

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 IPR2018-01680
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.”)¹ 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 11. With our authorization, Mylan filed a Reply and Sanofi a Sur-Reply to the Preliminary Response. Papers 13, 15. 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-

¹ As described in our Order (Paper 17), Petitioner confirmed that Paper 3 is a duplicate of Paper 2. In that same order, we ordered Paper 3 expunged.

IPR2018-01680
Patent 9,526,844 B2

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 6, 2; Paper 7, 2; Exs. 1029, 1030.

The parties state that the '844 patent is also challenged in Cases IPR2018-01682 and IPR2018-01696. Pet. 1–2 (misidentifying the -01696 case as “-01689”); Paper 6, 3; Paper 9, 2–3; Paper 10, 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 6, 2–3; Paper 9, 3; Paper 10, 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.

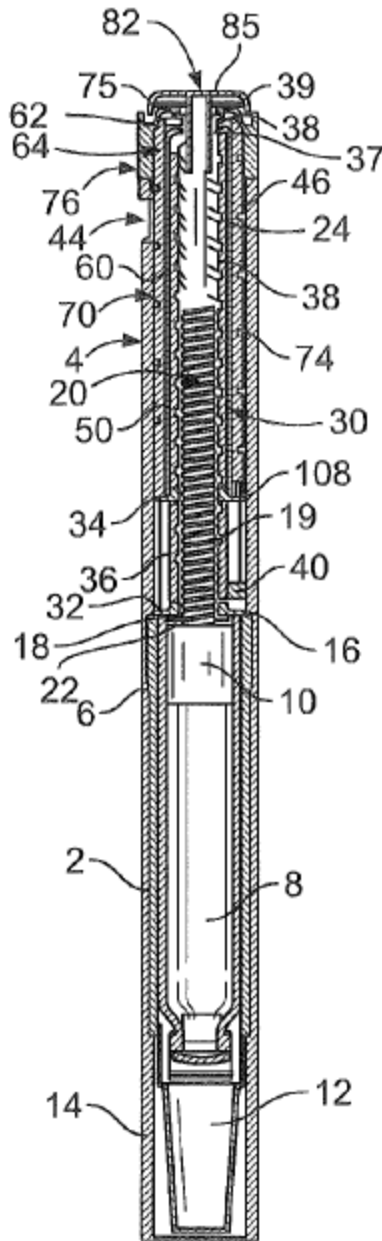


FIG. 1

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:

Giambattista	US 6,932,794 B2	Aug. 23, 2005	Ex. 1016
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 three grounds of unpatentability: (1) claims 21–29 are unpatentable under 35 U.S.C. § 102(a)² as anticipated by Giambattista; (2) claims 24–29 are unpatentable under 35 U.S.C. § 103 over Giambattista and Steinfeldt-Jensen; and (3) claim 30 is unpatentable under 35 U.S.C. § 103 over Giambattista and Klitgaard. Pet. 3.

F. Overview of the Applied References

We provide a brief summary of the applied references below.

1. Giambattista

Giambattista, titled “Medication Delivery Pen,” issued August 23, 2005, from an application filed April 3, 2003. Ex. 1016, [54], [45], [22]. Mylan asserts that the ’844 patent is entitled to a priority date of May 17, 2016, making Giambattista prior art under AIA 35 U.S.C. § 102(a).³ Pet. 15–18. Giambattista is directed to “medication delivery pens, such as those used in administering insulin.” Ex. 1016, 1:6–7. We reproduce Giambattista’s Figure 2, below.

² We reference the AIA version of § 102.

³ Sanofi disputes Mylan’s contention with respect to the priority date of the ’844 patent. Prelim. Resp. 27–32. We address this dispute *infra*.

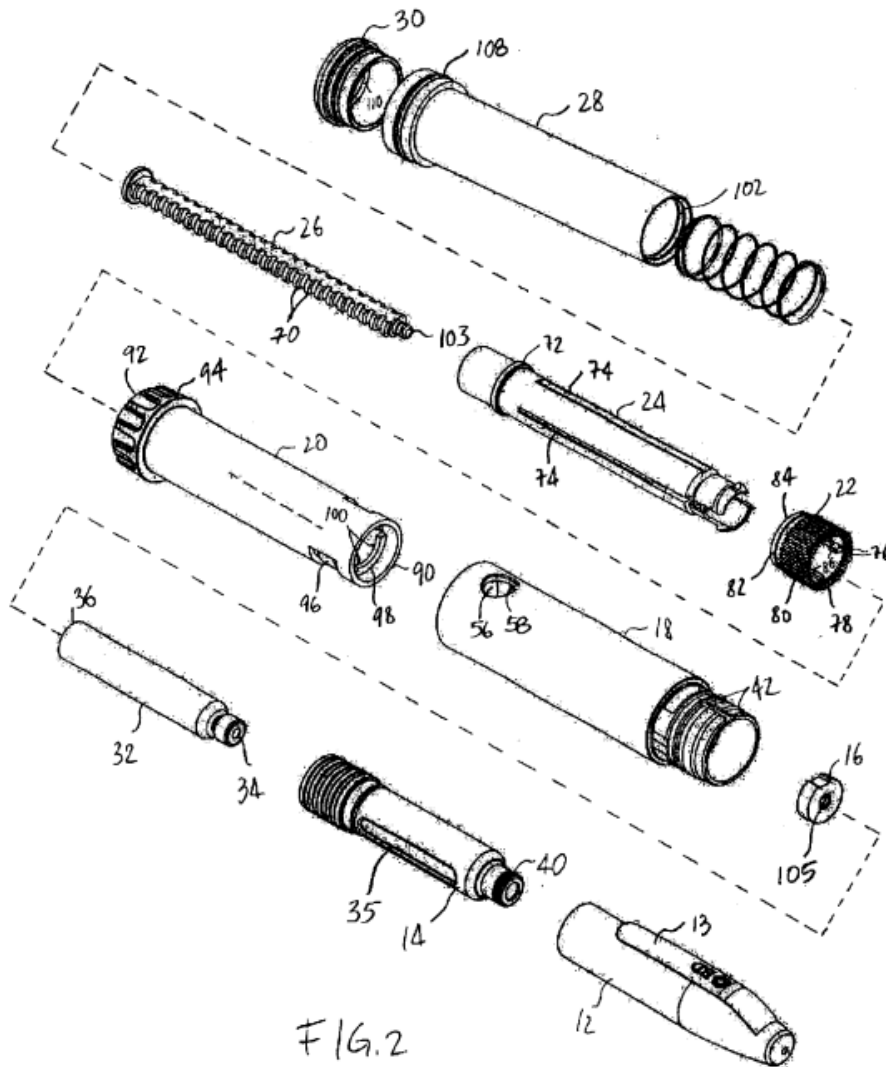


Figure 2 depicts “an exploded view of a medication delivery pen constructed in accordance with [Giambattista’s] invention.” *Id.* at 2:1–2. Giambattista’s medication delivery pen includes cap 12, cartridge holder 14, spinner 16, body 18, dose knob 20, dosing ring 22, driver 24, leadscrew 26, dosing ring adaptor 28, and thumb button 30. *Id.* at 2:36–40. Spinner 16 is configured to engage plunger 38 to expel drug from drug cartridge 32. *Id.* at 2:47–50.

Body 18 is generally cylindrical and includes bulkhead 44, which extends across the interior of body 18 and contains aperture 46. Ex. 1016, 2:66–3:3. Aperture 46 allows leadscrew 26 to pass through, but has a

rectangular shape to prevent leadscrew 26 from rotating when positioned through aperture 46. *Id.* at 3:3–6. Driver 24 is fixed axially relative to body 18, yet rotates relative to body 18. *Id.* at 3:21–22.

Dosing ring 22 and dosing ring adaptor 28 are mounted onto driver 24 with splines 86 extending into the keyways 74. Ex. 1016, 3:43–46, Fig. 9. As a result, dosing ring 22 cannot rotate relative to driver 24, yet splines 86 are formed to allow dosing ring 22 to axially move along the length of keyways 74. *Id.* at 3:46–49, Fig. 9.

Dose knob 20 is generally tubular and is used to set the dose for the pen. Ex. 1016, 3:56–60. Dose knob 20 rotates within body 18, translating that rotation to axial displacement of dose knob 20 relative to body 18 in setting a desired dosage. *Id.* at 3:63–66, Fig. 11. Dose knob 20 includes one or more ratchet arms 96, which are aligned with longitudinal ribs 80 so that rotation of dose knob 20 relative to dosing ring 22 results in ratchet arms 96 acting against ribs 80 to provide a user an audible signal of the dose being set. *Id.* at 4:1–8.

Giambattista’s pen allows dose knob 20 to be “dialed back” if the user inadvertently passes the intended dose setting. Ex. 1016, 4:61–64.

2. *Steenfeldt-Jensen*

Steenfeldt-Jensen, titled “Injection Syringe,” issued May 22, 2001, from an application filed October 28, 1999. Ex. 1014, [54], [45], [22]. Steinfeldt-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. Relevant to this decision, Steinfeldt-Jensen 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 Steinfeldt-Jensen’s pen represent one unit of dose.

3. 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.

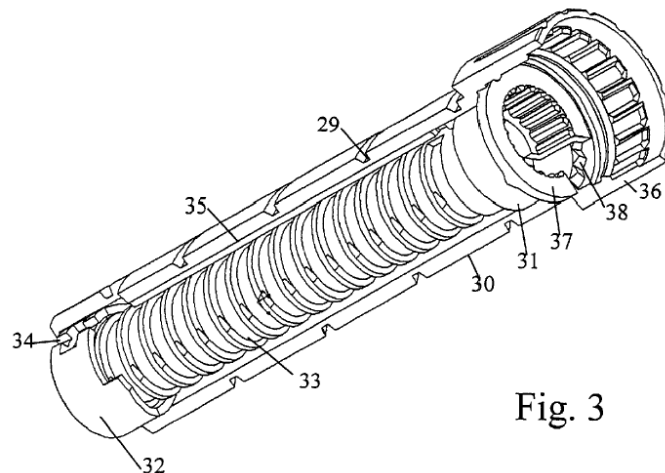


Fig. 3

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) and 324(a)⁴ 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. 5–6. Sanofi provides a procedural history leading to the related district court litigation and filing of the Petition in this proceeding. *Id.* at 7–9. 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-

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

on insulin glargine product and subsequently providing Sanofi with a “Paragraph IV” certification. *Id.*

Sanofi indicates that it filed a patent infringement case against Petitioner on October 24, 2017, Mylan served its invalidity contentions in the parallel district court litigation on Sanofi on January 25, 2018 (which it amended April 25, 2018), and Sanofi responded with its validity contentions on August 12, 2018. Prelim. Resp. 8. The Petition in this proceeding was filed on September 10, 2018. *See* Paper 8. Sanofi alleges that the district court invalidity contentions identify the same art presented in the Petition. Prelim. Resp. 8; *see also* Paper 15, 4–5 (“The invalidity grounds in the Petition are also asserted in [Mylan’s] District Court invalidity contentions.”) (citing Paper 11, 12).

Sanofi additionally indicates that the parties in the case have jointly requested trial in the district court for October 2019, to reach resolution before the end of the FDA’s 30-month stay of regulatory approval of Mylan’s FDA application of its insulin glargine product on March 18, 2020. Prelim. Resp. 9 (citing Ex. 2005 ¶ 8); *see also* Paper 15, 1–2 (arguing that Mylan has sought trial in advance of March 2020) (citing Ex. 2020, 1; Ex. 2011, 19; Ex. 2012, 1; Ex. 2013, 1; Ex. 2014, 7–8, 12). Sanofi argues that “even if the trial date shifts to later in 2019, there is simply no basis to suggest that the district court will not resolve all of the issues in this case, including validity, before the March 2020 transition date and expiration of

the stay.” Paper 15, 3.⁵ 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.

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. 6, 9–10 (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. 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. Prelim. Resp. 11–13. 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. *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; *see also* Paper 15, 5 n.1 (contending that

⁵ Sanofi states that “[a] *Markman* hearing is likely to occur in March 2019.” Prelim. Resp. 9. We note that this hearing has now been delayed to April 12, 2019. Also, an amended scheduling order in the case indicates that Sanofi proposed, and the court accepted, a trial date in January 2020, subject to the court’s availability. *See* Ex. 3001.

Mylan “can still tailor its District Court invalidity grounds to address weaknesses identified in the Patent Owner’s Preliminary Response or the institution decision”).

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. 14–19. 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 contentions in the litigation listed exemplary combinations, including Giambattista in combination with thirty-three additional references. Paper 13, 1–2. 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 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 13, 2–3. 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 3.

Mylan also argues that Sanofi speculates that a final written decision in this case will issue after related litigation has been resolved. Paper 13, 3–4. 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) were filed on the same day almost two months before the deadline. *Id.* 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. *Id.* at 5–7, 8–10.

Sanofi responds that the parallel litigation will conclude by March 2020 and notes that the District of New Jersey and Judge Chesler are known to resolve Hatch-Waxman litigation “expeditiously and in advance of stay expiration.” Paper 15, 2 (referencing Ex. 2015, 31:15–32:3). 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. Sanofi states again that Mylan is asserting duplicate grounds in the litigation and in this *inter partes* review proceeding. *Id.* at 4.

In view of the arguments presented, we are not persuaded to exercise our discretion under 35 U.S.C. § 314(a) to deny the Petition. We understand that the facts in *NHK Spring* and the circumstances of this case may seem similar. The record, however, does not indicate that trial in the related district court case is scheduled for, and will occur, in October 2019 or even

in January 2020, in light of the latest schedule.⁶ *See* Ex. 3001. Although the record indicates that the district court and the parties are working together towards resolving the related litigation before March 18, 2020, the end of the FDA’s 30-month stay, the record does not provide enough indications that the related litigation will in fact be resolved before the end of the 30-month stay. Indeed, as indicated in the latest scheduling order in the district court litigation, the parties will not propose trial dates to the court until October 2019. *See* Ex. 3001. Adding to the uncertainty of when a trial may begin, many of the schedule’s milestones are dependent on the district court issuing its claim construction order, something completely out of the parties’ hands. *See id.*; Paper 13, 4 (explaining that “most deadlines” are tied to the issuing of a *Markman* order). In this proceeding, by statute, barring 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.

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. 14. 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 16. The excerpts of Mylan’s invalidity contentions, however,

⁶ 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)).

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. 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 these contentions. Thus, we are not persuaded that Mylan’s receipt of Sanofi’s response to the invalidity contentions in the related district court litigation amounts to a petitioner receiving the benefit of a preliminary response or decision on institution before filing a second petition challenging the same patent, the circumstances addressed by the *General Plastic* factors. Therefore, we are not persuaded those factors apply. Moreover, even if we did apply *General Plastic* to this case, the differences between 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 ¶¶ 105–106). Sanofi does not dispute, at this time, 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,⁷ and that the broadest reasonable interpretation of those terms should at least encompass Sanofi’s proposed constructions. *Id.* at 19.

Mylan also asserts that, in the parallel district court litigation, Mylan proposed means-plus-function constructions for the terms “clutch,” “clicker,” and “holder.” *Id.* at 20. Mylan identifies the functions and structures related to these three terms. *See id.* at 20–22.

Sanofi contends that Mylan fails to satisfy its obligations under our rules to “clearly identify[] how the claims are to be construed.” Prelim. Resp. 33. 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 33–34. 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.* at 36.

⁷ 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.

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. 60 (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 first asserted ground of unpatentability is based on anticipation. *See* Pet. 3. A “prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)).

The other two asserted 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).⁸ The question of obviousness is resolved on the basis of underlying

⁸ 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.

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 art⁹; and (4) when available, secondary considerations, such as commercial success, long felt but unsolved needs, and failure of others.¹⁰ *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

1. *Claims 21–29 as allegedly anticipated by Giambattista*

a. Giambattista as prior art.

As we discussed above, Mylan asserts that the '844 patent is entitled to a priority date of May 17, 2016, making Giambattista prior art under AIA 35 U.S.C. § 102(a). *See* Pet. 15. 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. 27; Ex. 1004 (30). We address the parties' contentions below.

Mylan contends that none of the applications in the chain of applications to which the '844 patent claims priority provides written description support for the claimed subject matter of a piston rod that comprises an *internal* fourth thread that engages a third thread of a driving member.¹¹ Pet. 15–16; *see also* Ex. 1011 ¶ 100 (declaring that “the earlier applications to which the '844 patent claims priority lack written description support for” a piston rod with an internal thread that engages a thread of a

⁹ We addressed the level of ordinary skill in the art in Section II.B., *supra*.

¹⁰ Sanofi does not present any evidence concerning secondary considerations at this stage of the proceeding.

¹¹ Independent claim 21 recites, in relevant part, “a piston rod comprising either an *internal* or an external fourth thread that is engaged with the third thread.” Ex. 1004, 8:25–26 (emphasis added).

driving member). Mylan argues that none of the applications in the priority chain discloses an internally-threaded piston rod or engaging internal threads with an external thread of a driving member. Pet. 16. Mylan explains that each of the applications in the priority chain consistently describes an externally-threaded piston rod, with a driving member (drive sleeve and insert) located between the piston rod and housing. *Id.* at 17; *see* Ex. 1011 ¶¶ 101–102 (declaring that the application that matured into the '844 patent “exclusively describes an injector device that has a piston rod having external threading” and that the same is true for all of the other applications in the priority chain); *see, e.g.*, Ex. 1026, 12, 7–14 (“A drive sleeve 30 extends about the piston rod 20. . . . A helical groove 38 extends along the internal surface of the drive sleeve 30. The second thread 24 of the piston rod 20 is adapted to work within the helical groove 38.”).

Sanofi responds that Great Britain patent application 0304822.0 provides written description support for an internally-threaded piston rod. Prelim. Resp. 27. Sanofi argues that the application describes broadly a piston rod with a threaded portion, and that a person having ordinary skill in the art would have recognized that the inventors were in possession of a piston rod that is either internally or externally threaded. *Id.*

Sanofi counters Mylan’s assertion that the priority documents describe a driving member between the housing and piston rod (that is, radially between), demonstrating that the piston rod is externally threaded, by arguing that the word “between” is not limited to the radial direction. Prelim. Resp. 28–29.

Sanofi argues that, considering Mylan’s declarant opines that providing threading was routine in the art, a person having ordinary skill in

the art, reading the Great Britain patent application disclosure, would have recognized that the application discloses threading broadly, including internal threading. Prelim. Resp. 30.

Sanofi also argues that, even if the Great Britain patent application disclosure is limited to an externally-threaded piston rod, the disclosure of this species would have informed a person having ordinary skill in the art that the inventors were in possession of the genus of externally- or internally-threaded piston rods. Prelim. Resp. 30–32. Sanofi argues that its position is supported, in part, by Mylan’s declarant opining that threading was well known. *Id.* at 32.

“Under [35 U.S.C.] section 119, the claims set forth in a United States application are entitled to the benefit of a foreign priority date if the corresponding foreign application supports the claims in the manner required by section 112, ¶ 1.” *In re Gosteli*, 872 F.2d 1008, 1010 (Fed. Cir. 1989). Moreover, when a priority claim involves a chain of priority documents, “each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112.” *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997). As the Federal Circuit has noted, however, “[i]n order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.” *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). Rather, “the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad*

Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

We determine, for the purposes of this Decision only, that Mylan has sufficiently demonstrated that the '844 patent is not entitled to a priority claim prior to the filing date of the application that matured into the '844 patent—May 17, 2016. We are not persuaded, on the limited record before us, that a person having ordinary skill in the art would have recognized that the inventors were in possession of a piston rod that was broadly threaded, that is, either internally or externally threaded. We read the Great Britain patent application as disclosing a single embodiment with an externally-threaded piston rod. *See* Ex. 1026, 12, 7–14. This disclosure expressly states that the drive sleeve extends about the piston rod and that *internal* groove 38 of the drive sleeve works with thread 24 of the piston rod. *See id.*; *see also id.* at Fig. 1 (showing, somewhat illegibly, that piston rod 20 is externally threaded); *id.* at 13–14 (describing clicker 50 and clutch 60 as disposed about the drive sleeve and between the drive sleeve and dose dial 70, which is provided outside the clicker and clutch and radially inward of the main housing).

Also, on the limited record before us, we determine that Mr. Leising's testimony that threaded structures were well known does not support a conclusion that a person having ordinary skill in the art would have recognized that the inventors were in possession of a piston rod that was broadly threaded, that is, either internally or externally threaded. We do not read Mr. Leising's testimony to state that internal and external threading were interchangeable or otherwise regarded as comparable. Instead, this testimony merely states that threading was known. *See* Ex. 1011 ¶ 120.

Importantly, the issue is not whether threading was known, but whether a person having ordinary skill in the art would have recognized that the inventors possessed a piston rod with an internal fourth thread that engages with a third thread of a driving member, such that the piston rod and driving member are configured to rotate relative to one another during dose dispensing. *See* Ex. 1004, 8:16–49 (providing the limitations of claim 21).

Also, Sanofi does not provide any evidentiary support for its contention that a person having ordinary skill in the art would have recognized that the inventors were in possession of the genus of internal and external threaded piston rods. We appreciate that, at this stage of the proceeding, our rules weigh factual disputes between declarants in favor of a petitioner, such that a patent owner may be less inclined to provide declaration testimony with a preliminary response. *See* 37 C.F.R. § 42.108(c). Sanofi is free to pursue this issue during trial to more fully develop the record.¹²

¹² The parties are directed to the Federal Circuit’s discussion in *Dynamic Drinkware* of shifting burdens of production. *See Dynamic Drinkware, LLC, v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378–81 (Fed. Cir. 2015). As the Federal Circuit noted, a petitioner bears the burden of persuasion to prove unpatentability of the challenged claims, and this burden never shifts to a patent owner. *Id.* at 1378. The burden of production, however, may shift to a patent owner. *See id.* at 1379–80 (“Dynamic . . . had the initial burden of production, and it satisfied that burden by arguing that Raymond anticipated the asserted claims The burden of production then shifted to National Graphics to argue or produce evidence that either Raymond does not actually anticipate, or, . . . that Raymond is not prior art.”).

b. Independent claim 21.

In support of its contention that Giambattista anticipates independent claim 21, Mylan provides annotated versions of Giambattista's Figures 2 and 7, which we reproduce below.

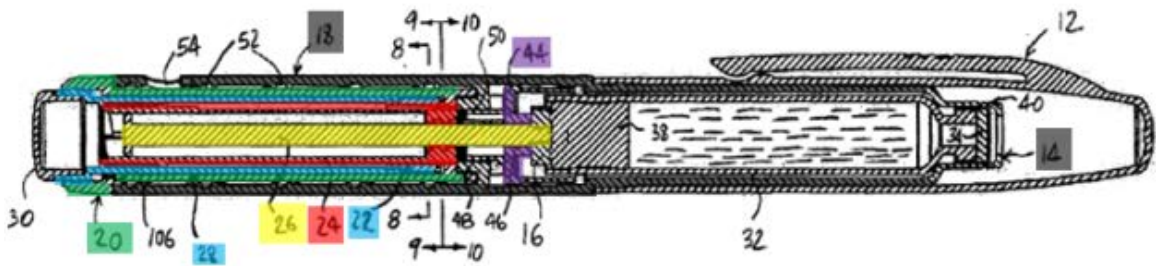


FIG. 7

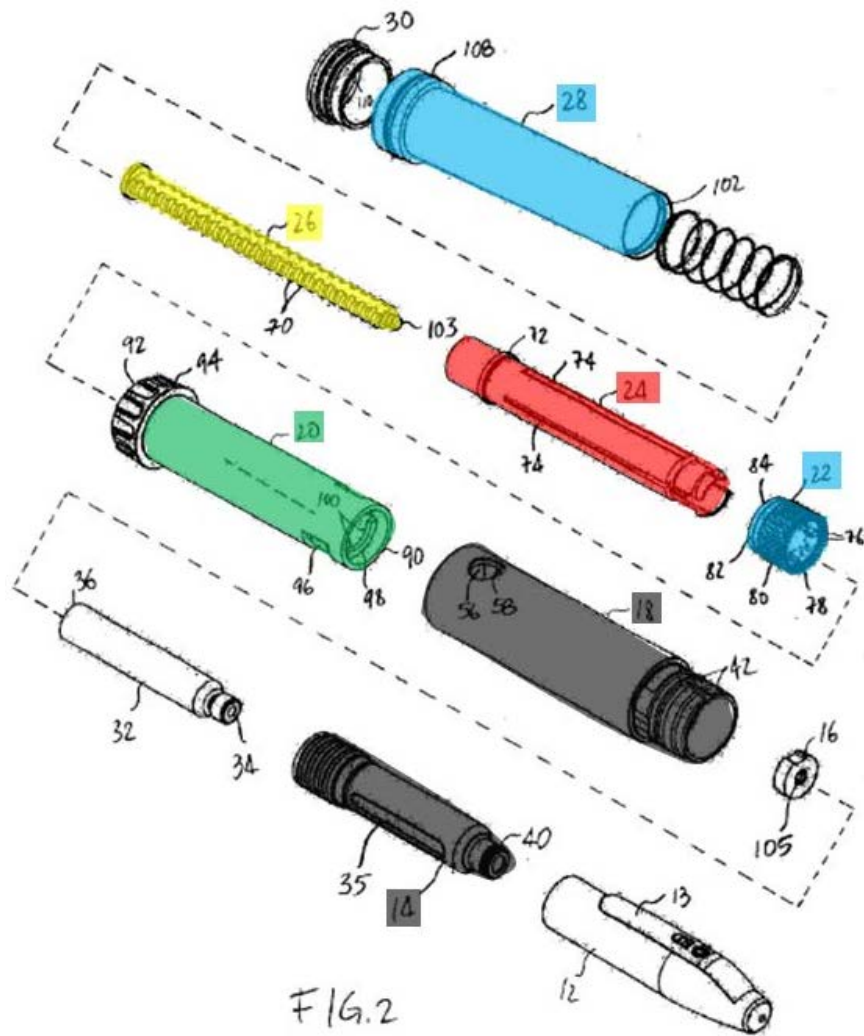


FIG. 2

Pet. 24–25. These annotated figures show in color certain components of Giambattista’s injection pen. *See id.* at 22–23. Mylan’s annotations show body 18 and cartridge holder 14 in grey, dose knob 20 in green, lead screw 26 in yellow, driver 24 in red, dosing ring adaptor 28 and dosing ring 22 in blue, and bulkhead 44 having aperture 46 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; *see also id.* at 7 (showing colorized versions of the embodiment of Figures 1 and 2 of the ’844 patent).

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 body 18 and cartridge holder 14 correspond to the recited housing. Pet. 29–30. Mylan adds that this housing has a dose dispensing end, as medication is expelled from cartridge 32 that is mounted onto cartridge holder 14. *Id.* at 30. Mylan also contends that dose-setting thread 54, formed on the interior of body 18 corresponds to the recited first thread. *Id.* at 31.

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Giambattista 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 Giambattista’s dose knob 20 corresponds to the recited dose indicator. Pet. 31–32. Mylan explains that dose knob 20

includes one or more threaded portions 95 that engage thread 54 of body 18. *Id.* at 32; *see* Ex. 1016, 3:60–62. Mylan continues that “dose knob 20 is ‘rotated within the body 18’ to set ‘a desired dosage,’ [and] that ‘dosage indicia’ may be disposed externally on dose knob 20 so that pointer 58 in window 56 on body 18 can ‘clearly point out a selected dosage level.’” *Id.* at 33; *see* Ex. 1016, 3:10–15, 3:60–67, Figs. 2–3.

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Giambattista 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 Giambattista’s driver 24 corresponds to the recited drive member. Pet. 33–34. Mylan explains that drive member 24 includes internal threads 68 that engage threads 70 of leadscrew 26. *Id.* at 34; *see* Ex. 1016, 3:16–24; Fig. 5; *see also* Ex. 1016, Figs. 11, 12 (depicting internal threads from drive member 24 engaging external threads from leadscrew 26).

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Giambattista discloses the subject matter of the “drive member” limitation of claim 21.

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 Giambattista’s dosing ring adaptor 28 and dosing ring 22 correspond to the recited sleeve. Pet. 36. Giambattista discloses that these two components may be formed as a unitary piece or dosing ring 22 is mounted to dosing ring adaptor 28, such that they move in concert with each other.

See id. at 36–37; Ex. 1016, 21–27. Mylan explains that dosing ring adaptor 28 and dosing ring 22 are positioned within body 18 and dose knob 20, with leadscrew 26 and driver 24 fitting within the internal diameter of dosing ring adaptor 28 and dosing ring 22. Pet. 37. Mylan continues that “[d]osing ring adaptor 28 is releasably connected to dose knob 20 due to its connection to dosing ring 22, which has grooves 76 that releasably engage teeth 100 on lip 98 of dose knob 20.” *Id.* (referencing Ex. 1016, 3:39–40, 4:49–51).

Mylan explains that “[w]hen force is not being applied to the [thumb] button, grooves 76 of dosing ring 22 are ‘spaced apart from the teeth 100 of the dose knob,’ permitting the dose knob to ‘be freely rotated without rotating dosing ring 22.’” Pet. 37–38 (referencing Ex. 1016, 4:49–53). Mylan continues that “[d]epression of thumb button 30 causes ‘interengagement of the grooves 76’ of the dosing ring adaptor 28 and the teeth 100 of the dose knob such that ‘the dosing ring 22 rotates with the dose knob 20.’” *Id.* at 38 (referencing Ex. 1016, 5:8–16).

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Giambattista 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 leadscrew 26 corresponds to the recited piston rod. Pet. 38–39. Mylan explains that leadscrew 26 includes external threads 70 that engage internal threads 68 of driver 24 (that is, the structure for which Mylan alleges corresponds to the third thread). *Id.* at 39.

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Giambattista 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 aperture 46 in bulkhead 44 corresponds to the recited piston rod holder. Pet. 40–41. Mylan explains that “[b]ulkhead holds leadscrew 26 within aperture 46” and “[b]ulkhead 44 and aperture 46 prevent rotation of leadscrew 26 within aperture 46 ‘relative to said body.’” *Id.* at 41. Giambattista discloses that aperture 26 has a rectangular shape such that leadscrew 26 cannot rotate when it is within the aperture but leadscrew 26 does move axially within the aperture. *Id.*; *see* Ex. 1016, 3:1–6, 5:20–24.

We note, however, that, to the extent 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. 40–42. 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), 40–42 (identifying a comparable structure in Giambattista).

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Giambattista discloses the subject matter of the “piston rod holder” limitation of claim 21.

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 Giambattista discloses that body 18 and cartridge holder 14 are disposed at the outermost position of Giambattista’s injection pen. Pet. 43–44. We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Giambattista 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 provides an annotated version of Giambattista’s Figure 9, which we reproduce below.

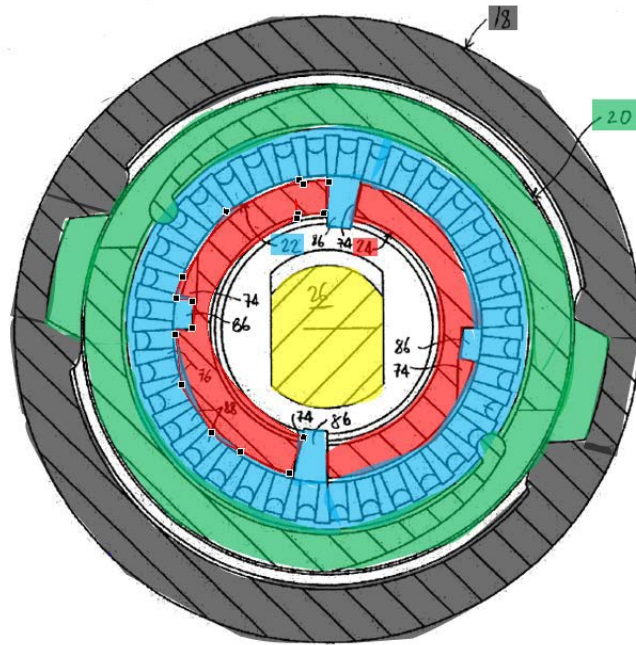


FIG. 9

Pet. 45. This annotated figure colorizes certain components in the figure. Mylan contends that dose knob 20 (the alleged dose indicator, in green) is positioned, axially, between body 18 (a component of the alleged housing, in grey) and dosing ring 22/dosing ring adaptor 28 (the alleged sleeve, in blue). *See id.* at 45–47. Mylan explains that dose knob 20 rotates within body 18, which translates that rotation into axial displacement and that the movement during dose setting is away from the dispensing end. *Id.* at 47–48. Mylan continues that, during dose dispensing, dose knob 20 rotates and descends along dose setting thread 54 towards the dose dispensing end. *Id.* at 48; *see also id.* at 49 (discussing the disclosure of U.S. Patent No. 6,248,095 (Ex. 1021), incorporated by reference into Giambattista as it relates to the movement of the dose indicator).

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Giambattista 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 Giambattista discloses that driver 24 (the alleged drive member) rotates relative to body 18 and leadscrew 26 (the alleged piston rod) cannot rotate relative to body 18, since the leadscrew’s rotation is fixed by aperture 46. Pet. 49–50. Mylan explains that, because driver 24 rotates relative to leadscrew 26, driver 24 drives leadscrew 26 towards the drug dispensing end (to dispense the drug). *Id.* at 50.

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Giambattista 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 “dosing-ring adaptor 28 and dosing ring 22 are rotatably fixed relative to driver 24 and configured to traverse axially with dose knob 20.” Pet. 51. Mylan explains that dosing ring 22 is mounted to driver 24 with splines 86 (on dosing ring 22) and keyways 74 (on driver 24) so that dosing ring 22 does not rotate relative to driver 24. *Id.* Mylan continues that Giambattista discloses that, when dose knob 20 moves axially during dose setting, dosing ring 22 moves with dose knob 20. *Id.*

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Giambattista 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 that Giambattista discloses that “[d]river 24 ‘is able to rotate relative’ to body 18, whereas leadscrew 26 cannot rotate relative to body 18 because of its ‘fixed positioning in the aperture 46’” and “[d]river 24 drives leadscrew 26 towards the drug-dispensing end by rotating about threads 70 of leadscrew 26.” Pet. 52.

We determine, based on the current record at this stage of the proceeding, that Mylan has made the requisite showing that Giambattista 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 “[d]river 24 is configured to transfer force to the leadscrew and thereby drives leadscrew 26 towards the drug-dispensing end by rotating its threads 68 about threads 70 of the leadscrew 26.” Pet. 53 (referencing Ex. 1016, 5:16–24).

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

In its Preliminary Response, Sanofi does not raise any additional arguments directed to Mylan’s contentions as to how Giambattista discloses the subject matter of claim 21.

We determine, on the current record at this stage of the proceeding, that the information in the Petition demonstrates a reasonable likelihood that Mylan will prevail in showing that independent claim 21 is unpatentable as anticipated by Giambattista.

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 the anticipation of independent claim 21 by Giambattista, we institute *inter partes* review on all Challenged Claims and grounds.

Still, we have reviewed Mylan’s contentions with respect to Giambattista 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 anticipated by Giambattista. Sanofi’s Preliminary Response does not raise any additional arguments directed to Mylan’s contentions with respect to the dependent claims and Giambattista.

We take this opportunity to address Mylan’s position with respect to dependent claim 24. Claim 24 depends from claim 21 through claim 23 and recites “where the clutch provides audible and tactile feedback indicative of unit doses of medicament.” Ex. 1004, 8:54–56. With respect to Giambattista disclosing that the feedback is “indicative of unit doses of medicament,” Mylan relies on testimony by Mr. Leising to explain

Giambattista's disclosure. *See* Pet. 56–60. Mylan asserts that, “[a]s Leinsing explains, the disclosure of Giambattista that the holding force at each longitudinal rib 80 is large enough to maintain the desired radial position of dose knob 20 to drive 24 establishes each audible signal (i.e., click) at a unit dose of medicament.” *Id.* at 59 (referencing Ex. 1011 ¶¶ 582, 594). We determine that, at this stage of the proceeding, this testimony is sufficient to support Mylan's contention. We also note that Mylan's second ground of unpatentability also addresses claim 24.

2. *Additional Grounds*

Mylan contends that claims 24–29 are unpatentable under 35 U.S.C. § 103 over Giambattista and Steinfeldt-Jensen, and that claim 30 is unpatentable under 35 U.S.C. § 103 over Giambattista and Klitgaard. Pet. 3.

We have reviewed Mylan's contentions with respect to these grounds, 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 claims 24–29 are unpatentable under 35 U.S.C. § 103 over Giambattista and Steinfeldt-Jensen, and that claim 30 is unpatentable under 35 U.S.C. § 103 over Giambattista and Klitgaard. Sanofi's Preliminary Response does not raise any additional arguments directed to Mylan's contentions with respect to these obviousness grounds.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition, including its supporting testimonial evidence, the Preliminary Response, Reply, and Sur-Reply 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.

IPR2018-01680
Patent 9,526,844 B2

For 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

For PATENT OWNER:

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