 in turn relies on Exhibit 1014, column 5, line 66 to column 6, line 41. Ex. 1011 ¶ 725. As explained below, we determine that these citations do not provide sufficient support for Mylan’s contention.

Steenfeldt-Jensen’s column 5, lines 55 to 57 merely states that ampoule holder 2 is closed by wall 4, which is consistent with Sanofi’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. Steinfeldt-Jensen's column 8, lines 35 to 42 states that end wall 4 is provided in member 40, which is mounted in an end of the housing. Again, 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, for example, that end wall 4 cannot rotate relative to member 40, which cannot rotate relative to housing 1. Nor does the Petition adequately explain how the different embodiments of Steinfeldt-Jensen affect how wall 4 rotates relative to housing 1 or on which embodiment Mylan relies. *Compare* Pet. 44 (identifying the embodiment of Steinfeldt-Jensen's Figure 7) *with* Ex. 1014, 8:35–42 (discussing the embodiment of Steinfeldt-Jensen's Figures 11–13).

Mr. Leinsing's reliance on Steinfeldt-Jensen's column 5, line 66 to column 6, line 41 is equally unpersuasive. This extensive section in Steinfeldt-Jensen describes the structure of a number of components of the embodiment of Steinfeldt-Jensen's Figure 1. Mr. Leinsing fails to identify, with any specificity, how this disclosure would have demonstrated to a person having ordinary skill in the art that wall 4 cannot rotate relative to housing 1.

As Sanofi points out, Steinfeldt-Jensen discloses that ampoule holder 2 (of which wall 4 is a part) snaps into a snap lock such that “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, 5:38–46 (emphasis

added); *see also id.* at Figs. 2, 7 (depicting wall 4 as an integral part of ampoule holder 2). The Petition fails to explain adequately how this disclosure is consistent with Mylan's contention that a person having ordinary skill in the art would have understood that wall 4 is rotatably fixed relative to the housing as required by the "piston rod holder" limitation of claim 21. Indeed, this disclosure at least suggests that wall 4 rotates relative to the housing.

For the reasons above, we determine, on the current record, that the information in the Petition fails to demonstrate a reasonable likelihood that independent claim 21 is unpatentable under 35 U.S.C. § 103 over Moller and Steinfeldt-Jensen.

c. Dependent claims 22–29.

As claims 22–29 depend, directly or indirectly, from independent claim 21, we determine, on the current record, that the information in the Petition fails to demonstrate a reasonable likelihood that dependent claims 22–29 are unpatentable over Moller and Steinfeldt-Jensen for the same reasons discussed above.

*2. Claim 30 as allegedly unpatentable under 35 U.S.C. § 103 over Moller, Steinfeldt-Jensen, and Klitgaard*

Mylan relies on its position that claim 21 is obvious over Moller and Steinfeldt-Jensen in asserting that claim 30 is obvious. Pet. 70. Because claim 30 depends from claim 21, we determine, on the current record, that the information in the Petition fails to demonstrate a reasonable likelihood that claim 30 is unpatentable under 35 U.S.C. § 103 over Moller, Steinfeldt-Jensen, and Klitgaard for the same reasons discussed above.

### III. CONCLUSION

After considering the evidence and arguments presented in the Petition, including its supporting testimonial evidence, and the Preliminary Response, we determine that Mylan has not established a reasonable likelihood that it would prevail with respect to at least one of the Challenged Claims. Accordingly, we do not institute an *inter partes* review.

### IV. ORDER

After due consideration of the record before us, it is:  
ORDERED that that the Petition is *denied* as to all challenges and no trial is instituted.

IPR2018-01696  
Patent 9,526,844 B2

For PETITIONER:

Richard Torczon  
Douglas Carsten  
Wesley Derryberry  
Tasha Thomas  
Lorelei Westin  
Nicole Stafford  
rtorczon@wsgr.com  
dcarsten@wsgr.com  
wderryberry@wsgr.com  
tthomas@wsgr.com  
lwestin@wsgr.com  
nstafford@wsgr.com

For PATENT OWNER:

Elizabeth Weiswasser  
Anish Desai  
William Ansley  
elizabeth.weiswasser@weil.com  
anish.desai@weil.com  
sutton.ansley@weil.com