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Paper 100
Entered: May 29, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and PFIZER INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

IPR2018-01679[1]
Patent 8,992,486 B2

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

JUNG, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Patent Owner's Motion to Amend
Denying-in-Part, Dismissing-in-Part Petitioner's Motion to Exclude
35 U.S.C. § 318(a)

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[1] Pfizer Inc., who filed a petition in IPR2019-00981, has been joined as petitioner in this proceeding. Paper 36.

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Mylan Pharmaceuticals Inc. and Pfizer Inc. (collectively, "Petitioner") have shown by a preponderance of the evidence that claims 51–57 of U.S. Patent No. 8,992,486 B2 are unpatentable. We also deny Patent Owner's Corrected Revised Contingent Motion to Amend and deny-in-part and dismiss-in-part Petitioner's Motion to Exclude.

A. Background and Summary

Mylan Pharmaceuticals Inc. ("Mylan") 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. Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review of the '486 patent. Paper 14 ("Dec. to Inst."). In particular, we instituted review of all challenged claims on all presented challenges. Dec. to Inst. 2, 12, 14.

After institution, Pfizer Inc. ("Pfizer") also filed a Petition challenging the same claims of the '486 patent along with a motion for joinder with this proceeding. *See Pfizer Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-00981, Paper 2 (PTAB May 2, 2019) (Petition); *Pfizer*, Paper 3; Paper 36, 2. We also instituted *inter partes* review of the '486 patent in IPR2019-00981 and granted the motion for joinder. Paper 36, 2, 8.

Patent Owner filed a Response (Paper 23, "PO Resp."), to which Petitioner filed a Reply (Paper 43, "Pet. Reply"). Patent Owner thereafter filed a Sur-reply (Paper 57, "PO Sur-reply"). Patent Owner also filed a

Contingent Motion to Amend (Paper 25), to which Petitioner filed an Opposition (Paper 45).

Because review was instituted after March 15, 2019, this proceeding is part of the new pilot program concerning motion to amend practice and procedures. Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedure in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 84 Fed. Reg. 9,497 (Mar. 15, 2019). We issued Preliminary Guidance for the Motion to Amend (Paper 56), and Patent Owner thereafter filed a Revised Contingent Motion to Amend (Paper 63, "Mot. to Amend").[2] Petitioner subsequently filed an Opposition to the Revised Contingent Motion to Amend (Paper 70, "Pet. Opp."), and Patent Owner filed a Reply (Paper 80, "PO Reply") to which Petitioner filed a Sur-Reply (Paper 87, "Pet. Sur-reply").

Petitioner also filed a Motion to Exclude (Paper 82, "Mot. to Excl."), and Patent Owner filed an Opposition to the Motion to Exclude (Paper 85, "PO Opp."), to which Petitioner filed a Reply (Paper 86, "Reply to Mot. to Excl."). An oral hearing in this proceeding was held on February 5, 2020; a transcript of the hearing is included in the record (Paper 94, "Tr.").

[2] We granted Patent Owner's request to file a corrected Revised Contingent Motion to Amend and to refile exhibits that were filed with duplicate exhibit numbers. Paper 61. Citations to the Revised Contingent Motion to Amend are to the corrected motion (Paper 63), but references to the claims appendix are to the appendix of the originally filed Revised Contingent Motion to Amend (Paper 56) because the corrected motion does not include such an appendix. *See* Ex. 1111, 17:23–18:3 (Patent Owner's counsel confirming that the panel should refer to the claims appendix of the originally filed Revised Contingent Motion to Amend).

B. Real Parties in Interest

Mylan indicates that Mylan Pharmaceuticals Inc., Mylan Inc., Mylan GmbH (Mylan N.V. subsidiaries), Biocon Research Ltd., Biocon Ltd., and Becton, Dickinson and Company are real parties in interest. Pet. 1; Paper 7, 2. Pfizer states that the "real parties-in-interest are Pfizer Inc. and Hospira, Inc." *Pfizer*, Paper 2 at 1. Patent Owner indicates that Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis U.S. LLC, and Sanofi Winthrop Industrie are real parties in interest. Paper 5, 2; Paper 18, 2.

C. Related Matters

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; Paper 12, 2 (indicating that claims 51–55 and 57 of the '486 patent are no longer asserted); Paper 49, 2; Exs. 1029, 1030.

The parties state that the '486 patent is also challenged in IPR2018-01677, IPR2018-01678, IPR2019-00122, IPR2019-00980, and IPR2019-00982. Pet. 2; Paper 5, 3; Paper 7, 3; Paper 9, 3; Paper 18, 2–4; Paper 49, 3–4. Petitioner's motion to dismiss the petition in IPR2018-01677 was granted.

Patents related to the '486 patent are challenged in IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01680, IPR2018-01682, IPR2018-01684, IPR2018-01696, IPR2019-00977, IPR2019-00978, IPR2019-00979, IPR2019-00987, IPR2019-01022, and IPR2019-01023. Pet. 1–2; Paper 5, 2–3; Paper 7, 2–3; Paper 9, 2–3; Paper 18, 2–4; Paper 49, 2–4.

D. 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. 1003, codes (22), (45), (63), 1:6–11. The '486 patent also claims priority to a foreign application filed on March 3, 2003. *Id.* at code (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.

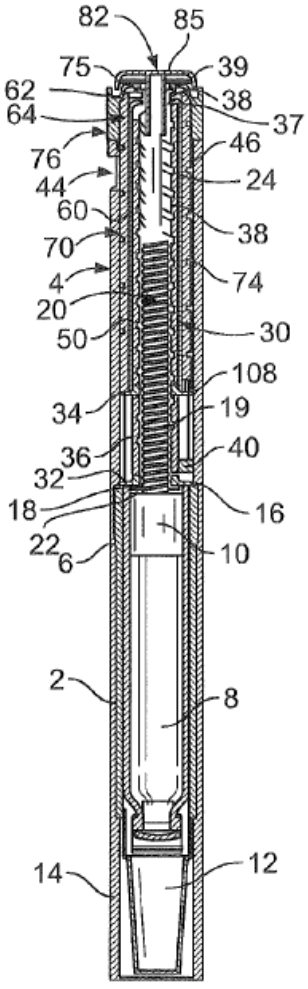

FIG. 1

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.[3] Ex. 1003, 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 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.

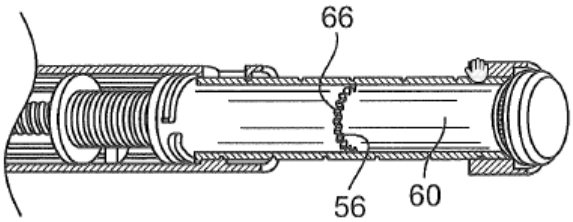

FIG. 7

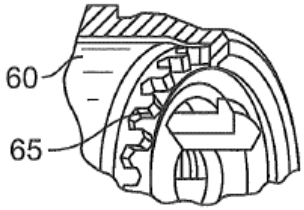

FIG. 8

Figures 7 and 8 show partially cut-away views of the pen-injector of Figure 1. Ex. 1003, 2:66–3:2. Clutch 60 is generally cylindrical and provided with circumferentially directed saw teeth 66 at a first end and

[3] 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”).

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.

E. Illustrative Claims

The ’486 patent has 57 claims, of which Petitioner challenges claims 51–57 in this proceeding. Of those, claim 51 is the only independent claim. Claims 51 and 56 are reproduced below.

> 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.
>
> 56. The clutch of claim 51, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch.

Ex. 1003, 10:31–37, 10:51–53.

F. Evidence

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

U.S. Patent No. 6,221,046 B1, issued April 24, 2001 (Ex. 1013, "Burroughs");

U.S. Patent No. 6,235,004 B1, issued May 22, 2001 (Ex. 1014, "Steenfeldt-Jensen"); and

U.S. Patent Application Publication No. US 2002/0052578 A1, published May 2, 2002 (Ex. 1015, "Moller").

Petitioner provides a Declaration of Karl R. Leinsing, MSME, PE (Ex. 1011), a Reply Declaration of Karl R. Leinsing, MSME, PE (Ex. 1095), a Declaration of Karl R. Leinsing, MSME, PE, in support of Petitioner's Opposition to Patent Owner's Motion to Amend (Ex. 1096), and a Declaration of Karl R. Leinsing, MSME, PE, in support of Petitioner's Opposition to Patent Owner's Revised Motion to Amend (Ex. 1113).

Patent Owner provides a Declaration of Alexander Slocum, Ph.D. (Ex. 2107), a Declaration of Alexander Slocum, Ph.D. in support of Patent Owner's Motion to Amend (Ex. 2307), a Declaration of Alexander Slocum, Ph.D. in support of Patent Owner's Revised Motion to Amend (Ex. 2325), and a Declaration of Alexander Slocum, Ph.D. in support of Patent Owner's

Reply concerning the Revised Motion to Amend (Ex. 2332).[4] Deposition transcripts were filed for Mr. Leinsing (Exs. 2163, 2164, 2316) and Dr. Slocum (Exs. 1053, 1054).

Patent Owner submits Observations from Mr. Leinsing's cross-examination in *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105-SRC-CLW (D.N.J.). Paper 74. The cross-examination is filed as Exhibit 2227. Petitioner submits Observations from the testimony of Dr. Slocum from the same district court case. Paper 75. The testimony is filed as Exhibit 1115. Both parties also filed Responses to each other's Observations. Papers 76, 77.

[4] Patent Owner filed declarations from Henry G. Grabowski, Ph.D. (Ex. 2109) and Dr. Robin S. Goland (Ex. 2111) primarily in support of objective indicia of nonobviousness. *See* Ex. 2109 ¶ 7 (stating that "I have been retained by counsel for Sanofi to opine on the commercial success of Lantus® SoloSTAR®"); Ex. 2111 ¶ 14 (stating in "Summary of Opinions" that "it is my opinion that patients who require insulin or insulin analog therapy need an easy-to-use injection pen device"). In response, Petitioner provides declarations from Dr. William C. Biggs (Ex. 1048) and DeForest McDuff, Ph.D. (Ex. 1060). *See* Ex. 1048 ¶ 16 (stating that "[m]y opinions are directed principally to long-felt, unmet need arguments"); Ex. 1060 ¶ 6 (stating that the scope of work is to review and respond to the Grabowski declaration regarding commercial success). Deposition transcripts were filed for Prof. Grabowski (Ex. 1055), Dr. Goland (Ex. 1056), Dr. Biggs (Ex. 2317), and Dr. McDuff (Ex. 2318). Patent Owner's counsel, however, agreed at oral hearing that objective evidence of nonobviousness were not presented in this proceeding. Tr. 58:20–59:5.

G. Asserted Grounds

Petitioner asserts that claims 51–57 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
51–55, 57	§ 102[5]	Burroughs
54, 55	§ 103	Burroughs
51–53, 56, 57	§ 102	Steenfeldt-Jensen
56	§ 103	Steenfeldt-Jensen
54, 55	§ 103	Steenfeldt-Jensen, Burroughs
51–53, 56, 57	§ 102	Moller
54, 55	§ 103	Moller, Burroughs

Pet. 3, 22–66.

II. ANALYSIS

A. Legal Standards

In an *inter partes* review, Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail in its challenges, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

[5] The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011), took effect on March 16, 2013. The application from which the '486 patent issued is the latest application in a series of continuation applications, the first of which was filed on March 2, 2004, and the '486 patent claims priority to a foreign application filed on March 3, 2003. Because the first application in the chain of continuation applications and the foreign application were filed before March 16, 2013, the effective date of the relevant amendment, the pre-AIA versions of §§ 102 and 103 apply.

To anticipate a claim under 35 U.S.C. § 102, "a single prior art reference must expressly or inherently disclose each claim limitation." *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). That "single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art." *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002).

The U.S. Supreme Court set forth the framework for applying the statutory language of 35 U.S.C. § 103 in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966):

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

As explained by the Supreme Court in *KSR International Co. v. Teleflex Inc.*:

> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.

550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere

conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")).

"Whether an ordinarily skilled artisan would have been motivated to modify the teachings of a reference is a question of fact." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1327 (Fed. Cir. 2016). "[W]here a party argues a skilled artisan would have been motivated to combine references, it must show the artisan 'would have had a reasonable expectation of success from doing so.'" *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017) (quoting *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)).

As discussed below, the parties' disputes are related to the scope and content of the asserted prior art, differences between claim 56 and the asserted prior art, and the level of ordinary skill in the art.

After reviewing the complete record, we conclude that Petitioner has shown by a preponderance of the evidence that the asserted references disclose, teach, or suggest each limitation of claims 51–57, and that a person of ordinary skill in the art would have had a reason to modify or combine the asserted references in the manner asserted by Petitioner with a reasonable expectation of success.

B. Level of Ordinary Skill in the Art

Petitioner asserts that one of ordinary skill in the art "had at least a bachelor's degree in mechanical engineering, or an equivalent degree, plus three-years' experience" and "understood the basics of medical-device design and manufacturing, and mechanical elements (*e.g.*, gears, pistons) involved in drug-delivery devices." Pet. 13–14 (citing Ex. 1011 ¶ 106). In

our Decision to Institute, we preliminarily adopted Petitioner's unopposed proposal. Dec. to Inst. 9.

Patent Owner contends that a person of ordinary skill in the art would have understood "the mechanical elements (e.g., lead screws, clutches, gears) used in drug injection delivery devices as well as the principles governing the interactions of such mechanical elements, and further understands the basics of device design and manufacturing" and would have had "a bachelor's degree in mechanical engineering or an equivalent degree." PO Resp. 6 (citing Ex. 2017 ¶ 102). Patent Owner states that "the slight differences between Patent Owner and Petitioner's level of ordinary skill do not affect the arguments made below." *Id.* at 7.

In determining the level of ordinary skill in the art, various factors may be considered, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation and internal quotation marks omitted).

Based on the full record before us, we see no reason to disturb our preliminary finding regarding the level of ordinary skill in the art. Accordingly, we maintain and reaffirm that one of ordinary skill in the art "had at least a bachelor's degree in mechanical engineering, or an equivalent degree, plus three-years' experience" and "understood the basics of medical-device design and manufacturing, and mechanical elements (*e.g.*, gears, pistons) involved in drug-delivery devices." Dec. to Inst. 9 (quoting Pet. 12). This level of skill in the art is consistent with the disclosure of the '486 patent and the prior art of record.

We agree with the parties that any differences in the parties' proposals would not affect our analysis. PO Resp. 7; *see also* Tr. 39:15–23 (Petitioner's counsel agreeing that any differences in the parties' proposals would not affect the analysis).

C. Claim Construction

In this proceeding, claim terms are interpreted according to their broadest reasonable construction in light of the Specification of the '486 patent. 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).[6]

Petitioner states that "[c]laims should be given their ordinary and customary meaning, consistent with the specification, as a [person of ordinary skill in the art] understood them" and that the "grounds rely on the ordinary and customary meaning." Pet. 14, 16. Petitioner provides Patent Owner's proposed interpretations of "driver," "main housing," "piston rod," "thread/threaded/threading," "tubular clutch," "clicker," and "insert" that were proffered in related litigation. *Id.* at 14–15 (citing Ex. 1019, 21, 23, 25, 27, 30–32). Petitioner also notes that it proffered means-plus-function interpretations for "clutch," "clicker," and "insert" in related litigation and proposes the same interpretations in this proceeding, if they are applicable.

[6] 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) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)). This rule change does not apply to this proceeding. *Id.*; *see* Paper 8, 1 (according a filing date of November 7, 2018, to the Petition).

Pet. 15–16 (citing Ex. 1003, Abstract, 2:1–3, 2:16–35, 4:33–67, 5:1–6, 5:44–60, 6:16–43, Figs. 1, 3–11; Ex. 1028, 104, 106, 112–116). Petitioner states that the "grounds . . . also address the 'clutch,' 'clicker,' and 'insert' limitations as means-plus-function limitations." *Id.* at 16.

In our Decision instituting review, we did not interpret expressly any claim term. Dec. to Inst. 9. "Patent Owner submits no express interpretation is required for any claim term with the exception of 'an interior of a flange' as recited in claim 56." PO Resp. 7–8.

1. "an interior of a flange" (claim 56)

According to Patent Owner, the "broadest reasonable interpretation of 'an interior of the flange' for a disk-shaped flange is 'at the inner diameter of a flange.'" PO Resp. 8 (citing Ex. 2107 ¶¶ 123–128). Patent Owner presents support from the '486 patent. *Id.* at 9–12 (citing Ex. 1003, 3:53–55, 4:12–13, 4:20–21, 4:54–55, 4:58–60, Figs. 5, 8). Patent Owner argues that broadest reasonable interpretation "does not encompass the outer diameter (*i.e.*, exterior), distal side (*i.e.*, needle side), or the proximal side (*i.e.*, button side) portions of a disk-shaped flange." *Id.* at 12; *see also id.* at 8–9 (arguing that the interior of a flange in Steenfeldt-Jensen and Moller are the distal and proximal sides of a flange), 12–13 (identifying the interior, exterior, proximal, and distal ends of Steenfeldt-Jensen's flange 83 as shown in Figs. 16, 17) (citing also Ex. 1014, 11:26–33). Patent Owner further contends that Mr. Leinsing confirmed "that the inner diameter of a circular flange would be the interior of the flange, and that the proximal, distal, and exterior sides of the flange are different." *Id.* at 13–15 (citing Ex. 2102; Ex. 2163, 148:18–19, 149:20–25, 151:18–159:6).

a) Petitioner's Reply

Petitioner replies that Patent Owner's proposed interpretation is unreasonably narrow and reads out the sole embodiment of the '486 patent. Pet. Reply 2–3 (citing PO Resp. 8, 9). Petitioner also argues that the basis for Patent Owner's proposed interpretation is incorrect. *Id.* at 3 (citing Ex. 1052; Ex. 1053; Ex. 1054, 397:15–404:19). According to Petitioner, Patent Owner "acknowledges that dog teeth 65 correspond to the plurality of axially-extending teeth recited in claim 56." *Id.* at 3–5 (citing PO Resp. 9–10; Ex. 1003, Fig. 1; Ex. 1053, 163:8–19; Ex. 2107 ¶ 124). Petitioner argues that Dr. Slocum confirmed that flange 62 is the top portion of a clutch and the location of an "inner diameter." *Id.* at 5–6 (citing Ex. 1053, 158:11–19, 161:14–162:2, 164:16–165:16; Ex. 1095 ¶ 20; Ex. 2107 ¶ 124).

Petitioner contends that Dr. Slocum "omits the portion of flange 62 extending radially inward beyond dog teeth 65" and thus, "incorrectly characterize[s] the position of the teeth on the flange," which are formed on the button side of flange 62. *Id.* at 6–10 (citing Ex. 1026, Fig. 1; Ex. 1050 ¶ 124; Ex. 1053, 106:13–107:15, 138:18–23; Ex. 1095 ¶¶ 18–24, 27; Ex. 2107 ¶ 124; Ex. 2157, 2, Figs. 1–5, 7–11). Petitioner also contends that the Specification of the '486 patent confirms that dog teeth 65 are formed on the button side. *Id.* at 10–11 (citing Ex. 1003, 2:17–19, 4:27–35, 4:55–58, 5:3–5, 6:29–31, Figs. 1, 9–11; Ex. 1011 ¶¶ 38–39; Ex. 1095 ¶ 28). Petitioner points to testimonial evidence and Patent Owner's animation of the '486 patent's pen that also indicate dog teeth 65 are formed on the button side. *Id.* at 11–16 (citing Ex. 1052, 2; Ex. 1053, 147:20–149:20, 166:22–168:20, 169:13–170:11, 173:3–20, 181:4–182:17, 186:21–189:23, 191:21–193:4, 228:9–15; Ex. 1095 ¶¶ 23, 28, 29; Ex. 2107 ¶¶ 65, 123–128, 334–354; Ex. 2117).

Petitioner further argues that Patent Owner incorrectly characterizes Mr. Leinsing's testimony. Pet. Reply 16 (citing PO Resp. 13–15; Ex. 1095 ¶ 30; Ex. 2107 ¶ 127; Ex. 2163, 151:18–159:6). According to Petitioner, Patent Owner presents a new theory that is incorrect. *Id.* at 17–20 (citing Ex. 1052; Ex. 1054, 147:20–149:18, 170:22–171:10, 177:25–179:10, 392:19–404:19, 409:9–410:3; Ex. 1095 ¶ 31; Ex. 2117). Petitioner additionally argues that Dr. Slocum's testimony regarding claim interpretation should be accorded little or no weight because it is inconsistent with evidence and relies on an incorrect understanding of the '486 patent's disclosure. *Id.* at 20.

b) Patent Owner's Sur-Reply

Patent Owner replies that claim construction does not need to be decided because the asserted references do not disclose teeth formed "in an interior of a flange" under either party's proposed interpretation. PO Sur-reply 2. Patent Owner also argues that the intrinsic record and Dr. Slocum's testimony support Patent Owner's proposed interpretation. *Id.* at 3–4 (citing PO Resp. 10–15; Ex. 1003, 3:53–55, Fig. 5; Ex. 2107 ¶¶ 123, 126; Ex. 2163, 150:11–151:6).

Patent Owner also replies that Figure 8 of the '486 patent is not the only disclosure of dog teeth. *Id.* at 4–5 (citing Pet. Reply 2–16; Ex. 1003, 2:17–19). Patent Owner argues that, even if Figure 8 showed the only embodiment, "[t]here is no lexicography or disavowal in the [S]pecification compelling a departure from the plain and ordinary meaning," "the 486 Patent does not include any clear, deliberate, and precise definition of 'an interior of a flange' that departs from the construction proffered by [Patent Owner]," and "the 486 Patent does not include any clear and unmistakable disavowal that narrows the scope of 'an interior of a flange' to

exclude the flange's inner diameter." PO Sur-reply 6–7. Patent Owner also argues that claim 56 "narrows the clutch to having a particular positioning of dog teeth, 'formed in an interior of a flange of said clutch'" and "[n]othing in this claim language (or the specification) compels a construction inconsistent with the plain and ordinary meaning of 'an interior of a flange.'" *Id.* at 7.

Patent Owner further replies that Petitioner argues for an interpretation that leads to absurd results. *Id.* at 8–10 (citing Pet. Reply 21, 25; Ex. 1003, 3:53–55, Fig. 5; Ex. 2102; Ex. 2107 ¶¶ 123, 126; Ex. 2316, 35:16–23, 150:21–151:6). According to Patent Owner, Petitioner attempts to walk back Mr. Leinsing's testimony that supports Patent Owner's interpretation and mischaracterizes the record to discredit Dr. Slocum's testimony. *Id.* at 10–15 (citing Pet. Reply 10–14, 16–20; Ex. 1003, 4:27–32, 4:54–58, Fig. 4; Ex. 1052; Ex. 1053, 144:13–14, 145:24–146:3, 148:22–149:3, 170:22–171:10, 172:16–21, 174:13–176:14, 178:5–12, 184:25–185:3, 185:17–22, 192:11–17, 197:3–5, 197:12–25; Ex. 1054, 397:4–398:11; Ex. 2157, Fig. 4; Ex. 2163, 152:19–159:5, 168:2–7, 170:17–20, 170:23–24).

c) Analysis

Claim 56 recites the "clutch of claim 51, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch." Ex. 1003, 10:51–53. The express language of claim 56 does not require the plurality of axially extending teeth be formed only in an interior of a flange so that the teeth cannot also be formed on "the outer diameter (*i.e.*, exterior), distal side (*i.e.*, needle side), or the proximal side (*i.e.*, button side) portions of a disk-shaped flange," as argued by Patent Owner. *See* PO Resp. 12; Ex. 1003, 10:51–53.

Turning to the Specification, we agree with Patent Owner that the Specification does not provide a clear definition for the phrase "an interior of a flange" and does not include a disavowal of the scope of the phrase. PO Sur-reply 6–7. We also agree that the embodiment shown in Figure 8 is not the only embodiment. PO Sur-reply 4–5; Ex. 1003, 2:17–19. Patent Owner provides arguments based on synonyms of "an interior." PO Resp. 9–12 (citing Ex. 1003, 3:53–55, 4:12–13, 4:20–21, 4:54–55, 4:58–60, Figs. 5, 8). We find that the cited portions of the '486 patent describe "an internal thread," "internal surface," and "inwardly directed flange 62," and these portions do not address directly the phrase "an interior of a flange." Ex. 1003, 3:53–55, 4:12–13, 4:20–21, 4:54–55, 4:58–60; Ex. 2107 ¶ 125. They also do not limit the plurality of axially extending teeth from being formed both at in an interior and "the outer diameter (*i.e.*, exterior), distal side (*i.e.*, needle side), or the proximal side (*i.e.*, button side) portions of a disk-shaped flange." *See* Ex. 1003, 3:53–55, 4:12–13, 4:20–21, 4:54–55, 4:58–60; Ex. 2107 ¶ 125.

Neither party presents any arguments for "an interior of a flange" based on prosecution history. *See* Pet. 12–13; PO Resp. 7–15; Tr. 83:24–84:5. Regarding extrinsic evidence, both parties present declarant testimony that reasonably shows one of ordinary skill in the art would have understood the phrase "an interior of a flange" can refer to a radially inward position or the button side of a flange. Ex. 1095 ¶¶ 19–23; Ex. 2107 ¶ 125. Taken together, both parties' declarant testimony indicates that one of ordinary skill in the art would have understood that the scope of "an interior of the flange" is broader than Patent Owner's proposed interpretation. Both parties' declarants also support our determination that the scope of "an interior of the flange" does not exclude teeth formed on an interior from also being formed

on "the outer diameter (*i.e.*, exterior), distal side (*i.e.*, needle side), or the proximal side (*i.e.*, button side) portions of a disk-shaped flange," as argued by Patent Owner. PO Resp. 12.

For the reasons above, we do not adopt entirely Patent Owner's proposed interpretation for "an interior of a flange." PO Resp. 7–8. Instead, based on the full record, we interpret "an interior of the flange" to mean "at the inner diameter of a flange," as Patent Owner proposes, but contrary to Patent Owner's assertions, we determine that the phrase does not exclude the recited plurality of axially extending teeth from also being formed on the outer diameter or exterior, distal or needle side, and the proximal or button side of a disk-shaped flange. *See also* PO Sur-reply 2 (arguing that an express interpretation is not necessary because Petitioner fails to show the limitation under either party's proposed interpretation); Tr. 79:8–13 (Patent Owner's counsel stating that the Board need not decide which party's interpretation is correct).

We determine that no other claim term requires express construction. *Vivid Techs.*, 200 F.3d at 803.

D. Anticipation Based on Burroughs

Petitioner contends that Burroughs anticipates claims 51–55 and 57. Pet. 22–32. Patent Owner does not address Petitioner's challenges based on Burroughs. PO Resp. 16; Tr. 85:13–18 (Patent Owner's counsel agreeing that no arguments were presented for claims 51–55 and 57). Patent Owner also states that "[s]ubstitute claims for claims 51–55 and 57 are addressed in the motion to amend submitted concurrently with this Response." PO Resp. 22.

For the reasons explained below, based on the full record before us, Petitioner persuades us by a preponderance of the evidence that Burroughs anticipates claims 51–55 and 57.

1. Burroughs (Ex. 1013)

Burroughs discloses a "multi-use medication dispensing pen . . . made of a minimal number of parts, which include a housing, a dial mechanism, a generally cylindrical button assembly located within the proximal end of the dial mechanism, an internally threaded nut, and an externally threaded leadscrew." Ex. 1013, Abstract. It particularly relates to "recyclable dispensing devices that permit selectively measured dosages of a liquid to be dispensed." *Id.* at 1:13–16. Figure 2 of Burroughs is reproduced below.

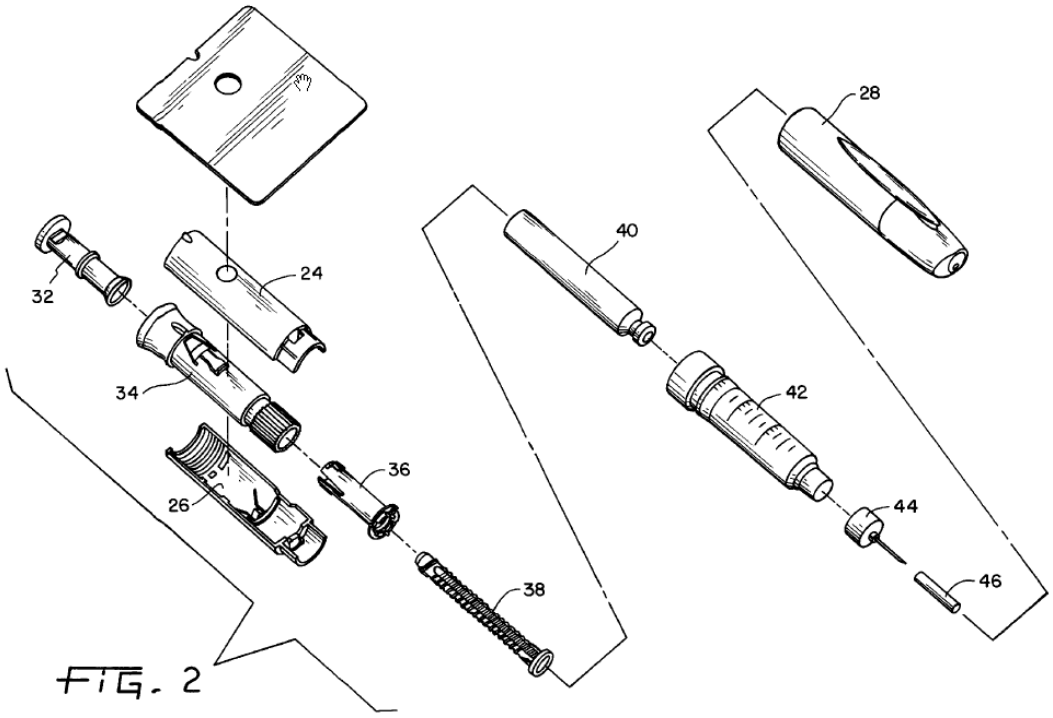

Figure 2 shows an exploded view of injection medication device 20. *Id.* at 6:42–43, 7:15–16. Medication device 20 includes mechanism housing 22 made from housing parts 24 and 26, button 32, dial

mechanism 34, nut 36, and leadscrew 38 that forms a drive stem. Ex. 1013, 7:17–18, 7:32–34, 9:12–13. Figure 14 of Burroughs is reproduced below.

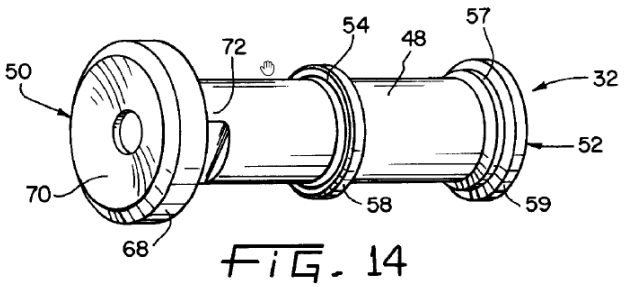

FIG. 14

Figure 14 shows "a perspective view of the button." *Id.* at 6:66. Burroughs describes that "button 32 comprises a hollow cylindrical portion 48 having a proximal end 50" and "includes a distal end 52 in the form of a double-stopped annular bead." *Id.* at 7:46–50, Fig. 14. "[S]econd step 59 is used both to keep button 32 centered within dial mechanism 34 and also prevent button 32 from inadvertently falling or being removed from dial 34." *Id.* at 7:55–56. "When button 32 is depressed, enlarged diameter portion 54 is also depressed and thereby pushes against ramped surfaces 96, which in turn forces fingers 94 outward and legs 102 and 104 inward" so that "[d]ial mechanism 34 is then able to travel axially towards cartridge 40 during injection of the medical product." *Id.* at 8:11–20. 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. Burroughs describes that "a plurality of splines 144 extending circumferentially about the interior surface of intermediate portion 80 of dial mechanism 34" that "engage with teeth 192 (FIGS. 10, 11) provided on nut 36 when the clutch is engaged to set a dosage." *Id.* at 8:42–48, Fig. 9.

"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."

Ex. 1013, 10:60–63. 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. Analysis of Claim 51

a) A clutch for use within a pen type drug delivery device

Petitioner argues that, to the extent that the preamble is limiting, Burroughs discloses the preamble of independent claim 51. Pet. 22–25 (citing Ex. 1011 ¶¶ 448–451; 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). Petitioner contends that "button 32 serves as a clutch that allows dial mechanism 34 to disengage from (1) its rotational connection with housing 22, and (2) its rotational connection with nut 36."

If the preamble is limiting, we find that a relied-upon portion of Burroughs disclose a "multi-use medication dispensing pen . . . made of a minimal number of parts, which include a housing, a dial mechanism, a generally cylindrical button assembly located within the proximal end of the dial mechanism, an internally threaded nut, and an externally threaded leadscrew." Ex. 1013, Abstract. We also find that another relied-upon portion of Burroughs describes that, "[w]hen button 32 is depressed, enlarged diameter portion 54 is also depressed and thereby pushes against ramped surfaces 96, which in turn forces fingers 94 outward and legs 102 and 104 inward" so that "[d]ial mechanism 34 is then able to travel axially towards cartridge 40 during injection of the medical product." *Id.* at 8:11–20. We additionally find that another relied-upon portion of Burroughs

describes that "a plurality of splines 144 extending circumferentially about the interior surface of intermediate portion 80 of dial mechanism 34" that "engage with teeth 192 (FIGS. 10, 11) provided on nut 36 when the clutch is engaged to set a dosage." *Id.* at 8:42–48. We further credit the Mr. Leinsing's testimony because Burroughs supports it. Ex. 1011 ¶¶ 448–451 (citing Ex. 1013, Abstract, 7:14–19, 7:46–52, 8:11–20, 8:24–29, 8:62–9:1, 10:21–26, 10:34–42, 11:5–12, 11:14–20, 11:27–34, Figs. 1–3, 5–9, 11, 14, 15).

Patent Owner does not address Petitioner's challenges based on Burroughs. PO Resp. 16; Tr. 85:13–18. Because Burroughs discloses a medication dispensing pen with button 32 that can disengage dial mechanism 34 from housing 22 and nut 36, Petitioner persuades us that Burroughs discloses a "clutch for use within a pen type drug delivery device."

b) said clutch comprising a tubular body, said tubular body extending from a distal end to a proximal end;

Petitioner argues that Burroughs discloses a clutch with a tubular body extending from a distal end to a proximal end, as required by claim 51. Pet. 25–26 (citing Ex. 1011 ¶ 452; Ex. 1013, 7:46–52, Figs. 14, 15).

We find that the relied-upon portions of Burroughs disclose that "button 32 comprises a hollow cylindrical portion 48 having a proximal end 50" and "includes a distal end 52 in the form of a double-stopped annular bead." Ex. 1013, 7:46–50. We also find that at least Figure 14 of Burroughs shows button 32 with distal end 52 and proximal end 50. We further credit Mr. Leinsing's testimony because Burroughs supports it. Ex. 1011 ¶ 452 (citing Ex. 1013, Fig. 14).

Patent Owner does not address Petitioner's challenges based on Burroughs. PO Resp. 16; Tr. 85:13–18. Because Burroughs discloses button 32 with hollow cylindrical portion 48 that extends between proximal end 50 and distal end 52, Petitioner persuades us that Burroughs discloses "said clutch comprising a tubular body, said tubular body extending from a distal end to a proximal end."

> *c) 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.*

Petitioner argues that Burroughs discloses the above-quoted recitation of claim 51. Pet. 26 (citing Ex. 1011 ¶ 454; Ex. 1013, Figs. 1, 14).

We find that Figures 1 and 14 of Burroughs show button 32 fitting within dial mechanism 34. Specifically, Figure 14 of Burroughs shows that distal end 52 and a portion of hollow cylindrical body 48 of button 32 is received within proximal end 78 of dial mechanism 34. *See also* Ex. 1013, Abstract ("a generally cylindrical button assembly located within the proximal end of the dial mechanism"), 7:55–56 (describing that "second step 59 is used both to keep button 32 centered within dial mechanism 34 and also prevent button 32 from inadvertently falling or being removed from dial 34"), Fig. 2 (showing in an exploded view button 32 at proximal end of dial mechanism 34), Figs. 6–9 (showing proximal end 78 of dial mechanism 34). We further credit Mr. Leinsing's testimony because Burroughs supports it. Ex. 1011 ¶ 454 (citing Ex. 1013, Figs. 1, 14).

Patent Owner does not address Petitioner's challenges based on Burroughs. PO Resp. 16; Tr. 85:13–18. Because Burroughs shows distal end 52 of button 32 within proximal end 78 of dial mechanism 34, Petitioner persuades us that Burroughs discloses "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."

d) Determination for Independent Claim 51

Based on the full record before us and our findings from Burroughs discussed above, Petitioner persuades us by a preponderance of the evidence that Burroughs discloses each limitation of claim 51 and thus anticipates claim 51.

3. Analysis of Claim 52

Claim 52 recites the "clutch of claim 51, wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob." Ex. 1003, 10:38–40. Petitioner argues that Burroughs discloses the subject matter of dependent claim 52. Pet. 26–28 (citing Ex. 1011 ¶¶ 457–459; Ex. 1013, 7:65–67, 8:2–6, 10:34–42, Figs. 1, 2, 6–9).

We find that the relied-upon portions of Burroughs disclose that "[d]ial mechanism 34 is generally cylindrical in shape and is hollow throughout its axial length" and "comprises proximal portion 78, intermediate portion 80, and distal portion 82." Ex. 1013, 7:65–67, 8:2–4. We also find that Burroughs discloses that "[p]roximal portion 78 comprises enlarged diameter portion 84, tapered portion 86, and ring 90 extending about the circumference of proximal portion 78." *Id.* at 8:4–6, Fig. 7 (showing proximal portion 78 and enlarged diameter portion 84). Figure 1 of Burroughs shows proximal end 50 of button 32 within proximal portion 78 of dial mechanism 34.

A relied-upon portion of Burroughs describes rotating dial mechanism 34 to set a dose. *See id.* at 10:34–42. We further credit Mr. Leinsing's testimony because Burroughs supports it. Ex. 1011 ¶¶ 457–459 (citing Ex. 1013, 10:34–42, Fig. 1).

Because Burroughs describes proximal end 50 of button 32 within proximal portion 78 of dial mechanism 34, Petitioner persuades us that Burroughs discloses "wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob," as recited by claim 52. Patent Owner does not present any arguments regarding Petitioner's challenge of claim 52 based on Burroughs. PO Resp. 16; Tr. 85:13–18.

For the reasons discussed above, Petitioner persuades us that Burroughs discloses each limitation of claim 51, from which claim 52 depends. Based on the full record before us and our findings from Burroughs regarding the limitations of claim 52, Petitioner persuades us by a preponderance of the evidence that Burroughs discloses each limitation of dependent claim 52 and thus anticipates claim 52.

4. Analysis of Claim 53

Claim 53 recites the "clutch of claim 52, wherein when said dose knob is activated to dispense a dose of a medicament contained within said pen type delivery device, said clutch is moved in a distal direction." Ex. 1003, 10:41–44. Petitioner argues that Burroughs discloses the subject matter of dependent claim 53. Pet. 28–29 (citing Ex. 1011 ¶ 461; Ex. 1013, 11:13–26).

We find that the relied-upon portion of Burroughs discloses that "[o]nce a desired dosage has been set, . . . recessed surface 70 of button 32 is pushed" and "[a]s button surface 70 is pushed into dial mechanism 34, button distal end 52 moves out of engagement with legs 102 and 104" so that dial mechanism 34 "move[s] forward because threads 110, 112 are not in engagement with groove 158." Ex. 1013, 11:13–20. As button 32 is pressed further, "an audible 'click' sound . . . provid[es] an audible

confirmation that the entire dosage has been injected." Ex. 1013, 11:20–26. We also credit Mr. Leinsing's testimony because Burroughs supports it. Ex. 1011 ¶ 461 (citing Ex. 1013, 11:5–6, 11:13–23, 11:27–34).

Because Burroughs describes that dial mechanism 34 moves forward to inject a dosage when button 32 is pushed into dial mechanism 34, Petitioner persuades us that Burroughs discloses "wherein when said dose knob is activated to dispense a dose of a medicament contained within said pen type delivery device, said clutch is moved in a distal direction," as recited by claim 53. Patent Owner does not present any arguments regarding Petitioner's challenge of claim 53 based on Burroughs. PO Resp. 16; Tr. 85:13–18.

For the reasons discussed above, Petitioner persuades us that Burroughs discloses each limitation of claims 51 and 52, from which claim 53 depends. Based on the full record before us and our findings from Burroughs regarding the limitations of claim 53, Petitioner persuades us by a preponderance of the evidence that Burroughs discloses each limitation of dependent claim 53 and thus anticipates claim 53.

5. Analysis of Claim 54

Claim 54 recites the "clutch of claim 52, wherein said pen type drug delivery device further comprises a cartridge containing a medicament, said cartridge comprising a reservoir, a stopper, a septum and a ferrule." Ex. 1003, 10:45–48. Petitioner argues that Burroughs discloses the subject matter of dependent claim 54. Pet. 29–30 (citing Ex. 1011 ¶¶ 463, 464; Ex. 1013, 9:32–46, Figs. 1, 2).

We find that the relied-upon portion of Burroughs discloses that "plunger engagement portion 206 of leadscrew 38 is in engagement with piston 210 of cartridge 40" and that "[c]artridge 40 . . . comprises a tube

defining an inner chamber 212 which openly terminates at its distal end in a neck 214 having a cap 216 including a rubber disc 218 disposed thereover." Ex. 1013, 9:32–46; *see also id.* at 2:42–44 (stating that a "liquid medication product is housed in a variable volume cartridge within the housing of the device"). Figure 1 of Burroughs shows that cartridge 40 includes chamber 212, piston 210, rubber disc 218, and cap 216. We credit Mr. Leinsing's testimony that one of ordinary skill in the art would have understood chamber 212, piston 210, rubber disc 218, and cap 216 to be, respectively, a reservoir, a stopper, a septum and a ferrule because it finds support in Burroughs. Ex. 1011 ¶¶ 463, 464 (citing Ex. 1013, Abstract, 2:42–48, 9:34–40, Figs. 1, 2).

Because we find that Burroughs describes a cartridge with liquid medication and that one of ordinary skill would have understood that cartridge 40 of Burroughs includes a reservoir, stopper, septum and ferrule, Petitioner persuades us that Burroughs discloses "wherein said pen type drug delivery device further comprises a cartridge containing a medicament, said cartridge comprising a reservoir, a stopper, a septum and a ferrule," as recited by claim 54. Patent Owner does not present any arguments regarding Petitioner's challenge of claim 54 based on Burroughs. PO Resp. 16; Tr. 85:13–18.

For the reasons discussed above, Petitioner persuades us that Burroughs discloses each limitation of claims 51 and 52, from which claim 54 depends. Based on the full record before us and our findings from Burroughs regarding the limitations of claim 54, Petitioner persuades us by a preponderance of the evidence that Burroughs discloses each limitation of dependent claim 54 and thus anticipates claim 54.

6. Analysis of Claim 55

Claim 55 recites the "clutch of claim 54, wherein said cartridge comprises a multidose cartridge." Ex. 1003, 10:49–50. Petitioner argues that Burroughs discloses the subject matter of dependent claim 55. Pet. 31 (citing Ex. 1011 ¶ 466; Ex. 1013, Abstract).

We find that the Abstract of Burroughs discloses a "multi-use medication dispensing pen made of a plastic material that is recyclable after the contents of the medication cartridge have been exhausted." *See also* Ex. 1013, 2:42–44 (describing that a "liquid medication product is housed in a variable volume cartridge within the housing of the device"), 10:49–52 (describing that "[o]nce a dosage has been selected, that dosage may be made larger or smaller by rotating the dial assembly in either the clockwise or counterclockwise direction"), 12:12–14 (describing that "[t]his rotational stop mechanism provides a very accurate indication to the user of the dosage remaining in the cartridge"). We also credit Mr. Leinsing's testimony because Burroughs supports it. Ex. 1011 ¶ 466 (citing Ex. 1013, Abstract, 5:62–65, 10:49–52).

Because Burroughs describes a multi-use medication dispensing pen and as discussed above, describes a cartridge housing liquid medication, Petitioner persuades us that Burroughs discloses "wherein said cartridge comprises a multidose cartridge," as recited by claim 55. Patent Owner does not present any arguments regarding Petitioner's challenge of claim 55 based on Burroughs. PO Resp. 16; Tr. 85:13–18.

For the reasons discussed above, Petitioner persuades us that Burroughs discloses each limitation of claims 51, 52, and 54, from which claim 55 depends. Based on the full record before us and our findings from Burroughs regarding the limitations of claim 55, Petitioner persuades us by a

preponderance of the evidence that Burroughs discloses each limitation of dependent claim 55 and thus anticipates claim 55.

7. Analysis of Claim 57

Claim 57 recites the "clutch of claim 51, wherein said clutch is positioned within an open proximal end of said dial member and located adjacent a distal end of said dose knob and operatively coupled to said dose knob, and wherein said dial member extends circumferentially around at least a portion of said clutch." Ex. 1003, 10:54–59.

Petitioner argues that Burroughs discloses that button 32 is within an open end of dial mechanism 34 and adjacent proximal portion 78 and that button 32 is operatively coupled to proximal portion 78 via dial mechanism 34. Pet. 31–32 (citing Ex. 1011 ¶¶ 467–469; Ex. 1013, 8:2–6, Fig. 1).

We find that the relied-upon portions of Burroughs disclose that "[d]ial mechanism 34 comprises proximal portion 78" and that "[p]roximal portion 78 comprises enlarged diameter portion 84, tapered portion 86, and ring 90 extending about the circumference of proximal portion 78." Ex. 1013, 8:2–6, Fig. 7 (showing proximal portion 78 and enlarged diameter portion 84). We also find that Figure 1 of Burroughs shows that proximal end 50 of button 32 is within and circumferentially surrounded by proximal portion 78 of dial mechanism 34 and that button 32 is operatively coupled to proximal portion 78. We credit Mr. Leinsing's testimony regarding claim 57 because Burroughs supports it. Ex. 1011 ¶¶ 467–469 (citing Ex. 1013, 2:17–19, 6:28–31, Figs. 1, 9).

Because Burroughs describes that button 32 is within and next to proximal portion 78 of dial mechanism 34 and that button 32 is operatively coupled to proximal portion 78, Petitioner persuades us that Burroughs

discloses "wherein said clutch is positioned within an open proximal end of said dial member and located adjacent a distal end of said dose knob and operatively coupled to said dose knob, and wherein said dial member extends circumferentially around at least a portion of said clutch," as recited by claim 57. Patent Owner does not present any arguments regarding Petitioner's challenge of claim 57 based on Burroughs. PO Resp. 16; Tr. 85:13–18.

For the reasons discussed above, Petitioner persuades us that Burroughs discloses each limitation of claim 51, from which claim 57 depends. Based on the full record before us and our findings from Burroughs regarding the limitations of claim 57, Petitioner persuades us by a preponderance of the evidence that Burroughs discloses each limitation of dependent claim 57 and thus anticipates claim 57.

E. Obviousness Based on Burroughs

Petitioner also contends that Burroughs would have rendered obvious claims 54 and 55. Pet. 32–34. Patent Owner does not address Petitioner's challenges based on Burroughs. PO Resp. 16; Tr. 85:13–18 (Patent Owner's counsel agreeing that no arguments were presented for claims 51–55 and 57). Patent Owner also states that "[s]ubstitute claims for claims 51–55 and 57 are addressed in the motion to amend submitted concurrently with this Response." PO Resp. 22; *see also id.* at 23 (stating for the obviousness challenge based on Burroughs that "[s]ubstitute claims for claims 54–55 are addressed in the motion to amend submitted concurrently with this Response").

For the reasons explained below, based on the full record before us, Petitioner persuades us by a preponderance of the evidence that Burroughs would have rendered obvious claims 54 and 55.

1. Scope and Content of the Asserted Prior Art

We discuss Burroughs above in Section II.D.1.

2. Analysis of Claim 54

Claim 54 recites the "clutch of claim 52, wherein said pen type drug delivery device further comprises a cartridge containing a medicament, said cartridge comprising a reservoir, a stopper, a septum and a ferrule." Ex. 1003, 10:45–48. Petitioner argues that Burroughs would have rendered obvious claim 54. Pet. 32–34 (citing Ex. 1011 ¶¶ 471, 472; Ex. 1013, 9:32–46).

We find that the relied-upon portion of Burroughs teaches that "plunger engagement portion 206 of leadscrew 38 is in engagement with piston 210 of cartridge 40" and that "[c]artridge 40 . . . comprises a tube defining an inner chamber 212 which openly terminates at its distal end in a neck 214 having a cap 216 including a rubber disc 218 disposed thereover." Ex. 1013, 9:32–46; *see also id.* at 2:42–44 (describing that a "liquid medication product is housed in a variable volume cartridge within the housing of the device"), 10:49–52 (describing that "[o]nce a dosage has been selected, that dosage may be made larger or smaller by rotating the dial assembly in either the clockwise or counterclockwise direction"), 12:12–14 (describing that "[t]his rotational stop mechanism provides a very accurate indication to the user of the dosage remaining in the cartridge").

We also credit the testimony of Mr. Leinsing that "[i]t was well-known by those skilled in the art that cartridge used to hold and dispense medicine from pen-type injectors often contained a reservoir for holding the medicine within the cartridge, a stopper for abutting the piston rod of the drive mechanism, a septum f[or] separating the inner contents of the reservoir from an external chamber or environment, and a ferrule for

providing securement of the septum to the cartridge." Ex. 1011 ¶ 472 (citing Ex. 1013, 3:34–37). We find persuasive Mr. Leinsing's testimony that "a person of ordinary skill would have immediately recognized that these structures functionally operate as the terms recited" (*id.* ¶ 471) and "would have considered those components to be included in injector cartridges from the teachings of Burroughs" (*id.* ¶ 472).

Because we find that Burroughs teaches or suggests the limitations of claim 54, Petitioner persuades us that Burroughs teaches or suggests "wherein said pen type drug delivery device further comprises a cartridge containing a medicament, said cartridge comprising a reservoir, a stopper, a septum and a ferrule." Patent Owner does not present any arguments regarding Petitioner's obviousness challenge of claim 54 based on Burroughs. PO Resp. 16, 22, 23; Tr. 85:13–18.

For the reasons discussed above, Petitioner persuades us that Burroughs discloses each limitation of claims 51 and 52, from which claim 54 depends. Based on the full record before us, Petitioner persuades us that one of ordinary skill in the art would have understood that Burroughs teaches or suggests the limitations of claim 54.

3. Analysis of Claim 55

Claim 55 recites the "clutch of claim 54, wherein said cartridge comprises a multidose cartridge." Ex. 1003, 10:49–50. Petitioner argues that Burroughs would have rendered obvious claim 55 because "Burroughs specifically teaches that its pen dispenses multiple doses of medication" and, thus, one of ordinary skill in the art "would have understood that the cartridge would contain multiple doses of the medication." Pet. 33–34 (citing Ex. 1011 ¶ 473; Ex. 1013, Abstract).

We find that Burroughs teaches a "multi-use medication dispensing pen made of a plastic material that is recyclable after the contents of the medication cartridge have been exhausted." Ex. 1013, Abstract; *see also id.* at 2:42–44 (describing that a "liquid medication product is housed in a variable volume cartridge within the housing of the device"), 10:49–52 (describing that "[o]nce a dosage has been selected, that dosage may be made larger or smaller by rotating the dial assembly in either the clockwise or counterclockwise direction"), 12:12–14 (describing that "[t]his rotational stop mechanism provides a very accurate indication to the user of the dosage remaining in the cartridge"). We also credit Mr. Leinsing's testimony regarding claim 55 because Burroughs supports it. Ex. 1011 ¶ 473 (citing Ex. 1011 ¶ 466; Ex. 1013, 3:34–37).

Because we find that Burroughs teaches or suggests the limitations of claim 55, Petitioner persuades us that Burroughs teaches or suggests "wherein said cartridge comprises a multidose cartridge." Patent Owner does not present any arguments regarding Petitioner's obviousness challenge of claim 54 based on Burroughs. PO Resp. 16, 22, 23; Tr. 85:13–18.

For the reasons discussed above, Petitioner persuades us that Burroughs discloses, teaches, and suggests each limitation of claims 51, 52, and 54, from which claim 55 depends. Based on the full record before us, Petitioner persuades us that one of ordinary skill in the art would have understood that Burroughs teaches or suggests the limitations of claim 55.

4. Objective Indicia of Nonobviousness

The parties do not dispute any objective indicia of nonobviousness. *See generally* Pet.; PO Resp.; PO Sur-reply; *see also* Pet. Reply 26 (arguing that "Sanofi does not allege any secondary considerations to prove non-obviousness in its response, thus waiving any such argument").

Petitioner notes that "Sanofi submitted a declaration by Dr. Goland that claims to support Sanofi's response by alleging satisfaction of a long-felt need by the SoloSTAR® pen," but "[g]iven Sanofi's failure to cite to Dr. Goland's declaration in its Response, the declaration is not properly before the Board in this proceeding." Pet. Reply 26–27 (citing PO Resp. iii; Ex. 2011).

Patent Owner does not present any arguments asserting any objective indicia of nonobviousness or direct us to any such evidence in the record, even though it has had the opportunity in this proceeding and presented such evidence in other related proceedings. *See* Tr. 58:20–59:5 (Patent Owner's counsel agreeing that objective evidence of nonobviousness were not presented in this proceeding). For these reasons, we determine that no relevant objective evidence of nonobviousness has been presented in connection with claims 54 and 55.

5. Weighing the Graham *Factors*

"Once all relevant facts are found, the ultimate legal determination [of obviousness] involves weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan." *Arctic Cat*, 876 F.3d at 1361. Above, based on full record before us, we provide our factual findings regarding (1) the level of ordinary skill in the art, (2) the scope and content of the prior art, (3) any differences between the claimed subject matter and the prior art, and (4) objective evidence of nonobviousness.

In particular, we find that (1) Petitioner's proposed level of ordinary skill in the art is consistent with the prior art of record, (2) Burroughs teaches or suggests all the limitations of claims 54 and 55, (3) one of ordinary skill in the art would have understood that the cartridge of

Burroughs has the features required by claims 54 and 55, and (4) no objective evidence of nonobviousness has been presented in relation to claims 54 and 55. Weighing these underlying factual determinations, a preponderance of the evidence persuades us that claims 54 and 55 of the '486 patent are unpatentable over Burroughs.

F. Anticipation Based on Steenfeldt-Jensen

Petitioner contends that Steenfeldt-Jensen anticipates claims 51–53, 56, and 57. Pet. 34–46. Patent Owner does not address Petitioner's challenges based on Steenfeldt-Jensen. PO Resp. 23; Tr. 85:13–18 (Patent Owner's counsel agreeing that no arguments were presented for claims 51–55 and 57). Patent Owner states that "[s]ubstitute claims for claims 51–53 and 56–57 are addressed in the motion to amend" and argues that "the Petition fails to show that Steenfeldt-Jensen teaches a clutch 'comprising a plurality of axially extending teeth formed in an interior of a flange' as required by claim 56." PO Resp. 23.

For the reasons explained below, based on the full record before us, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen anticipates claims 51–53, 56, and 57.

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.

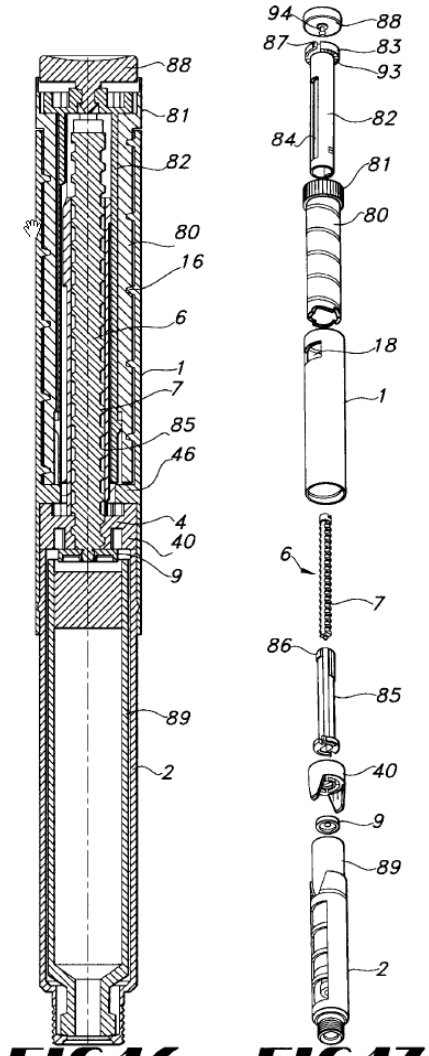

FIG 16 FIG 17

Figures 16 and 17 show side sectional views of a syringe. Ex. 1014, 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. Ex. 1014, 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. Analysis of Claim 51

a) A clutch for use within a pen type drug delivery device

Petitioner argues that, to the extent that the preamble is limiting, Steenfeldt-Jensen discloses the preamble of independent claim 51. Pet. 34–37 (citing Ex. 1011 ¶¶ 477–479; Ex. 1014, 1:12–15, 11:26–51, 12:1–13, Figs. 15–17). Petitioner contends that "Steenfeldt-Jensen discloses the claimed 'clutch' in the form of a bushing, as flange 83 of bushing 82 has a rosette of teeth 93, which is configured to releasably engage corresponding rosettes on the button-end of dose-setting button 81, which is positioned at the button-end of scale drum 80." *Id.* at 36.

If the preamble is limiting, we find that the relied-upon portions of Steenfeldt-Jensen disclose "an injection syringe [that] comprises a housing

including a holder for containing a cartridge of medicine" and "injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses." Ex. 1014, Abstract, 1:12–15.

We also find that a relied-upon portion of Steenfeldt-Jensen discloses that one embodiment includes bushing 82 with structural features "whereby the bushing 82 and the driver tube 85 is coupled to each other so that rotation but not longitudinal displacement is transmitted between said two elements," "[w]hen a dose is set by rotating the dose setting button 81 in a clockwise direction, . . . bushing is kept non rotated due to its coupling to the driver tube," "[w]hen the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81," and the "bushing will rotate the driver tube 85 in an anticlockwise direction" so that "the piston rod is thereby screwed further into an ampoule 89 in the ampoule holder 2." *Id.* at 11:26–33 12:1–13. We further credit Mr. Leinsing's testimony regarding bushing 82 because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 477–479 (citing Ex. 1013, 11:26–49, 11:52–62, 12:1–13, Figs. 15–17).

Patent Owner does not present any arguments regarding the preamble of claim 51. PO Resp. 23; Tr. 85:13–18. Because Steenfeldt-Jensen discloses an injection syringe with a cartridge of medicine and bushing 82 is not rotated during dose setting rotates driver tube 85 when injecting a dose, Petitioner persuades us that Steenfeldt-Jensen discloses a "clutch for use within a pen type drug delivery device."

b) said clutch comprising a tubular body, said tubular body extending from a distal end to a proximal end;

Petitioner argues that Steenfeldt-Jensen discloses a clutch with a tubular body extending from a distal end to a proximal end. Pet. 37–38 (citing Ex. 1011 ¶ 481; Ex. 1014, 11:26–27, 12:4–13, Figs. 15–17).

We find that Figure 17 of Steenfeldt-Jensen shows bushing 82 having a tubular body with proximal and distal ends. We also find that a relied-upon portion of Steenfeldt-Jensen discloses "bushing 82 having a flange 83 at its proximal end." Ex. 1014, 11:26–27. We further credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 481 (citing Ex. 1014, Fig. 17).

Patent Owner does not present any arguments regarding this limitation of claim 51. PO Resp. 23; Tr. 85:13–18. Because Steenfeldt-Jensen discloses bushing 82 having a tubular body that extends from a proximal end to another end, Petitioner persuades us that Steenfeldt-Jensen discloses "said clutch comprising a tubular body, said tubular body extending from a distal end to a proximal end."

c) 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.

Petitioner argues that Steenfeldt-Jensen discloses the above-quoted recitation of claim 51. Pet. 38–40 (citing Ex. 1011 ¶ 482; Ex. 1014, 11:26–28, Figs. 15, 16). Petitioner contends that "scale drum 80 corresponds to the recited 'dial member'—also referred to as the 'dose dial sleeve' in the specification—since the user 'dials' a dose for injection by rotating scale drum 80." *Id.* at 39.

We find that a relied-upon portion of Steenfeldt-Jensen discloses that "bushing 82 . . . fits into the scale drum 80" (Ex. 1014, 11:26–28) and that

Figure 16 shows bushing 82 fitting within scale drum 80. *See also* Ex. 1014, 11:52 (describing that "[w]hen a dose is set by rotating the dose setting button 81 in a clockwise direction . . . "). We further credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 482 (citing Ex. 1014, 11:28–30, Figs. 15, 16).

Patent Owner does not present any arguments regarding this limitation of claim 51. PO Resp. 23; Tr. 85:13–18. Because Steenfeldt-Jensen discloses an end of the tubular body of bushing 82 fitting into scale drum 80, Petitioner persuades us that Steenfeldt-Jensen discloses "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."

d) Determination for Independent Claim 51

Based on the full record before us and our findings from Steenfeldt-Jensen discussed above, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen anticipates claim 51.

3. Analysis of Claim 52

Claim 52 recites the "clutch of claim 51, wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob." Ex. 1003, 10:38–40.

Petitioner argues that Steenfeldt-Jensen discloses the subject matter of claim 52. Pet. 40–41 (citing Ex. 1011 ¶¶ 484, 485; Ex. 1014, 11:20–42, 11:52–54, Figs. 15–17). Petitioner contends that "a dose knob, referred to as 'dose setting button 81,' is located at the proximal end of scale drum 80." Pet. 41 (citing Ex. 1011 ¶ 484; Ex. 1014, 11:20–25).

We find that the relied-upon portions of Steenfeldt-Jensen disclose that "bushing 82 . . . fits into the scale drum 80" and that "[w]hen a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale

drum is screwed out of the housing." Ex. 1014, 11:26–28, 11:52–54, Figs. 15, 16. We also find that Figures 15 and 16 of Steenfeldt-Jensen show a proximal end of bushing 82 within dose setting button 81. We further credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 484, 485 (citing Ex. 1014, 11:22–25, 11:52–62, Figs. 15–17).

Patent Owner does not present any arguments regarding Petitioner's challenge of claim 52 based on Steenfeldt-Jensen. PO Resp. 23; Tr. 85:13–18. Because Steenfeldt-Jensen discloses a proximal end of bushing 82 within dose setting button 81, Petitioner persuades us that Steenfeldt-Jensen discloses "wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen discloses each limitation of claim 51, from which claim 52 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 52, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen discloses each limitation of dependent claim 52 and thus anticipates claim 52.

4. Analysis of Claim 53

Claim 53 recites the "clutch of claim 52, wherein when said dose knob is activated to dispense a dose of a medicament contained within said pen type delivery device, said clutch is moved in a distal direction." Ex. 1003, 10:41–44.

Petitioner argues that Steenfeldt-Jensen discloses the subject matter of claim 53. Pet. 41–42 (citing Ex. 1011 ¶¶ 487, 488; Ex. 1014, 11:34–42, 12:1–13, Figs. 15–17). Petitioner contends that "when the user activates the dose knob by pressing injection button 88, bushing 82 moves in the distal direction (i.e. toward the needle end of the device)" and "rotation of bushing

82 is then transmitted to driver tube 85, which moves the piston rod downward to dispense a dose of a medicament contained within the pen." Pet. 42 (citing Ex. 1011 ¶ 487; Ex. 1014, 12:1–13).

We find that the relied-upon portions of Steenfeldt-Jensen disclose that "[d]uring the setting the rosette in the dose setting button forces the rosette 93 on the flange 83 of the bushing 82 out of engagement," "[w]hen the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81," and the "bushing will rotate the driver tube 85 in an anticlockwise direction" so that "the piston rod is thereby screwed further into an ampoule 89 in the ampoule holder 2." Ex. 1014, 12:1–7, 12:10–13. We also credit Mr. Leinsing's testimony that bushing 82 moves axially into the housing during injection because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 487, 488 (citing Ex. 1014, 12:4–13).

Patent Owner does not present any arguments regarding Petitioner's challenge of claim 53 based on Steenfeldt-Jensen. PO Resp. 23; Tr. 85:13–18. Because Steenfeldt-Jensen discloses that, when injection button 88 is pressed, dose setting button 81 and bushing 82 rotate back into the housing to cause the piston rod to move into ampoule 89, Petitioner persuades us that Steenfeldt-Jensen discloses "wherein when said dose knob is activated to dispense a dose of a medicament contained within said pen type delivery device, said clutch is moved in a distal direction."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen discloses each limitation of claims 51 and 52, from which claim 53 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 53, Petitioner persuades

us by a preponderance of the evidence that Steenfeldt-Jensen discloses each limitation of dependent claim 53 and thus anticipates claim 53.

5. Analysis of Claim 56

Claim 56 recites the "clutch of claim 51, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch." Ex. 1001, 10:51–53.

Petitioner argues that Steenfeldt-Jensen discloses claim 56 because "bushing 82 includes a rosette of teeth 93" that "extend axially from a flange 83 at the needle-end of bushing 82" and "Figure 17 also shows that teeth 93 extend axially and are formed in an interior of flange 83." Pet. 42–43 (citing Ex. 1011 ¶ 489; Ex. 1014, 11:34–42, Fig. 17).

Patent Owner responds that Petitioner does not show that Steenfeldt-Jensen discloses claim 56 because teeth 93 are not formed along an inner diameter of a flange, in accordance with Patent Owner's proposed interpretation of "formed in an interior of a flange." PO Resp. 23–24 (citing Pet. 42–43; Ex. 1014, Fig. 17). Patent Owner contends that rosette 93 of teeth are formed on a distal end of flange 83. *Id.* at 24–25 (citing Ex. 1014, Figs. 16, 17; Ex. 2107 ¶¶ 340–346). Patent Owner also asserts that Mr. Leinsing confirmed that an interior of a flange is an inner diameter of the flange and that an underside of the flange is the distal side, not the interior. *Id.* at 25 (citing Ex. 2012, Fig. 4; Ex. 2163, 148:9–20, 155:7–9, 155:13–18, 158:10–21).

Petitioner replies that Patent Owner "does not dispute that Steenfeldt-Jensen discloses or suggests a clutch having axially-extending teeth formed on a flange" and only argues "based on a flawed interpretation of claim 56." Pet. Reply 21 (citing PO Resp. 23–27; Ex. 2107 ¶ 344). Petitioner argues that "Steenfeldt-Jensen discloses forming axially-extending teeth on a flange

in a position that is substantially similar to what is described by the '486 patent (i.e. radially inward of the flange's outermost diameter)" (Pet. Reply 21 (citing Pet. 42–43, 46; Ex. 1095 ¶ 90)), and that Mr. Leinsing explains how Steenfeldt-Jensen meets the plain and ordinary meaning of "formed in an interior of a flange" (*id.* at 22 (citing PO Resp. 24–25; Ex. 1095 ¶ 90)).

Patent Owner replies that "Steenfeldt-Jensen does not teach or suggest axially extending teeth formed in an interior of a flange under either Sanofi's or Petitioners' constructions for 'an interior of a flange.'" PO Sur-reply 16. In particular, Patent Owner refers to its argument in its Response for why Steenfeldt-Jensen's teeth do not meet Patent Owner's proposed interpretation of "formed in an interior of a flange," and Patent Owner contends that Petitioner does not dispute it. *Id.* (citing PO Resp. 23–25; Pet. Reply 21–22). Patent Owner also argues that Steenfeldt-Jensen's teeth do not meet Petitioner's proposed interpretation because "the position of the teeth includes the outermost diameter" and "[b]ecause teeth 93 do not begin recessed from the outermost diameter, teeth 93 are not formed radially inward of the outermost diameter, but are instead formed beginning ***at the outermost diameter***." *Id.* (citing Ex. 1014, 11:40–42, Fig. 17); *see also id.* at 17 (providing cropped and annotated Fig. 17).

We find that the relied-upon portion of Steenfeldt-Jensen discloses that "[i]n the dose setting button a compartment is provided having . . . a bottom with a rosette of teeth having a triangular cross-section," and "[t]he flange 83 of the bushing 82 is adopted in said compartment." Ex. 1014, 11:34–38. The relied-upon portion of Steenfeldt-Jensen also discloses that "[a]t its distal side the flange 83 has a rosette 93 of teeth which can be

brought into engagement with the rosette at the bottom of the compartment." *Id.* at 11:40–42.

We also find that Figure 17 of Steenfeldt-Jensen shows flange 83 at one end of bushing 82 and rosette 93 of teeth on one side of flange 83. Figure 17 also shows that rosette 93 of teeth extend to an outermost circumference of flange 83. We further credit Mr. Leinsing's testimony regarding what Steenfeldt-Jensen discloses in connection with rosette 93 of teeth because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 489 (citing Ex. 1014, 11:34–36, 11:40–42, Fig. 17).

The parties do not dispute whether Steenfeldt-Jensen discloses "a plurality of axially extending teeth" and "a flange of said clutch;" rather, the parties dispute whether Steenfeldt-Jensen's rosette 93 of teeth is "formed in an interior of a flange." *See* Pet. 42–43; PO Resp. 24–25; Pet. Reply 21; PO Sur-reply 16–17; *see also* Tr. 79:8–13, 79:19–20, 79:23–24. Both parties agree that Steenfeldt-Jensen's rosette 93 of teeth extend from flange 83 at the needle-end of bushing 82. Pet. 43 (citing Ex. 1014, 11:40–42); PO Resp. 24 (citing Ex. 2107 ¶¶ 340–346); *see also* Tr. 82:13–18 (Patent Owner's counsel agreeing that the teeth are formed at inner and outer diameters).

Because Steenfeldt-Jensen discloses rosette 93 of teeth that extend from an edge of flange 83 to an inner diameter of bushing 82 and under our interpretation of "an interior of a flange" to mean "at the inner diameter of a flange," not excluding teeth that are also formed at the outer diameter and the distal or needle side of a disk-shaped flange, Petitioner persuades us that Steenfeldt-Jensen discloses "a plurality of axially extending teeth formed in an interior of a flange of said clutch."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen discloses each limitation of claim 51, from which claim 56

depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 56, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen discloses each limitation of dependent claim 56 and thus anticipates claim 56.

Patent Owner also contends that Petitioner asserts a new theory not set forth in the Petition, specifically that Steenfeldt-Jensen's teeth are formed in an interior of a flange because "they are purportedly formed radially inward of the flange's outermost diameter." PO Sur-reply 16 (comparing Pet. 43, 46–47 with Pet. Reply 21–22). Because the argument and evidence presented in the Petition alone persuade us that Steenfeldt-Jensen anticipates claim 56, the issue of whether Petitioner presents a new theory in its Reply is moot.

6. Analysis of Claim 57

Claim 57 recites the "clutch of claim 51, wherein said clutch is positioned within an open proximal end of said dial member and located adjacent a distal end of said dose knob and operatively coupled to said dose knob, and wherein said dial member extends circumferentially around at least a portion of said clutch." Ex. 1003, 10:54–59.

Petitioner argues that Steenfeldt-Jensen discloses the subject matter of claim 57. Pet. 44–46 (citing Ex. 1011 ¶¶ 491–493; Ex. 1014, 11:20–42, Figs. 15–17).

We find that a relied-upon portion of Steenfeldt-Jensen discloses that "bushing 82 having a flange 83 at its proximal end . . . fits into the scale drum 80 and over the driver tube 85" and that "bushing 82 and the driver tube 85 [are] coupled to each other." Ex. 1014, 11:26–33. We also find that a relied-upon portion of Steenfeldt-Jensen discloses that "[i]n the dose setting button a compartment is provided having . . . a bottom with a rosette

of teeth having a triangular cross-section," "flange 83 of the bushing 82 is adopted in said compartment," and "[a]t its distal side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment." Ex. 1014, 11:34–42. We additionally find that Figure 16 of Steenfeldt-Jensen shows "bushing 82 is positioned within an open proximal end of dose-scale drum 80 and located adjacent a distal end (button-end) of dose-setting button 81," as argued by Petitioner. *See* Pet. 46 (citing Ex. 1011 ¶ 491). We further credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 491–493 (citing Ex. 1014, 11:28–30, 11:34–42, 12:4–13, Figs. 15–17).

Patent Owner does not present any arguments regarding Petitioner's challenge of claim 57 based on Steenfeldt-Jensen. PO Resp. 23; Tr. 85:13–18. Because Steenfeldt-Jensen discloses that bushing 82 is at the open end of scale drum 80 and adjacent to dose setting button 81 and that bushing 82 couples to dose setting button 81 through rosettes of teeth, Petitioner persuades us that Steenfeldt-Jensen discloses "wherein said clutch is positioned within an open proximal end of said dial member and located adjacent a distal end of said dose knob and operatively coupled to said dose knob, and wherein said dial member extends circumferentially around at least a portion of said clutch."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen discloses each limitation of claim 51, from which claim 57 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 57, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen discloses each limitation of dependent claim 57 and thus anticipates claim 57.

G. Obviousness Based on Steenfeldt-Jensen

Petitioner contends that Steenfeldt-Jensen would have rendered obvious claim 56. Pet. 46–47. Patent Owner responds that Steenfeldt-Jensen does not disclose "a plurality of axially extending teeth formed in an interior of a flange." PO Resp. 26–27. Although we find above that Steenfeld-Jensen anticipates claim 56, we further consider whether Petitioner has also shown that claim 56 would have been obvious over Steenfeldt-Jensen.

1. Scope and Content of the Asserted Prior Art

We discuss Steenfeldt-Jensen above in Section II.G.1.

2. Analysis of Claim 56

Claim 56 recites the "clutch of claim 51, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch." Ex. 1001, 10:51–53.

Petitioner argues that Steenfeldt-Jensen would have rendered obvious claim 56. Pet. 46–47 (citing Ex. 1011 ¶ 495; Ex. 1014, 11:34–42). Petitioner states that "Steenfeldt-Jensen does not explicitly state i[f] the teeth of rosette 83 extend in an axial direction" but argues that "[t]o the extent it is not immediately apparent from FIG. 17 and the corresponding description at col. 11:34–42 that the teeth of rosette 93 extend axially from an interior of flange 83, a [person of ordinary skill in the art] would have found it obvious to implement the teeth in this manner." *Id.* at 47 (citing Ex. 1011 ¶ 495). Petitioner contends that "since the corresponding rosette of teeth is at the bottom of the compartment axially below flange 83, it would have been obvious to have the teeth extend axially toward the corresponding rosette to facilitate engagement" with "a reasonable expectation of success given the

simplicity and predictability of this rosette-based clutching mechanism." Pet. 47 (citing Ex. 1011 ¶ 495).

Patent Owner responds that "Petitioner's sole obviousness argument is that it would have been obvious to extend the teeth axially" but "does not address the entire claim limitation required by claim 56: "comprising a plurality of axially extending teeth ***formed in an interior of a flange***." PO Resp. 26 (citing Pet. 47). Patent Owner argues that "Petitioner does not address that Steenfeldt-Jensen's teeth 93 are formed on the distal side (i.e., needle-end side) of flange 83, and not on 'an interior of a flange' as required by claim 56," Petitioner does not "suggest that it would have been obvious to relocate teeth that are on the distal side of the flange to the interior of the flange," and Petitioner only suggests extending the teeth axially. *Id.* (citing Ex. 2107 ¶¶ 347–349). Patent Owner also argues that Steenfeldt-Jensen would not have rendered obvious claim 56 for the same reasons regarding Petitioner's anticipation challenge of claim 56.

Petitioner and Patent Owner provide the same replies for both the anticipation and obviousness challenges of claim 56 based on Steenfeldt-Jensen. *See* Pet. Reply 21–22; PO Sur-reply 16–17. We summarize those reply arguments above in Section II.F.5.

For the reasons stated in Section II.F.5., we find that Steenfeldt-Jensen's rosette 93 of teeth extending on flange 83 of bushing 82 also teaches or suggests the limitations of claim 56. Ex. 1014, 11:34–38, 11:40–42, Fig. 17; Ex. 1011 ¶ 489. We credit Mr. Leinsing's testimony that one of ordinary skill in the art would have extended the teeth axially "to facilitate engagement" with a corresponding rosette of teeth and would have had "a reasonable expectation of success given the simplicity and predictability of

this rosette-based clutching mechanism" because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 495 (citing Ex. 1014, Fig. 17).

3. Objective Indicia of Nonobviousness

The parties do not dispute any objective indicia of nonobviousness. *See generally* Pet.; PO Resp.; PO Sur-reply; *see also* Pet. Reply 26 (arguing that "Sanofi does not allege any secondary considerations to prove non-obviousness in its response, thus waiving any such argument").

As discussed above in Section II.E.4., Petitioner notes that "Sanofi submitted a declaration by Dr. Goland that claims to support Sanofi's response by alleging satisfaction of a long-felt need by the SoloSTAR® pen" but "[g]iven Sanofi's failure to cite to Dr. Goland's declaration in its Response, the declaration is not properly before the Board in this proceeding." Pet. Reply 26–27 (citing PO Resp. iii; Ex. 2011).

Also, as discussed above, Patent Owner does not present any arguments asserting any objective indicia of nonobviousness or direct us to any such evidence in the record, even though it has had the opportunity in this proceeding and presented such evidence in other related proceedings. *See* Tr. 58:20–59:5 (Patent Owner's counsel agreeing that objective evidence of nonobviousness were not presented in this proceeding). For these reasons, we determine that no relevant objective evidence of nonobviousness has been presented in connection with claim 56.

4. Weighing the Graham *Factors*

Above, based on full record before us, we find that (1) Petitioner's proposed level of ordinary skill in the art is consistent with the prior art of record, (2) Steenfeldt-Jensen teaches all the limitations of claim 56, (3) one of ordinary skill in the art would have had a reason to modify Steenfeldt-Jensen with a reasonable expectation of success, and (4) no objective

evidence of nonobviousness has been presented in connection with claim 56. Weighing these underlying factual determinations, a preponderance of the evidence persuades us that claim 56 of the '486 patent is unpatentable over Steenfeldt-Jensen.

H. Remaining Grounds

Petitioner argues that Moller anticipates claims 51–53, 56, and 57. Pet. 47–63. Petitioner also contends that the combinations of (1) Steenfeldt-Jensen and Burroughs and (2) Moller and Burroughs would have rendered obvious claims 54 and 55. *Id.* at 63–66. Patent Owner responds that "[s]ubstitute claims for claims 54–55 are addressed in the motion to amend submitted concurrently with this Response." PO Resp. 29; Tr. 85:13–18.

Because we determine above that Burroughs anticipates claims 51–55 and 57; Burroughs would have rendered obvious claims 54 and 55; Steenfeldt-Jensen anticipates claims 51–53, 56, and 57; and Steenfeldt-Jensen would have rendered obvious claim 56, we do not reach Petitioner's additional challenges to the same claims based on (1) Moller, (2) Steenfeldt-Jensen combined with Burroughs, and (3) Moller combined with Burroughs.

III. MOTION TO AMEND

In its Corrected Revised Contingent Motion to Amend, Patent Owner states that "[s]hould an original claim of the '486 Patent be found unpatentable, this Motion should be granted." Mot. to Amend 1. For the reasons explained above, Petitioner persuades us by a preponderance of the evidence that claims 51–57 of the '486 patent are anticipated or would have been obvious, and thus, we analyze below Patent Owner's proposed substitute claims 58–64.

The originally filed Patent Owner's Revised Contingent Motion to Amend included a claims appendix; however, Patent Owner's Corrected Revised Contingent Motion to Amend does not include such an appendix. During a telephone conference on December 13, 2019, Patent Owner confirmed that the claims appendix of the originally filed Revised Contingent Motion to Amend is referred to in the Corrected Revised Contingent Motion to Amend. Ex. 1111, 17:23–18:3. Thus, like Patent Owner, we refer to Patent Owner's originally filed Revised Contingent Motion to Amend for its claims appendix.

A. Proposed Substitute Claims 58–64

Proposed substitute claim 58 recites, with underlining indicating language added to original claim 51 and brackets and strikethroughs indicating language deleted:

> Proposed substitute claim 58. A <u>disposable pen type drug delivery device, comprising:</u>
>
> <u>a</u> clutch for use within [[a]]<u>the</u> 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 <u>dose</u> dial member <u>of the device,</u>
>
> <u>wherein the drug delivery device has only one arc shaped body that is both within a main housing and configured to track each set dose of medicament as said dose dial member is rotated relative to the arc shaped body, the arc shaped body comprising proximal and distal surfaces, end-most side surfaces, and inner and outer curved surfaces, the end-most side surfaces being circumferentially spaced apart, one of the curved surfaces comprising a first thread that is engaged with a second thread, and wherein the arc shaped body is configured to (i) during dose setting, move axially relative to the housing of the device without rotating relative to the housing, and (ii) abut a radial stop when</u>

at a final dose position, said radial stop disposed separate from the second thread; and

wherein the drug delivery device comprises a zero dose stop on the housing, and wherein the zero dose stop protrudes radially inward and prevents the dose dial member from rotating in a dialing down direction past an end position.

Paper 56, Claims Appendix.

Patent Owner states that "[s]ubstitute claims 59 and 61 represent a redrafting of original dependent claims 52 and 54 into independent form." Mot. to Amend 4. Claims 59 and 61 with underlining indicating language added and brackets and strikethroughs indicating language deleted are reproduced below.

Proposed substitute claim 59. A disposable pen type drug delivery device, comprising:

a clutch for use within the 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 dose dial member; ~~The clutch of claim 51,~~

wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob that is at the proximal end of the dose dial member, and

wherein said pen type drug delivery device further comprises:

a first clicker feature comprising teeth configured to provide audible clicks (i) by dragging the teeth over corresponding teeth on said clutch and (ii) only during dialing down of a dose without dispensing medicament, where each click relates to a unit dose of medicament, and

a second clicker feature spaced axially apart from the first clicker feature and disposed adjacent a distal end of the dose dial member, the second clicker feature comprising a flexible arm configured (i) to move axially relative to splines in only a first axial direction during dialing up of a dose and to move axially relative to the splines in only a second, opposite, axial

direction during dose dispensing and (ii) to provide audible clicks by dragging a tooth member over the splines while rotating and moving axially relative to the splines.

Proposed substitute claim 61. A disposable pen type drug delivery device, comprising:

a clutch for use within the 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 dose dial member;

wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob ~~The clutch of claim 52,~~

wherein said pen type drug delivery device further comprises

a cartridge containing a medicament, said cartridge comprising a reservoir,

a stopper,

a septum[[and]],

a ferrule; and

a clicker configured to provide audible clicks relating to a unit dose of the medicament contained in the cartridge during dose setting, the clicker comprising:

a flexible arm extending from a fixed end circumferentially to a free end thereof, the flexible arm comprising a tooth on the free end, the flexible arm configured to: (i) provide audible clicks while rotationally fixed relative to the clutch and while the clicker is moving axially relative to a housing of the device in a first direction during dialing up of a dose, where each click relates to a unit dose of the medicament, and (ii) not provide audible clicks while the clicker is moving axially relative to the housing in a second, opposite, direction, during dialing down of a dose without dispensing the medicament; and

one-way teeth configured to: (i) provide audible clicks by dragging over corresponding teeth of the clutch while the clicker is moving axially relative to the housing in the second

> direction during dialing down of a dose without dispensing the medicament, where each click relates to a unit dose of the medicament and, (ii) not provide audible clicks while the clicker is moving axially relative to the housing in the first direction during dialing up of a dose.

Paper 56, Claims Appendix.

Turning to the proposed dependent claims, proposed substitute claims 60 and 62–64 amend, respectively, original claims 53 and 55–57 to recite the "disposable pen type drug delivery device." *See* Mot. to Amend 4. Additionally, proposed substitute claim 60 amends original claim 53 to depend from proposed substitute claim 59; proposed substitute claim 62 amends original claim 55 to depend from proposed substitute claim 61; and proposed substitute claims 63 and 64 amend original claims 56 and 57 to depend from proposed substitute claim 58. *See id.* Proposed substitute claim 63 recites first and second clickers similar to the first and second clickers of proposed substitute claim 59, and proposed substitute claim 64 recites a flexible arm and one-way teeth similar to those found in proposed substitute claim 61. *See id.*

B. Requirements Under 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121

Petitioner argues that proposed substitute claims 58–64 improperly enlarge the scope of the claims and have insufficient written description support. Pet. Opp. 1–10. Patent Owner provides responsive arguments. PO Reply 1–8.

For the reasons below, whether or not the requirements under 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121 are met, Petitioner persuades us that proposed substitute claims 58–64 are unpatentable. Thus, we do not reach the arguments mentioned above.

C. Level of Ordinary Skill

The parties do not present any additional arguments regarding the level of ordinary skill that should be applied for the proposed substitute claims. For the reasons discussed above in Section II.B., we apply the same level of ordinary skill.

In particular, we apply Petitioner's proposal that one of ordinary skill in the art "had at least a bachelor's degree in mechanical engineering, or an equivalent degree, plus three-years' experience" and "understood the basics of medical-device design and manufacturing, and mechanical elements (*e.g.*, gears, pistons) involved in drug-delivery devices." Pet. 13–4 (citing Ex. 1011 ¶ 106). Also, as discussed above in Section II.B., we agree with the parties that any differences between the parties' proposals would not affect our analysis. *See* PO Resp. 7 (stating that "the slight differences between Patent Owner and Petitioner's level of ordinary skill do not affect the arguments made below"); Tr. 39:15–23 (Petitioner's counsel agreeing that any differences in the parties' proposed level of skill would not affect the analysis).

D. Claim Construction

Patent Owner states that "[n]o express constructions are required to find substitute claims 58–64 patentable" and that "[a]ll terms should therefore be given their plain and ordinary meanings consistent with the '486 Patent's [S]pecification as understood by a person of ordinary skill in the art." Mot. to Amend 14.

Based on the full record, we agree with Patent Owner and determine that no further claim interpretation is required to resolve the parties' disputes regarding Patent Owner's Corrected Revised Contingent Motion to Amend. *Vivid Techs.*, 200 F.3d at 803. We apply the same interpretation of "an

interior of the flange" as determined above in Section II.C.4. In particular, we determine that the phrase means "at the inner diameter of a flange" and does not exclude the recited plurality of axially extending teeth from also being formed on the outer diameter or exterior, distal or needle side, and the proximal or button side of a disk-shaped flange.

E. Obviousness Based on Steenfeldt-Jensen and Klitgaard

Patent Owner "does not bear the burden of persuasion to demonstrate the patentability of [the proposed] substitute claims." *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 4 (PTAB Feb. 25, 2019) (precedential) (citing *Bosch Auto. Servs. Sols., LLC v. Iancu*, 878 F.3d 1027 (Fed. Cir. 2017); *Aqua Prods., Inc. v. Matal*, 82 F.3d 1290 (Fed. Cir. 2017)). "Rather, as a result of the current state of the law and [Office] rules and guidance, the burden of persuasion will ordinarily lie with the petitioner to show that any proposed substitute claims are unpatentable by a preponderance of the evidence." *Id.*

1. Scope and Content of the Asserted Prior Art

Above in Section II.F.1, we discuss the disclosure of Steenfeldt-Jensen.

a. Klitgaard (Ex. 1017)

Klitgaard "relates to injection devices wherein the contents of a cartridge are injected as a number of individually set doses." Ex. 1017, 1:13–15. Figure 3 of Klitgaard is reproduced below.

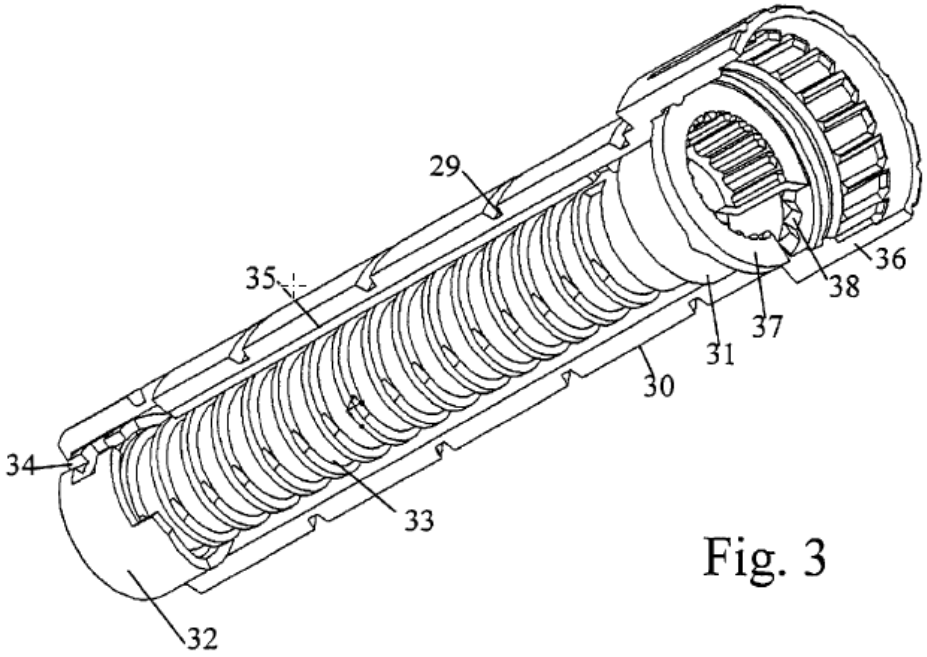

Fig. 3

Figure 3 "shows the dose setting member, the driver, and the track follower of . . . an injection syringe." Ex. 1017, 2:60–62. Dose setting member 30 surrounds driver 31 and has helical track 29 so that dose setting member can be screwed out from or into a housing when setting a dose. *Id.* at 4:16–22. Dose setting member 30 rotates freely relative to the driver 31. *Id.* at 4:24–25. "Between the dose setting member 30 and the driver 31 a nut member 32 is coupled which can when it is rotated relative to the driver 31 be screwed up along this driver which is at its outer surface provided with a helical track 33," and "[a]t its outer wall the nut member 32 is in the axial direction provided with a recess 34 which is engaged by a ridge 35 in the axial direction on the inner side of the dose setting element 30." *Id.* at 4:26–32.

"During the setting of a dose the nut member 32 is due to the engagement between the ridge 35 and the recess 34 rotated with the dose setting member 30 relative to the driver 31 so that the position of the nut member 32 on this driver is dependent on the dose set." *Id.* at 4:33–37.

During dose injection, dose setting member 30 and driver 31 rotate but "during this rotation the nut member 32 will maintain its position on the driver 31." Ex. 1017, 4:37–52. "This way the position of the nut member 32 on the driver 31 will always indicate the total sum of set and injected doses." *Id.* at 4:52–54.

2. Proposed Substitute Claim 58

a) A disposable pen type drug delivery device, comprising:

To the extent that the preamble is limiting, Petitioner argues that "[d]isposable pen injectors were well known at the time, and Steenfeldt-Jensen teaches 'disposable' devices that must be 'cheap and made of materials suited for recycling." Pet. Opp. 14 (citing Ex. 1014, 1:12–30; Ex. 1113 ¶ 214).

If the preamble is limiting, we find that the relied-upon portion of Steenfeldt-Jensen teaches "injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses." Ex. 1014, 1:12–15. We also credit Mr. Leinsing's testimony because the record supports it. Ex. 1113 ¶ 214 (citing Ex. 1011 ¶¶ 334, 475–482; Ex. 1014, 1:24–26). Patent Owner does not provide an argument specifically for the preamble of proposed substitute claim 58. *See* PO Reply 14–18; *see also* Mot. to Amend 15–17 (addressing other amended features of proposed substitute claim 58).

Because Steenfeldt-Jensen discloses an injection syringe with a cartridge of medicine, Petitioner persuades us that Steenfeldt-Jensen discloses a "disposable pen type drug delivery device."

> b) *a clutch for use within [[a]]the 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 dose dial member of the device,*

Petitioner argues that the above-quoted limitation "is substantially the same as in original claim 51" and taught by Steenfeldt-Jensen. Pet. Opp. 14 (citing Ex. 1011 ¶¶ 476–482; Ex. 1014, 11:43–51, 12:1–12, Figs. 15–17). Patent Owner does not provide an argument specifically for the recited clutch of proposed substitute claim 58. *See* PO Reply 14–18; *see also* Mot. to Amend 15–17 (addressing other amended features of proposed substitute claim 58).

Based on our findings and reasons stated above in Section II.F.2., Petitioner persuades us that Steenfeldt-Jensen teaches the recited clutch of proposed substitute claim 58.

> c) *wherein the drug delivery device has only one arc shaped body that is both within a main housing and configured to track each set dose of medicament as said dose dial member is rotated relative to the arc shaped body,*

For the recited arc shaped body, Petitioner contends that it is a conventional feature that would have been obvious. Pet. Opp. 13–14 (citing Ex. 1113 ¶¶ 214–217). In particular, Petitioner argues that Klitgaard teaches single nut member 32 that would have been incorporated into Steenfeldt-Jensen. *Id.* at 14–15 (citing Ex. 1017, Abstract, 1:34–37, 4:16–58, Fig. 3; Ex. 1113 ¶¶ 153–158, 215).

According to Petitioner, because of "the relative rotation between bushing 82 and scale drum 80 during dose setting but not injection," one of ordinary skill in the art "would have had reason to place a dose-tracking nut

between these components with a threaded engagement on one side and a splined engagement on the other." Pet. Opp. 15 (citing Ex. 1113 ¶¶ 153–158, 215). Petitioner contends that "[r]otation of the scale drum during dose setting would cause the nut to rotate along the track due to the relative movement between the drum and bushing" and "[d]uring dose-dispensing, the bushing and drum would not experience relative rotation, so the nut maintains its position." *Id.* (citing Ex. 1113 ¶¶ 153–158, 215).

Petitioner also contends that "Klitgaard describes an internally threaded nut with external splines" but one of ordinary skill in the art "would have understood that there were a finite number of choices (two) for placing the thread/splines." *Id.* (citing Ex. 1054, 387:7–23; Ex. 1096 ¶ 81; Ex. 1113 ¶ 155). Petitioner further contends that one of ordinary skill in the art "would have had reason to select either placement, because the nut's function would be the same" and "would have preferred an externally threaded nut engaging a thread on the internal surface of drum 80, given the preexisting splines on bushing 82." *Id.* (citing Ex. 1113 ¶ 154). According to Petitioner, "this implementation merely involves routine combination of well-known components performing their same, predictable function." *Id.* (citing Ex. 1113 ¶ 216).

Petitioner argues that "Klitgaard has only one 'arc shaped body' that, in the context of Steenfeldt-Jensen, is 'within a main housing and configured to track each set dose of medicament as said dose dial member is rotated relative to the arc shaped body.'" *Id.* at 15–16 (citing Ex. 1113 ¶ 215). Petitioner also argues that one of ordinary skill in the art would have "form[ed] the nut member as a single, partial nut" because "partial nuts were conventional, including in pen injectors" and one of ordinary skill in the art "would have known that a second half nut was redundant in Steenfeldt-

Jensen, since a single dose-tracking half nut operates just as well without a second half." Pet. Opp. 17 (citing Ex. 1113 ¶¶ 85, 159); *see also id.* at 13 (arguing partial nuts, split nuts, and half-nuts were known) (citing Ex. 1056 ¶ 36; Ex. 1103, Figs. 1, 2; Ex. 1104, Figs. 1–4; Ex. 1105, 4:60–5:15, Figs. 4A, 4B; Ex. 1113 ¶¶ 84–85). Petitioner points to U.S. Patent No. 6,277,099 B1 to Strowe (Ex. 1105) for teaching "half nuts 12 that rotate about a threaded leadscrew for dose tracking" and a stop "to prevent dialing below zero or dialing beyond a maximum dose." *Id.* (citing Ex. 1105, 4:60–5:15, Figs. 4A, 4B; Ex. 1113 ¶¶ 84, 85).

Petitioner further argues that "making Klitgaard's dose-tracking body a single half nut would aid in assembling the device by making the nut easier to mount," "would reduce the number of parts, saving costs," and "would not alter the dose-tracking function." *Id.* at 17–18 (citing Ex. 1113 ¶ 84); *see also id.* at 13 (citing Ex. 1113 ¶¶ 84, 85) (arguing that the use of half-nuts to prevent further rotation provides stability, their implementation was routine, and ordinary skilled artisans "knew that using the second half of a split nut was unnecessary where the component's function did not require a full nut"). According to Petitioner, one of ordinary skill in the art would have considered making such a single half nut "routine and predictable." *Id.* at 18 (citing Ex. 1113 ¶ 84).

We find that Klitgaard teaches nut member 32 that "[d]uring the dose setting rotation the dose setting member 30 is rotated freely relative to the driver 31 which it surrounds" and "[b]etween the dose setting member 30 and the driver 31 a nut member 32 is coupled which can when it is rotated relative to the driver 31 be screwed up along this driver which is at its outer surface provided with a helical track 33." Ex. 1017, 4:23–29, Fig. 3. We agree with Petitioner and find that nut member 32 is internally threaded with

external splines and that it was within ordinary skill to make such a nut externally threaded with internal splines. Ex. 1017, 4:23–29, Fig. 3; Ex. 1113 ¶ 216.

The full record also supports finding that partial nuts, split nuts, and half-nuts were known (Ex. 1056 ¶ 36; Ex. 1103, Figs. 1, 2; Ex. 1104, Figs. 1–4; Ex. 1105, 4:60–5:15, Figs. 4A, 4B; Ex. 1113 ¶¶ 84, 85, 159); that such nuts prevent dialing past zero or maximum dose (Ex. 1105, 4:60–5:15, Figs. 4A, 4B; Ex. 1113 ¶¶ 84, 85); and that their implementation was within ordinary skill (Ex. 1103, Figs. 1, 2; Ex. 1104, Figs. 1–4; Ex. 1105, 4:60–5:15, Figs. 4A, 4B; Ex. 1015 ¶ 36; Ex. 1113 ¶¶ 84, 85). We also find that using a single half nut "would reduce the number of parts, saving costs," "would not alter the dose-tracking function," would prevent further rotation, would provide stability, and "using the second half of a split nut was unnecessary where the component's function did not require a full nut." Ex. 1015 ¶ 36; Ex. 1113 ¶¶ 84, 85.

Turning to the reasons to make the proposed modification, we credit Mr. Leinsing's testimony that one of ordinary skill in the art would have modified Steenfeldt-Jensen to include a single half nut in view of the teachings of Klitgaard because the modification would aid in assembly, reduce the number of parts, provide cost savings, and operate the same. Ex. 1113 ¶¶ 84, 159. Based on our findings above, we also agree with Petitioner that one of ordinary skill in the art would have made the proposed modification because one of ordinary skill in the art "would have preferred an externally threaded nut engaging a thread on the internal surface of drum 80, given the preexisting splines on bushing 82" and "would have known that a second half nut was redundant in Steenfeldt-Jensen, since a single dose-tracking half nut operates just as well without a second half."

Pet. Opp. 15, 17; Ex. 1113 ¶¶ 154, 159. We also agree with Petitioner that the proposed modification "would aid in assembling the device by making the nut easier to mount," "would reduce the number of parts, saving costs," and "would not alter the dose-tracking function." Pet. Opp. 17–18; Ex. 1113 ¶ 84. We further agree with Petitioner that the proposed modification would prevent further rotation and provide stability, and that "the second half of a split nut was unnecessary where the component's function did not require a full nut." Pet. Opp. 13; Ex. 1113 ¶¶ 84, 85.

Based on our findings discussed above, we determine Petitioner provides sufficient reasons to make the proposed modification and those reasons have rational underpinnings. We also agree that one of ordinary skill in the art would have had a reasonable expectation of success in making the proposed modification. Ex. 1113 ¶¶ 85, 216.

Patent Owner responds that "nut member 32 is a full nut that spans a full circle and not an arc" and "not an arc shaped body." PO Reply 14–15 (citing Ex. 1017, Fig. 3; Ex. 2332 ¶ 42). Patent Owner also argues that proposed substitute claim 58 requires "an 'arc shaped *body*,' not a body with some aspect that is arc shaped." *Id.* at 15 (citing Ex. 2316, 89–90; Ex. 2332 ¶ 42). Petitioner replies that "Klitgaard's nut member 32 is 'an arc shaped body,'" "nothing in the claim language itself bars a broader reading," and "the [S]pecification provides no guidance at all for construing 'arc shaped body' because it never uses the term." Pet. Sur-reply 10 (citing PO Reply 14–15). Petitioner argues that Mr. Leinsing's testimony supports that one of ordinary skill in the art would have understood a broader interpretation for "arc shaped body." *Id.* (citing Pet. Opp. 16–17; Ex. 1113 ¶ 156; Ex. 2316, 89:1–90:24).

Even if nut member 32 were a full nut, Petitioner argues that one of ordinary skill in the art would have made it a half nut because a half nut "would aid in assembling the device by making the nut easier to mount," "would reduce the number of parts, saving costs," and "would not alter the dose-tracking function." Pet. Opp. 17–18 (citing Ex. 1113 ¶ 84); *see also* Ex. 1113 ¶ 159 (stating "it is also my opinion that a person of ordinary skill in the art would have found it obvious to form the body as a single, partial nut" and describing the benefits of using a single half nut). We credit Mr. Leinsing's testimony that one of ordinary skill in the art would have known of half nuts and would have been able to implement half nuts because his testimony is supported by the record. Ex. 1113 ¶ 84 (citing Ex. 1103, Figs. 1, 2; Ex. 1104, Figs. 1–4; Ex. 1105, 4:60–5:15, Figs. 4A, 4B; Ex. 1015 ¶ 36), 159 (citing Ex. 1105, 4:60–5:15, Figs. 4A, 4B). Moller expressly describes making components "as two parts which are by the assembling of the device connected to each other to make the assembled parts act as one integral part." Ex. 1015 ¶ 36. As discussed above, Petitioner persuades us that one of ordinary skill in the art would have modified nut member 32 into a half nut.

Patent Owner also responds that no evidence shows that an arc shaped body was known and the combination lacks "only one arc shaped body that is . . . within a main housing." PO Reply 15 (citing Pet. Opp. 17). Patent Owner argues that Petitioner's asserted prior art "shows only split nuts, each having two nut halves joined together, and none of the prior art has 'only one' nut half within a housing." *Id.* (citing Pet. Opp. 17; Ex. 1103, Fig. 2; Ex. 1104, Fig. 4; Ex. 1105, Figs. 3A, 4A; Ex. 2332 ¶ 47). Petitioner replies that arc shaped bodies were known, as confirmed by Dr. Slocum and that the evidence shows that partial nuts were known and used for "dose-tracking

purposes with a reasonable expectation of success." Pet. Sur-reply 10–11 (citing PO Reply 15; Ex. 1117, 59:12–63:12). Petitioner further argues that Mr. Leinsing explained that one of ordinary skill in the art "would have readily appreciated the benefits of a single partial nut." *Id.* at 11 (citing Ex. 1113 ¶ 159).

The full record persuades us that partial nuts were known and would aid assembly. Ex. 1103, Figs. 1, 2; Ex. 1104, Figs. 1–4; Ex. 1105, 4:60–5:15, Figs. 4A, 4B; Ex. 1015 ¶ 36. Also, as discussed above, Petitioner proposes modifying nut member 32 into a half nut. Pet. Opp. 17–18 (citing Ex. 1113 ¶ 84); *see also* Ex. 1113 ¶ 159.

Patent Owner further responds that the proposed modification to add a split nut into Steenfeldt-Jensen's housing that does not have a nut "is based only on bare citation to conclusory expert testimony, devoid of any citation to prior art." PO Reply 16 (citing Pet. Opp. 13; Ex. 1113 ¶ 84). Patent Owner also argues that Petitioner's "assertions that 'a second half nut was redundant,' a 'single dose-tracking half nut operates just as well without a second half,' and a single half nut 'would reduce the number of parts, and provide cost savings,'" find no support in declarant testimony and are mere attorney argument. *Id.* (citing Ex. 1113 ¶ 159). As discussed above, we find that Petitioner points to other parts of the record that support the proposed modification of using a single half nut. *See* Pet. Opp. 14–18. For example, Petitioner also contends that the proposed modification would aid in assembling leading to additional benefits and provide a stop for zero or maximum dose. Ex. 1014, 9:57–62, Figs. 11–13; Ex. 1015 ¶ 36; Ex. 1105, 4:60–5:15, Figs. 4A, 4B; Ex. 1113 ¶ 85.

For the reasons above, based on the full record, Petitioner persuades us that one of ordinary skill in the art would arrive at "wherein the drug

delivery device has only one arc shaped body that is both within a main housing and configured to track each set dose of medicament as said dose dial member is rotated relative to the arc shaped body" in light of Steenfeldt-Jensen and Klitgaard.

> d) *the arc shaped body comprising proximal and distal surfaces, end-most side surfaces, and inner and outer curved surfaces, the end-most side surfaces being circumferentially spaced apart, one of the curved surfaces comprising a first thread that is engaged with a second thread,*

Petitioner argues that the asserted arc shaped body has the required side surfaces, curved surfaces, and the circumferentially spaced apart side surfaces. Pet. Opp. 16, 17 (citing Ex. 1017, Fig. 3; Ex. 1113 ¶ 156).

We find that Figure 3 of Klitgaard shows nut member 32 having proximal and distal surfaces, end-most side surfaces, and inner and outer curved surfaces being circumferentially spaced apart. Ex. 1017, Fig. 3. Figure 3 of Klitgaard also shows that nut member 32 has a thread on one of its curved surfaces that engage another thread. *Id.* We also credit Mr. Leinsing's testimony regarding nut member 32 because Klitgaard supports it. Ex. 1113 ¶ 156.

Patent Owner does not present an argument specifically for this limitation. *See* PO Reply 14–18. In the Corrected Revised Contingent Motion to Amend, Patent Owner argues that "Klitgaard's nut member 32 is a complete circular nut, and therefore does not have end-most side surfaces being circumferentially spaced apart." Mot. to Amend 15 (citing Ex. 2325 ¶ 93).

Because Petitioner's proposed modification would result in nut member 32 having the required side surfaces, curved surfaces, and the circumferentially spaced apart side surfaces with a thread on one of the

curved surfaces, Petitioner persuades us that the proposed combination of Steenfeldt-Jensen and Klitgaard would result in an "arc shaped body comprising proximal and distal surfaces, end-most side surfaces, and inner and outer curved surfaces, the end-most side surfaces being circumferentially spaced apart, one of the curved surfaces comprising a first thread that is engaged with a second thread."

e) and wherein the arc shaped body is configured to (i) during dose setting, move axially relative to the housing of the device without rotating relative to the housing, and

Petitioner contends that the internal splines of the nut during dose setting allow the nut to move axially relative to the housing and rotationally fix the nut to the bushing, and thus, the housing because the bushing does not rotate relative to the nut. Pet. Opp. 16 (citing Ex. 1113 ¶ 157). Petitioner also contends that an externally threaded nut would not work in the claimed device but "Steenfeldt-Jensen would avoid this interference because the nut would be between components that do not have substantial relative axial movement." *Id.* (citing Ex. 1096 ¶ 81; Ex. 1113 ¶ 155).

Patent Owner responds that "Klitgaard['s] nut 23 is internally threaded and keyed to the dose setting member 30 (i.e., the dose dial sleeve)" and "Klitgaard's nut 23 rotates relative to the housing during dose setting because the dose setting member 30 is rotated to set the dose." PO Reply 17 (citing Ex. 1017, 4:33–37; Ex. 2332 ¶ 42). Patent Owner also argues that Petitioner does not show sufficient motivation to provide threading on the exterior of nut member 32 and splines on the interior to engage drum 80 of Steenfeldt-Jensen. *Id.* (citing Pet. Opp. 15). Patent Owner further argues that there are no splines on bushing 82 as asserted by Petitioner. *Id.* at 17–18 (citing Pet. Opp. 15; Ex. 2332 ¶ 44).

Petitioner replies that Patent Owner attacks Klitgaard in isolation and "dismisses any reason to move the nut's internal threads to its external surface . . . but does not dispute the known design need for tracking delivered doses and the two predictable solutions to achieving that need." Pet. Sur-reply 11 (citing PO Reply 17). Petitioner further replies that Patent Owner ignores "Steenfeldt-Jensen's bushing with slots 84 for creating a splined connection between the bushing and the driver." *Id.* at 11–12 (citing PO Reply 17–18; Ex. 1014, 11:26–33, Fig. 17). Petitioner argues that "Mr. Leinsing explained how this structure would further prompt the [person of ordinary skill in the art] to spline the nut to the bushing rather than to the dose-setting drum." *Id.* at 12 (citing Pet. Opp. 14; Ex. 1113 ¶ 154).

As discussed above, we agree with Petitioner that one of ordinary skill in the art would have made the proposed modification because one of ordinary skill in the art "would have preferred an externally threaded nut engaging a thread on the internal surface of drum 80, given the preexisting splines on bushing 82" of Steenfeldt-Jensen. Pet. Opp. 15; Ex. 1113 ¶ 154. We find that Steenfeldt-Jensen teaches slots 84 are on bushing 82. Ex. 1014, 11:26–33, Fig. 17. We credit Mr. Leinsing's testimony that Steenfeldt-Jensen's existing structure would have motivated one of ordinary skill in the art to spline a nut. Ex. 1113 ¶ 154.

Based on our findings and determinations above, Petitioner persuades us that its proposed combination of Steenfeldt-Jensen and Klitgaard would result in "wherein the arc shaped body is configured to (i) during dose setting, move axially relative to the housing of the device without rotating relative to the housing."

> *f)* *and wherein the arc shaped body is configured to . . . (ii) abut a radial stop when at a final dose position, said radial stop disposed separate from the second thread; and*

Petitioner contends that Steenfeldt-Jensen teaches "a radial stop that prevents further rotation of a threaded component and is separate from the thread." Pet. Opp. 16–17 (citing Ex. 1014, 9:57–62; Ex. 1113 ¶ 158). Petitioner also contends that one of ordinary skill in the art "would have known that this stop would make a dose-tracking nut even more stable at the end-of-cartridge position" and "were familiar with such stops and would not face any difficulty implementing such a stop for a dose-tracking half nut." *Id.* at 17 (citing Ex. 1113 ¶ 158).

Patent Owner responds that Petitioner fails to show that one of ordinary skill in the art knew of and, thus, would have configured the arc shaped to abut a radial stop at a final dose position. PO Reply 18. Patent Owner argues that adding Klitgaard's nut member 32 to Steenfeldt-Jensen does not result in "a radial stop disposed separate from the sixth thread." *Id.* (citing Pet. Opp. 16–17; Ex. 1014, 9:57–62). Patent Owner further argues that Steenfeldt-Jensen does not describe the location of tooth 92 and it is not shown in any figures. *Id.* (citing Pet. Opp. 16–17; Ex. 1014, 9:57–62).

Petitioner replies that one of ordinary skill in the art "can apply known, predictable solutions to analogous situations, including stopping further relative rotation of the dose-tracking nut and dose-dial sleeve when the final dose is reached" and that Mr. Leinsing explains that "a separate radial stop adds stability to stopping rotation when the final-dose position is reached." Pet. Sur-reply 12 (citing Pet. Opp. 16–17; Ex. 1113 ¶ 158).

We find that the relied-upon portion of Steenfeldt-Jensen teaches:

> When the dose scale drum is displaced outwardly in the housing a steep front side of a saw tooth 91 at the proximal end of the

> dose scale drum 18 will abut a steep front side of a similar tooth 92 on the bushing whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set.

Ex. 1014, 9:57–62. We also credit Mr. Leinsing's testimony "[t]hose of skill in the art would have recognized that such a stop feature would similarly prevent further rotation of the body at the end-of-cartridge position and add stability when hitting the end-of-cartridge position" and "would have found it routine to implement a radial stop in the context of a dose-tracking body" because the record supports it. Ex. 1113 ¶ 158 (citing Ex. 1014, 9:52–62).

For the reasons above, Petitioner persuades us that Steenfeldt-Jensen teaches or suggests an "arc shaped body is configured to . . . (ii) abut a radial stop when at a final dose position, said radial stop disposed separate from the second thread."

> *g) wherein the drug delivery device comprises a zero dose stop on the housing, and wherein the zero dose stop protrudes radially inward and prevents the dose dial member from rotating in a dialing down direction past an end position.*

Petitioner argues that one of ordinary skill in the art would have understood that Steenfeldt-Jensen's wall 46 teaches a "zero-dose stop" because wall 46 "prevents further dialing down of scale drum 80 (the dose dial member) when it reaches the zero position." Pet. Opp. 18 (citing Ex. 1014, Fig. 16; Ex. 1113 ¶¶ 173, 216).

Petitioner also argues that "radial stops for preventing rotation of threaded components were commonplace and well understood." Pet. Opp. 18 (citing Ex. 1113 ¶ 173). Petitioner further argues that one of ordinary skill in the art "would have known such stops reduce stress on the threads when the drum rotates back to the zero-dose position and would have

viewed this as a routine and predictable implementation of a simple, common feature." *Id.* (citing Ex. 1113 ¶ 173).

We find that Figure 16 of Steenfeldt-Jensen shows wall 46 on housing 1 and wall 46 protrudes radially inward. Ex. 1014, Fig. 16; Ex. 1113 ¶ 173. We also credit Mr. Leinsing's testimony that one of ordinary skill in the art would have understood that wall 46 "prevents the dose dial member from rotating in a dialing down direction past an end position." Ex. 1113 ¶ 173 (citing Ex. 1013, 12:15–29, Figs. 4, 10, 11; Ex. 1014, 9:57–62).

Patent Owner does not present an argument addressing Petitioner's asserted zero dose stop. *See* PO Reply 8–18; *see also* Pet. Sur-reply 12 (arguing that Patent Owner "does not dispute the obviousness of its zero dose stop limitations") (citing PO Reply 8–18). In the Corrected Revised Contingent Motion to Amend, Patent Owner argues that neither Steenfeldt-Jensen nor Klitgaard teaches or suggests the zero dose stop of proposed substitute claim 58. Mot. to Amend 16–17.

In particular, Patent Owner contends that the fifth embodiment of Steenfeldt-Jensen does not teach or suggest "a radial stop that prevents a user from dialing below the zero dose position" and instead teaches "a user is preventing from dialing below the zero dose position by a form of axial stop when the distal end of the dose setting button 81 impacts the proximal end of the housing 1." *Id.* at 17 (citing Ex. 2325 ¶ 98). Patent Owner also contends that "Klitgaard does not disclose a radial stop that is separate from threading; instead nut member 32 stops when it reaches the end of helical track 33." *Id.* at 16 (citing Ex. 2325 ¶ 93). Dr. Slocum's declaration provides similar statements. Ex. 2325 ¶¶ 93, 98.

As discussed above, we find that wall 32 of Steenfeldt-Jensen teaches the recited zero dose stop. Because (1) Steenfeldt-Jensen teaches wall 32 on housing 1, (2) Steenfeldt-Jensen teaches that wall 32 protrudes radially inward, and (3) one of ordinary skill in the art would have understood that wall 32 prevents the dose dial member from rotating in a dialing down direction past an end position, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein the drug delivery device comprises a zero dose stop on the housing, and wherein the zero dose stop protrudes radially inward and prevents the dose dial member from rotating in a dialing down direction past an end position."

3. Weighing the Graham *Factors*

Above, based on full record before us, we find that (1) Petitioner's proposed level of ordinary skill in the art is consistent with the prior art of record, (2) Steenfeldt-Jensen and Klitgaard teach or suggest all the limitations of proposed substitute claim 58, (3) one of ordinary skill in the art would have had a reason to modify Steenfeldt-Jensen with the teachings of Klitgaard with a reasonable expectation of success, and (4) no objective evidence of nonobviousness has been presented in connection with proposed substitute claim 58. *See* Tr. 58:20–59:5 (Patent Owner's counsel agreeing that objective evidence of nonobviousness were not presented in this proceeding). Weighing these underlying factual determinations, a preponderance of the evidence persuades us that proposed substitute claim 58 is unpatentable over Steenfeldt-Jensen and Klitgaard.

F. Obviousness Based on Steenfeldt-Jensen and Atterbury

1. Scope and Content of the Asserted Prior Art

Above in Section II.F.1, we discuss the disclosure of Steenfeldt-Jensen.

a. Atterbury (Ex. 1097)

Atterbury describes a "medication injector apparatus such as an injection pen." Ex. 1097, Abstract. Among the advantages of Atterbury's apparatus is that "an injection clicker assembly can be provided that is readily tunable during manufacturing design . . . to provide the desired tone and loudness of the injection audible feedback." *Id.* at 11:6–9. Figure 27 of Atterbury is reproduced below.

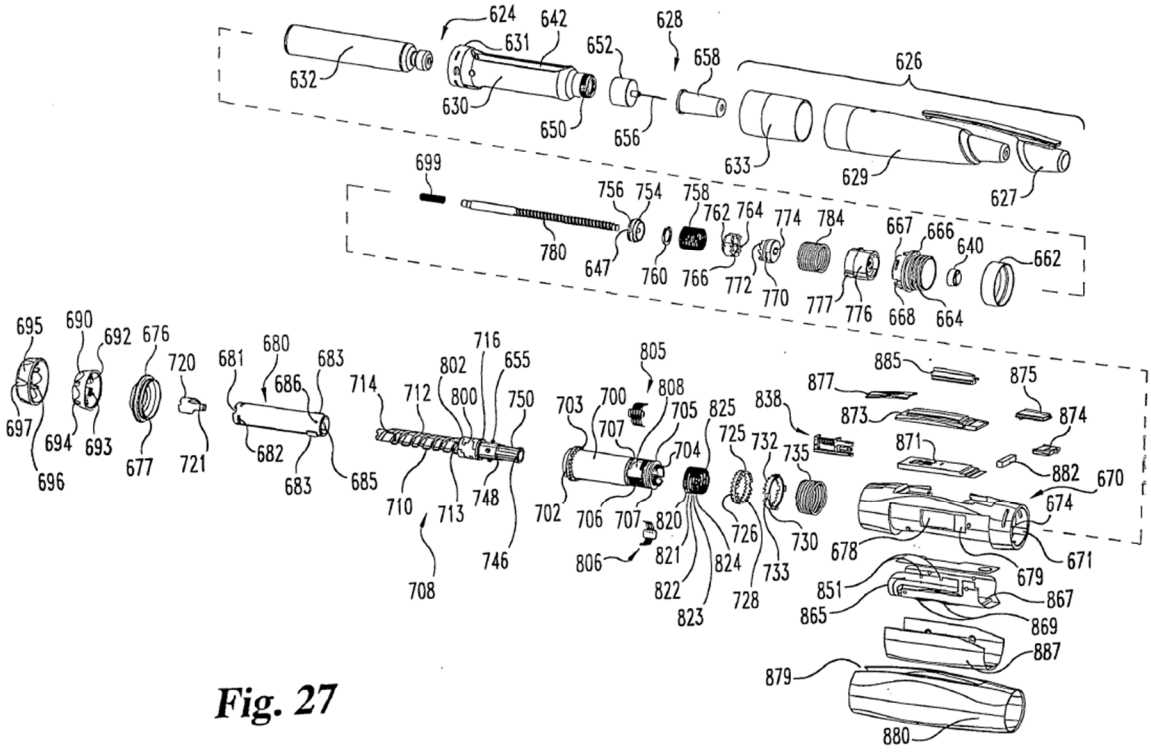

Fig. 27

Figure 27 "is an exploded rear perspective view of the injection pen." *Id.* at 15:1. Atterbury states that "when dial 680 is dialed up so as to axially move proximally, clicker teeth 728 slide past clutch teeth 732 as the meshing of clicker teeth 726 with the teeth 703 of the rotating barrel 700 causes rotation of clicker 725," "[w]hen dial 680 is dialed down, the barrel teeth 703 slide past clicker teeth 726 as clicker 725 is rotatably fixed by the meshing of clicker teeth 728 with teeth 732 of the rotatably fixed clutch

730," and "[a]s is known in the art, this sliding motion of the teeth produces the dial clicks." Ex. 1097, 46:4–16.

2. Proposed Substitute Claim 59

a) A disposable pen type drug delivery device, comprising:

If the preamble is limiting, we find that the relied-upon portion of Steenfeldt-Jensen teaches "injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses." Ex. 1014, 1:12–15.

Patent Owner does not provide an argument specifically for the preamble of proposed substitute claim 59. *See* PO Reply 10–14; *see also* Mot. to Amend 18–20 (addressing other amended features of proposed substitute claims 59–64).

Because Steenfeldt-Jensen discloses an injection syringe with a cartridge of medicine, Petitioner persuades us that Steenfeldt-Jensen discloses a "disposable pen type drug delivery device."

b) a clutch for use within the 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 dose dial member; ~~The clutch of claim 51,~~

Petitioner refers to its arguments for proposed substitute claim 58. Pet. Opp. 23; *see also id.* at 14 (citing Ex. 1011 ¶¶ 476–482; Ex. 1014, 11:43–51, 12:1–12, Figs. 15–17). Based on our findings above in Section II.F.2., Petitioner persuades us that Steenfeldt-Jensen teaches the clutch of proposed substitute claim 59.

c) *wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob that is at the proximal end of the dose dial member, and*

Petitioner argues that Steenfeldt-Jensen teaches the above-quoted limitation "by showing that the proximal end of the bushing's tubular body resides within an inner space of dose setting button 81." Pet. Opp. 23–24 (citing Ex. 1011 ¶¶ 484–485; Ex. 1014, 11:26–33, Figs. 15–17).

We find that the relied-upon portions of Steenfeldt-Jensen disclose that "bushing 82 . . . fits into the scale drum 80" and Figures 15 and 16 of Steenfeldt-Jensen show a proximal end of bushing 82 within dose setting button 81. Ex. 1014, 11:26–28, Figs. 15, 16. We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 484, 485 (citing Ex. 1014, 11:22–25, 11:52–62, Figs. 15–17).

Patent Owner does not provide an argument specifically for the above-quoted limitation of proposed substitute claim 59. *See* PO Reply 10–14; *see also* Mot. to Amend 18–20 (addressing other amended features of proposed substitute claims 59–64). Because Steenfeldt-Jensen discloses a proximal end of bushing 82 within dose setting button 81, Petitioner persuades us that Steenfeldt-Jensen discloses "wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob that is at the proximal end of the dose dial member."

d) *wherein said pen type drug delivery device further comprises: a first clicker feature comprising teeth configured to provide audible clicks (i) by dragging the teeth over corresponding teeth on said clutch and (ii) only during dialing down of a dose without dispensing medicament, where each click relates to a unit dose of medicament, and*

Petitioner refers to its arguments for proposed substitute claim 61 and argues that one of ordinary skill in the art "would have been motivated to

apply Atterbury's clicker teachings in the context of Steenfeldt-Jensen." Pet. Opp. 24 (citing Ex. 1113 ¶¶ 164–166, 220). In its opposition to proposed substitute claim 61, Petitioner argues that "Steenfeldt-Jensen teaches a clicker that provides audible clicks for each unit dose dialed" in the fifth embodiment. *Id.* at 19–20 (citing Ex. 1014, 9:48–52, 11:20–67, Figs. 15–17; Ex. 1096 ¶ 68). Petitioner also argues that "Atterbury teaches a two-way ratchet with separate features that each click only during one of either dialing-up or dialing-down." *Id.* at 20 (citing Ex. 1096 ¶¶ 69–71; Ex. 1097, 46:4–16, Fig. 27); *see also id.* at 11–12 (arguing that clickers were known mechanisms in pen injectors) (citing Ex. 1098, 8:2–20; Ex. 1013, 9:4–8, 10:2–47; Ex. 1014, 11:34–67; Ex. 1032, 3:10–26; Ex. 1097, 46:4–16, Fig. 27; Ex. 1113 ¶¶ 79, 123, 124), 12–13 (arguing that one-way and two-way ratchet mechanisms, their uses, and their benefits were known) (citing Ex. 1058 ¶¶ 7–15, Figs. 2, 3, 7, 8; Ex. 1097, 11:3–18, 46:4–16, Fig. 27; Ex. 1099 ¶ 15, Fig. 5; Ex. 1100, 3:6–21, Figs. 9, 10; Ex. 1101, Figs. 1–27; Ex. 1102, 2:25–4:15, Figs. 3, 4; Ex. 1113 ¶¶ 80–83).

Petitioner contends that "the suggested clicker (i.e. a ring with two sets of oppositely disposed, radially extending flexible arms) includes an inner set of flexible arms with one-way teeth that click by dragging over corresponding ridges on the clutch only during dialing down without dispensing medicament" and that Steenfeldt-Jensen teaches "configuring a clicker such that each click relates to a unit dose." *Id.* at 24 (citing Ex. 1014, 11:62–67; Ex. 1113 ¶ 167).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "[i]n the dose setting button a compartment is provided having a cylindrical side wall circumferentially provided with longitudinal recesses," "flange 83 of the bushing 82 is adopted in said compartment and has at its periphery a

radial protrusion 87 which is biased toward the side wall of the compartment," and "by the rotation of the dose setting button 81 in any direction the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 to the next one." Ex. 1014, 11:34–40, 11:62–67. We also credit Mr. Leinsing's testimony because Steenfeldt-Jensen supports it. Ex. 1096 ¶ 68 (citing Ex. 1014, 9:48–52, 11:20–67, 12:1–3, Figs. 15–17).

We further find that the relied-upon portions of Atterbury teach that "when dial 680 is dialed up so as to axially move proximally, clicker teeth 728 slide past clutch teeth 732 as the meshing of clicker teeth 726 with the teeth 703 of the rotating barrel 700 causes rotation of clicker 725," "[w]hen dial 680 is dialed down, the barrel teeth 703 slide past clicker teeth 726 as clicker 725 is rotatably fixed by the meshing of clicker teeth 728 with teeth 732 of the rotatably fixed clutch 730," and "[a]s is known in the art, this sliding motion of the teeth produces the dial clicks." Ex. 1097, 46:4–16, Fig. 27. Atterbury also teaches that "an injection clicker assembly can be provided that is readily tunable during manufacturing design . . . to provide the desired tone and loudness of the injection audible feedback." *Id.* at 11:6–9. We credit Mr. Leinsing's testimony because Atterbury supports it. Ex. 1096 ¶¶ 69–71 (citing Ex. 1097, 46:4–16, Fig. 27).

Patent Owner responds that Petitioner concedes that Steenfeldt-Jensen lacks the recited clickers and relies on Atterbury for those features. PO Reply 10. Patent Owner also argues that neither Steenfeldt-Jensen nor Atterbury teaches or suggests a clicker ring. *Id.* In particular, Patent Owner argues the asserted references do not teach or suggest a clicker ring with two sets of oppositely flexible arms because Atterbury teaches teeth and Steenfeldt-Jensen teaches protrusions. *Id.* at 10–11 (citing Pet. Opp. 20;

Ex. 1014, Fig. 17; Ex. 2332 ¶¶ 57–70). According to Patent Owner, the predictable result of combining these references would not result in a clicker ring with flexible arms. PO Reply 11 (citing Ex. 2332 ¶¶ 64–70).

Petitioner replies that express disclosure is not required for obviousness and ordinary skill should be considered. Pet. Sur-reply 7 (citing PO Reply 10–11). Petitioner argues that "the prior art demonstrates the known mechanical elements for achieving a clicking function (*e.g.*, flexible arms, saw teeth) and the predictable understanding of their nature (*i.e.*, relative rotation over opposing structures—*e.g.*, splines, saw teeth—to cause clicking)" and that Steenfeldt-Jensen teaches these options. *Id.* (citing Pet. Opp. 10–13; Ex. 1014, 9:48–52, 11:20–12:12; Ex. 1113 ¶¶ 79–85, 142, 149 n.8; Ex. 1117, 93:25–97:20). Petitioner also argues that "[o]ne-way ratchet systems consisting of flexible arms are familiar elements to the [person of ordinary skill in the art] and their implementation is a predictable solution for accomplishing a clicking function." *Id.* at 8 (citing Ex. 2332 ¶¶ 61–70).

Based on the full record and our findings above, we agree with Petitioner that Steenfeldt-Jensen and Atterbury teach or suggest a "first clicker feature comprising teeth configured to provide audible clicks (i) by dragging the teeth over corresponding teeth on said clutch and (ii) only during dialing down of a dose without dispensing medicament, where each click relates to a unit dose of medicament." Ex. 1014, 11:34–40, 11:62–67; Ex. 1097, 46:4–16, Fig. 27; Ex. 1096 ¶¶ 68–71. As discussed above, Steenfeldt-Jensen teaches radial protrusion 87 that clicks as it passes recesses of dose setting button 81, and Atterbury teaches clicker teeth 726 that slide past barrel teeth 703 and click when dialing down a dose. Ex. 1014, 11:34–40, 11:62–67; Ex. 1097, 46:4–16, Fig. 27; Ex. 1096 ¶¶ 68–

71. Moreover, the full record includes evidence that one of ordinary skill in the art would have known of other similar mechanisms. Ex. 1013, 9:4–8, 10:2–47; Ex. 1032, 3:10–26; Ex. 1098, 8:2–20; Ex. 1099 ¶ 15, Fig. 5; Ex. 1100, 3:6–21, Figs. 1–27; Ex. 1113 ¶¶ 79–83, 123, 124.

Turning to the reason to modify Steenfeldt-Jensen in view of Atterbury, Petitioner contends that one of ordinary skill in the art would have recognized that Atterbury's teachings applied to Steenfeldt-Jensen because Steenfeldt-Jensen's device has a flexible arm clicking over splines. Pet. Opp. 20 (citing Ex. 1014, 11:34–67, Figs. 15–17; Ex. 1113 ¶¶ 144–147, 226).

According to Petitioner, modifying Steenfeldt-Jensen with Atterbury's two-way ratchet would have been "achievable with minimal modifications;" "would operate analogously to the saw-tooth mechanism in Atterbury, with each set of ratchet arms having opposite handedness;" and would provide a "tuning capability" that would have "facilitated different clicking sounds for the different clicker components, aiding visually-impaired users in distinguishing between dialing-up and dialing-down." *Id.* at 20–21 (citing Ex. 1096 ¶ 72; Ex. 1097, 11:3–18; Ex. 1113 ¶¶ 144–147). Petitioner argues that one of ordinary skill in the art would have been motivated to apply Atterbury's clicker with reference to arguments for proposed substitute claim 61. *Id.* at 24 (citing Ex. 1113 ¶¶ 164–166, 220). In arguments for proposed substitute claim 61, Petitioner contends that "Steenfeldt-Jensen teaches a clicker that provides audible clicks for each unit dose dialed" in the fifth embodiment. *Id.* at 19–20 (citing Ex. 1014, 9:48–52, 11:20–67, Figs. 15–17; Ex. 1096 ¶ 68). Petitioner also argues that "Atterbury teaches a two-way ratchet with separate features that each click only during one of either

dialing-up or dialing-down." Pet. Opp. 20 (citing Ex. 1096 ¶¶ 69–71; Ex. 1097, 46:4–16, Fig. 27).

Petitioner also contends that one of ordinary skill in the art "would have also recognized that the mechanism could be implemented without significantly impacting pen size," "would have been familiar with ratchet mechanisms like Atterbury's—as well other conventional ratchet implementations such as flexible arms with one-way teeth," and "would have considered implementation of a two-way ratchet as described above to be routine." *Id.* at 21 (citing Ex. 1096 ¶ 73; Ex. 1097, 11:3–18; Ex. 1113 ¶ 147).

Patent Owner responds that "the alleged motivation to combine relies on a misinterpretation of Atterbury's teachings." PO Reply 10. Patent Owner contends that the tunable clicking does not pertain to the two-way ratchet's teeth. *Id.* at 11 (citing Pet. Opp. 21; Ex. 1097, 11:3–18; Ex. 2332 ¶ 55). According to Patent Owner, "Atterbury teaches only that the injection clicker can be tuned separately from the two-way ratchet, not that dual teeth sets of the two-way ratchet would be tuned separately." *Id.* at 12 (citing Ex. 1097, 11:3–18; Ex. 2332 ¶ 55).

Patent Owner also responds that Steenfeldt-Jensen "already accomplishes the functionality" asserted as the motivation to combine, and thus, there is no reason for the combination. *Id.* at 10. Patent Owner contends that "a user, even if visually impaired, could easily determine if the device is being turned clockwise and out of the device (dialed up) or counterclockwise and into the device (dialed down) *without needing distinguishable clicks*" and "[d]istinguishable clicks would be redundant." *Id.* at 12–13 (citing Pet. Opp. 21; Ex. 2332 ¶ 56).

Petitioner replies that Patent Owner reads Atterbury too narrowly and "admits that Atterbury teaches the benefit of providing different sounds between two distinct steps during the dose-administration process." Pet. Sur-reply 8 (citing PO Reply 11–13). Petitioner also argues that misdialing would not be as apparent as the difference in dialing and injecting. *Id.* (citing PO Reply 13; Ex. 1117, 8:4–11). Petitioner further argues that Atterbury teaches the benefit of "provid[ing] distinct sounds to further aid in signaling distinct steps in the dose-administration process" and that one of ordinary skill in the art "would have readily understood [Atterbury's] even greater applicability to providing different tuning during dose setting." *Id.* at 9.

We find that Petitioner's relied-upon portion of Atterbury teaches that "an injection clicker assembly can be provided that is readily tunable during manufacturing design . . . to provide the desired tone and loudness of the injection audible feedback." Ex. 1097, 11:6–9. We agree with Petitioner that Atterbury teaches tuning a clicker assembly and that this teaching or suggestion would have motivated one of ordinary skill in the art to modify the dose setting clicker of Steenfeldt-Jensen so as to result in two dose setting clickers with tunable audible feedback to "facilitate[] different clicking sounds for the different clicker components, aiding visually-impaired users in distinguishing between dialing-up and dialing-down." Pet. Opp. 20–21; Ex. 1014, 11:34–67, Figs. 15–17; Ex. 1096 ¶ 72; Ex. 1097, 11:3–18; Ex. 1113 ¶¶ 144–147, 164–166, 226.

Petitioner's evidence indicates that one of ordinary skill would have been motivated to apply Atterbury's teaching or suggestion of a tunable clicker to Steenfeldt-Jensen's dose setting clicker. Ex. 1096 ¶ 72; Ex. 1097, 11:3–18; Ex. 1113 ¶¶ 146, 164, 220. Patent Owner's arguments and

evidence indicate that one of ordinary skill in the art would not have done so because Atterbury teaches providing tuning to an injection clicker assembly. PO Reply 10–11; Ex. 2332 ¶ 55. The full record provides no reason why one of ordinary skill in the art would have understood Atterbury's teaching or suggestion to apply only to injection clicker assemblies and not to clickers generally, or would have required bodily incorporation instead of application to other types of clickers. *See* PO Reply 10–11; Ex. 2332 ¶ 55.

Patent Owner does not dispute that Petitioner's proposed modification would have "facilitated different clicking sounds for the different clicker components, aiding visually-impaired users in distinguishing between dialing-up and dialing-down." *See* Pet. Opp. 20–21; PO Reply 10–13. We credit Mr. Leinsing's testimony regarding why one of ordinary skill in the art would have made the proposed modification because the full record supports it. Ex. 1096 ¶ 72; Ex. 1097, 11:3–18; Ex. 1113 ¶ 146.

Steenfeldt-Jensen also combines clicking with dialing in one direction to set a dose and dialing in another direction to reduce the set dose. *See* Ex. 1014, 11:53–54 (stating that "a dose is set by rotating the dose setting button 81 in a clockwise direction"), 11:57–58 (stating that "a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction"), 11:62–64 (stating that "by the rotation of the dose setting button 81 in any direction the radial protrusion 87 on the flange 83 of the bushing 82 will click"). Steenfeldt-Jensen, thus, indicates that one of ordinary skill in the art would *not* have considered clicks in addition to dialing up or down a dose to be redundant, as argued by Patent Owner. *See* PO Reply 12–13. Steenfeldt-Jensen, instead, supports Petitioner's reason for its proposed modification. *See* Ex. 1014, 3:26–27 ("The clicks may be taken as an audible signal indicating the size of the set dose."). We, therefore, credit

Petitioner's declarant testimony that the proposed modification would benefit visually impaired patients (*see* Ex. 1096 ¶ 72; Ex. 1113 ¶ 146) over Patent Owner's declarant testimony that the proposed modification would be redundant (*see* Ex. 2332 ¶ 56) because Steenfeldt-Jensen supports Petitioner's position.

For the reasons above, based on the full record, Petitioner persuades us that one of ordinary skill in the art would have made the proposed modification. In particular, Petitioner persuades us that the proposed modification of Steenfeldt-Jensen in view of Atterbury would arrive at "a first clicker feature comprising teeth configured to provide audible clicks (i) by dragging the teeth over corresponding teeth on said clutch and (ii) only during dialing down of a dose without dispensing medicament, where each click relates to a unit dose of medicament," as recited by proposed substitute claim 59.

Patent Owner does not dispute whether the proposed modification would have had a reasonable expectation of success. *See* PO Reply 10–13. Based on the full record, Petitioner persuades us that one of ordinary skill in the art would have had a reasonable expectation of success. Pet. Opp. 20–23; Ex. 1096 ¶ 73; Ex. 1113 ¶ 147.

> *e) a second clicker feature spaced axially apart from the first clicker feature and disposed adjacent a distal end of the dose dial member, the second clicker feature comprising a flexible arm configured (i) to move axially relative to splines in only a first axial direction during dialing up of a dose and to move axially relative to the splines in only a second, opposite, axial direction during dose dispensing and (ii) to provide audible clicks by dragging a tooth member over the splines while rotating and moving axially relative to the splines.*

Petitioner argues that the recited second clicker is suggested by Steenfeldt-Jensen. Pet. Opp. 24. In particular, Petitioner argues that Steenfeldt-Jensen's fifth embodiment has a piston rod with a thread that engages a threaded opening on a flange of a housing and that Steenfeldt-Jensen teaches the reverse configuration. *Id.* (citing Ex. 1014, 1:30–40, 3:15–17, 3:41–47, 7:41–47, 11:6–19, 12:4–12, Figs. 15–17, claim 6; Ex. 1113 ¶¶ 133, 221). Petitioner also argues that one of ordinary skill in the art would have applied the suggestion to the fifth embodiment and "would have recognized that the relevant aspects of the drive mechanisms (i.e. the driver tube, piston rod, and wall 4) are substantially the same in the first and fifth embodiments, making the suggestion equally applicable to the fifth embodiment." *Id.* at 24–25 (citing Ex. 1113 ¶ 136; Ex. 1115, 531:12–22). Petitioner further addresses increased injection force and argues that flexible arms on a pawl mechanism would be modified so that they would avoid being broken. *Id.* at 25–27 (citing Ex. 1016, 3:1–26, Figs. 2, 3, 5–7; Ex. 1053, 28:18–29:1; Ex. 1095 ¶ 76; Ex. 1113 ¶¶ 137, 165, 166; Ex. 2107 ¶¶ 239–241).

Petitioner additionally argues that one of ordinary skill in the art "would have recognized that the depicted housing thread need not extend all the way down the housing, since a portion of the thread at the top would be

sufficient to provide a stable threaded engagement with drum 80" and the "modification would have been a routine implementation of common, well underst[oo]d ratchet mechanisms and threads." Pet. Opp. 27 (citing Ex. 1113 ¶ 166). According to Petitioner, the pawl mechanism in the proposed modification would be the second clicker and would be spaced axially from a first clicker, adjacent the distal end of drum 80, include the recited flexible arm, and provide audible clicks. *Id.* (citing Ex. 1113 ¶ 167).

Patent Owner responds that, to reach a second clicker spaced apart from a first clicker, Petitioner's proposed combination "requires extending bushing 82 past the dose member 80, and moving the pawl mechanism from driver tube 85 to the newly created interface between the bushing 82 and the housing 1." PO Reply 13 (citing Pet. Opp. 26–27). According to Patent Owner, Petitioner's reason that one of ordinary skill in the art "would have considered alternative configurations" is insufficient and Mr. Leinsing's testimony that the proposed combination would perform the same function does not support making the proposed combination because "it is prompted by problems with his prior ineffectual modifications to S[teenfeldt-]J[ensen] aimed at reaching other claim limitations." *Id.* at 13–14 (citing Ex. 1113 ¶¶ 165, 166; Ex. 2332 ¶ 74).

Petitioner replies that another solution within ordinary skill is "to move the pawl mechanism to the bushing," which undisputedly "would result in the pawl mechanism performing its same function or that the move would have been viewed as a predictable implementation to those in the art." Pet. Sur-reply 9 (citing PO Reply 13–14; Ex. 1113 ¶¶ 165–167; Ex. 2332 ¶ 73). Petitioner also argues that one of ordinary skill in the art would have "pursued the use of flexible arms sliding axially along and over splines for clicking purposes without concern about potential increases to injection

force." *Id.* at 10 (citing PO Reply 14; Ex. 1013, 10:42–52, Figs. 5, 8; Ex. 1113 ¶ 166).

As discussed above for the recited first clicker feature, we find that Steenfeldt-Jensen teaches radial protrusion 87 on flange 83 of bushing 82 and that protrusion 87 clicks when moved along inner wall of dose setting button 81. Ex. 1014, 11:34–40, 11:62–67; Ex. 1096 ¶ 68. We also find that Atterbury teaches one clicker that clicks in one direction, another clicker that clicks in the opposite direction, and an injection clicker assembly that is tunable. Ex. 1096 ¶¶ 69–71; Ex. 1097, 11:6–9, 46:4–16, Fig. 27. Further, for the reasons above, the full record persuades us that one of ordinary skill in the art would have applied Atterbury to Steenfeldt-Jensen to modify Steenfeldt-Jensen's clicking mechanism so as to result in two dose setting clickers with tunable audible feedback to "facilitate[] different clicking sounds for the different clicker components, aiding visually-impaired users in distinguishing between dialing-up and dialing-down." Pet. Opp. 20–21; Ex. 1014, 11:34–67, Figs. 15–17; Ex. 1096 ¶ 72; Ex. 1097, 11:3–18 ; Ex. 1113 ¶¶ 144–147, 164–166, 226.

Also, as discussed above for the first clicker feature, Patent Owner does not dispute Petitioner's asserted reason for making proposed modification—"different clicking sounds for the different clicker components, aiding visually-impaired users in distinguishing between dialing-up and dialing-down." *See* Pet. Opp. 20–21; PO Reply 10–14. In view of the full record, Petitioner's relied-upon portions of the references, the asserted teachings or suggestions, and Petitioner's reason for combining the references are more persuasive than Patent Owner's arguments that raise issues with how the modification would be accomplished and that address Petitioner's contention that one of ordinary skill in the art would have

considered alternative configurations (PO Reply 13–14). The full record shows that clickers, ratchet mechanisms, and their application to injection pens were well known. *See* Pet. Opp. 11–12 (arguing that clickers were known mechanisms in pen injectors) (citing Ex. 1098, 8:2–20; Ex. 1013, 9:4–8, 10:2–47; Ex. 1014, 11:34–67; Ex. 1032, 3:10–26; Ex. 1097, 46:4–16, Fig. 27; Ex. 1113 ¶¶ 79, 123, 124), 12–13 (arguing that one-way and two-way ratchet mechanisms, their uses, and their benefits were known) (citing Ex. 1058 ¶¶ 7–15, Figs. 2, 3, 7, 8; Ex. 1097, 11:3–18, 46:4–16, Fig. 27; Ex. 1099 ¶ 15, Fig. 5; Ex. 1100, 3:6–21, Figs. 9, 10; Ex. 1101, Figs. 1–27; Ex. 1102, 2:25–4:15, Figs. 3, 4; Ex. 1113 ¶¶ 80–83).

For the reasons above, based on the full record, Petitioner persuades us that one of ordinary skill in the art would have made the proposed modification to arrive at the recited second clicker feature of proposed substitute claim 59.

3. Proposed Substitute Claim 60

Proposed substitute claim 60 recites "[t]he ~~clutch~~ disposable pen type drug delivery device of claim [[52]] 59, wherein when said dose knob is activated to dispense a dose of a medicament contained within said pen type delivery device, said clutch is moved in a distal direction." Paper 56, Claims Appendix.

Petitioner argues that proposed claim 60 recites the limitation of original claim 53 and would have been obvious over Steenfeldt-Jensen and Atterbury. Pet. Opp. 23 (citing Ex. 1113 ¶¶ 218–223). In particular, Petitioner argues that, "[u]pon pressing the button to inject a dose, the rosette of teeth 93 engage the corresponding teeth in drum 80, thus 'activating' the dose knob as bushing 82 (the 'clutch') rotates and moves in a

distal direction." Pet. Opp. 27 (citing Ex. 1011 ¶¶ 487–488; Ex. 1014, 11:34–42, 12:1–13, Figs. 15–17).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "[i]n the dose setting button a compartment is . . . provided with . . . a bottom with a rosette of teeth having a triangular cross-section" (Ex. 1014, 11:34–37), "flange 83 of the bushing 82 is adopted in said compartment" (*id.* at 11:37–38), and "[a]t its distal side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment" (*id.* at 11:40–42).

We also find that the relied-upon portions of Steenfeldt-Jensen disclose that "[d]uring the setting the rosette in the dose setting button forces the rosette 93 on the flange 83 of the bushing 82 out of engagement," "[w]hen the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81," and the "bushing will rotate the driver tube 85 in an anticlockwise direction" so that "the piston rod is thereby screwed further into an ampoule 89 in the ampoule holder 2." *Id.* at 12:1–7, 12:10–13. We also credit Mr. Leinsing's testimony that bushing 82 moves axially into the housing during injection because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 487, 488 (citing Ex. 1014, 12:4–13). Patent Owner does not provide an argument specifically for proposed substitute claim 60. *See* PO Reply 10–14; *see also* Mot. to Amend 18–20 (addressing other amended features of proposed substitute claims 59–64).

Because Steenfeldt-Jensen discloses that, when injection button 88 is pressed, dose setting button 81 and bushing 82 rotate back into the housing to cause the piston rod to move into ampoule 89, Petitioner persuades us that Steenfeldt-Jensen discloses "wherein when said dose knob is activated to

dispense a dose of a medicament contained within said pen type delivery device, said clutch is moved in a distal direction."

For the reasons discussed above, Petitioner persuades us that Steenfeldt-Jensen and Atterbury teach or suggest each limitation of proposed substitute claim 59, from which claim 60 depends. Based on the full record before us and our findings from Steenfeldt-Jensen regarding the limitations of claim 60, Petitioner persuades us by a preponderance of the evidence that Steenfeldt-Jensen and Atterbury teach or suggest the limitations of proposed substitute claim 60.

4. Weighing the Graham *Factors*

Above, based on full record before us, we find that (1) Petitioner's proposed level of ordinary skill in the art is consistent with the prior art of record, (2) Steenfeldt-Jensen and Atterbury teach or suggest all the limitations of proposed substitute claims 59 and 60, (3) one of ordinary skill in the art would have had a reason to modify Steenfeldt-Jensen with the teachings of Atterbury with a reasonable expectation of success, and (4) no objective evidence of nonobviousness has been presented in connection with proposed substitute claims 59 and 60. *See* Tr. 58:20–59:5 (Patent Owner's counsel agreeing that objective evidence of nonobviousness were not presented in this proceeding). Weighing these underlying factual determinations, a preponderance of the evidence persuades us that proposed substitute claims 59 and 60 are unpatentable over Steenfeldt-Jensen and Atterbury.

G. Obviousness Based on Steenfeldt-Jensen, Burroughs, and Atterbury

1. Scope and Content of the Asserted Prior Art

Above in Sections II.D.1., II.F.1., and III.G.1.a., we discuss the disclosures of Burroughs, Steenfeldt-Jensen, and Atterbury.

2. Proposed Substitute Claim 61

a) A disposable pen type drug delivery device, comprising:

Petitioner refers to its arguments for proposed substitute claim 58 and original claim 51. Pet. Opp. 19 (citing Ex. 1113 ¶ 225).

If the preamble is limiting, we find that the relied-upon portion of Steenfeldt-Jensen teaches "injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses." Ex. 1014, 1:12–15. Patent Owner does not provide an argument specifically for the preamble of proposed substitute claim 61. *See* PO Reply 10–14; *see also* Mot. to Amend 18–20 (addressing other amended features of proposed substitute claims 59–64).

Because Steenfeldt-Jensen discloses an injection syringe with a cartridge of medicine, Petitioner persuades us that Steenfeldt-Jensen discloses a "disposable pen type drug delivery device."

b) a clutch for use within the 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 dose dial member;

Petitioner refers to its arguments for proposed substitute claim 58 and original claim 51. Pet. Opp. 19 (citing Ex. 1113 ¶ 225). Patent Owner does not provide an argument specifically for the recited clutch of proposed substitute claim 61. *See* PO Reply 10–14; *see also* Mot. to Amend 18–20 (addressing other amended features of proposed substitute claims 59–64).

Based on our findings above in Section II.F.2., Petitioner persuades us that Steenfeldt-Jensen teaches the clutch of proposed substitute claim 61.

c) *wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob* ~~*The clutch of claim 52,*~~

Petitioner refers to its arguments for original claim 52 and argues that Figures 15–17 of Steenfeldt-Jensen "show that the proximal end of the bushing's tubular body resides within an inner space of dose setting button 81." Pet. Opp. 19 (citing Ex. 1011 ¶¶ 484–486; Ex. 1014, 11:20–33).

For the reasons stated for original claim 52, because Steenfeldt-Jensen discloses a proximal end of bushing 82 within dose setting button 81, Petitioner persuades us that Steenfeldt-Jensen discloses "wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob." Patent Owner does not provide an argument specifically for this limitation of proposed substitute claim 61. *See* PO Reply 10–14; *see also* Mot. to Amend 18–20 (addressing other amended features of proposed substitute claims 59–64).

Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob," as recited by proposed substitute claim 61.

d) *wherein said pen type drug delivery device further comprises a cartridge containing a medicament, said cartridge comprising a reservoir, a stopper, a septum[[and]], a ferrule; and*

Petitioner argues that Steenfeldt-Jensen teaches the recited cartridge features. Pet. Opp. 19. Petitioner also argues that Burroughs teaches these limitations. *Id.* (citing Ex. 1011 ¶¶ 463–464; Ex. 1013, 9:32–46, Fig. 1).

We find that the relied-upon portion of Burroughs discloses that "plunger engagement portion 206 of leadscrew 38 is in engagement with piston 210 of cartridge 40" and that "[c]artridge 40 . . . comprises a tube defining an inner chamber 212 which openly terminates at its distal end in a

neck 214 having a cap 216 including a rubber disc 218 disposed thereover." Ex. 1013, 9:32–46. Figure 1 of Burroughs shows that cartridge 40 includes chamber 212, piston 210, rubber disc 218, and cap 216. We credit Mr. Leinsing's testimony that one of ordinary skill in the art would have understood chamber 212, piston 210, rubber disc 218, and cap 216 to be, respectively, a reservoir, a stopper, a septum and a ferrule because it finds support in Burroughs. Ex. 1011 ¶¶ 463, 464 (citing Ex. 1013, Abstract, 2:42–48, 9:34–40, Figs. 1, 2). Patent Owner does not provide an argument specifically for the recited cartridge of proposed substitute claim 61. *See* PO Reply 10–14; *see also* Mot. to Amend 18–20 (addressing other amended features of proposed substitute claims 59–64).

Because we find that Burroughs describes a cartridge with liquid medication and that one of ordinary skill would have understood that cartridge 40 of Burroughs includes a reservoir, stopper, septum and ferrule, Petitioner persuades us that Burroughs teaches "wherein said pen type drug delivery device further comprises a cartridge containing a medicament, said cartridge comprising a reservoir, a stopper, a septum, a ferrule."

> *e) a clicker configured to provide audible clicks relating to a unit dose of the medicament contained in the cartridge during dose setting, the clicker comprising: a flexible arm extending from a fixed end circumferentially to a free end thereof, the flexible arm comprising a tooth on the free end, the flexible arm configured to: (i) provide audible clicks while rotationally fixed relative to the clutch and while the clicker is moving axially relative to a housing of the device in a first direction during dialing up of a dose, where each click relates to a unit dose of the medicament, and (ii) not provide audible clicks while the clicker is moving axially relative to the housing in a second, opposite, direction, during dialing down of a dose without dispensing the medicament; and one-way teeth configured to: (i) provide audible clicks by dragging over corresponding teeth of the clutch while the clicker is moving axially relative to the housing in the second direction during dialing down of a dose without dispensing the medicament, where each click relates to a unit dose of the medicament and, (ii) not provide audible clicks while the clicker is moving axially relative to the housing in the first direction during dialing up of a dose.*

Petitioner argues that "Steenfeldt-Jensen teaches a clicker that provides audible clicks for each unit dose dialed" in the fifth embodiment. Pet. Opp. 19–20 (citing Ex. 1014, 9:48–52, 11:20–67, Figs. 15–17; Ex. 1096 ¶ 68). Petitioner also argues that "Atterbury teaches a two-way ratchet with separate features that each click only during one of either dialing-up or dialing-down." *Id.* at 20 (citing Ex. 1096 ¶¶ 69–71; Ex. 1097, 46:4–16, Fig. 27).

Petitioner contends that one of ordinary skill in the art would have recognized that Atterbury's teachings applied to Steenfeldt-Jensen because Steenfeldt-Jensen's device has a flexible arm clicking over splines. *Id.* (citing Ex. 1014, 11:34–67, Figs. 15–17; Ex. 1113 ¶¶ 144–147, 226). Petitioner also contends that modifying Steenfeldt-Jensen with Atterbury's

two-way ratchet would have been "achievable with minimal modifications;" "would operate analogously to the saw-tooth mechanism in Atterbury, with each set of ratchet arms having opposite handedness;" and would provide a "tuning capability" that would have "facilitated different clicking sounds for the different clicker components, aiding visually-impaired users in distinguishing between dialing-up and dialing-down." Pet. Opp. 20–21 (citing Ex. 1096 ¶ 72; Ex. 1097, 11:3–18; Ex. 1113 ¶¶ 144–147).

Petitioner further contends that one of ordinary skill in the art "would have also recognized that the mechanism could be implemented without significantly impacting pen size," "would have been familiar with ratchet mechanisms like Atterbury's—as well other conventional ratchet implementations such as flexible arms with one-way teeth," and "would have considered implementation of a two-way ratchet as described above to be routine." *Id.* at 21 (citing Ex. 1096 ¶ 73; Ex. 1097, 11:3–18; Ex. 1113 ¶ 147). Petitioner explains that the proposed modification would operate in the manner recited by proposed substitute claim 61. *Id.* at 21–23 (citing Ex. 1014, 11:62–67; Ex. 1113 ¶¶ 148–149).

Patent Owner responds with the same arguments summarized above for the clicker features of proposed substitute claims 59 and 60. *See* PO Reply 10–14 (presenting arguments for proposed substitute claims 59–64 together). Based on the full record, for the reasons discussed above for proposed substitute claims 59 and 60, Petitioner persuades us that one of ordinary skill would have been motivated to make the proposed modification of Steenfeldt-Jensen in view of Atterbury to arrive at the clicker of proposed substitute claim 61.

3. Proposed Substitute Claim 62

Proposed substitute claim 62 recites "[t]he ~~clutch~~ disposable pen type drug delivery device of claim [[54]] 61, wherein said cartridge comprises a multidose cartridge." Paper 56, Claims Appendix.

Petitioner refers to its arguments for the challenge of original claim 55 based on Burroughs and argues that one of ordinary skill in the art would have understood the cartridge of Burroughs is a multidose cartridge. Pet. Opp. 19 (citing Ex. 1011 ¶ 466; Ex. 1013, Abstract). Patent Owner does not provide an argument specifically for proposed substitute claim 62. *See* PO Reply 10–14; *see also* Mot. to Amend 18–20 (addressing other amended features of proposed substitute claims 59–64).

For the reasons discussed above, because Burroughs describes a multi-use medication dispensing pen and as discussed above, describes a cartridge housing liquid medication, Petitioner persuades us that Burroughs discloses "wherein said cartridge comprises a multidose cartridge," as recited by proposed substitute claim 62.

Also as discussed above, Petitioner persuades us that Steenfeldt-Jensen, Burroughs, and Atterbury teach or suggest the limitations of proposed substitute claim 61, from which proposed substitute claim 62 depends. Petitioner, thus, persuades us that Steenfeldt-Jensen, Burroughs, and Atterbury teach or suggest all of the limitations of proposed substitute claim 63.

4. Weighing the Graham *Factors*

Above, based on full record before us, we find that (1) Petitioner's proposed level of ordinary skill in the art is consistent with the prior art of record, (2) Steenfeldt-Jensen, Burroughs, and Atterbury teach or suggest all the limitations of proposed substitute claims 61 and 62, (3) one of ordinary

skill in the art would have had a reason to modify Steenfeldt-Jensen with the teachings of Burroughs and Atterbury with a reasonable expectation of success, and (4) no objective evidence of nonobviousness has been presented in connection with proposed substitute claims 61 and 62. *See* Tr. 58:20–59:5 (Patent Owner's counsel agreeing that objective evidence of nonobviousness were not presented in this proceeding). Weighing these underlying factual determinations, a preponderance of the evidence persuades us that proposed substitute claims 61 and 62 are unpatentable over Steenfeldt-Jensen, Burroughs, and Atterbury.

H. Obviousness Based on Steenfeldt-Jensen, Atterbury, and Klitgaard

1. Scope and Content of the Asserted Prior Art

Above in Sections II.F.1., III.F.1.a., and III.G.1.a., we discuss the disclosures of Steenfeldt-Jensen, Klitgaard, and Atterbury.

2. Proposed Substitute Claim 63

a) The ~~clutch~~ disposable pen type drug delivery device of claim [[51]] 58, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch;

Petitioner refers to its arguments for original claim 56 and proposed substitute claim 59. Pet. Opp. 28. Petitioner also argues that one of ordinary skill in the art would have considered Steenfeldt-Jensen's rosette 93 of teeth as teaching the limitations of proposed substitute claim 63. *Id.* (citing Ex. 1014, 11:34–42, Figs. 15–17; Ex. 1113 ¶¶ 69, 229–231).

Patent Owner does not provide an argument specifically for proposed substitute claim 63. *See* PO Reply 10–18; *see also* Mot. to Amend 18–20 (addressing other limitations of proposed substitute claims 59–64). For the reasons discussed above in Sections II.F.5 and II.G.2. for original claim 56,

Petitioner persuades us that Steenfeldt-Jensen teach or suggest the plurality of axially extending teeth recited by proposed substitute claim 63.

Also as discussed above, Petitioner persuades us that Steenfeldt-Jensen and Klitgaard teach or suggest the limitations of proposed substitute claim 58, from which proposed substitute claim 63 depends. Petitioner, thus, persuades us that Steenfeldt-Jensen and Klitgaard teach or suggest the teeth limitations of proposed substitute claim 63.

b) *a first clicker feature comprising teeth configured to provide audible clicks (i) by dragging the teeth over corresponding teeth on said clutch and (ii) only during dialing down of a dose without dispensing medicament, where each click relates to a unit dose of medicament, and*

Petitioner refers to its arguments for original claim 56 and proposed substitute claim 59. Pet. Opp. 28. Patent Owner responds with the same arguments summarized above for the first clicker feature of proposed substitute claim 59. *See* PO Reply 10–14 (presenting arguments for proposed substitute claims 59–64 together).

Based on the full record, for the reasons discussed above for proposed substitute claim 59, Petitioner persuades us that one of ordinary skill would have been motivated to make the proposed modification of Steenfeldt-Jensen in view of Atterbury to arrive at the first clicker feature of proposed substitute claim 63.

c) a second clicker feature spaced axially apart from the first clicker feature and disposed adjacent a distal end of the dose dial member, the second clicker feature comprising a flexible arm configured (i) to move axially relative to splines in only a first axial direction during dialing up of a dose and to move axially relative to the splines in only a second, opposite, axial direction during dose dispensing and (ii) to provide audible clicks by dragging a tooth member over the splines while rotating and moving axially relative to the splines.

Petitioner refers to its arguments for original claim 56 and proposed substitute claim 59. Pet. Opp. 28. Patent Owner responds with the same arguments summarized above for the clicker features of proposed substitute claims 59 and 60. *See* PO Reply 10–14 (presenting arguments for proposed substitute claims 59–64 together).

Based on the full record, for the reasons discussed above for proposed substitute claims 59 and 60, Petitioner persuades us that one of ordinary skill would have been motivated to make the proposed modification of Steenfeldt-Jensen in view of Atterbury to arrive at the second clicker feature of proposed substitute claim 63.

3. Proposed Substitute Claim 64

a) The ~~clutch~~ disposable pen type drug delivery device of claim [[51]] 58, wherein said clutch is positioned within an open proximal end of said dose dial member and located adjacent a distal end of [[said]]a dose knob and operatively coupled to said dose knob, and wherein said dose dial member extends circumferentially around at least a portion of said clutch; and

Petitioner refers to its arguments for original claim 57 and proposed substitute claims 58 and 59. Pet. Opp. 28. Petitioner also argues that "Steenfeldt-Jensen describes a clutch (bushing 82), dial member (drum 80), and dose knob (dose-setting button 81)," "Figures 15–16 show bushing 82 positioned within an open proximal end of drum 80 and located adjacent a

distal end (button-end) of dose-setting button 81," "[b]ushing 82 is operatively coupled to dose-setting button 81 due to the toothed engagement of rosette 93," and "Figures 15–16 also show that dose-scale drum 80 extends circumferentially around at least a portion of bushing 82." *Id.* at 28–29 (citing Ex. 1011 ¶¶ 491–493; Ex. 1014, 11:20–42, 11:34–42, 12:1–2, Figs. 15–17).

For the reasons discussed above in Section II.F.6. for original claim 57, Petitioner persuades us that Steenfeldt-Jensen discloses this limitation of proposed substitute claim 64.

> *b) wherein said pen type drug delivery device further comprises a clicker configured to provide audible clicks relating to a unit dose of medicament during dose setting, the clicker comprising: a flexible arm extending from a fixed end circumferentially to a free end thereof, the flexible arm comprising a tooth on the free end, the flexible arm configured to: (i) provide audible clicks while rotationally fixed relative to the clutch and while the clicker is moving axially relative to the housing in a first direction during dialing up of a dose, where each click relates to a unit dose of the medicament, and (ii) not provide audible clicks while the clicker is moving axially relative to the housing in a second, opposite, direction during dialing down of a dose without dispensing the medicament; and*

Petitioner refers to its arguments for original claim 57 and proposed substitute claims 58 and 59. Pet. Opp. 28. Patent Owner responds with the same arguments summarized above for the first clicker feature of proposed substitute claim 59. *See* PO Reply 10–14 (presenting arguments for proposed substitute claims 59–64 together).

Based on the full record, for the reasons discussed above for proposed substitute claim 59, Petitioner persuades us that one of ordinary skill would have been motivated to make the proposed modification of Steenfeldt-Jensen

in view of Atterbury to arrive at the above-quoted recitation of proposed substitute claim 64.

> c) *one-way teeth configured to: (i) provide audible clicks by dragging over corresponding teeth of the clutch while the clicker is moving axially relative to the housing in the second direction during dialing down of a dose without dispensing the medicament, where each click relates to a unit dose of the medicament and, (ii) not provide audible clicks while the clicker is moving axially relative to the housing in the first direction during dialing up of a dose.*

Petitioner refers to its arguments for original claim 57 and proposed substitute claims 58 and 59. Pet. Opp. 28. Patent Owner responds with the same arguments summarized above for the clicker features of the proposed substitute claims. *See* PO Reply 10–14 (presenting arguments for proposed substitute claims 59–64 together).

Based on the full record, for the reasons discussed above for proposed substitute claim 59, Petitioner persuades us that one of ordinary skill would have been motivated to make the proposed modification of Steenfeldt-Jensen in view of Atterbury to arrive at the one-way teeth of proposed substitute claim 64.

4. Weighing the Graham *Factors*

Above, based on full record before us, we find that (1) Petitioner's proposed level of ordinary skill in the art is consistent with the prior art of record, (2) Steenfeldt-Jensen, Atterbury, and Klitgaard teach or suggest all the limitations of proposed substitute claims 63 and 64, (3) one of ordinary skill in the art would have had a reason to modify Steenfeldt-Jensen with the teachings of Atterbury and Klitgaard with a reasonable expectation of success, and (4) no objective evidence of nonobviousness has been presented in connection with proposed substitute claims 63 and 64. *See* Tr. 58:20–

59:5 (Patent Owner's counsel agreeing that objective evidence of nonobviousness were not presented in this proceeding). Weighing these underlying factual determinations, a preponderance of the evidence persuades us that proposed substitute claims 63 and 64 are unpatentable over Steenfeldt-Jensen, Atterbury, and Klitgaard.

I. Remaining Challenges

Petitioner also argues that proposed substitute claims 58–64 are unpatentable over Moller combined with at least one of Klitgaard, Atterbury, and Burroughs. Pet. Opp. 29–40. Petitioner further contends that the terms "arc shaped body" and "end-most side surfaces" are indefinite.
Pet. Opp. 10.

Because we determine above that Steenfeldt-Jensen combined with at least one of Klitgaard, Atterbury, and Burroughs would have rendered obvious proposed substitute claims 58–64, we do not reach Petitioner's additional challenges to the same claims based on Moller and indefiniteness.

IV. PETITIONER'S MOTION TO EXCLUDE

Petitioner moves to exclude Exhibits 1054, 1109, 2100, 2103–2107, 2111–2152, 2157–2162, 2164–2201, 2203–2212, 2214–2218, 2223–2225, 2302, 2304–2310, 2312, 2316, 2323–2325, 2327, and 2332–2334. Mot. to Excl. 1. Petitioner notes that objections were filed. *Id.* (citing Papers 28, 29, 58, 81). Petitioner, as the "moving party," "has the burden of proof to establish that it is entitled to the requested relief." 37 C.F.R. § 42.20 (2017).

A. Exhibits 2100, 2101, 2103–2106, 2111–2116, 2118–2146, 2151, 2152, 2157–2162, 2164–2201, 2203–2205, 2208–2212, 2214–2218, 2223–2225, 2304–2310, 2312, 2323, 2324, and 2327

Petitioner contends the above-listed exhibits should be excluded pursuant to FRE 402 and 403 "because they were not discussed in the substantive papers, cannot be relevant to them, and consequently serve only to confuse and create prejudice through belated surprise." Mot. to Excl. 1. Petitioner also requests that, to the extent any exhibit is not excluded, the use of the exhibit should be limited. *Id.* at 6 (citing FRE 105); Reply to Mot. to Excl. 2 (citing FRE 105).

Patent Owner contends that Exhibits 2103–2106 are exhibits to the deposition of Mr. Leinsing and are relevant because they "provide necessary context for Mr. Leinsing's cross-examination, which Petitioner has not sought to exclude." PO Opp. 1. Patent Owner also contends that Exhibits 2224 and 2225 "are exhibits to the deposition of Mr. McDuff, one of Petitioner's experts on objective indicia, and are therefore relevant because they provide context for Mr. McDuff's cross-examination, which Petitioner has not sought to exclude." *Id.* According to Patent Owner, Exhibit 2157 "is expressly cited in Patent Owner's sur-reply." *Id.* (citing PO Sur-reply 14).

Additionally, Patent Owner contends that "at least EX2100–2101, 2103, 2111, 2113, 2116, 2120, 2123, 2126, 2131, 2134–2135, 2136–2138, 2153, 2144, 2158–2161, 2164–2171, 2173–2183, 2206–2207, 2211, 2214–2218, 2304, and 2310 were expressly cited by Dr. Slocum in his declaration testimony." *Id.* at 1–2 (citing Ex. 2107 ¶¶ 26, 27, 29, 33, 36, 41, 44–46, 48–53, 56, 95–97, 114, 127, 149, 150, 428, 432, 462, 474; Ex. 2302, 9, 10, 18, 27–30, 29, 30, 66, 118, 152, 153, 162, 167–169; Ex. 2325, 5, 14, 19, 24, 26,

27, 30, 31, 33, 36, 45, 46). Patent Owner also contends that "EX2124, 2145, 2146, 2186-2199, 2203-2205, and 2208-2210 were also considered and expressly cited by Dr. Grabowski in forming his opinions" and "EX2112, 2116, 2121, 2123, 2125, 2140-2141, 2143, 2144, and 2200 were also considered and expressly cited by Dr. Goland in forming her opinions." PO Opp. 2 (citing Ex. 2109 ¶¶ 32–34, 39–45, 51, 53–55, 66–68; Ex. 2111 ¶¶ 23, 25, 43).

Patent Owner further contends that Exhibits 2304–2310 and 2312 are referenced in Exhibit 2303, which Petitioner does not seek to exclude, and the same exhibits are cited in the Corrected Revised Motion to Amend to show written description support. *Id.* at 3. Patent Owner argues that Exhibits 2323, 2324, and 2327 support that Patent Owner complied with its duty of candor under 37 C.F.R § 42.11. *Id.*

Petitioner repeats that the exhibits at issue were not discussed and replies that incorporation by reference is not a justification for failing to cite an exhibit. Reply to Mot. to Excl. 1. Petitioner also notes that Patent Owner did not always file the basis of testimony as an exhibit. *Id.* (citing Ex. 2111, 7 n.1). Petitioner further argues that 37 C.F.R § 42.11 does not provide authority for submission. *Id.* at 2 (citing Ex. 2315, 12:25–15:13).

We do not rely on these exhibits in our analysis. Additionally, the sole basis argued in Petitioner's Motion to Exclude—that the exhibits were not cited in substantive papers—is not, in and of itself, dispositive as to whether an exhibit should be excluded. Accordingly, Petitioner has not satisfied its burden to show that these exhibits should be excluded. We do agree with Petitioner that their use shall be limited to showing the basis for testimony.

B. Exhibits 1054, 1109, 2107, 2302, 2316, 2325, and 2332

Petitioner seeks to exclude Dr. Slocum's entire declaration (Ex. 2107) and the deposition redirect examination of Dr. Slocum (Ex. 1054, 391; Ex. 1109, 77) pursuant to FRE 702, 703, and 705. Mot. to Excl. 2–5. Petitioner raises three primary reasons. First, that Dr. Slocum did not have personal knowledge of injection pens or the industry during the relevant time period. *Id.* at 2 (citing Ex. 1053, 30:23–33:13; 37:21–38:3; 40:20–42:13; 46:23–47:2; 47:25–51:13; 54:2–22; 75:8–21; 203:2–5; 209:15–213:5; Ex. 1054, 316:22–323:18; 329:13–331:11; 332:23–333:25), 3. Second, that Dr. Slocum relied upon Mr. Veasey, one of the named inventors of the '486 patent, for certain data and upon Dr. Goland for a discussion about injection force that is not supported by her experience. *Id.* at 3–4 (citing Ex. 1056, 52:6–9; Ex. 2107 ¶¶ 44, 230). And, third, that Exhibit 2017 should be excluded for the additional reason that it "does not provide sufficient facts or data, is not the product of reliable principles and methods, and has not applied the proper principles to the facts of this proceeding." *Id.* at 4. As an example, Petitioner contends that Appendices A through F "do not set forth the principles used nor do they demonstrate the calculations used in generating the spreadsheets" and, thus, "should be excluded for failing to disclose the underlying facts and data, and failing to set forth the bases of Dr. Slocum's opinions." Mot. to Excl. 4–5. Petitioner contends that, at least, paragraphs 13–33, 36, and 69 of Exhibit 2332 similarly fail to disclose the underlying facts, data, and bases of Dr. Slocum's opinion. *Id.* at 5. Petitioner also requests that, to the extent any exhibit is not excluded, the use of the exhibit should be limited. *Id.* at 6 (citing FRE 105).

Patent Owner responds to each of Petitioner's challenges. First, with respect to Dr. Slocum's personal knowledge, Patent Owner correctly

observes that neither party's proposed definition of the ordinary level of skill in the art requires specific knowledge of, or experience with, pen injectors. PO Opp. 5 (citing Ex. 1011 ¶ 106; Ex. 2107 ¶ 102). Additionally, Patent Owner contends that there is no requirement that an expert have personal knowledge of the subject matter upon which the expert's opinion is based at the time of the invention. *Id.* Further, Patent Owner asserts that Dr. Slocum acquired the relevant knowledge by "(i) research[ing] the prior art, (ii) canvass[ing] literature on pre-critical date pen injectors, design considerations, and design standards, and (iii) convers[ing] with those in the industry (*i.e.*, Mr. Veasey and Dr. Goland)." *Id.* at 5–6 (citing Ex. 2107 ¶¶ 25–61). Patent Owner also contends Dr. Slocum documented his opinions with facts and data. *Id.* at 6.

Second, Patent Owner asserts that Petitioner's criticism of Dr. Slocum's reliance upon the information and model obtained from Mr. Veasey are unfounded. In particular, Patent Owner asserts that Dr. Slocum performed his own investigation and research into design considerations and the state of the art, as documented in his declaration. *Id.* at 7 (citing Ex. 2107 ¶¶ 25–61). Patent Owner raises additional arguments regarding the specific discussions between Dr. Slocum and Mr. Veasey. *Id.* at 7–8 (discussing measurements of the FlexPen and embodiments in Steenfeldt-Jensen). Patent Owner notes that Petitioner does not assert that any of the design considerations noted by Dr. Slocum are incorrect. *Id.* at 9–10.

Third, Patent Owner contends that Petitioner ignores that Patent Owner "served as supplemental evidence the native Excel spreadsheets that specify [the] principles and show the calculations" set forth in Appendices A through F. *Id.* at 9 (citing Ex. 2226). Patent Owner further asserts that "the

measurements provided by Mr. Veasey are corroborated, unrebutted, and reliable." PO Opp. 9.

Petitioner's Motion Reply reiterates Petitioner's contentions regarding Dr. Slocum, including that even if he could be an expert, he "objectively failed to act as an expert in this case." Reply to Mot. to Excl. 2. Petitioner also challenges Dr. Slocum's acceptance of Mr. Veasey's data "without question," contending that Dr. Slocum only did so because "he had no relevant knowledge or experience." *Id.* at 4. Petitioner also asserts that Patent Owner hid Mr. Veasey's involvement in Dr. Slocum's testimony precluding Petitioner from cross-examining Mr. Veasey. *Id.*

To begin, Dr. Slocum is undisputedly an expert in mechanical engineering with knowledge and experience *beyond* the level of ordinary skill in the art as the parties have proposed and we have adopted. *See Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008) (noting that "[a] witness possessing merely ordinary skill will often be qualified to present expert testimony both in patent trials and more generally") (citations omitted). Additionally, as both parties acknowledge, there is no requirement that an expert have personal knowledge of the technology during the specific relevant time period in order to qualify as an expert. In this regard, we find that Patent Owner and Dr. Slocum have established sufficient support, as detailed above, as to how he acquired knowledge of the specific technology at issue—the mechanical operation and design of injection pens. Further, Dr. Slocum's reliance upon other individuals, including Mr. Veasey, to provide information upon which he based his opinions does not render him unqualified to offer an expert opinion. To the extent the credibility of any of the individuals upon which Dr. Slocum relied may be in doubt, e.g., Mr. Veasey's potential bias as a

named inventor on the '486 patent, those issues are the proper subject of cross-examination, go to the weight accorded the evidence, and do not justify excluding Dr. Slocum's testimony on the facts presented here. And, to the extent Petitioner questions the data or model provided by Mr. Veasey, the proper recourse is to probe the bases for such during cross-examination, as discussed further below. Therefore, Petitioner has not shown that Dr. Slocum should be disqualified as an expert in this proceeding. Accordingly, Petitioner's Motion as directed to the redirect examination testimony of Exhibit 1054 and Dr. Slocum's declaration (Ex. 2107) is denied.

We find that Petitioner's assertions that Patent Owner hid Mr. Veasey's involvement are unfounded. In particular, Dr. Slocum acknowledged in Appendix B of his declaration that the "[i]nput values were provided by Mr. Robert Veasey of DCA Engineering." Ex. 2107, App. B at 2. Thus, we find that Petitioner could have, but did not, seek to depose Mr. Veasey and therefore Petitioner's arguments regarding Mr. Veasey's involvement do not justify excluding Dr. Slocum's declaration (Ex. 2107) or redirect testimony (Ex. 1054). *See also* Tr. 35:15–36:7 (Petitioner's counsel describing decision not to cross-examine Mr. Veasey), 93:16–25 (Petitioner's counsel acknowledging that Appendix B states Mr. Veasey provided inputs).

C. Exhibit 2111

Petitioner contends that Exhibit 2111 should be excluded under FRE 702 and 703 because the testimony is not the product of reliable principles and methods. Mot. to Excl. 5. According to Petitioner, "Dr. Goland provides extensive testimony about the criticality of injection force to her patients, but admitted under cross examination that it is not

something her patients even ask about," and thus, is "contrary to her own experience." Mot. to Excl. 5 (citing Ex. 1056, 52:6–9). Petitioner also requests that, to the extent any exhibit is not excluded, the use of the exhibit should be limited. *Id.* at 6 (citing FRE 105).

Patent Owner responds that the testimony is consistent with Dr. Goland's practice because she has switched patients from one injection pen to another because of injection force. PO Opp. 10–11 (citing Ex. 1056, 52:6–9, 66:16–67:10). Petitioner replies that Patent Owner does not dispute that the testimony is contrary and the testimony regarding injection force is also contradicted by Dr. Goland's prescribing practice. Reply to Mot. to Excl. 4–5 (citing Ex. 1056, 71:13–16).

Because objective indicia of nonobviousness has not been properly presented, we dismiss Petitioner's Motion to Exclude with respect to Exhibit 2111 as moot.

D. Exhibits 2117, 2147–2152, 2162, 2167, 2168, 2206, 2207, 2211, and 2215–2218[7]

Petitioner contends the above-listed exhibits are animations "offered to show animated operations of prior art and non-prior art injection pens" and should be excluded pursuant to FRE 801–804 "because they are offered for the truth of their contents without satisfying any of the hearsay exceptions." Mot. to Excl. 6. Petitioner also requests that, to the extent any

[7] Petitioner's challenge to the admissibility of these exhibits pursuant to FRE 402 and 403 is discussed above. This section is directed to Petitioner's challenge based on FRE 801–804, which Petitioner discusses separately. *Compare* Mot. to Excl. 1 (addressing FRE 402 and 403), *with id.* at 6 (addressing FRE 801–804).

exhibit is not excluded, the use of the exhibit should be limited. Mot. to Excl. 6 (citing FRE 105).

Patent Owner responds that Dr. Slocum relied upon each in formulating his opinions. PO Opp. 11 (citing Ex. 1053, 34:8–36:19; Ex. 2107 ¶¶ 34, 65, 90, 101, 137, 142, 145, 150, 156, 226, 237, 246, 249–251, 428, 430, 432, 434, 462). Petitioner replies that Patent Owner does not explain how relying on hearsay makes them admissible and that Patent Owner "prejudicially launders the testimony of Mr. Veasey through an expert to prevent the petitioners from cross-examining him." Reply to Mot. to Excl. 5.

Patent Owner does not dispute that the exhibits listed above constitute hearsay, and Petitioner does not dispute that Dr. Slocum was permitted to rely upon it in formulating his opinions. Petitioner has not satisfied its burden to show that these exhibits should be excluded. We agree with Petitioner that their use shall be limited to showing the basis for Dr. Slocum's testimony.

E. Exhibits 2333 and 2334

Petitioner contends that Exhibits 2333 and 2334 "should be excluded under FRE 402, 403" because they "are not relevant," "are not cited in the reply," "have no evidentiary value," and "appear to be illustrated argument." Mot. to Excl. 6. Patent Owner responds that these exhibits are discussed in Dr. Slocum's declaration and undermine Petitioner's written description arguments regarding "piston rod" and "arc shaped body." PO Opp. 11–12 (citing Ex. 2332 ¶¶ 30, 36). Petitioner replies that the exhibits at issue were not discussed in substantive papers. Reply to Mot. to Excl. 1.

We do not rely on these exhibits in our analysis, and we agree with Patent Owner that they support written description arguments. Accordingly,

Petitioner has not satisfied its burden to show that Exhibits 2333 and 2334 should be excluded.

F. Exhibits 2225, 2323, and 2324

Petitioner contends that Exhibits 2225, 2323, and 2324 "should be excluded under FRE 403 and 802" because they "were not cited in any substantive papers," "are prejudicial because it risks confusion by diverting attention away from the actual issues under review," and are "hearsay without exception." Mot. to Excl. 6. Patent Owner responds that Exhibit 2225 is a deposition exhibit and provides context for Mr. McDuff's cross-examination. PO Opp. 12. Patent Owner also argues that Exhibits 2323 and 2324 are relevant to Patent Owner's duty of candor and are not hearsay because they are not offered for their truth. *Id.* Petitioner replies that the exhibits at issue were not discussed in substantive papers. Reply to Mot. to Excl. 1.

We do not rely on these exhibits in our analysis, and the basis argued for exclusion—that the exhibits were not cited in substantive papers—is not, in and of itself, dispositive as to whether an exhibit should be excluded. Accordingly, Petitioner has not satisfied its burden to show that these Exhibits 2225, 2323, and 2324 should be excluded.

V. CONCLUSION[8]

In summary:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
51–55, 57	§ 102	Burroughs	51–55, 57	
54, 55	§ 103	Burroughs	54, 55	
51–53, 56, 57	§ 102	Steenfeldt-Jensen	51–53, 56, 57	
56	§ 103	Steenfeldt-Jensen	56	
54, 55	§ 103	Steenfeldt-Jensen, Burroughs[9]		
51–53, 56, 57	§ 102	Moller[10]		
54, 55	§ 103	Moller, Burroughs[11]		
Overall Outcome			51–57	

[8] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

[9] As explained in Section II.H., we do not reach the challenge to claims 54 and 55 based on Steenfeldt-Jensen and Burroughs because the same claims are determined to be anticipated by and unpatentable over Burroughs.

[10] As explained in Section II.H., we do not reach the challenge to claims 51–53, 56, and 57 based on Moller because the same claims are determined to be anticipated by Steenfeldt-Jensen.

[11] As explained in Section II.H., we do not reach the challenge to claims 54 and 55 based on Moller and Burroughs because the same claims are determined to be anticipated by and unpatentable over Burroughs.

Motion to Amend Outcome	Claims
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	58–64
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	58–64
Substitute Claims: Not Reached	

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 51–56 of U.S. Patent No. 8,992,486 B2 have been shown, by a preponderance of the evidence, to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 82) is denied-in-part and dismissed-in-part;

FURTHER ORDERED that Patent Owner's Corrected Revised Motion to Amend (Paper 63) is denied; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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