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Paper No. 19
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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 IPR2018-01682
Patent 9,526,844 B2

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

MAYBERRY, *Administrative Patent Judge*.

DECISION TO INSTITUTE
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 established a reasonable likelihood that it would prevail with respect to at least one of the Challenged Claims. So, we institute an *inter partes* review of all Challenged Claims on all grounds. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018) (holding that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition).

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 IPR2018-01696. Pet. 2 (identifying the -01680 case only); Paper 5, 3; Paper 7, 3.

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.*, [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.

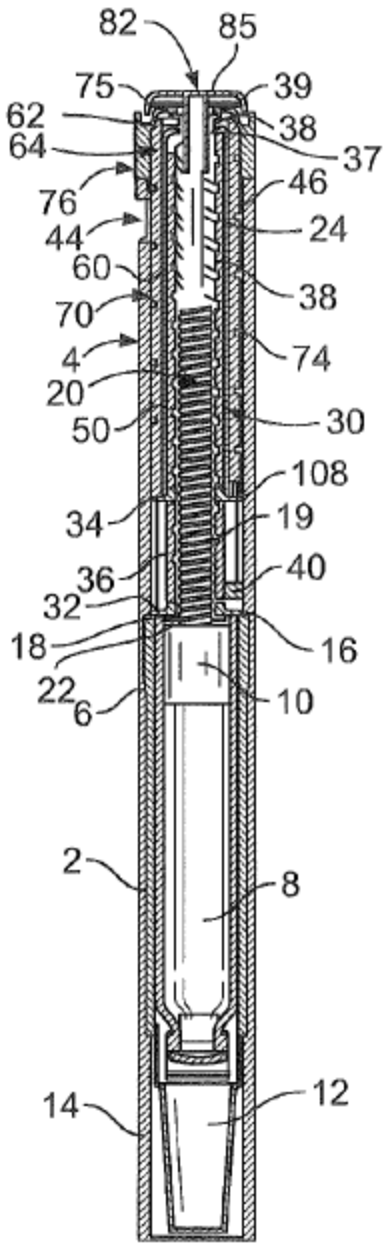


FIG. 1

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 two references:

Steenfeldt-Jensen	US 6,235,004 B1	May 22, 2001	Ex. 1014
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 Steenfeldt-Jensen alone; and (2)

claim 30 is unpatentable under 35 U.S.C. § 103 over Steenfeldt-Jensen and Klitgaard. Pet. 3.

F. Overview of the Applied References

We provide a brief summary of the applied references below.

1. 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.

Mylan directs us to the embodiment of Steenfeldt-Jensen's Figures 16 and 17. Pet. 22. We reproduce Steenfeldt-Jensen's Figures 15–17, below.

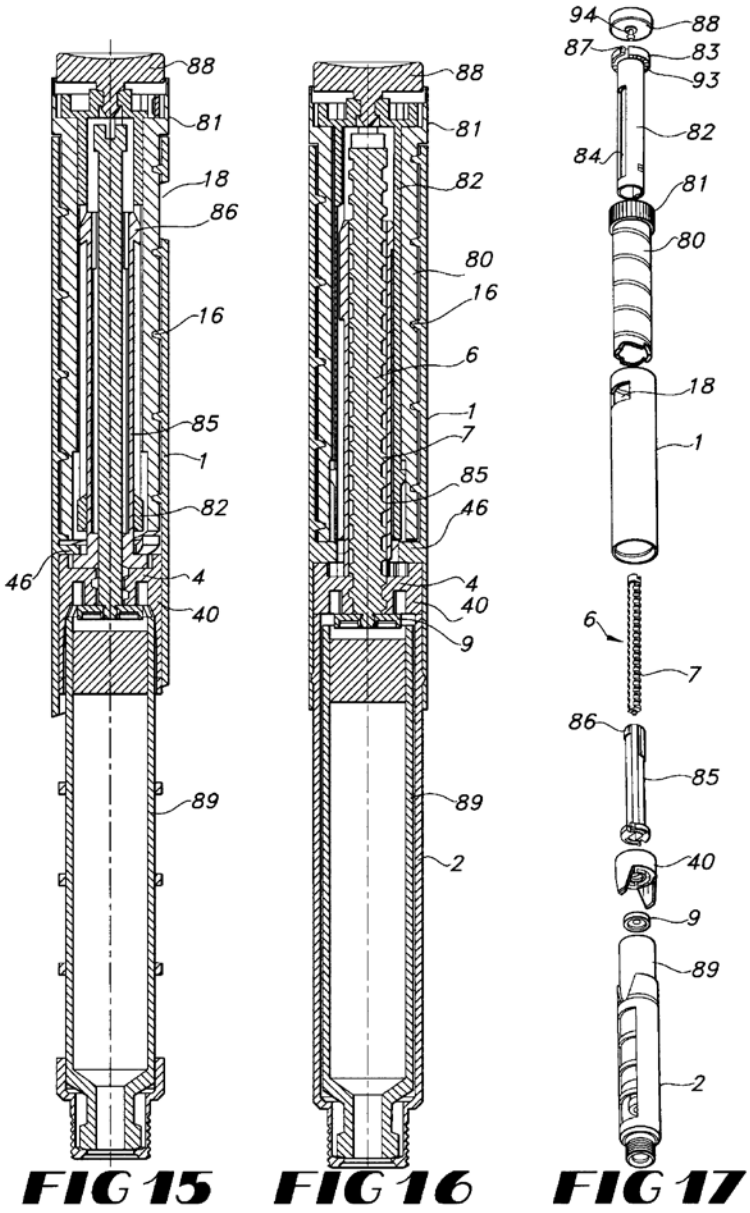


FIG 15 FIG 16 FIG 17

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. Steenfeldt-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.* 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 move longitudinally. *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.

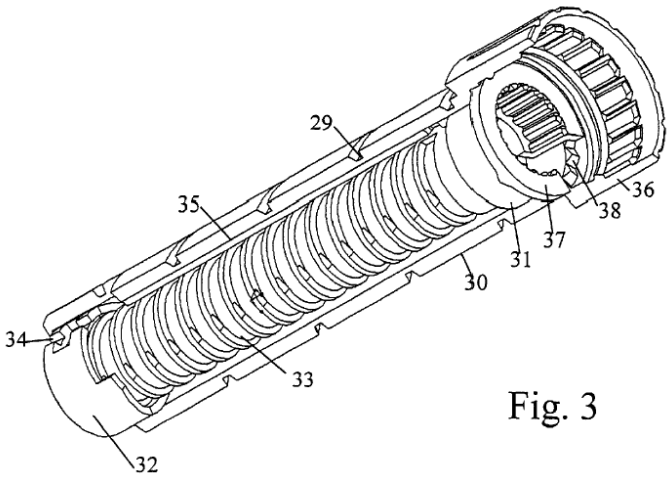


Fig. 3

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 transmit 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) and 324(a)[1] to deny the Petition, as instituting trial "would waste the Board's finite resources and is fundamentally unfair and inefficient to require [Sanofi] to expend resources on an IPR trial where the final written decision will issue only after the conclusion and resolution of Petitioner's invalidity challenge in the related District Court case." Prelim. Resp. 4–5. Sanofi provides a procedural history leading to the related district court litigation and filing of the Petition in this proceeding. *Id.* at 6–8. Sanofi indicates that it initiated district court litigation as part of the Hatch-Waxman Act process, which was triggered by Mylan submitting an application to the Food and Drug Administration (FDA) to market a follow-on insulin glargine product and subsequently providing Sanofi with a "Paragraph IV" certification. *Id.* at 6–7.

Sanofi indicates that it filed a patent infringement case against Petitioner on October 24, 2017, Mylan served its invalidity contentions in the district court litigation on Sanofi on January 25, 2018 (which it amended

[1] 35 U.S.C. § 324 applies to post-grant reviews, which this is not. Therefore, our focus is on § 314.

April 25, 2018), and Sanofi responded with its validity contention on August 12, 2018. Prelim. Resp. 7–8. The Petition in this proceeding was filed on September 10, 2018. *See* Paper 8. Sanofi alleges that the district court invalidity contentions identify "substantially the same invalidity grounds" presented in the Petition. Prelim. Resp. 7; *see also id.* at 11–12 (contending that Mylan relies on the same prior art in this Petition as in the parallel district court litigation).

Sanofi initially indicated 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 Mylan's FDA application of its insulin glargine product on March 18, 2020. Prelim. Resp. 8 (citing Ex. 2005 ¶ 8). In its Sur-Reply, Sanofi asserts that the "District Court will hold its *Markman* hearing on April 12th, will issue its *Markman* order promptly thereafter, and the case will proceed immediately to expert discovery and trial preparation. Indeed, the district court has now entered an amended scheduling order setting trial for 'January 2020, subject to the Court's availability.'" Paper 16, 2 (referencing Ex. 2023). Thus, according to Sanofi, the related district court litigation will be decided before a final written decision is issued in this proceeding. Prelim. Resp. 5–6; Paper 16, 2.

Sanofi argues that the Board has discretion to deny under 35 U.S.C. § 314(a), given the "foundational" purpose of the *inter partes* review system to establish a more efficient patent system and limit unnecessary litigation costs. Prelim. Resp. 5, 8–9 (citing H.R. Rep. 112-98, pt. 1, at 48 (2011); Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (Aug. 13, 2018)). Sanofi also notes that the Board has done so in

circumstances similar to the ones of this proceeding. Prelim. Resp. 9–10 (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, Case IPR2018-00752 (PTAB Sept. 12, 2018) (Paper 8) ("*NHK Spring*")).

Sanofi 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, Mylan is relying on prior art in this proceeding that is at issue in the litigation, and the district court trial will conclude before a final written decision is issued. *Id.* at 10–12. Sanofi also argues that instituting trial in this proceeding gives Mylan a tactical advantage because Mylan was able to review Sanofi's response to Mylan's invalidity contentions in the related litigation, which amounts to "two bites at the apple." *Id.* at 13–14. Sanofi asserts that Mylan was aware of the timing of the district court case and engaged in gamesmanship that is highly prejudicial to Sanofi. *Id.* at 14.

Sanofi also applies the factors discussed in *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, Case IPR2016-01357 (PTAB Sept. 6, 2017) (Paper 19) ("*General Plastic*") to the facts of this case and contends that all of those factors favor denying the Petition. Prelim. Resp. 15–19. Sanofi 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 15. In its analysis of the factors, Sanofi points to Mylan's duplication of invalidity arguments in the related court case and the present proceeding, the filing of the Petition after Mylan received Sanofi'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 16–18.

In its Reply to the Preliminary Response, Mylan argues that the invalidity contentions in the parallel litigation listed exemplary combinations, including Steenfeldt-Jensen in combination with thirty-three additional references. Paper 14, 1. Mylan adds that Sanofi provides no evidence of its "detailed validity positions," other than an email that demonstrates service of the contentions. *Id.* at 2. Mylan asserts that "to simplify the issues for institution, Mylan agrees to not pursue in the district court action any specific ground that the Board institutes for this [P]etition." *Id.* at 2.

Mylan also contends that the number of patents asserted by Sanofi in the parallel litigation and the word limits in our rules necessitated Mylan to file ten petitions. Paper 14, 3–4. Mylan argues that our discretionary denial of Mylan's timely-filed petitions would penalize Mylan merely because Sanofi asserted multiple patents in the litigation. *Id.* at 4.

Mylan also argues that Sanofi speculates that a final written decision in this case will issue after related litigation has been resolved. Paper 14, 4–5. Mylan asserts that, contrary to Sanofi's contentions, Mylan did not stagger the filing of the petitions and, also contrary to Sanofi's contentions, did not file the petitions on the eve of the one-year time limit. *Id.* at 4–5. Instead, the petitions (with one exception, which corrected a filing error) were filed on the same day almost two months before the deadline. *Id.* at 6–7.

Mylan also argues how Sanofi's arguments affect the scope of our discretion under 35 U.S.C. § 314(a) and run afoul of statute, case law, and the Administrative Procedure Act. Paper 14, 8–14. Mylan argues that Sanofi's position would effectively nullify Congressional intent embodied in

§ 315(b) for all ANDA suits. *Id.* at 9. Mylan further notes that Congress has considered, but not adopted, legislation that would address a perceived redundancy between *inter partes* review and Hatch-Waxman litigation. *Id.*

Sanofi responds that, "in view of Judge Chesler's expertise in Hatch-Waxman cases and the District Court's express recognition of the importance of resolving *this case* before March 2020," validity issues will likely be resolved by March 2020. Paper 16, 2. Sanofi also 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 can seem similar. The record does not indicate, however, 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.[2] *See* Ex. 2023. Indeed, contrary to Sanofi's characterization, the amended scheduling order does not set a trial date. Instead, it indicates Sanofi's proposal of a January 2020 trial date, subject to the court's availability. *See* Ex. 2023. The parties will not propose trial dates to the court until October 2019. *See id.*

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 of regulatory approval of Mylan's

[2] In the district court case running parallel to *NHK Spring*, the court ultimately moved the trial date back six months, illustrating the uncertainty associated with litigation schedules. *See Intri-Plex Techs. v. NHK Int'l Corp.*, 3:17-cv-01097-EMC (N.D. Cal.) (docket entry 173 (providing new schedule), docket entry 175 (providing order granting new schedule)).

FDA application, the record does not provide enough indications that the related litigation will in fact be resolved before the end of the 30-month stay. 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* Ex. 2023; Paper 14, 5 (explaining that "most deadlines" are tied to the issuing of a *Markman* order). In this proceeding, by statute, barring any good cause, 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.

Also, Sanofi's assertion the district court expressly recognized the importance of resolving the parallel litigation before March 2020 is not supported by the record. Sanofi cites to Exhibit 2013 at page 6, lines 17 to 24. *See* Paper 16, 2. The Magistrate Judge, however, merely states that she is "optimistic" that the October 29, 2019 trial date can be preserved, a date that has already slipped. *See* Ex. 2013, 6:17–24.

We are also not persuaded to apply the factors enumerated in *General Plastic* to the facts of this case. As Sanofi notes, the *General Plastic* factors were articulated in the context of follow-on petitions. Prelim. Resp. 15. Here, in contrast, Sanofi does not complain of a follow-on petition. Rather, Sanofi complains that Mylan received Sanofi's response to Mylan's invalidity contentions in related litigation before Mylan filed the present Petition. *Id.* at 15–17. The excerpts of Mylan's invalidity contentions, however, show that Mylan identified only exemplary combinations and provided a claim chart showing how an extensive list of references disclosed the subject matter of the limitations of the Challenged Claims. *See* Exs.

2007–2008. From these contentions, we cannot discern whether the identical combinations are asserted in the district court litigation and this proceeding. Indeed, the contentions merely state that "Steenfeldt-Jensen, alone or in combination with Judson and/or Burroughs" "render[s] the asserted claims obvious." Ex. 2007, 414; *see also* Ex. 2008 (matching the disclosures of a number of references to the limitations of the Challenged Claims). Also, we cannot discern from Exhibit 2009 the substance of Sanofi's response to the invalidity contentions, so it is unclear what, if any, tactical advantage, Mylan may have gained by receiving that response to these contentions before filing the Petition. Thus, we are not persuaded that Mylan being served with Sanofi'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 Mylan's invalidity contentions in the related litigation and the grounds at issue in this case do not indicate clearly what benefit, if any, Mylan could have had in drafting its Petition for this proceeding. Also, Mylan filed its Petition well within the timeframe allowed by statute, weighing heavily in Mylan's favor.

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

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. 18 (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) (2018). Under the broadest reasonable interpretation 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. 18. Mylan also asserts that, in the parallel district court litigation, Sanofi has taken claim construction positions for certain claim terms,[3] and that the broadest reasonable interpretation of those term should at least encompass Sanofi's proposed constructions. *Id.* at 18–20.

Mylan also asserts that, in the parallel district court litigation, Mylan proposed means-plus-function constructions for the terms "clutch," "clicker," and "holder." Pet. 20. Mylan identifies the functions and structures related to these three terms. *See id.* at 20–21.

Sanofi contends that Mylan fails to satisfy its obligations under our rules to "clearly identify[] how the claims are to be construed." Prelim. Resp. 59. 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 60–62. Sanofi argues that the Petition "puts the onus on [Sanofi] to guess what constructions were applied. This unfairly prejudices [Sanofi's] ability

[3] 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.

to defend its patent, and independently warrants denying the Petition." *Id.* at 60.

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. Mylan provides alternative constructions for three terms, should those terms be deemed means-plus-function terms. Mylan applies means-plus-function constructions in demonstrating how the prior art satisfies the claims as an alternative analysis. *See, e.g.*, Pet. 62 (applying means-plus-function analysis to dependent claim 29, which recites a "clicker"). Finally, Mylan's assertion that the broadest reasonable construction of the terms should encompass Sanofi's proposed constructions in the parallel district court litigation is not inconsistent with the terms being given their ordinary and customary meaning. In reviewing Mylan's application of the prior art to the claim terms, we determine that Sanofi is not unfairly prejudiced, as Sanofi is able to determine how Mylan interprets the claim terms based on how Mylan applies the prior art to the claims.

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.

The parties are hereby given notice that claim construction, in general, is an issue to be addressed at trial and claim constructions expressly or implicitly addressed in this Decision are *preliminary* in nature. Claim construction will be determined at the close of all the evidence and after any hearing. The parties are expected to assert all of their claim construction arguments and evidence in the Patent Owner's Response, Petitioner's Reply, or otherwise during trial, as permitted by our rules.

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).[4] 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 differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art;[5] and (4) when available, secondary considerations, such as commercial success, long felt but unsolved needs,

[4] 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.
[5] We addressed the level of ordinary skill in the art in Section II.B., *supra*.

and failure of others.[6] *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 Steenfeldt-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 Steenfeldt-Jensen prior art under AIA 35 U.S.C. § 102(a). *See* Pet. 14–17. 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, as Steenfeldt-Jensen and Klitgaard, would be prior art under § 102(b) even with an effective filing date of March 3, 2003.

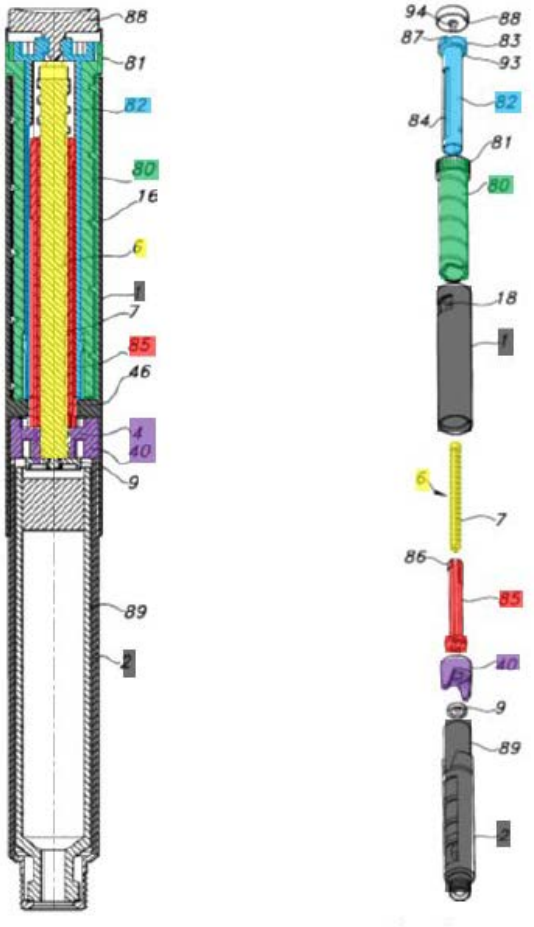
Given that the differences between the pre-AIA and AIA versions of 35 U.S.C. § 103 are immaterial to our analysis in this Decision, we agree with Sanofi that we need not reach this issue here.

b. Independent claim 21.

Subject matter of claim 21

In support of its contention that Steenfeldt-Jensen renders obvious independent claim 21, Mylan provides annotated versions of Steenfeldt-Jensen's Figures 16 and 17, which we reproduce below.

[6] Sanofi does not present any evidence concerning secondary considerations at this stage of the proceeding.



Pet. 24. These annotated figures show in color certain components of Steenfeldt-Jensen's syringe. *See id.* at 22–23. Mylan's annotations show tubular housing 1 and ampoule holder 2 in grey, scale drum 80 in green, piston rod 6 in yellow, driver tube 85 in red, bushing 82 in blue, and member 40 in purple. *See id.* These colors correspond to Mylan's identification of recited components in claim 21: the housing in grey, the dose indicator in green, the piston rod in yellow, the driving member in red, the sleeve in blue, and the piston rod holder in purple. *See id.* at 6–7; *see also id.* at 7 (showing colorized versions of the embodiment of Figures 1 and 2 of the '844 patent), *id.* at 7–13 (describing the '844 patent injection pen).

With this background, we turn to the limitations of claim 21. Claim 21 recites "a housing comprising a dose dispensing end and a first thread." Ex. 1004, 8:17–18 (the "housing" limitation). Mylan contends that Steenfeldt-Jensen's housing 1 and ampoule holder 2 correspond to the recited housing. Pet. 27–29. Mylan adds that these structures extend from a dose dispensing end to the button end. *Id.* at 28–29. Mylan also contends that housing 1 includes an inner thread on its inner wall. *Id.* at 29 (referencing Ex. 1014, 3:34–44, 6:7–11, 11:20–22).

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen discloses the subject matter of the "housing" limitation of claim 21.

Claim 21 also recites "a dose indicator comprising a second thread that engages with the first thread." Ex. 1004, 8:19–20 (the "dose indicator" limitation). Mylan contends that Steenfeldt-Jensen's dose scale drum 17 or scale drum 80 corresponds to the recited dose indicator. Pet. 29–31. Mylan explains that "[t]he drum includes a 'helical groove provided along an outer surface' in the form [of] a helical track, which extends along the drum's outer wall." *Id.* at 30 (referencing Ex. 1014, 3:34–44, 6:7–11, 11:20–22, Figs. 16–17; Ex. 1011 ¶ 615). Mylan continues that helical track engages the threading in housing 1 through helical rib 16. *Id.* at 30–31. "A dose is set by screwing the scale drum out of the housing and scale drum 80 is pressed back into the housing during dose dispensing" and "[n]umbers indicating set doses are printed on an outer wall of the dose drum and viewable outside the housing via a window." *Id.* at 31 (referencing

Ex. 1014, 6:18–21, 7:11–16, 9:52–56, 10:40–45, 11:52–54, 12:4–9; Ex. 1011 ¶ 617).[7]

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen discloses the subject matter of the "dose indicator" limitation of claim 21.

Claim 21 also recites "a driving member comprising a third thread." Ex. 1004, 8:21 (the "drive member" limitation). Mylan contends that Steenfeldt-Jensen's driver tube 85 corresponds to the recited drive member. Pet. 31–33. Mylan recognizes that "driver tube 85 rotationally engages with the rod through a bore having a non-circular cross-section, rather than an internal threading near a distal portion." *Id.* at 34 (citing Ex. 1011 ¶ 620). Mylan argues that a person having ordinary skill in the art "would have considered it obvious to modify the piston rod drive to provide the 'driving member' of claim 21." *Id.* We address Mylan's proposed modification and reasons for this modification and Sanofi's arguments related to Mylan's reasoning, below (after addressing the subject matter of each claim limitation of claim 21).

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen, as modified, discloses the subject matter of the "drive member" limitation of claim 21.

[7] Mylan indicates that "Steenfeldt-Jensen explains that analogous elements in different embodiments are provided with the same reference number." Pet. 31 (referencing Ex. 1014, 7:49–51).

Claim 21 also recites "a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator." Ex. 1004, 8:22–24 (the "sleeve" limitation). Mylan contends that Steenfeldt-Jensen's bushing 82 corresponds to the recited sleeve. Pet. 36. Mylan explains that "bushing 82 is a tubular structure that is disposed between dose indicator 80 and drive member 85." *Id.* (referencing Ex. 1014, 11:26–27, 12:4–13; Figs. 15–17; Ex. 1011 ¶ 628). Mylan continues that bushing 82 is releasably connected to scale drum 80 because dose-setting button 81 is integrally formed with scale drum 80. *Id.* (referencing Ex. 1014, 11:22–25; Ex. 1011 ¶ 629).

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen discloses the subject matter of the "sleeve" limitation of claim 21.

Claim 21 also recites "a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread." Ex. 1004, 8:25–26 (the "piston rod" limitation). Mylan contends that piston rod 6 corresponds to the recited piston rod. Pet. 37–38. Mylan explains that, modified as Mylan proposes, piston rod 6 with external threading 7 would engage internal threads of driver tube 85. *Id.* at 38.

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen, modified as Mylan proposes, discloses the subject matter of the "piston rod" limitation of claim 21.

Claim 21 also 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 member 40 corresponds to the recited piston rod holder. Pet. 38–43. Mylan explains that "[b]y virtue of being rotatably fixed relative to the housing, member 40 is configured to prevent the piston rod from rotating relative to the housing during dose setting via the interaction of its pawl wheel teeth with the pawl wheel of driver tube 85." *Id.* at 41. Mylan further contends that it would have been obvious for a person having ordinary skill in the art to "modify the piston rod drive so that the internal threads of the piston rod drive are located on driver tube 85 instead of on member 40 and so that member 40 (instead of driver tube 85) mates with the not circular cross section of the piston rod." *Id.* at 42. Mylan contends that:

> Swapping the location of the threads and the non-circular cross section between driver tube 85 and member 40 would result in member 40 being configured to (i) prevent the piston rod from rotating relative to the housing during dose setting; and (ii) permit the piston rod to traverse axially towards the dose dispensing end during dose dispensing, as recited in [the piston rod holder limitation].

Id. at 43. Again, we address Mylan's reasoning in support of this modification, below.

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen, modified as Mylan proposes, discloses the subject matter of the "piston rod holder" limitation of claim 21.

We note, however, that, to the extent that Mylan contends that "piston rod holder" is a means-plus-function limitation, the Petition provides no express, alternative analysis under this interpretation for the "piston rod

holder" limitation. *See* Pet. 38–43. We do not find the Petition deficient in this respect, at this stage of the proceeding. *See id.* at 21 (identifying the function of a "holder" as "prevent[ing] the piston rod from rotating during dose setting and permit[ting] the piston rod to traverse axially towards the distal end during dose dispensing" and the disclosed structure in the '844 patent as component 16), 41–43 (identifying a comparable structure in Steenfeldt-Jensen that performs the identified function).

Claim 21 further recites "wherein: the housing is disposed at an outermost position of the drug delivery device." Ex. 1004, 8:32–34. Mylan contends that Steenfeldt-Jensen discloses that housing 1 and ampoule holder 2 are disposed at an outermost position of Steenfeldt-Jensen's syringe. Pet. 43–44. We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen discloses the recited positioning of the housing.

Claim 21 also requires "the dose indicator [to be] disposed between the housing and the sleeve and [be] 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." Ex. 1004, 8:35–39. Mylan contends that Steenfeldt-Jensen's scale drum 80 is disposed between housing 1 and bushing 82. Pet. 45 (referencing Ex. 1014, 11:20–28; Ex. 1011 ¶ 642).

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen discloses the recited positioning and movement of the dose indicator.

Claim 21 also requires "the driving member [to be] configured to rotate relative to the piston rod." Ex. 1004, 8:40–41. Mylan contends that

Steenfeldt-Jensen discloses member 40 rotates relative to piston rod 6 and pawl 13 engages with member 40 to allow member 40 to rotate relative to driver tube 85 during dose dispensing. Pet. 46. Mylan contends that it would have been obvious to modify Steenfeldt-Jensen's "piston rod drive so that the internal threads of the piston rod drive are located on driver tube 85 instead of member 40 and so that member 40 (instead of driver tube 85) mates with the not circular cross section of the piston rod." *Id.*

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen, modified as Mylan proposes, discloses the recited configuration for the drive member.

Claim 21 also requires "the sleeve [to be] rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator." Ex. 1004, 8:42–44. Mylan contends that "[b]ushing 82 is rotatably fixed relative to driver tube 85." Pet. 48. Mylan explains that bushing 82 and driver tube 85 are coupled so that they rotate together but that longitudinal displacement is not transmitted between the two components. *Id.* Mylan further explains that "[b]ushing 82 is also configured to traverse axially with the dose indicator" and "with scale drum 80 during dose dispensing." *Id.* at 48, 49.

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen discloses the recited configuration for the sleeve.

Claim 21 also requires "the piston rod and the driving member [to be] configured to rotate relative to one another during dose dispensing." Ex. 1004, 8:45–46. Mylan contends, as we have indicated above, that a

person having ordinary skill in the art would have found it "obvious to modify the piston rod drive so the internal threads of the piston rod drive are located on driver tube 85 instead of member 40 and so member 40 (instead of the driver tube 85) mates with the not circular cross section of the piston rod." Pet. 51.

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen, modified as Mylan proposes, discloses the recited configuration for the piston rod and driving member.

Finally, claim 21 requires "the piston rod [to be] configured to traverse axially towards the dose dispensing end during dose dispensing." Ex. 1004, 8:47–49. Mylan contends that "[b]oth with and without [Mylan's proposed] modification, piston rod 16 is configured to traverse axially towards the dose-dispensing end during dose dispensing." Pet. 52 (referencing Ex. 1011 ¶ 656); *see id.* at 52–53 (explaining the configuration of piston rod 16 with and without the proposed modification).

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen discloses the recited configuration for the piston rod.

Sanofi does not dispute these contentions associated with how Steenfeldt-Jensen discloses the subject matter of claim 21 at this time (except as discussed below concerning Mylan's proposed modification).

Mylan's proposed modification and reasoning supporting the modification

Mylan recognizes that, in the embodiment of Figures 15–17 (the "fifth embodiment"), driver tube 85 (the alleged driver member) is not shown with internal threading as required by claim 21. Pet. 53. Mylan contends that:

> Steenfeldt-Jensen suggests an alternative embodiment in which (1) driver tube 85 does have such threading and rotates relative to piston rod 6 during injection to drive the piston rod through member 40 and (2) member 40 operates as a non-threaded piston-rod guide, preventing rotation of piston rod 6 relative to the housing but allowing axial displacement.

Id. Mylan asserts that this suggested modification would satisfy the requirements of the recited "driver member" and "piston rod holder" of claim 21. *Id.* (citing Ex. 1011 ¶¶ 620–621).

Mylan explains that Steenfeldt-Jensen discloses alternative ways to drive the piston rod: (1) "rotation of the scale drum can rotate the piston rod relative to the nut member," or (2) "rotation of the scale drum can rotate the nut member relative to the piston rod." Pet. 54 (referencing Ex. 1014, 3:15–20, 3:41–47; Ex. 1011 ¶ 622). Mylan continues that the first way represents the approach in the fifth embodiment. *Id.* Mylan contends that Steenfeldt-Jensen suggests that the second approach (from the "first embodiment") can be implemented in other embodiments with the statement: "Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention." *Id.* at 54–55 (quoting Ex. 1014, 7:44–47). Mylan concludes that its proposed modification "would have involved the use of well-known, familiar elements performing their same, predictable functions." *Id.* at 56.

Sanofi responds that Mylan relies on the fifth embodiment of Steenfeldt-Jensen and concedes that "driver tube 85 (the driver) does not show internal threading." as required by claim 21. Prelim. Resp. 45. Sanofi argues that Mylan's reasoning in support for its modification of the fifth embodiment is based on a misinterpretation of Steenfeldt-Jensen. *Id.* at 46.

Specifically, Sanofi argues that the disclosure of Steenfeldt–Jensen relied on by Mylan (Ex. 1014, 7:44–47) does not teach that the nut element and driver tube are the same, but instead are discrete components. Prelim. Resp. 46.

Sanofi argues that the cited passage from Steenfeldt-Jensen is directed to the first embodiment only, as evidenced by its reference to piston rod guide 14 and driver tube 26 and its reference, earlier in the paragraph to "the shown embodiment" and that there is no comparable statement with respect to the fifth embodiment. Prelim. Resp. 48. Sanofi explains that the cited passage could not apply to the fifth embodiment "because it does not include a driver tube 26 or a rotatable ampoule holder 2 with threaded end wall 4." *Id.* Sanofi argues that it is not surprising that this passage does not relate to the fifth embodiment, as it operates differently from the first embodiment. *Id.* at 49.

Sanofi additionally responds that one of ordinary skill in the art would not have been motivated to make Mylan's proposed modification to Steenfeldt-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 49–55 (comparing the operation of the first and fifth embodiments).

Sanofi also responds that Mylan's proposed modification would result in an inferior pen injector. *Id.* at 55–58. Sanofi contends that making the proposed modification to Steenfeldt-Jensen's fifth embodiment would make the syringe harder to use. *Id.* at 58.

In view of the arguments and evidence at this early stage of the proceeding, we are satisfied that Mylan sufficiently demonstrates, with

citations to evidence of record, that a person having ordinary skill in the art would have modified the fifth embodiment of Steenfeldt-Jensen so that the internal threading of its member 40 is in driver tube 85 and the non-circular opening of driver tube 85 is in member 40. In support of its proposed modification, Mylan quotes column 7, lines 44–47 of Steenfeldt-Jensen, which states that "[e]mbodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiments will not be beyond the scope of the invention." Pet. 54–55. Mylan's position is also supported by testimony from Mr. Leinsing. *See id.* at 53–56 (referencing Ex. 1011 ¶¶ 620–626).

For purposes of deciding whether to institute, we determine that this disclosure in Steenfeldt-Jensen provides adequate reason for one of ordinary skill in the art to modify the fifth embodiment in the manner asserted by Mylan. This determination is not final, however, 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 Steenfeldt-Jensen's first embodiment and whether the same teaching would have been further applied to the fifth embodiment with its alternative arrangement of structures.

Also, the present record does not support Sanofi's contention that moving the internal threads of Steenfeldt-Jensen's fifth embodiment from one component to another nearby component would result in new or additional friction. *See* Prelim. Resp. 49–55. Sanofi's argument presents another factual issue with respect to Mylan's proposed modification that would also benefit from further developing the record.

Conclusion as to claim 21

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Steenfeldt-Jensen, modified as Mylan proposes, discloses the subject matter of claim 21. We also determine, on the limited record before us, that Mylan has sufficiently presented reasons, with a rational underpinning, for its proposed modification. So, we determine, on the current record at this stage of the proceeding, that the information in the Petition demonstrates a reasonable likelihood that independent claim 21 is unpatentable under 35 U.S.C. § 103 over Steenfeldt-Jensen.

c. Dependent claims 22–29.

We must institute trial, if at all, on all challenged claims and grounds. *See SAS Inst., Inc.*, 138 S. Ct. at 1359–60; U.S. Patent and Trademark Office, Guidance on the impact of *SAS* on AIA trial proceedings, available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial (Apr. 26, 2018); *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) ("Equal treatment of claims and grounds for institution purposes has pervasive support in *SAS*."). Since we determine that the Petition demonstrates a reasonable likelihood of prevailing as to independent claim 21 as obvious over Steenfeldt-Jensen, we institute on all Challenged Claims and grounds. Still, we have reviewed Mylan's contentions and supporting evidence with respect to Steenfeldt-Jensen disclosing the subject matter of the dependent claims. We determine, on the current record at this stage of the proceeding, that the information in the Petition demonstrates a reasonable likelihood that dependent claims 22–29 are unpatentable as obvious over Steenfeldt-Jensen,

as modified as Mylan proposes. Sanofi does not raise any additional arguments directed to Mylan's contentions with respect to the dependent claims and Steenfeldt-Jensen at this time.

2. Claim 30 as allegedly unpatentable under 35 U.S.C. § 103 over Steenfeldt-Jensen and Klitgaard

We have reviewed Mylan's contentions and supporting evidence with respect to claim 30, including Mylan's reasons to combine the teachings of the references as proposed, and we determine, on the current record at this stage of the proceeding, that the information in the Petition demonstrates a reasonable likelihood that claim 30 is unpatentable under 35 U.S.C. § 103 over Steenfeldt-Jensen and Klitgaard. Sanofi does not does not raise any additional arguments directed to Mylan's contentions with respect to this obviousness ground at this time.

III. CONCLUSION

After considering all the evidence and arguments presently before us, we determine that Mylan has established a reasonable likelihood that it would prevail with respect to at least one of the Challenged Claims. Accordingly, we institute an *inter partes* review on all challenged claims and grounds. 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.

IV. ORDER

After due consideration of the record before us, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 21–30 of the ’844 patent on all asserted grounds of unpatentability; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which commences on the entry date of this Order.

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