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Paper 12
Entered: August 15, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2019-00979
Patent 8,679,069 B2

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

JUNG, *Administrative Patent Judge.*

DECISION
Instituting *Inter Partes* Review
and
Denying Motion for Joinder
35 U.S.C. §§ 314, 315(c)

I. INTRODUCTION

Pfizer Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting institution of an *inter partes* review of claims 1–3 of U.S. Patent No. 8,679,069 B2 (Ex. 1001, "the '069 patent"). Sanofi-Aventis Deutschland GmbH ("Patent Owner") waived filing a Preliminary Response. Paper 9.

Petitioner also filed a Motion for Joinder Under 35 U.S.C. § 315(c) and 37 C.F.R. §§ 42.22, 42.122(b) with *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, Case IPR2018-01670. Paper 3. Patent Owner filed a Response to Petitioner's Motion for Joinder (Paper 8), to which Petitioner filed a Reply in Support of Petitioner's Motion for Joinder Under 35 U.S.C. § 315(c) and 37 C.F.R. §§ 42.22, 42.122(b) (Paper 10).

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 present record 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 claim 1. As such, we institute an *inter partes* review of claims 1–3 of the '069 patent on all presented challenges. Also, we *deny* Petitioner's Motion for Joinder.

II. BACKGROUND

A. Related Proceedings

As noted by Petitioner, the '069 patent is also at issue in IPR2018-01670. Pet. 1.

Petitioner and Patent Owner both indicate that related patents are being challenged in Cases IPR2018-01675, IPR2018-01676, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01684, IPR2018-01696, IPR2019-00122, IPR2019-00977, IPR2019-00978, IPR2019-00980, IPR2019-00981, IPR2019-00982, IPR2019-00987, IPR2019-01022, and IPR2019-01023. Pet. 2; Paper 6, 3–4.

The parties also indicate that the '069 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.); *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, No. 1:14-cv-00113-RGA-MPT (D. Del.); *Sanofi-Aventis U.S. LLC v. Eli Lily and Co.*, 1:14-cv-00884 (D. Del.); and *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, 1:17-cv-00181 (N.D. W. Va.). Pet. 1–2; Paper 3, 2–3; Paper 6, 2; Exs. 1029, 1030. Petitioner states that the "real parties-in-interest are Pfizer Inc. and Hospira, Inc." and that they "are not parties to these litigations." Pet. 1.

B. The '069 Patent (Ex. 1001)

The '069 patent issued March 25, 2014, from an application filed November 11, 2010, which is a continuation of an application filed on July 11, 2006, which, in turn, is a continuation of an application filed on March 2, 2004. Ex. 1001, [22], [45], [63], 1:6–12. The '069 patent also claims priority to a foreign application filed on March 3, 2003. *Id.* at [30], 1:10–11; *see also* Pet. 19 (arguing that "[n]umerous pen-type injectors were known in the art before *March 3, 2003*, including many that used the same six-component structure claimed by claim 1" (emphasis added)).

The ’069 patent “relates to pen-type injectors . . . where a user may set the dose.” Ex. 1001, 1:13–17. Figures 1 and 2 of the ’069 patent are reproduced below.

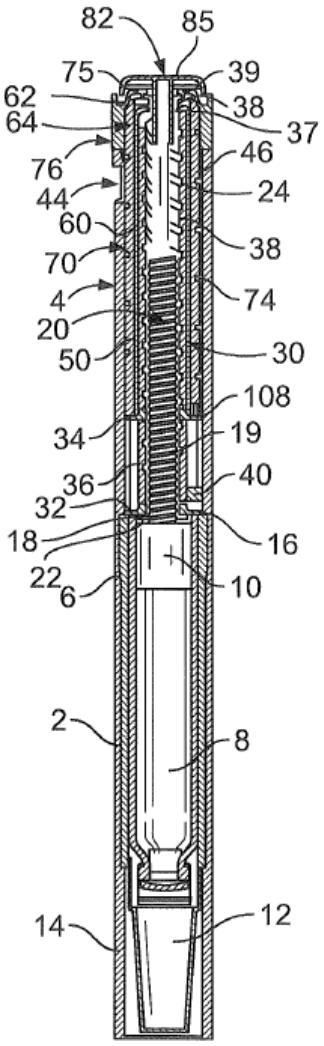

FIG. 1

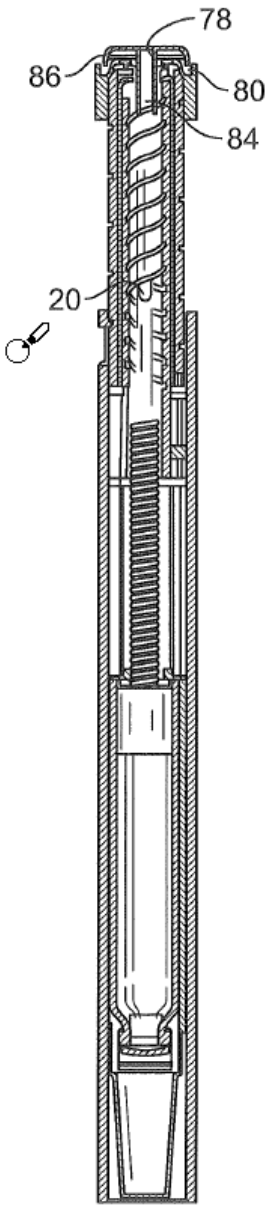

FIG. 2

Figure 1, reproduced above, “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 2:38–42. The injector includes first cartridge retaining part 2 and second main housing part 4.[1] *Id.* at 3:8–9. Insert 16 is at a first end of main housing 4 and is fixed rotationally and longitudinally to main housing 4. *Id.* at 3:29–30. Insert 16 includes threaded circular opening 18, through which piston rod 20 extends. *Id.* at 3:31–33, 3:37–39. Piston rod 20 includes first thread 19. *Id.* at 3:36. Piston rod 20 also includes pressure foot 22 that abuts piston 10 of cartridge 8. *Id.* at 3:39–41.

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 3:41–42, 3:51, 3:58–60. Clutch 60 is disposed about drive sleeve 30 adjacent its second end. *Id.* at 4:12–14, 4:28–29. Clutch 60 is keyed to drive sleeve 30 by splines to prevent relative rotation between clutch 60 and drive sleeve 30. *Id.* at 4:39–41.

Dose-dial sleeve 70 is outside of clutch 60 but within main housing 4. *Id.* at 4:49–51. Dose-dial sleeve 70 has helical groove 74 on its outer surface. *Id.* at 4:51–52. 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 5:3–4, 5:6–8.

A user rotates dose-dial grip 76 to set a dose and to cause dose-dial sleeve 70 and drive sleeve 30 to rotate together out of main housing 4. *Id.* at 5:29–32, 5:42–44, Fig. 9. The dose can be reduced by turning dose-dial grip 76 in the opposite direction. *Id.* at 5:65–66, Fig. 10. The user then presses button 82, which causes clutch 60 to disengage from dose-dial

[1] The '069 patent refers to "second main housing part 4" and "main housing 4" interchangeably. *Compare* Ex. 1003, 3:9 ("second main housing part 4") *with id.* at 3:30 ("main housing 4").

sleeve 70 so that clutch 60 moves axially and dose-dial sleeve 70 rotates back into housing part 4. *Id.* at 6:6–9, 6:11–13, 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 6:23–25.

C. Illustrative Claim

The '069 patent has three claims, all of which Petitioner challenges. Claims 2 and 3 depend from claim 1, which is reproduced below:

> 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, said helical groove provided along an outer surface of said dose dial sleeve;
>
> a dose dial grip 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 drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, 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 dial grip, said tubular clutch operatively coupled to said dose dial grip,
>
> wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

Ex. 1003, 6:37–60.

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").

Petitioner also provides a Declaration of Charles E. Clemens (Ex. 1011). "Petitioner here asserts that the same independent claim 1 is obvious over the same prior art based on substantially the same arguments presented in [IPR2018-01670]." Paper 3, 1

E. Asserted Grounds

Petitioner challenges, under 35 U.S.C. § 103, (1) claims 1–3 as unpatentable over Burroughs, (2) claim 1 as unpatentable over Steenfeldt-Jensen, and (3) claim 1 as unpatentable over Moller and Steenfeldt-Jensen. Pet. 5, 27–96; *see also* Paper 3, 1 (stating "Petitioner here asserts that the same independent claim 1 is obvious over the same prior art based on substantially the same arguments presented in [IPR2018-01670]" and "additionally challenges the two dependent claims 2 and 3 using exactly the same prior art that was applied to the independent claim 1 in Ground 1 of [IPR2018-01670]").

III. CHALLENGES UNDER 35 U.S.C. § 103

A. Claim Construction

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 applies to petitions filed on or after November 13, 2018, so the revised claim construction standard applies to this proceeding. *Id.*; *see* Paper 4, 1 (according a filing date of May 2, 2019, to the Petition).

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]. . . ." Pet. 17 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–1313 (Fed Cir. 2005) (en banc); Ex. 1011 ¶ 108). Petitioner notes that Patent Owner proffered interpretations of "drive sleeve," "main housing," "piston rod," "thread/threaded/threading," and "tubular clutch" in related litigation. *Id.* at 17–18 (citing Ex. 1019, 19−24, 27–28, 30–31) (emphasis omitted). Petitioner also notes that a means-plus-function interpretation for "tubular clutch" was proffered in related litigation and proffers the same interpretation in this proceeding if the broadest reasonable interpretation of "tubular clutch" is a means-plus-function interpretation. *Id.* at 18–19 (citing Ex. 1001, 2:5–7, 4:42–44, 6:14–22, 11:58–12:4, Figs. 1, 5–11; Ex. 1028, 80–85).

With respect to the claim terms discussed above,[2] 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 challenges. *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" and "would have understood the basics of medical-device design and manufacturing, and the basic mechanical elements (*e.g.*, gears, pistons) involved in drug-delivery devices." Pet. 17 (citing Ex. 1011 ¶ 106). Patent Owner waived filing a preliminary response.

We preliminarily adopt Petitioner's, 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 challenged claims.

[2] In IPR2018-01670, we adopted Patent Owner's proposed interpretation of "helical groove" to mean "a groove formed in the shape of a spiral" to determine whether Petitioner in that proceeding demonstrated a reasonable likelihood of prevailing in its challenges to claim 1. *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, Case IPR2018-01670, slip op. at 14–15 (PTAB Apr. 3, 2019) (Paper 19).

C. Challenge Based on Burroughs

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.

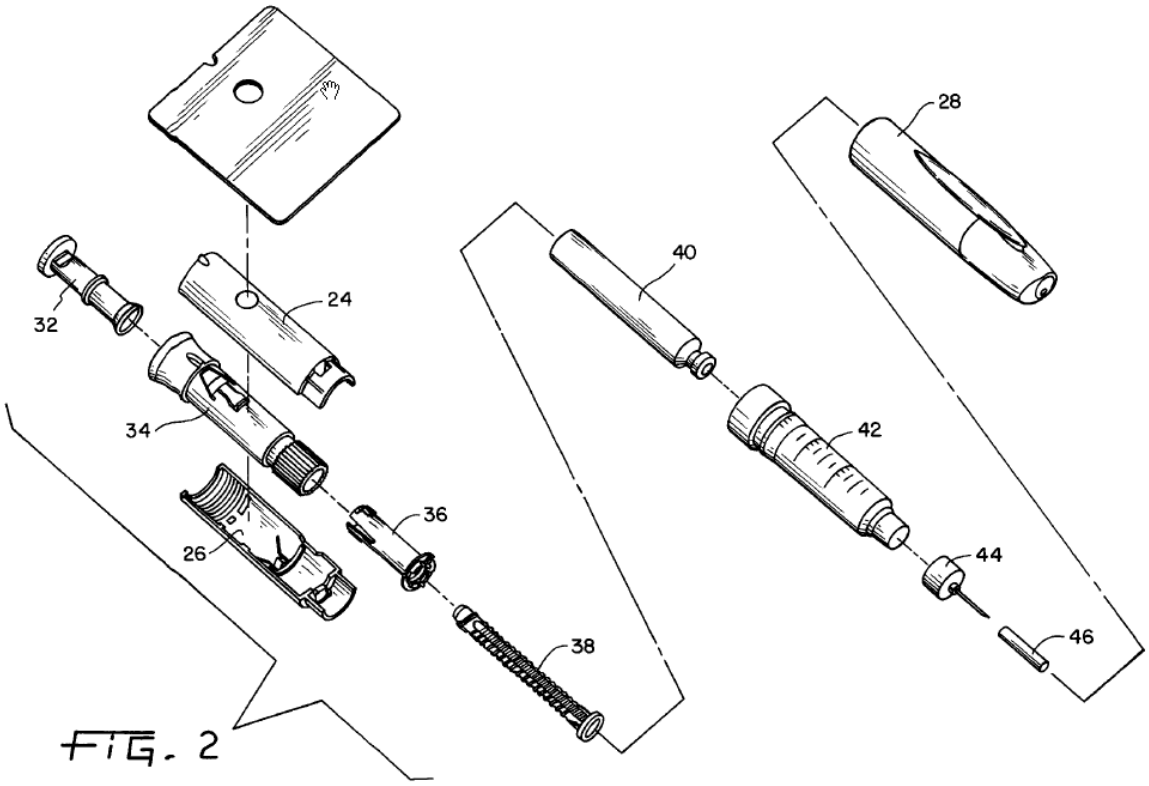

Figure 2, reproduced above, shows an exploded view of injection medication device 20. *Id.* at 6:42–43, 7:15–16. Medication device 20 includes mechanism housing 22 made from housing parts 24 and 26, button 32, dial mechanism 34, nut 36, and leadscrew 38 that forms a drive stem. *Id.* at 7:17–18, 7:32–34,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

2. Claim 1

Petitioner contends that Burroughs teaches all of the components recited by claim 1, but the dial mechanism of Burroughs has threads on its outer surface that engage a helical groove of a main housing. Pet. 27. Petitioner asserts that it would have been obvious to modify Burroughs so that its dial mechanism has, on its outer surface, a helical groove that engages with a thread on the main housing. *Id.*

Petitioner provides a chart that explains where Burroughs teaches or suggests the limitations of claim 1. *Id.* at 28–46 (citing Ex. 1011 ¶¶ 126, 158, 161–167, 173–188; Ex. 1013, Abstract, 7:9–20, 7:31–32, 7:46–55, 7:65–67, 8:2–6, 8:11–20, 8:24–29, 8:33–36, 8:42–48, 8:62–9:1, 9:8–11, 9:12–34, 10:26–42, 11:5–20, 11:27–30, 11:52–56, Figs. 1, 2, 3, 5–15).

Petitioner asserts that (1) one of ordinary skill in the art would have known of the alternative configuration of a helical groove, (2) the use of rib-to-groove threaded engagement was known and interchangeable on parts to be engaged, and (3) its proposed modification would have been the predictable use of prior art elements according to their established functions. *Id.* at 46–48 (citing Ex. 1011 ¶¶ 166–171; Ex. 1013, 10:34–38, 10:60–63).

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, said helical groove provided along an outer surface of said dose dial sleeve," as recited by claim 1. Ex. 1001, 6:41–45. 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. 30–31 (citing Ex. 1011 ¶¶ 161–167; Ex. 1013, 7:31–32, 7:65–67, 8:24–29, 8:33–36, 8:62–9:1, 10:34–37, Figs. 1–3, 5–9). 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 configured to releasably engage with helical spiral groove 158 provided on an inner surface of housing 22" and that "dial mechanism 34 includes a 'helical rib,' in the form of threads 110, 112, along its outer surface that engages with threading on housing 22." *See* Pet. 32–33 (citing Ex. 1011 ¶ 164; Ex. 1013, 8:62–9:1, Figs. 1, 3, 5–9).

Also, at this stage, Petitioner sufficiently shows for purposes of institution 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" and would have had a reasonable expectation of success. *See* Pet. 46–48 (citing Ex. 1011 ¶¶ 166–171).

3. Claims 2 and 3

Petitioner also contends that Burroughs teaches the limitations of claims 2 and 3. Pet. 48–49 (citing Ex. 1013, 2:42–44, 7:46–64, 8:24–29, 9:32–41, 10:34–52, Figs. 1, 6–9, 14, 15; Ex. 1011 ¶¶ 858–860, 862–863).

We have reviewed Petitioner's arguments and evidence. At this stage of the proceeding, we are satisfied that Petitioner sufficiently demonstrates that Burroughs teaches the limitations of claims 2 and 3. *See* Pet. 48–49.

4. Conclusion as to Institution

For the reasons above and on the present record, Petitioner demonstrates a reasonable likelihood of success in proving that claim 1 of the '069 patent is unpatentable over Burroughs. Thus, we institute on all presented challenges. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); 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").

D. Challenge Based on Steenfeldt-Jensen

1. Steenfeldt-Jensen (Ex. 1014)

Steenfeldt-Jensen "relates to injection syringes of the kind apportioning set doses of medicine from a cartridge." Ex. 1014, 1:12–13.

Figures 16 and 17 of Steenfeldt-Jensen are reproduced below.

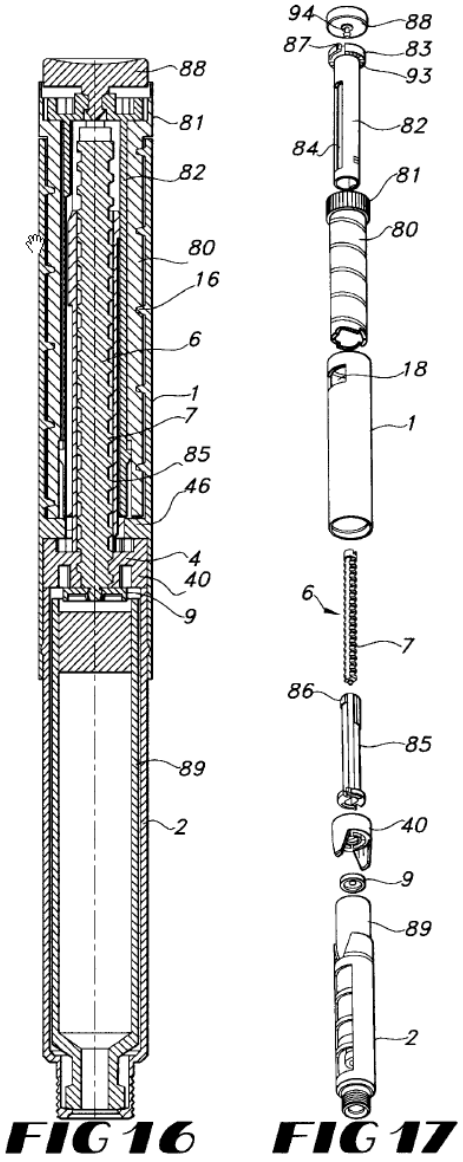

FIG 16 FIG 17

Figures 16 and 17, reproduced above, show side-sectional views of a syringe. *Id.* at 5:25–28. The syringe of Steenfeldt-Jensen includes tubular housing 1 that is partitioned so that a first division has ampoule holder 2. *Id.* at 5:38–40. Ampoule holder 2 has a central bore with thread 5 that engages external thread 7 of piston rod 6. *Id.* at 5:55–58. Driver tube 85 is disposed about piston rod 6. *See id.* at Figs. 15–17. "The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding

not round cross-section" so that "rotation is transmitted" and "the piston rod is allowed to move longitudinally through the driver tube." *Id.* at 11:15–19.

Within housing 1 is scale drum 80, and scale drum 80 has on its outer wall a helical track that is engaged with a helical rib on the inner wall of housing 1. *Id.* at 11:20–22. One end of scale drum 80 has a larger diameter so as to form dose setting button 81. *Id.* at 11:22–24. Bushing 82 fits within scale drum 82 and over driver tube 85. *Id.* at 11:26–29. Bushing 82 is coupled to driver tube 85 so that both can rotate but not longitudinally move. *Id.* at 11:30–33. Injection button 88 is rotatably mounted at an end of bushing 82. *Id.* at 49–51.

A dose is set by rotating dose setting button 81, which causes scale drum 80 to rotate out of housing 1. *Id.* at 11:52–55. Injection button 88 is pressed to inject the set dose. *Id.* at 12:4–5. Scale drum 80 is pressed back into housing 1. *Id.* at 12:9–10. Dose setting button 81 rotates because of the engagement between the helical track of scale drum 80 and the helical rib of housing 1. *Id.* at 12:6–9. Piston rod 6 is screwed into ampoule 89 in ampoule holder 2. *Id.* at 12:12–13.

2. Claim 1

Petitioner contends that Steenfeldt-Jensen teaches all of the structural limitations of claim 1. Pet. 50. Petitioner also contends that, to the extent that Steenfeldt-Jensen does not teach or suggest a drive sleeve, it would have been obvious to include such a drive sleeve. *Id.*

Petitioner provides a chart that explains where Steenfeldt-Jensen teaches or suggests the limitations of claim 1. Pet. 50–69 (citing Ex. 1011 ¶¶ 131, 261, 263–268, 270, 271, 273, 274, 280–283, 285; Ex. 1014, 1:12–15, 5:38–44, 5:55–58, 7:49–51, 8:35–38, 11:6–42, 11:52–62, 12:1–13, Figs. 15–

17, claim 11). Petitioner asserts a reason to modify Steenfeldt-Jensen so that driver tube 85 would have internal threading near its distal end and asserts that one of ordinary skill in the art would have had a reasonable expectation of success. *Id.* at 64 (citing Ex. 1011 ¶¶ 275–279), 69–71 (citing Ex. 1011 ¶¶ 274–278; Ex. 1014, 2:46–53, 3:15–20, 3:44–47, 7:44–47).

We have reviewed Petitioner's arguments and evidence. At this stage of the proceeding, we are satisfied that Petitioner sufficiently demonstrates that Steenfeldt-Jensen would have rendered obvious claim 1. *See* Pet. 50–71. We are also satisfied at this early stage that Petitioner sufficiently argues with citations to evidence of record that one of ordinary skill in the art would have modified the fifth embodiment of Steenfeldt-Jensen so that the internal threading of its member 40 is in driver tube 85 and the non-circular opening of driver tube 85 is in member 40. *See id.* at 64, 69–71. In support of its proposed modification, Petitioner quotes column 7, lines 44–47, of Steenfeldt-Jensen, which states that "[e]mbodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment[s] will not be beyond the scope of the invention." *Id.* at 69. Petitioner shows sufficiently that Steenfeldt-Jensen includes "[e]mbodiments . . . wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube." Ex. 1014, 7:44–47.

We note, however, that whether this sentence in Steenfeldt-Jensen, which Petitioner cites in support of its proposed modification, provides adequate reason for one of ordinary skill in the art to modify the fifth embodiment in the manner asserted by Petitioner will be reanalyzed after fully developing the record. A fully developed record would aid in

determining whether the teaching applies only to Steenfeldt-Jensen's first embodiment or whether the same teaching would have been applied to the fifth embodiment with its alternative arrangement of structures, as argued by Petitioner. *See* Pet. 55, 60–62.

E. Challenge Based on Moller and Steenfeldt-Jensen

1. Moller (Ex. 1015)

Moller "relates to syringes by which a dose can be set by rotating a dose setting member and by which an injection button elevates from an end of the syringe a distance proportional to the set dose." Ex. 1015 ¶ 1. Figure 1 of Moller is reproduced below.

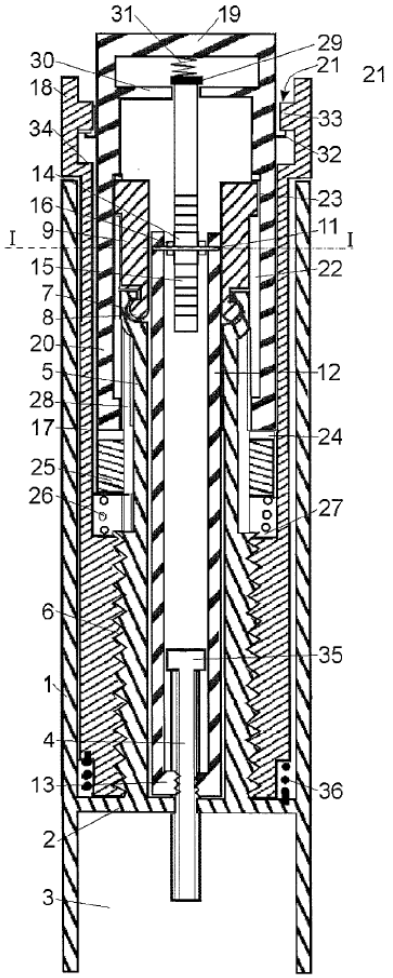

Fig. 1

Figure 1, reproduced above, shows a sectional view of an injection device. *Id.* ¶ 17. The device includes housing 1 with partitioning wall 2 that divides housing 1 into two compartments, one with a dose setting mechanism and the other for accommodating an ampoule. *Id.* ¶ 22. Threaded piston rod 4 extends through an opening in wall 2 so that it can move longitudinally but not rotationally because threaded piston rod 4 has a non-circular cross section. *Id.* Tubular element 5 extends from the opening around threaded piston rod 4 and engages gearbox 9 so that gearbox 9 can rotate within housing 1. *Id.* ¶ 23.

Nut 13 engages the threads of the threaded piston rod 4 and connects to gearbox 9 via connection bars 12. *Id.* ¶ 24. Dose setting drum 17 engages thread 6 of tubular element 5 at one end and at the opposite end has an enlarged diameter forming dose setting button 18. *Id.* ¶ 25. Dose setting drum 17 can be screwed into or out of housing 1 and includes a scale on its outer surface. *Id*

A cup shaped element that fits over gearbox 9 and into dose setting drum 17 forms an injection button. *Id.* ¶ 26. The cup shaped element is coupled to dose setting drum 17 so that the cup shaped element, dose setting drum 17, and gearbox 9 rotate together. *Id.*

Dose setting button 18 is rotated to set a dose, which causes dose setting drum 17 to screw out with the cup shaped element. *Id.* ¶ 29. Bottom 19 of the cup shaped element is pressed to inject the set dose. *Id.* ¶ 32.

2. Claim 1

Petitioner argues that Moller teaches the same structural limitations of claim 1. Pet. 71. Petitioner asserts that it would have been obvious to

modify drum 17 of Moller to have a helical groove on its outer surface instead of its inner surface. *Id.* at 71–72. Petitioner additionally notes that its analysis primarily relies on the embodiment of Moller shown in Figures 1 and 2, but that the challenged claim is unpatentable over the embodiment shown in Figures 3–5. *Id.* at 72 (citing Ex. 1011 ¶ 139 n.16; Ex. 1015 ¶¶ 22–40, Figs. 1–5).

Petitioner provides a chart that explains where Moller or Moller and Steenfeldt-Jensen teach or suggest the limitations of claim 1. Pet. 73–93 (citing Ex. 1011 ¶¶ 343–350, 352–362, 364–367, 370–376, 378–381; Ex. 1014, 6:7–17, 11:52–54, 12:4–9, Figs. 3, 8, 13, 17; Ex. 1015, Abstract, ¶¶ 22–27, 29, 30, 32, 33, 36, 38–40, Figs. 1, 3–5). Petitioner asserts a reason to modify Moller to have the outer helical groove of Steenfeldt-Jensen so that it engages a housing for rotational movement and asserts that one of ordinary skill in the art would have had a reasonable expectation of success. *Id.* at 94–96 (citing Ex. 1011 ¶¶ 354–361; Ex. 1014, 6:7–17, Figs. 3, 8, 13, 17; Ex. 1015 ¶¶ 8, 11, 12, 14, 33).

At this stage of the proceeding, Petitioner sufficiently shows a reasonable likelihood that it would prevail in demonstrating that Moller and Steenfeldt-Jensen would have rendered obvious claim 1. *See id.* at 71–96.

IV. MOTION FOR JOINDER

As discussed above, Petitioner filed a motion to join the present proceeding to IPR218-01670. Paper 3 ("Mot."). Petitioner contends that joinder is appropriate because both proceedings present substantially the same grounds and evidence. Mot. 5. As indicated by Petitioner, the present proceeding "additionally challenges the two dependent claims 2 and 3 using

exactly the same prior art that was applied to the independent claim 1 in Ground 1" of IPR2018-01670 and "Dr. Clemens's declaration substantively differ[s] only in that it also addresses the two dependent claims 2 and 3 of the '069 patent." *Id.* at 1, 4, 5.

Patent Owner opposes joinder as to claims 2 and 3 "because claims 2 and 3 are not challenged in [IPR2018-01670]" and "would therefore introduce new arguments and issues not present" in that IPR. Paper 8, 1. In its Reply, Petitioner states that "the parties have had discussions to try to resolve any dispute as to joinder" and "have reached the following agreements," which include, *inter alia*, Petitioner "withdraw[ing] its expert declaration of Mr. Clemens as it pertains to all but two of the challenged claims" and "rely[ing] on the declaration and testimony of Mylan's expert Mr. Leinsing." Paper 10, 1–2. "Specifically, Pfizer will withdraw Mr. Clemens' expert declaration as to all challenged claims except for claims 2 and 3 of the '069 patent, which were not challenged by Mylan or addressed by Mr. Leinsing." *Id.* at 2. Petitioner also "withdraws its motion for joinder with respect to claims 2 and 3 of the '069 patent." *Id.*

In view of the additional challenges to claims 2 and 3 and accompanying declarant testimony presented in this proceeding, we are not persuaded that this proceeding presents substantially the same evidence as in IPR2018-01670. Because claims 2 and 3 include the limitations of claim 1 by virtue of their dependency from claim 1, we would need to consider arguments and evidence regarding the limitations of claim 1 in deciding Petitioner's challenge of claims 2 and 3.

Also, withdrawing declarant testimony regarding claim 1 in accordance with the parties' agreement would leave us without such

evidence for the limitations of claim 1 incorporated into claims 2 and 3. The testimonial evidence that would remain for claims 2 and 3 after withdrawal refers to the withdrawn testimony for the limitations of claim 1. *See, e.g.*, Ex. 1011 ¶ 857 ("As I explained above, Burroughs renders obvious the housing part of claim 1 of the '069 patent. *See supra*, ¶¶ 152–200"). Thus, withdrawing declarant testimony regarding claim 1 in accordance with the parties' agreement would not be appropriate in view of the need for such testimony in reaching whether claims 2 and 3 are unpatentable for the reasons asserted by Petitioner.

Further, we would still need to consider the subject matter of claim 1 for this proceeding for one of the three challenges presented, thus reducing some efficiency gained by joining the present proceeding with IPR2018-01670. Moreover, during a conference held on July 25, 2019, "Petitioner indicated that there would be no issues if the panel instituted *inter partes* review in this proceeding, but denied Petitioner's Motion." Paper 11, 3; *see also* Ex. 1043 in IPR2018-01670, 10:14–11:23 (answering in response to panel questions that there are no objections by any of the involved parties to denying joinder in this proceeding), 12:22–24 (stating in the transcript of the conference that "for the 979 case, one of the options [the Board is] considering is not joining it to the 1670 case and letting it proceed on its own").

In view of the reasons above and the particular circumstances of this proceeding, we determine that joining only Petitioner's challenges of claim 1, but not the challenge of claims 2 and 3, to IPR2018-01670 would not be appropriate or efficient. We, therefore, deny Petitioner's Motion for Joinder.

V. CONCLUSION

After considering the evidence and arguments presented in the record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in proving that claims 1–3 of the '069 patent are unpatentable. Accordingly, we institute an *inter partes* review of all challenged claims on all presented challenges. We also deny Petitioner's Motion for Joinder.

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.

VI. 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 1–3 of U.S. Patent No. 8,679,069 B2 is instituted with respect to all grounds set forth in the Petition;

FURTHER ORDERED that Petitioner's Motion for Joinder is *denied*; 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. 8,679,069 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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