

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 IPR2019-00122  
Patent 8,992,486 B2

---

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

JUNG, *Administrative Patent Judge*.

DECISION TO INSTITUTE  
*35 U.S.C. § 314*

## I. INTRODUCTION

Mylan Pharmaceuticals Inc. (“Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting institution of an *inter partes* review of claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of U.S. Patent No. 8,992,486 B2 (Ex. 1003, “the ’486 patent”). Sanofi-Aventis Deutschland GmbH (“Patent Owner”) filed a Preliminary Response (Paper 9, “Prelim. Resp.”). After obtaining authorization, Petitioner filed a Motion to Correct the Petition, which was unopposed by Patent Owner. Paper 7; *see also* Ex. 1037 (providing page 28 of the Petition that shows the proposed change). We granted Petitioner’s motion. Paper 11. As authorized in our Order (Paper 12), Petitioner filed a Reply to the Preliminary Response (Paper 14), and Patent Owner filed a Sur-Reply (Paper 16). Under 35 U.S.C. § 314, an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Upon consideration of the corrected Petition, Preliminary Response, Reply, and Sur-Reply and for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. As such, we institute an *inter partes* review of all challenged claims on the single presented challenge, and thus, institute an *inter partes* review of claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of the ’486 patent.

## II. PETITIONER’S MOTION TO CORRECT

We granted Petitioner’s request to correct the citation “*cf.* EX1003, 3:42–44 (threads may include part threads)” on page 28 of the Petition to

read “*cf.* EX1003, 3:62–64 (threads may include part threads),” thereby changing, in particular, “42–44” to “62–64.” Paper 11; *see also* Paper 7, 1 (requesting correction). Petitioner also filed Exhibit 1037 which is page 28 of the Petition with the requested correction shown using strikethrough and proposed replacement over the strikethrough. Patent Owner indicates that its Preliminary Response includes arguments made in consideration of Petitioner’s requested correction. *See* Prelim. Resp. 52 (providing argument if Petitioner intended to cite Ex. 1003, 3:62–64); Ex. 1039, 6:24–7:10.

Thus, page 28 of the Petition is understood to include the citation “*cf.* EX1003, 3:62–64” in place of “*cf.* EX1003, 3:42–44.” All citations to the Petition in this Decision and following papers will be to the originally filed Petition with the correction shown in Exhibit 1037.

### III. BACKGROUND

#### A. *Related Proceedings*

The parties indicate that the ’486 patent has been asserted in *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105-SRC-CLW (D.N.J.); *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812-RGA-MPT (D. Del.); and *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, No. 1:14-cv-00113-RGA-MPT (D. Del.). Pet. 1; Paper 5, 2; Paper 8, 2; Exs. 1029, 1030.

The parties state that the ’486 patent is also challenged in Cases IPR2018-01678 and IPR2018-01679. Pet. 2; Paper 5, 3; Paper 8, 3. The ’486 patent is additionally challenged in Case IPR2018-01677, and Petitioner’s motion to dismiss the petition in IPR2018-01677 was granted.

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

*B. The '486 Patent (Ex. 1003)*

The '486 patent issued March 31, 2015, from an application filed June 4, 2013, which is the latest application in a series of continuation applications, the first of which was filed on March 2, 2004. Ex. 1001, [22], [45], [63], 1:6–11. The '486 patent also claims priority to a foreign application filed on March 3, 2003. *Id.* at [30], 1:12–14.

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

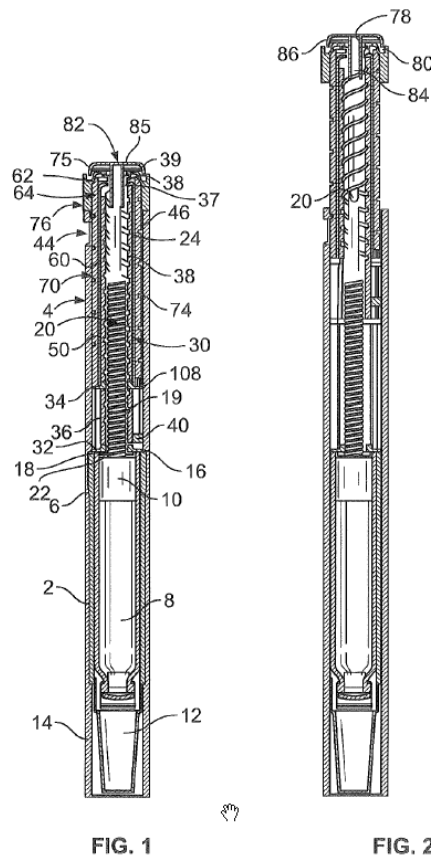


Figure 1 “shows a sectional view of a pen-type injector . . . in a first, cartridge full position,” and Figure 2 “shows a sectional view of the pen-type injector . . . in a second, maximum first dose dialed, position.” *Id.* at 2:53–57. The injector includes first cartridge retaining part 2 and main housing part 4.<sup>1</sup> *Id.* at 3:27–28. Insert 16 is at a first end of main housing 4 and is fixed rotationally and axially to main housing 4. *Id.* at 3:49–51. Insert 16 includes threaded circular opening 18, through which piston rod 20 extends. *Id.* at 3:51–53, 3:57–59. Piston rod 20 includes first thread 19 that engages threaded circular opening 18. *Id.* at 3:56.

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

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

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

---

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

A user rotates dose-dial grip 76 to set a dose and to cause dose-dial sleeve 70, clutch 60, and drive sleeve 30 to rotate together out of main housing 4. *Id.* at 5:50–53, 5:61–65, Fig. 9. The dose can be reduced by turning dose-dial grip 76 in the opposite direction. *Id.* at 6:19–20, Fig. 10. The user then presses button 82, which causes clutch 60 to disengage from dose-dial sleeve 70 so that clutch 60 moves axially and dose-dial sleeve 70 rotates back into main housing 4. *Id.* at 6:28–35, 6:38–40, Fig. 11. Drive sleeve 30 also moves axially and causes piston rod 20 to rotate through threaded opening 18 to dispense medicine from cartridge 8. *Id.* at 6:45–47.

*C. Illustrative Claim*

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

1. A housing part for a medication dispensing apparatus, said housing part comprising:
  - a main housing, said main housing extending from a distal end to a proximal end;
  - a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing;
  - a dose knob disposed near a proximal end of said dose dial sleeve;
  - a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;
  - a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod; and,
  - a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob,

wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

Ex. 1003, 6:59–7:12.

*D. Evidence Relied Upon*

Petitioner identifies U.S. Patent No. 6,221,046 B1, issued April 24, 2001 (Ex. 1013, “Burroughs”) as prior art in the asserted ground of unpatentability. Petitioner also provides a Declaration of Karl R. Leinsing (Ex. 1011).

*E. Asserted Ground*

Petitioner challenges, under 35 U.S.C. § 103, claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 as unpatentable over Burroughs. Pet. 3, 22–67.

IV. 35 U.S.C. § 314(a)

Patent Owner urges us to exercise our discretion under 35 U.S.C. §§ 314(a) and 324(a)<sup>2</sup> to deny the Petition because instituting trial “would waste the Board’s finite resources and is fundamentally unfair and inefficient to require Patent Owner to expend resources on an IPR trial where the final written decision will issue only after the conclusion and resolution of validity challenges in the related District Court case that are based on the same prior art at issue here.” Prelim. Resp. 4. Patent Owner provides a procedural history leading to the related district court litigation and filing of the Petition in this proceeding. *Id.* at 5–8. Patent Owner indicates that it filed a patent infringement case against Petitioner on

---

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

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

According to Patent Owner, the invalidity contentions included the same prior art presented in the Petition. *Id.* at 7; *see also id.* at 29–31 (arguing that Petitioner asserts that same prior art grounds in this proceeding and related litigation). Patent Owner also notes that Petitioner received Patent Owner’s response to those contentions on August 12, 2018, approximately one month before the present Petition was filed. *Id.* at 7; *see also id.* at 32 (arguing that “each petition seeks a second bite at duplicative invalidity grounds and provides a tactical advantage to Petitioner”); Paper 16, 3 (arguing that “Mylan continues its quest for its ‘second bite’ by seeking to preserve its ability to assert invalidity positions in the District Court that Mylan contends are not ‘specific[ally]’ identical to those in the IPR”).

Patent Owner additionally indicates that the parties in the case have jointly requested trial in the District Court for October 2019, to reach resolution before the end of the FDA’s 30-month stay of regulatory approval of Petitioner’s FDA application of its insulin glargine product on March 18, 2020. Prelim. Resp. 7–8 (citing Ex. 2005 ¶ 8); *see also id.* at 25–27 (citing Ex. 2006 ¶ 8; Ex. 2019, 1; Ex. 2020, 19; Ex. 2022, 1; Ex. 2023, 7–8; Ex. 2024, 31:15–32:3); Paper 16, 1–2 (citing Ex. 2017, 6:17–24; Ex. 2026 (amended scheduling order proposing trial for “January 2020, subject to the [District] Court’s availability”)). Thus, according to Patent Owner, the related district court litigation will be decided before a final written decision is issued in this proceeding. Prelim. Resp. 1, 4, 8; *see also id.* at 25–27 (arguing that related litigation will be tried by March 2020); Paper 16, 1–2.



Patent Owner argues that the Board has discretion to deny under 35 U.S.C. §§ 314(a) and 324(a) to establish a more efficient patent system and limit unnecessary litigation costs. Prelim. Resp. 1–2, 8 (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) (“Trial Practice Guide Update”)). Patent Owner also notes that the Board has done so in circumstances similar to the ones of this proceeding. *Id.* at 8 (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, Case IPR2018-00752 (PTAB Sept. 12, 2018) (Paper 8) (“*NHK Spring*”). Patent Owner further argues that exercising discretion in this proceeding will not impact broadly Hatch-Waxman litigants. *Id.* at 27–28 (citing Ex. 2020, 19); Paper 16, 3–4 (arguing that Petitioner admits that this case would not affect broadly Hatch-Waxman cases).

Patent Owner contends that the facts here are similar to the facts of *NHK Spring*, because the parties are at an advanced stage in district court litigation, Petitioner is relying on prior art that is at issue in that litigation, the district court trial will conclude before a final written decision is issued, and the district court recognizes the importance of resolving the infringement case before the 30-month stay ends. Prelim. Resp. 9–13 (citing Pet. 3; Exs. 2007–2009, 2017, 2018); *see also* Paper 16, 8 (arguing that this proceeding can be distinguished from other Board cases where *NHK Spring* was not applied). Patent Owner also argues that instituting trial in this proceeding gives Petitioner a tactical advantage because Petitioner was able to review Patent Owner’s response to Petitioner’s invalidity contentions in the related litigation, which amounts to “two bites at the apple.” Prelim. Resp. 13–14, 31–32. Patent Owner asserts that Petitioner was aware of the

timing of the district court case and engaged in gamesmanship that is highly prejudicial to Patent Owner. *Id.* at 14.

Patent Owner also provides its application of the factors discussed in *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, Case IPR2016-01357 (PTAB Sept. 6, 2017) (Paper 19) (“*General Plastic*”) to the facts of this case and contends that all of those factors favor denying the petition. Prelim. Resp. 14–19; *see also* Paper 16, 9 (arguing that *General Plastic* apply to this proceeding). Patent Owner argues that, although those factors were articulated in the context of denying follow-on petitions, the underlying logic applies to the present proceeding. Prelim. Resp. 15. In its analysis of the factors, Patent Owner points to Petitioner’s duplication of invalidity arguments in the related court case and the present proceeding, the filing of the Petition after Petitioner received Patent Owner’s response to the invalidity contentions in related litigation, and the likelihood that the invalidity contentions pending in district court will be decided no later than March 18, 2020. *See id.* at 15–18.

In an attempt to preemptively address Petitioner’s arguments in a reply filed in a related case with a similar challenge, Patent Owner contends that Petitioner misstates and misapplies the law regarding discretionary denial under § 314(a). *Id.* at 19–25 (addressing the Administrative Procedures Act; *Click-to-Call Tech., LP v. Ingenio, Inc.*, 899 F.3d 1321 (Fed. Cir. 2018) (“*Click-to-Call*”); 157 Cong. Rec. S1360, 1377 (Mar. 11, 2018)). Patent Owner argues that the Board has discretion to deny a petition in circumstances similar to the ones in this case. *Id.* at 20; Paper 16, 5–8 (replying to Petitioner’s arguments based on Administrative Procedures Act;

*Click-to-Call*; Trial Practice Guide Update), 10 (reply to Petitioner’s arguments based on legislative history).

In its Reply to the Preliminary Response, Petitioner provides arguments that the challenge in this proceeding has not been shown to be the same as, and is not the same as, the invalidity contentions in related litigation. Paper 14, 1–3 (citing Ex. 2009, 518; Ex. 2010, 11–12; Ex. 2011). Petitioner also contends that it filed multiple petitions to address five patents and to meet rules regarding word limits (*id.* at 3–4) and that it filed all related petitions on the same day (*id.* at 6–7). According to Petitioner, Patent Owner speculates as to when the related district court case will be tried. *Id.* at 4–6 (citing Ex. 2019, 1; Ex. 2020, 19; Ex. 2021, 1), 14. Petitioner also provides arguments regarding the scope of our discretion under 35 U.S.C. § 314(a) (*id.* at 7–9, 21) and argues that Patent Owner’s arguments regarding that discretion run afoul of statute, case law, the Administrative Procedures Act, certain Board decisions, and the legislative history of the America Invents Act (*id.* at 9–24).

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 will occur in January 2020.<sup>3</sup> *See* Ex. 2026 (scheduling trial “subject to Court’s availability”). Although the record indicates that the

---

<sup>3</sup> 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)).

district court and the parties are working together towards resolving the related litigation before March 18, 2020, the end of the FDA's 30-month stay, the record does not provide enough indications that the related litigation will in fact be resolved before the end of the 30-month stay. Indeed, as indicated in the latest scheduling order in the district court litigation, the parties will not even propose trial dates to the court until October 2019. *See* Ex. 2026. 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 14, 4–5 (explaining that “most deadlines are tied to the issuance of a Markman order”). In this proceeding, by statute, barring good cause for extending pendency, review will be completed within one year of institution. For these reasons, we are not persuaded that instituting review in this proceeding will be an inefficient use of Board resources.

We are also not persuaded to apply the factors enumerated in *General Plastic* to the facts of this case. As Patent Owner notes, the *General Plastic* factors were articulated in the context of follow-on petitions. Prelim. Resp. 14. Here, in contrast, Patent Owner does not complain of a follow-on petition. Rather, Patent Owner complains that Petitioner received Patent Owner's response to Petitioner's invalidity contentions in related litigation before Petitioner filed the Petition. *Id.* at 7. The excerpts of Petitioner's invalidity contentions provided by Patent Owner, however, show that, in that related litigation, other references are relied upon for teaching limitations of the claims challenged in this proceeding, and the reference asserted in this proceeding is cited only for some, not all, of the limitations of the challenged claims. *See* Ex. 2007 (asserting Burroughs in combination with other

references not asserted in this proceeding); Ex. 2008 (not asserting Burroughs for any limitation of claims 3, 4, 6, 20, 23, 26–29, 40); Ex. 2009 (asserting Burroughs in combination with other references not asserted in this proceeding). Also, we cannot discern from the exhibits the substance of Patent Owner’s response to the invalidity contentions, so it is unclear what, if any, tactical advantage Petitioner may have gained by receiving that response before filing the Petition in this matter. Thus, we are not persuaded that Petitioner’s receipt of Patent Owner’s response to invalidity contentions in the related district court litigation amounts to a petitioner receiving the benefit of a preliminary response or decision on institution before filing a second petition challenging the same patent, the circumstances addressed by the *General Plastic* factors. Therefore, we are not persuaded those factors apply. Moreover, even if we did apply *General Plastic* to this case, the differences between Petitioner’s invalidity contentions in related litigation and the ground at issue in this case do not indicate clearly what benefit, if any, Petitioner could have had in drafting its petition for this proceeding. Also, Petitioner filed its Petition well within the timeframe allowed by statute, weighing heavily in its favor.

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

## V. CHALLENGE UNDER 35 U.S.C. § 103

### A. *Claim Construction*

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b)

(2018); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard).<sup>4</sup>

Petitioner states that “claim terms should be given their ordinary and customary meaning, consistent with the specification and how they would have been understood by [a person of ordinary skill in the art]” and that the “ground presented below relies on the ordinary and customary meaning of the claim terms.” Pet. 13, 16. Petitioner provides interpretations of “driver,” “main housing,” “piston rod,” “thread/threaded/threading,” “tubular clutch,” “clicker,” and “insert” that were proffered by Patent Owner in related litigation. *Id.* at 13–14 (citing Ex. 1019, 20, 21, 24, 25, 27, 29). Petitioner also notes that it proffered means-plus-function interpretations for “clutch,” “clicker,” and “insert” in related litigation and proposes means-plus-function interpretations for those terms in this proceeding. *Id.* at 15–16 (citing Ex. 1003, 2:16–18, 2:20–35, 4:33–62, 6:36–44, Figs. 1, 3–11; Ex. 1009, 1:63–65, 3:58–64; Ex. 1028, 101–106, 112–116). Petitioner also states that the “ground also addresses the ‘clutch,’ ‘clicker,’ and ‘insert’ limitations to the extent that those terms may be construed as means-plus-function limitations.” *Id.* at 16.

Patent Owner responds that Petitioner does not state what the plain and ordinary meaning is for any term. Prelim. Resp. 37. Patent Owner also

---

<sup>4</sup> On October 11, 2018, the Office revised its rules to harmonize the Board’s claim construction standard with that used in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42). This rule change, however, applies to petitions filed on or after November 13, 2018, and the revised claim construction standard does not apply to this proceeding. *Id.*; see Paper 4, 1 (according a filing date of October 29, 2018 to the Petition).

contends that Petitioner fails to comply with 37 C.F.R. § 42.104(b) by not asserting clearly how the claims are construed for purposes of the petition. *Id.* at 57–58.

By providing Patent Owner’s proposed interpretations from related litigation, we understand Petitioner to contend that the broadest reasonable interpretation in view of the specification and the plain and ordinary meanings of these terms would encompass at least Patent Owner’s proposed interpretations. Also, Petitioner’s arguments provide sufficient indication as to how Petitioner is interpreting the challenged claims in its application of Burroughs to the claim limitations.

Patent Owner also disputes that “clutch,” “clicker,” and “insert” are means-plus-function limitations. Prelim. Resp. 37, 41–42. Patent Owner argues that, although Petitioner requests means-plus-function interpretations for these terms, Petitioner applies different interpretations or does not apply means-plus-function interpretations in its analysis, thereby prejudicing Patent Owner’s ability to defend its patent. *Id.* at 58–60.

At this stage of the proceeding, the mere fact that Petitioner proposed means-plus-function interpretations in related litigation does not, by itself, demonstrate that the broadest reasonable interpretation of these terms in view of the specification would be a means-plus-function interpretation. We need not determine, at this stage of the proceeding, if these terms are means-plus-function terms, as Petitioner provides alternative analyses with respect to claims reciting these terms. The parties, however, may address this issue further during trial if it is necessary. Also, we note that Petitioner does apply its asserted means-plus-function interpretations in its challenge. *See*

Pet. 54 (providing arguments if “clicker” is construed to be a means-plus-function limitation).

Patent Owner proposes to interpret “helical groove” to mean “a groove formed in the shape of a spiral.” Prelim. Resp. 23–24. Patent Owner provides citations to the specification of the ’486 patent and dictionary definitions. *Id.* at 38–41 (citing Ex. 1002, 5:5–6, Figs. 12–14; Ex. 2013, 10; Ex. 2014; Ex. 2015, 4, 5). Based on the arguments and evidence at this stage, we adopt Patent Owner’s proposed interpretation of “helical groove” for the purposes of this Decision. After the record has been developed at trial, we may revisit the interpretation of this term and Petitioner’s arguments regarding Burroughs related thereto.

With respect to the other claim terms discussed above, we determine that no express interpretation is required for any claim term for the purposes of determining whether Petitioner demonstrates a reasonable likelihood of prevailing in its challenge. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (construing explicitly only those claim terms in controversy and only to the extent necessary to resolve the controversy); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

#### *B. Level of Ordinary Skill*

Petitioner asserts that one of ordinary skill in the art “would have had at least a bachelor’s degree in mechanical engineering, or an equivalent degree, plus three-years’ experience” and “would have understood the basics of medical-device design and manufacturing, and mechanical elements (*e.g.*, gears, pistons) involved in drug-delivery devices.” Pet. 13 (citing Ex. 1011



¶ 106). Patent Owner does not propose a level of ordinary skill at this stage of the proceeding.

We note that the articulation of the asserted level of ordinary skill in the Petition of this proceeding differs from the articulation in the Petition for IPR2018-01679, which challenges the same patent. We also note that both Petitions reference the same paragraph of declarant testimony, which is the same testimony filed for each case. We preliminarily adopt Petitioner's, as-yet unchallenged, asserted level of ordinary skill solely to determine whether there is a reasonable likelihood that Petitioner would prevail with respect to at least 1 of the claims challenged in the Petition.

*C. Burroughs (Ex. 1013)*

Burroughs relates to “medical dispensing devices . . . that permit selectively measured dosages of a liquid to be dispensed.” Ex. 1013, 1:13–16. Figure 2 of Burroughs is reproduced below.

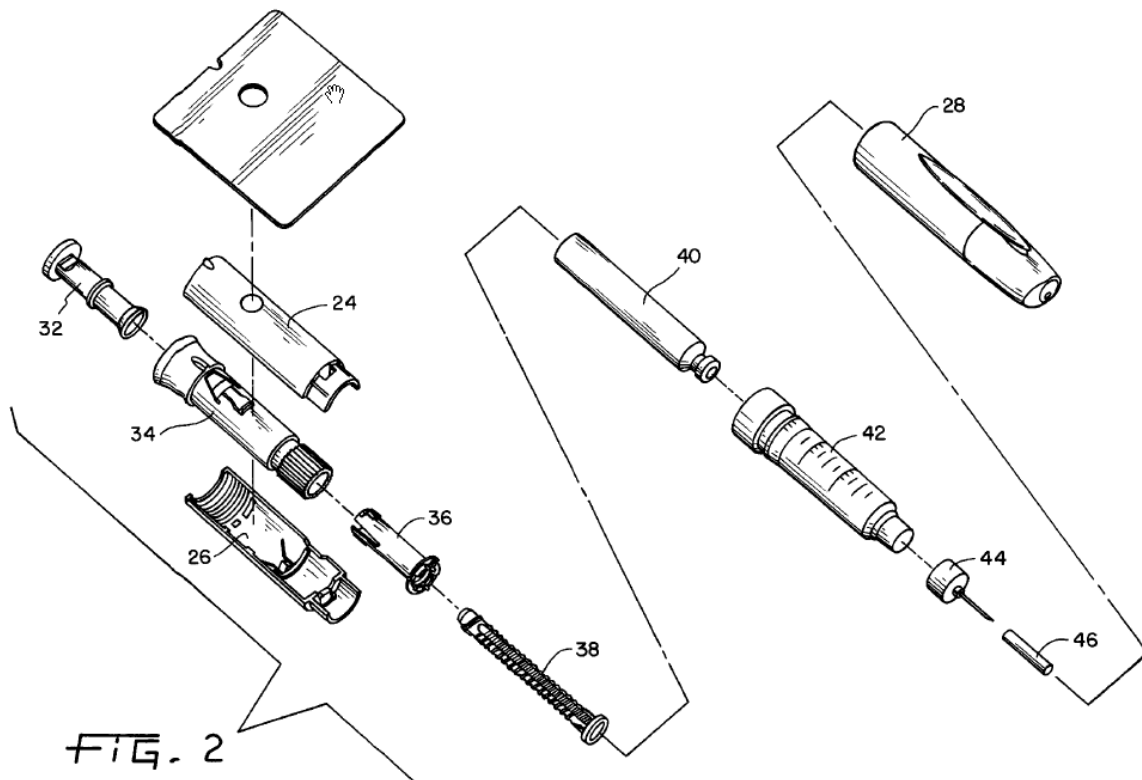


Figure 2 shows an exploded view of injection medication device 20. *Id.* at 6:42–43, 7:15–16. Medication device 20 includes mechanism housing 22 made from housing parts 24 and 26, button 32, dial mechanism 34, nut 36, and leadscrew 38 that forms a drive stem. *Id.* at 7:17–18, 7:32–34, 9:12–13.

Dial mechanism 34 engages button 32. *Id.* at 8: 9–14, Figs. 6, 8. Dial mechanism 34 also includes outwardly extending threads 110, 112 that “enter helical groove 158 during commencement of the dosing process.” *Id.* at 8:33–36, 8:62–9:1, Figs. 3, 5. “As a dosage is being set, outwardly extending threads 110 and 112 of dial mechanism 34 ride in helical groove 158 of housing parts 24 and 26.” *Id.* at 10:60–63.

When button 32 is depressed, dial mechanism 34 travels axially towards cartridge 40. *Id.* at 8:15–20. Splines 144 on the interior of dial mechanism 34 engage teeth 192 of nut 36 when the clutch is engaged to set a dosage. *Id.* at 8:42–48, Fig. 9. A series of numerals are printed on dial mechanism 34 to indicate a desired dosage. *Id.* at 10:5–9.

Rotating dial mechanism 34 causes nut 36 to rotate and move relative to housing 20, but rotation of leadscrew 38 is prevented. *Id.* at 10:25–27. Once a desired dosage has been set, button 32 is pushed to move dial mechanism 34, nut 36, and leadscrew 38 forward to deliver the set dosage. *Id.* at 11:13–19, 11:31–34.

*D. Claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40*

Petitioner contends that claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 are unpatentable over Burroughs. Pet. 3, 22–67. Petitioner provides claim charts and arguments with citations to where Burroughs teaches or suggests the elements of these claims and to supporting declarant

testimony. *Id.* at 23–38, 40–53, 55–60, 61–67. Petitioner contends that Burroughs’s housing 22, dial mechanism 34, proximal portion 78, leadscrew 38, nut 36, and button 32 teach, respectively, claim 1’s main housing, dose dial sleeve, dose knob, piston rod, driver, and clutch. *See id.* at 22–38.

Petitioner also asserts what one of ordinary skill in the art would have understood from Burroughs with supporting declarant testimony. *Id.* at 43, 52, 56, 63, 67. For claims 14–18 and 20, to the extent “clicker” is construed as a means-plus-function limitation, Petitioner contends that Burroughs teaches or suggests the asserted corresponding structure with citations to Burroughs and declarant testimony. *Id.* at 54.

Independent claim 1 recites “a dose dial sleeve . . . comprising a helical groove configured to engage a threading provided by said main housing.” Ex. 1003, 6:63–65. Petitioner argues that dial mechanism 34 of Burroughs teaches the required dose dial sleeve and that threads 110, 112 of dial mechanism 34 “are configured to releasably engage helical spiral groove 158 on an inner surface of housing 22.” Pet. 27 (citing Ex. 1013, 7:31–32, 7:65–67, 8:33–36, 8:62–9:1, Figs. 1–3; Ex. 1011 ¶¶ 161–167). According to Petitioner, “[t]hreads 110, 112 are spaced apart on opposite sides of dial mechanism 34, so proper engagement of the threads with helical spiral groove 158 requires that they be positioned helically relative to one another, thereby forming a discontinuous helical rib corresponding to the housing’s helical groove.” *Id.* at 27–28 (citing Ex. 1011 ¶¶ 168–170). Petitioner also argues that, if threads 110, 112 would not have been understood to be “helical grooves,” threads 110, 112 suggest a groove. *Id.* at 38 (citing Ex. 1011 ¶¶ 189–190).

Petitioner provides reasons for modifying Burroughs with support from testimonial evidence. *Id.* at 28, 38–40, 53–54, 60–61. In particular for the helical groove of claim 1, Petitioner contends that it would have been apparent to provide threads 110, 112 as a protruding helical groove instead of a protruding helical rib, and that one of ordinary skill in the art “would have recognized that such groove-to-rib implementation of the threading would be functionally equivalent and largely interchangeable with the depicted rib-to-groove implementation.” *Id.* at 39 (citing Ex. 1011 ¶¶ 189–190, 192–193). Petitioner also contends that such a modification would have been a routine task and a “predictable use of prior art elements according to their established functions” with a reasonable expectation of success in implementing threads 110, 112 as protruding helical grooves. *Id.* at 39–40 (citing Ex. 1011 ¶¶ 168–170, 193–196).

Patent Owner responds that Petitioner fails to show that Burroughs teaches or would have rendered obvious a “helical groove provided along an outer surface of said dose dial sleeve.” Prelim. Resp. 49–57. According to Patent Owner, “Petitioner admits that Burroughs does not disclose a helical groove on the outer surface of the dose dial sleeve,” and thus, “there is no dispute that Burroughs fails to disclose this limitation.” *Id.* at 50 (citing Pet. 28).

Patent Owner also argues that Petitioner’s “proposed modification does not result in a ‘helical groove’ as properly construed.” *Id.* Patent Owner contends that “threads 110 and 112 are *discrete, tooth-like protrusions* on the surface of dial mechanism 34, *not* a spiral-shaped rib or thread,” and “Petitioner’s assertions are both unsupported and unreliable.” *Id.* at 50. Patent Owner also contends that the cited portions of Petitioner’s

declarant testimony “relate to . . . purported uses of ‘rib-to-groove’ threaded connections in the prior art, rather than explaining why a [person of ordinary skill in the art] would have purportedly understood Burroughs’s threads 110 and 112 to form a ‘helical rib.’” *Id.* at 51 (citing Ex. 1011 ¶¶ 168–170). Patent Owner additionally contends that paragraph 165 of Petitioner’s declarant testimony is a conclusory opinion that threads 110, 112 are a helical rib. *Id.* Patent Owner further contends that Petitioner’s citations to the ’486 patent do not discuss threads or grooves. *Id.* at 51–53 (citing Ex. 1003, 3:42–44, 3:62–64, Figs. 1, 2; Ex. 2016, 5:24–6:8). Patent Owner states that “thread 24 [of the ’486 patent] is a thread formed in the shape of a spiral, even though it may have discontinuities” but “*Burroughs*’ threads 110 and 112 are a *helical rib*” and “clearly not *formed* in the shape of a spiral.” *Id.* at 53–54 (citing Ex. 1013, Figs. 7, 9).

Patent Owner further asserts that Petitioner’s declarant “fails to apply an appropriate construction of ‘helical’” and “admits that the threads 110 and 112 are formed in the shape of ‘rib-like protrusions,’ *not* in the shape of a spiral.” *Id.* at 54 (citing Ex. 1011 ¶ 165). Patent Owner also asserts that Petitioner’s declarant “erroneously bases his opinion on the alleged relative position between the two threads” and his testimony “is based on his contention that one could trace an imaginary, spiral-shaped path between the threads, rather than the threads themselves being formed in the shape of a spiral.” *Id.* (citing Ex. 1011 ¶ 165). According to Patent Owner, Petitioner provides no evidence “showing that it would have been obvious . . . to further modify threads 110 and 112 such that the threads, and not some imaginary line, are formed in the shape of a spiral.” *Id.* at 54–55.

Claim 1 recites “a dose dial sleeve . . . comprising a helical groove configured to engage a threading provided by said main housing,” not a “helical groove provided along an outer surface of said dose dial sleeve,” as argued by Patent Owner. Ex. 1003, 6:63–65. On the present record, Petitioner sufficiently shows for purposes of institution that Burroughs would have rendered obvious a “dose dial sleeve . . . comprising a helical groove configured to engage a threading provided by said main housing.” Petitioner relies on portions of Burroughs that teach “outwardly extending thread 110, 112” that “enter helical groove 158 during commencement of the dosing process.” *See* Pet. 27 (citing Ex. 1013, 7:31–32, 7:65–67, 8:33–36, 8:62–9:1, Figs. 1–3; Ex. 1011 ¶¶ 161–167). Burroughs also teaches “[a]s a dosage is being set, outwardly extending threads 110 and 112 of dial mechanism 34 ride in helical groove 158 of housing parts 24 and 26.” Ex. 1013, 10:60–63. These portions of Burroughs adequately support Petitioner’s contention that “[t]hreads 110, 112 are spaced apart on opposite sides of dial mechanism 34” and that “proper engagement of the threads with helical spiral groove 158 requires that they be positioned helically relative to one another, thereby forming a discontinuous helical rib corresponding to the housing’s helical groove.” *See* Pet. 27–28 (citing Ex. 1011 ¶¶ 168–170).

Even under Patent Owner’s proposed interpretation of “helical groove” as a “groove formed in the shape of a spiral” (Prelim. Resp. 38), which we have adopted for purposes of this Decision, based on the same teachings of Burroughs discussed above, Petitioner at this stage sufficiently argues that threads 110, 112 must have some spiral aspect to be able to engage helical spiral groove 158. *See* Pet. 27–28. Petitioner also provides

argument and evidence that threads 110, 112 would have been modified to be a helical groove. *See id.* at 39–40. Thus, in view of all the arguments and evidence, Petitioner adequately shows for institution that Burroughs would have rendered obvious a “dose dial sleeve . . . comprising a helical groove configured to engage a threading provided by said main housing,” as recited by claim 1.

Patent Owner also responds that Petitioner fails to provide a motivation for its proposed modification of Burroughs because Petitioner only asserts that its proposed modification “would have been ‘interchangeable’ with the structure disclosed in Burroughs and that the modified elements would have still performed the same functions.” *Id.* at 55–56 (citing Pet. 38–40). Patent Owner argues that Petitioner’s mere assertion is insufficient for obviousness and does not show why the modification would have been made, does not identify any problem solved by the proposed modification, and does not identify any improvement to Burroughs from the proposed modification. *Id.* at 56. Patent Owner also argues that Petitioner’s proposed modification increases the complexity of Burroughs and “would simply perform the same function as the structure already disclosed in Burroughs.” *Id.* at 56–57 (citing Pet. 40).

At this stage, Petitioner’s assertion that its proposed modification of threads 110, 112 to be protruding helical grooves represents a “predictable use of prior art elements according to their established functions” with a reasonable expectation of success is sufficient for purposes of institution. *See* Pet. 39–40 (citing Ex. 1011 ¶¶ 168–170, 193–196). After the record has been developed at trial, Petitioner’s reasons for modifying Burroughs will be further analyzed in view of all evidence presented.

For the reasons above and on the present record, Petitioner demonstrates a reasonable likelihood of success in proving that at least claim 1 of the '486 patent is unpatentable. We have also reviewed Petitioner's arguments and evidence directed to the challenged dependent claims and determine that Petitioner provides sufficient argument and evidence for purposes of institution. *See* Pet. 40–67. At this stage, Patent Owner does not provide arguments specifically for the challenged dependent claims. *See* Prelim. Resp. 32–44. Therefore, we determine that further analysis of Petitioner's challenge of claims 2–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 is best left for trial after full development of the record.

## VI. CONCLUSION

The Supreme Court held that a final written decision under 35 U.S.C. § 318(a) must decide the patentability of all claims challenged in the petition. *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). After considering the evidence and arguments presented in the present record, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one of claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of the '486 patent is unpatentable.

Because Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims, we institute an *inter partes* review of all challenged claims on the one presented challenge.

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.



## VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of U.S. Patent No. 8,992,486 B2 is instituted with respect to the one ground set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 8,922,486 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2019-00122  
Patent 8,992,486 B2

PETITIONER:

Richard Torczon  
Douglas Carsten  
Wesley Derryberry  
Tasha Thomas  
Jeffrey W. Guise  
Arthur Dykhuis  
Lorelei Westin  
Franklin Chu  
Nicole Stafford  
Elham F. Steiner

WILSON SONSINI GOODRICH & ROSATI

rtorczon@wsgr.com  
dcarsten@wsgr.com  
wderryberry@wsgr.com  
tthomas@wsgr.com  
jguise@wsgr.com  
adykhuis@wsgr.com  
lwestin@wsgr.com  
ychu@wsgr.com  
nstafford@wsgr.com  
esteiner@wsgr.com

PATENT OWNER:

Elizabeth Stotland Weiswasser  
Anish R. Desai  
Sundip K. Kundu  
Kathryn M. Kantha  
William S. Ansley  
Matthew D. Sieger  
Adrian C. Percer  
Brian C. Chang

WEIL, GOTSHAL & MANGES LLP

elizabeth.weiswasser@weil.com  
anish.desai@weil.com  
sundip.kundu@weil.com  
kathryn.kantha@weil.com

IPR2019-00122  
Patent 8,992,486 B2

sutton.ansley@weil.com  
matthew.sieger@weil.com  
adrian.percer@weil.com  
brian.chang@weil.com