

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 IPR2018-01679
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 51–57 of U.S. Patent No. 8,992,486 B2 (Ex. 1003, “the ’486 patent”). Sanofi-Aventis Deutschland GmbH (“Patent Owner”) did not file a Preliminary Response. Under 35 U.S.C. § 314, an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Upon consideration of the Petition and 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 all presented challenges, and thus, institute an *inter partes* review of claims 51–57 of the ’486 patent.

II. 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 7, 2; Paper 9, 2; Exs. 1029, 1030.

The parties state that the ’486 patent is also challenged in Cases IPR2018-01677, IPR2018-01678, and IPR2019-00122. Pet. 2; Paper 5, 3;

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Paper 7, 3; Paper 9, 3. 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. 1–2; Paper 5, 2–3; Paper 7, 2–3; Paper 9, 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. Figure 1 of the ’486 patent is reproduced below.

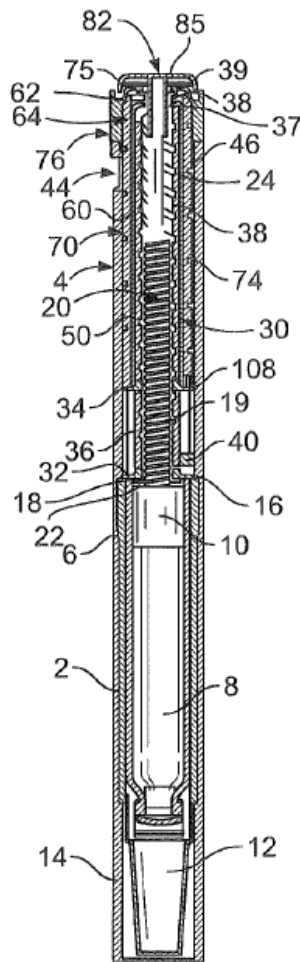


FIG. 1

Figure 1 “shows a sectional view of a pen-type injector . . . in a first, cartridge full position.” *Id.* at 2:53–55. The injector includes first cartridge retaining part 2 and main housing part 4.¹ *Id.* at 3:27–28. Insert 16 is at a first end of main housing 4 and is fixed rotationally and axially to housing part 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

¹ 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”).

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. Figures 7 and 8 of the '486 patent are reproduced below.

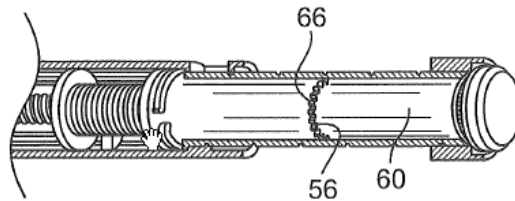


FIG. 7

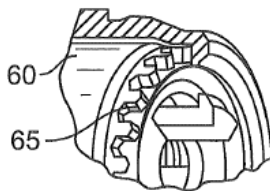


FIG. 8

Figures 7 and 8 show partially cut-away views of the pen-injector of Figure 1. *Id.* at 2:66–3:2. Clutch 60 is generally cylindrical and provided with circumferentially directed saw teeth 66 at a first end and radially inwardly directed flange 62 and dog teeth 65 at a second end. *Id.* at 4:50–52, 4:54–55, 4:58–60. 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.

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 to allow relative motion. *Id.* at 5:5–6, 5:9–11. 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 5:24–25, 5:27–28.

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 51–57 in this proceeding. Of those, claim 51, reproduced below, is the only independent claim.

51. A clutch for use within a pen type drug delivery device, said clutch comprising
a tubular body, said tubular body extending from a distal end to a proximal end; and said distal end of said tubular body having a diameter sized such that said distal end of said tubular body may be positioned within a proximal end of a dial member.

Ex. 1003, 10:31–37.

D. Evidence Relied Upon

Petitioner identifies the following references as prior art in the asserted grounds of unpatentability:

- (1) U.S. Patent No. 6,221,046 B1, issued April 24, 2001 (Ex. 1013, “Burroughs”);
- (2) U.S. Patent No. 6,235,004 B1, issued May 22, 2001 (Ex. 1014, “Steenfeldt-Jensen”); and
- (3) U.S. Patent Application Publication No. US 2002/0052578 A1, published May 2, 2002 (Ex. 1015, “Moller”).

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

E. Asserted Grounds

Petitioner challenges the claims as follows.

Reference(s)	Basis	Claim(s) Challenged
Burroughs	§ 102	51–55 and 57
Burroughs	§ 103	54 and 55
Steenfeldt-Jensen	§ 102	51–53, 56, and 57
Steenfeldt-Jensen	§ 103	56
Steenfeldt-Jensen and Burroughs	§ 103	54 and 55
Moller	§ 102	51–53, 56, and 57
Moller and Burroughs	§ 103	54 and 55

Pet. 3, 22–66.

III. ANALYSIS

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).²

Petitioner states that “claim terms should be given their ordinary and customary meaning, consistent with the specification and how they would be understood by [a person of ordinary skill in the art].” Pet. 12. Petitioner also notes that Patent Owner proffered interpretations for “clutch” and “tubular clutch” in related litigation. *Id.* at 12–13 (citing Ex. 1019, 23–25). Petitioner additionally notes that it proffered means-plus-function interpretations for those same terms in related litigation. *Id.* at 13 (citing Ex. 1028, 102–106). Petitioner states that, to the extent that those terms are considered means-plus-function limitations, it proposes such interpretations. *Id.* (citing Ex. 1003, 2:16–18, 4:49–65, 6:36–44, Figs. 1, 5–11; Ex. 1028, 103–104, 106). With respect to the terms “clutch” and “tubular clutch,” we need not determine, at this stage of the proceeding, if these terms are means-

² 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 8, 1 (according a filing date of September 10, 2018, to the Petition).

plus-function terms, as Petitioner provides alternative analyses with respect to claims reciting these terms.

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

B. Level of Ordinary Skill

Petitioner asserts that one of ordinary skill in the art “had at least a bachelor’s degree in mechanical engineering, or an equivalent degree, and design experience” and “understood the basics of medical-device design and manufacturing, and basic mechanical elements (*e.g.*, gears, pistons) involved in drug-delivery devices.” Pet. 12 (citing Ex. 1011 ¶ 106). As stated above, Patent Owner does not present any arguments at this stage.

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 IPR2018-01678, 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 one of the claims challenged in the Petition.

C. Challenge of Independent Claim 51 Based on Burroughs

Petitioner argues that independent claim 51 is anticipated by Burroughs. Pet. 3, 22–26.

1. 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.

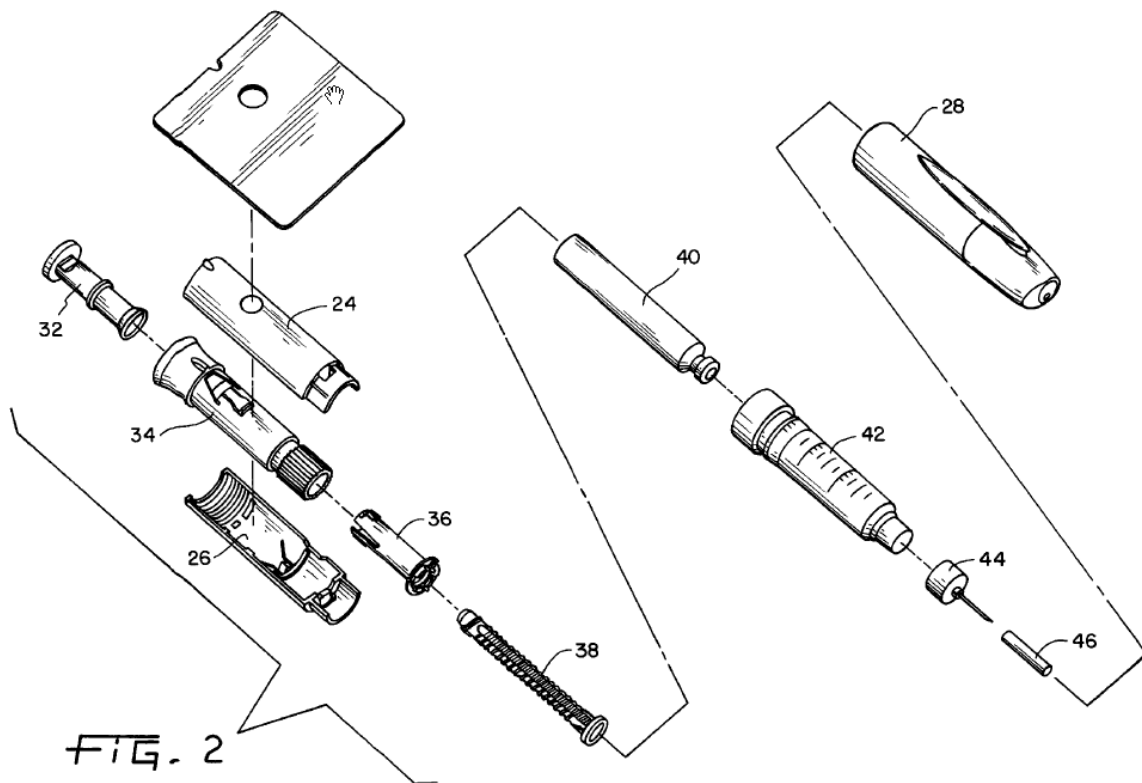


Figure 2 shows an exploded view of injection medication device 20. *Id.* at 6:42–43, 7:15–16. Medication device 20 includes mechanism housing 22 with housing parts 24 and 26, button 32, dial mechanism 34, nut 36, and leadscrew 38 that forms a drive stem. *Id.* at 7:17–18, 7:32–34, 9:12–13. Figure 14 of Burroughs is reproduced below.

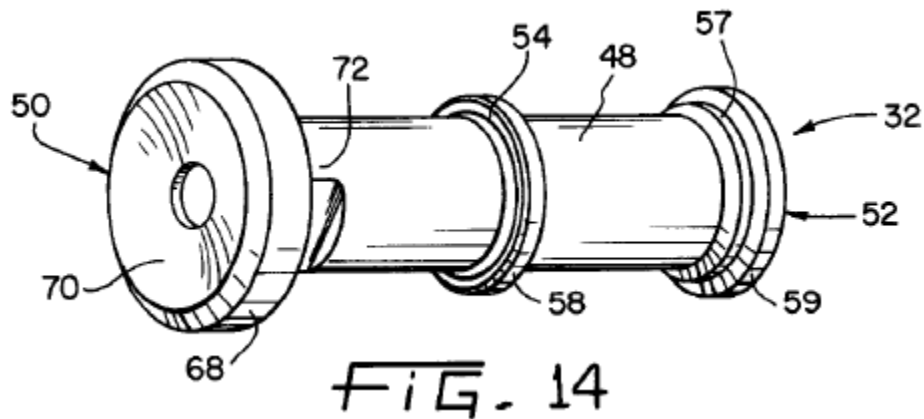


Figure 14 shows a perspective view of the button. *Id.* at 6:66. Button 32 comprises hollow cylindrical portion 48 having proximal end 50, distal end 52, and enlarged diameter ring 54. *Id.* at 7:46–51. The enlarged diameter portion engages flexible sections of dial mechanism 34. *Id.* at 8:11–20, Figs. 6, 8.

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.

2. Independent Claim 51

Petitioner argues in a claim chart that Burroughs discloses all the limitations of independent claim 51. Pet. 22–26 (citing Ex. 1011 ¶¶ 448–452, 454; Ex. 1013, Abstract, 7:46–52, 8:11–20, 8:42–48, 9:16–18, 11:5–20,

11:27–30, Figs. 1, 2, 6–11, 14, 15). In particular, Petitioner contends that button 32 of Burroughs anticipates the clutch with a tubular body extending between distal and proximal ends and the tubular body having a diameter sized so that the distal end may be positioned within a proximal end of a dial member, as required by claim 51. *See id.*

Patent Owner has not yet presented argument or evidence regarding the challenge to independent claim 51. Based on our review of Petitioner’s argument and evidence at this stage, however, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to independent claim 51 of the ’486 patent. As such, we institute *inter partes* review of all claims on all presented challenges. *See* 35 U.S.C. § 314(a); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

D. Remaining Challenges

Because Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to one claim of the ’486 patent, we institute review on all challenged claims and all grounds raised in the Petition. *SAS*, 138 S. Ct. at 1359–60; Guidance on the Impact of *SAS* on AIA Trial Proceedings (Apr. 26, 2018), <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial> (explaining that “the PTAB will institute as to all claims or none” and “if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition”). In the remaining challenges, we note that Petitioner argues in a claim chart that Burroughs discloses all the limitations of dependent claims 52–55 and 57 with citations to the reference and declarant testimony to support its contention that Burroughs anticipates these claims. Pet. 26–32

In another challenge, Petitioner argues that dependent claims 54 and 55 would have been obvious over Burroughs. Pet. 3, 32–34. In that challenge, Petitioner provides another claim chart asserting where Burroughs teaches the limitations of these claims with citations to the reference and declarant testimony. *Id.* at 32–33. Petitioner also argues that one of ordinary skill in the art would have understood that inner chamber 212, piston 210, cap 216, and rubber disc 218 operate, respectively, as the reservoir, septum, ferrule, and stopper of claim 54 and further argues that the components of claim 54 would have been apparent to one of ordinary skill in the art. *Id.* at 33–34 (citing Ex. 1011 ¶¶ 471–472). Petitioner additionally argues for claim 55 that one of ordinary skill in the art would have understood that a cartridge contains multiple doses. *Id.* at 34 (citing Ex. 1011 ¶ 473).

In challenges based on Steinfeldt-Jensen, Petitioner argues that claims 51–53, 56, and 57 are anticipated and claim 56 is unpatentable with citations to Steinfeldt-Jensen and declarant testimony. Pet. 3, 34–47. Petitioner additionally argues that claims 54 and 55 are unpatentable over Steinfeldt-Jensen and Burroughs with citations to the references and declarant testimony. *Id.* at 3, 63–66.

In challenges based on Moller, Petitioner argues that claims 51–53, 56, and 57 are anticipated with citations to Moller and declarant testimony. Pet. 3, 47–63. Petitioner also argues that claims 54 and 55 are unpatentable over Moller and Burroughs with citations to the references and declarant testimony. *Id.* at 3, 63–66.

Patent Owner has not yet presented its arguments and evidence against any of Petitioner’s challenges of claims 51–57. On the present

record, we determine that Petitioner's arguments and evidence are sufficient for instituting review of independent claim 51 as also anticipated by Steinfeldt-Jensen or Moller and for instituting review of dependent claims 52–57 as anticipated by or obvious over the asserted references. We determine that further analysis of Petitioner's challenges is best left for trial after full development of the record.

IV. 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*, 138 S. Ct. at 1359–60. After considering the evidence and arguments presented in the Petition, we determine that Petitioner has demonstrated a reasonable likelihood it would prevail in proving that at least one of claims 51–57 of the '486 patent is unpatentable.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or any underlying factual and legal issues.

V. ORDER

In consideration of the foregoing, it is hereby
ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 51–57 of U.S. Patent No. 8,992,486 B2 is instituted with respect to all grounds 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

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commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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