

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner

Case No. IPR2018-01670
U.S. Patent No. 8,679,069

PATENT OWNER'S PRELIMINARY RESPONSE

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2001 Merriam-Webster’s Collegiate Dictionary	34
2003 McGraw-Hill Dictionary of Scientific and Technical Terms	33
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EXHIBIT LIST

Exhibit #	Description
2001	Press Release, “Mylan Enhances Partnership with Biocon through Strategic Collaboration for Insulin Products,” Feb. 13, 2013 (PR Newswire), available at http://newsroom.mylan.com/press-releases?item=122834
2002	Press Release, “Mylan Commences Phase III Clinical Trials for its Generic Version of Advair Diskus [®] and Insulin Analog to Lantus [®] ,” Sept. 16, 2014 (PR Newswire), available at http://newsroom.mylan.com/press-releases?item=123251
2003	Press Release, “Mylan and Biocon Present Clinical Data on Insulin Glargine at the American Diabetes Association’s 77th Scientific Sessions,” June 10, 2017 (PR Newswire), available at http://newsroom.mylan.com/2017-06-10-Mylan-and-Biocon-Present-Clinical-Data-on-Insulin-Glargine-at-the-American-Diabetes-Associations-77th-Scientific-Sessions
2004	Complaint for Patent Infringement, <i>Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie v. Merck Sharp & Dohme Corp.</i> , C.A. No. 1-16-cv-00812-RGA (D. Del.), Dkt. No. 1
2005	Stipulation and Proposed Order, <i>Sanofi-Aventis U.S. LLC v. Mylan, N.V.</i> , Civil Action No. 17-9105-SRC-SLW (D.N.J. Feb 5, 2018), Dkt. No. 45
2006	Complaint for Patent Infringement, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J. Oct. 24, 2017), Dkt. No. 1
2007	Excerpts from Defendants’ Invalidation Contentions, dated Jan. 25, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2008	Mylan GMBH’s Exhibit D to Invalidation Contentions, dated Jan. 25, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2009	Excerpts from Mylan GMBH’s Amended Invalidation Contentions, dated April 25, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2010	Mylan GMBH’s Exhibit D to Amended Invalidation Contentions, dated April 25, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)

Exhibit #	Description
2011	Aug. 13, 2018 Service of Sanofi's Responses to Mylan's Amended Contentions, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2012	MP4 file of Sanofi's Patented Pen animation
2013	Excerpts from McGraw Hill Dictionary of Scientific and Technical Terms (Sixth edition, McGraw-Hill 2003), p. 972 and 1873
2014	Excerpts from Merriam-Webster's Collegiate Dictionary (10th edition, Merriam-Webster, Inc. 2001), p. 538
2015	The New Oxford American Dictionary (Oxford University Press 2001), p. 789-90
2016	Excerpt from Joint claim construction statement, Ex. A, dated October 8, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2017	Excerpts from Transcript, Conference Call dated Aug. 2, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.) (confidentiality designation removed)
2018	Report of the Local Patent Rules Committee, Explanatory Notes for 2016 Amendments
2019	Defendants' Opposition to Plaintiffs' Motion to Stay dated Nov. 22, 2017, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 1:17-cv-00181-IMK (N.D. W. Va.), Dkt. No. 44
2020	Joint Proposed Discovery Plan dated Dec. 14, 2017, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2021	Letter from A. Calmann to Judge Waldor dated Apr. 24, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 2:17-cv-09105-SRC-CLW (D.N.J.), Dkt. No. 90
2022	Motion to Expedite Defendants' Motion Requesting an Expedited Scheduling Conference dated Nov. 22, 2017, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 1:17-cv-00181-IMK (N.D. W. Va.), Dkt. No. 46
2023	Initial Planning Meeting Report and Discovery Proposals dated Dec. 22, 2017, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 1:17-cv-00181-IMK (N.D. W. Va.), Dkt. No. 61

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2024	Transcript of Motion / Scheduling Conference dated Jan. 3, 2018, <i>Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.</i> , Case No. 1:17-cv-00181-IMK (N.D. W. Va.), Dkt. No. 64
2025	Transcript, Conference Call for Case IPR2018-01675, -01676, -01678, -01680 (P.T.A.B. Feb. 5, 2019)
2026	International Patent WO 99/38554
2027	Animation depicting Møller's first embodiment
2028	Animation depicting Møller's second embodiment

I. INTRODUCTION

The Board should decline to institute a trial on the Petition. Petitioner asserts the same invalidity grounds that will be decided in a co-pending litigation in district court before any final written decision is due here, and fails to demonstrate a reasonable likelihood of success that at least one challenged claim is unpatentable.

First, the Board should exercise its discretion to deny institution under 35 U.S.C. §§ 314(a) and 324(a), because Petitioner raises the same invalidity grounds here as it did nearly a year ago in a co-pending district court case that is on schedule for trial before the end of this year. *Sanofi-Aventis U.S. LLC v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.) (“District Court case”). The 069 Patent is listed in the FDA’s Orange Book as covering Patent Owner’s (“Sanofi”) insulin glargine prefilled pen drug product since 2014 and Petitioner identified the 069 Patent in its Paragraph IV notice served over a year before filing this Petition. Moreover, Sanofi previously asserted the 069 Patent in a related lawsuit against Merck. Petitioner has thus long had notice of the 069 Patent but waited until the eve of the one-year statutory deadline to file the Petition. Because of Petitioner’s own delay, the identical invalidity grounds raised in this Petition will be tried in the co-pending District Court case *before* a final written decision on this Petition will be due. In these circumstances, instituting an IPR trial would not

serve as a “quick and cost effective alternative[] to litigation,” but would rather subject Petitioner to defending the same arguments in different forums and be highly inefficient. H.R. Rep. No. 112–98, pt. 1, at 48 (2011). *See also NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 19-20 (P.T.A.B. Sept. 12, 2018) (“NHK Spring”). The Board should not permit duplicative attacks on the same claims using the same invalidity grounds that waste the Board’s and the parties’ resources. Thus, the Board should exercise its discretion to deny institution under §§ 314(a) and 324(a).

Second, Petitioner’s obviousness grounds should be denied because they fail to disclose certain limitations of the challenged claims. In Ground 1, Petitioner admits that its prior art reference, U.S. Patent No. 6,221,046 (“Burroughs”), does not disclose the required “helical groove” on an outer surface of a dose dial sleeve in a pen-type injector. Petition at 30. Despite acknowledging this shortcoming in Burroughs, Petitioner proposes a modification to Burroughs that similarly does not include a helical groove on the dose dial sleeve, which Petitioner arrives at by applying a fundamentally flawed interpretation of the term “helical” that is unsupported by the intrinsic evidence or the knowledge of a person of ordinary skill in the art (“POSA”). Moreover, Petitioner fails to offer any motivation to modify Burrough’s disclosure in the manner suggested by Petitioner.

In Ground 2, Petitioner concedes that Steinfeldt-Jensen fails to disclose a drive sleeve that engages with a piston rod via a threaded connection as required by the challenged claims. Petition at 55. Petitioner and its expert argue obviousness, but a POSA would not have been motivated to make Petitioner's proposed modification. The modification would result in an inferior (if not inoperable) device without any beneficial tradeoff.

In Ground 3, Petitioner relies Møller combined with Steinfeldt-Jensen. A POSA, however, would not have been motivated to combine Steinfeldt-Jensen's scale drum with Møller's injection pen, because Møller disparages and rejects Steinfeldt-Jensen's scale drum. Møller also fails to teach or render obvious a "drive sleeve" as required by claim 1 of the 069 Patent.

For these reasons, as detailed further below, Sanofi respectfully requests that the Board deny institution of *inter partes* review.

II. THE BOARD SHOULD EXERCISE ITS DISCRETION UNDER 35 U.S.C. §§ 314(A) AND 324(A) TO DENY INSTITUTION

The Board should exercise its discretion and deny the Petition under 35 U.S.C. §§ 314(a) and 324(a). It would waste the Board's finite resources and it is fundamentally unfair and inefficient to require Sanofi to defend an IPR where the final written decision will issue after the District Court has already resolved the same validity challenges.

Efficiently resolving patent challenges is foundational to the IPR system and the AIA generally. It is “an objective of the AIA . . . to provide an effective and efficient alternative to district court litigation.” *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16–17 (P.T.A.B. Sept. 6, 2017) (precedential); *see also Microsoft Corp. v. Koninklijke Philips N.V.*, IPR2018-00277, Paper 10 at 7 (P.T.A.B. June 8, 2018) (explaining that “AIA proceedings ‘are not to be used as tools for harassment....Doing so would frustrate the purpose of the section as providing quick and cost effective alternatives to litigation’” (quoting H.R. Rep. No. 112-98, pt. 1, at 48 (2011))). This purpose is frustrated when, as here, a party delays filing a petition such that the IPR, if instituted, would result in a final written decision only after the overlapping validity issues have been resolved by a district court. *See NHK Spring*, IPR2018-00752, Paper 8.

The Board has also recognized “the potential for abuse of the review process by repeated attacks on patents” in deciding to exercise its discretion under §§ 314(a) and 324(a). *See Gen. Plastic*, IPR2016-01357, Paper 19 at 16-17. Here, Petitioner has filed its petition on the 069 Patent not as “an effective and efficient alternative to district court litigation,” *id.*, but instead in an inefficient and intentionally staggered attempt to challenge the same claims on the same prior art in different forums.

A. Procedural Background

Petitioner and its identified real-party-in-interest, Biocon, entered a collaboration to develop and commercialize a follow-on insulin glargine product in 2013 (Ex. 2001), commenced clinical trials by 2014 (Ex. 2002), and announced the results of those trials by June 10, 2017 (Ex. 2003). By then, Sanofi had already asserted the 069 Patent against another competitor seeking approval of follow-on glargine products. *See* Ex. 2004 at 12.

Relatedly, the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") has listed the 069 Patent since 2014 as covering Sanofi's Lantus® SoloSTAR® product (*i.e.*, Sanofi's insulin glargine formulation and injector pen device). Thus, Petitioner was long on notice of the 069 Patent, and that Sanofi was enforcing it against competitors.

On April 27, 2017, Petitioner submitted its application to market its follow-on insulin glargine product to the FDA. As required by the rules governing follow-on drug applications, 21 U.S.C. § 355(b)(2) & 3; 21 C.F.R. §§ 314.50(i) & 314.52, Petitioner sent Sanofi a letter dated September 15, 2017 that noticed Petitioner's FDA application and contained so-called "Paragraph IV" certifications alleging that the 069 Patent's claims are "not valid, unenforceable, and/or will not be infringed" by Petitioner's proposed glargine product. *See* 21 U.S.C. § 355(b)(3)(b)(ii); 21 C.F.R. § 314.50(i)(1)(i)(A)(4). On October 24, 2017 Sanofi sued Petitioner for patent infringement, asserting the 069 Patent, among others.

Under the Hatch-Waxman Act, Sanofi's District Court case against Petitioner triggered a 30-month stay during which the FDA will not approve Petitioner's follow-on application absent a District Court victory for Petitioner. *See* 21 U.S.C. § 355(c)(3)(C). In the District Court case, Petitioner served invalidity contentions on Sanofi on January 25, 2018 (further amended on April 25, 2018) that included the same prior art, asserted against the same claims, as in the Petition. *See* Section II.C.2., *infra*.

On August 13, 2018 (approximately a month before filing the Petition), Petitioner received and reviewed Sanofi's detailed validity contentions responding to these prior art arguments. Despite long having notice of the 069 Patent and its assertion against Petitioner, it was not until September 10, 2018—the eve of the one-year statutory bar—that Petitioner filed nine Petitions, including this one, asserting substantially the same invalidity grounds it alleged in the District Court case. *See* IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-1696, IPR2019-00122.

Concurrently, the parties have been actively litigating the District Court case. A *Markman* hearing is scheduled for March 22, 2019, and the parties have jointly requested an October 2019 trial to resolve the issues before the FDA's 30-month stay of regulatory approval of Petitioner's FDA application ends on March

18, 2020. *See* Ex. 2005, ¶ 8 (“The parties hereby agree to jointly request the Court to schedule trial in the Action in October 2019”). As discussed below, even if the trial occurs later in 2019 or early 2020, the parties and the District Court have firmly committed to resolving the District Court case, including invalidity, before March 2020, when the 30-month stay expires and the so-called “transition date” occurs. This “transition date” is unique to the insulin space and is the date in March 2020 when insulins will be governed by the biologics statute (BPCIA) and no longer by the Hatch-Waxman Act.

Accordingly, the District Court case will resolve well before the June 2020 due date for a final written decision in this IPR if a trial were to be instituted.

B. The Board Has Discretion to Deny Institution Under 35 U.S.C. §§ 314(a) and 324(a)

The Board has discretion under §§ 314(a) and 324(a) to deny institution. *See* August 2018 Update to the Office Patent Trial Practice Guide at 8 (Aug. 13, 2018) (“2018 Update”). This “discretion is informed by 35 U.S.C. §§ 316(b) and 326(b), which require the Director to ‘consider the effect of any such regulation [under this section] on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter.’” *Id.* at 9. In discussing this discretion, the 2018 Update recognizes that the “AIA was ‘designed to establish a more efficient and streamlined patent system that will improve patent quality and limit

unnecessary and counterproductive litigation costs.” *Id.* (citing H.R. Rep. No. 112-98, pt. 1, at 40 (2001), 2011 U.S.C.C.A.N. 67, 69). Indeed, the Board has exercised its discretion to deny institution on facts substantially similar to those before this Board. *See NHK Spring*, IPR2018-00752, Paper 8.

C. *NHK Spring Co. v. Intri-Plex Technologies, Inc.*, IPR2018-00752

In *NHK Spring*, like the instant case, (1) the parties were engaged in advanced district court litigation on the same patent, (2) the petitioner was relying on the same prior art in the petition as in the litigation, and (3) the district court trial would conclude before the IPR. *See NHK Spring*, IPR2018-00752, Paper 8. The Board denied institution, reasoning that “instituting a trial under the facts and circumstances here would be an inefficient use of Board resources,” and “would not be consistent with ‘an objective of the AIA . . . to provide an effective and efficient alternative to district court litigation.’” *Id.* at 20.

Given the near-identical circumstances¹ with *NHK Spring*, the Board should use its discretion to reach the same outcome here: it would be an inefficient use of Board resources to institute this IPR.

¹ Because the *NHK Spring* patent was expired, both the Board and District Court applied the *Phillips* standard for claim construction. Here, however, the 069 Patent is not expired and thus the Board will apply the BRI standard. This is a distinction

1. The parties are engaged in district court litigation on the same patent

In *NHK Spring*, the challenged patent was asserted by the patent owner against the petitioner in a co-pending District Court case. *NHK Spring*, IPR2018-00752, Paper 8 at 19. Here, too, the 069 Patent is asserted by Sanofi against Petitioner in *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW, filed October 24, 2017. *See* Ex. 2006.

2. Petitioner relies on the same prior art in the Petition as in the District Court case

In denying institution under § 314(a), the Board in *NHK Spring* noted that “Petitioner relies on the same prior art ... and arguments in its district court invalidity contentions as asserted in the Petition.” *NHK Spring*, Paper 8 at 19. Here, Petitioner asserts that claim 1 is obvious over Burroughs, Steinfeldt-Jensen, and Møller with Steinfeldt-Jensen. Petition at 3. Similarly, in the District Court case, Petitioner served invalidity contentions alleging, *inter alia*, that Burroughs, Steinfeldt-Jensen, and Møller with Steinfeldt-Jensen render obvious claim 1 of the 069 Patent (*see* Ex. 2007 at 26-27, 29-30, 209, 211-212, 214-215, 222-223, 224-

without a difference, however, because Petitioner does not contend that the grounds rely on any constructions that would be different under the two standards. Indeed, Petitioner cites *Phillips* to support its constructions. Petition at 15.

228, 235-238, 239, 242, 243-244, 250-251, 253-255, 256, 260-265, 266-267; Ex. 2008 at 16-17, 20-21, 27-28, 49-50, 53-58, 77-78, 81-83, 96-98, 115-119, 134-136, 137-139; Ex. 2009 at 40-42, 44-45, 284, 287-288, 291-292, 298-304, 312-316, 320-322, 329-330, 332-334, 335, 339-345, 346-353; Ex. 2010 at 16-17, 20-21, 28, 29, 49-50, 53-58, 78-80, 82-84, 98-100, 117-119, 120-121, 137-139, 141-143).

Further, Petitioner has purported to reserve the right in the District Court case to rely on certain “exemplary combinations that it may be more likely to rely on” as allegedly rendering the 069 Patent obvious, including Burroughs alone, Steinfeldt-Jensen alone, and Møller with Steinfeldt-Jensen. *See* Ex. 2007 at 266-267 (“Steenfeldt-Jensen, alone or in combination with...”; “Burroughs, alone or in combination with...”); Ex. 2009 at 348 (“Steenfeldt-Jensen, alone or in combination with ... Møller, ...”; “Burroughs, alone or in combination with...”; “Møller, alone or in combination with ... Steinfeldt-Jensen, ...”).

Thus, as in *NHK*, the same prior art combinations used in the IPR grounds are used in the litigation between the parties.² *See NHK Spring*, Paper 8 at 19-20.

² Moreover, this Petition is one among *nine petitions* filed by Petitioner that assert substantially the same arguments being litigated in the District Court case. *See* IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-1696, IPR2019-00122.

3. Trial in the District Court case will conclude before the IPR

When the Board in *NHK Spring* issued its decision, the district court proceeding was “nearing its final stages” with trial just over six months away. *Id.* at 1 (decision entered September 12, 2018), 20 (noting a March 25, 2019 trial date). The Board noted that the IPR trial “on the same asserted prior art will not conclude until September 2019,” approximately six months after the March 2019 trial date. *Id.* at 20.

The circumstances here are no different. In the District Court case, Petitioner and Sanofi jointly requested an October 2019 trial. *See* Section II.A. The Magistrate Judge in the District Court case has recognized the importance of resolving Petitioner’s validity challenges well before the 30-month stay ends. *See, e.g.,* Ex. 2017 at 6:17-24 (encouraging parties to resolve their disputes to maintain the October trial date). The District Court Judge—Judge Chesler—has presided over 50 Hatch-Waxman cases and chairs the Local Patent Rules Committee for the District of New Jersey. Ex. 2018 at 2. In 2016, that committee amended New Jersey Local Patent Rule 2.1 to require parties in Hatch-Waxman cases to address the 30-month stay in their initial case planning conference and joint discovery plan, explaining that the rule was amended “to expedite matters.” *Id.* at 1. Thus, even if the trial occurs later in 2019 or early 2020, there is no basis to suggest that the

District Court will not resolve all of the issues in this case, including validity, before the March 2020 transition date and expiration of the stay.

Here, a Final Written Decision on the same prior art would not be due until June 2020, eight months after the likely District Court case trial date. Thus, as the Board found in *NHK Spring*, instituting an IPR trial “ultimately would be inefficient.” *NHK Spring*, Paper 8 at 19-20.

4. Instituting the IPR permits Petitioner a tactical advantage

In *NHK Spring*, the patent owner argued that the petitioner waiting to file the petition until shortly before the one-year deadline expired is a factor favoring denial of institution. The Board disagreed, but stated that “the Patent Owner does not apprise us of any tactical advantage, or opportunity for tactical advantage, that the Petitioner gained by waiting to file the Petition.” *NHK Spring*, Paper 8 at 19. In contrast, here Petitioner waited to file the Petition until after it obtained Sanofi’s detailed validity positions in response to Petitioner’s invalidity contentions (as explained in Sections II.A. and II.C.2.). Petitioner seeks the proverbial two bites at the apple. If Petitioner loses at trial, Petitioner is asking this Board to revisit the very same validity issues a second time.

This gamesmanship is highly prejudicial to Sanofi, and antithetical to the statutory purpose of IPRs, which is to provide a “quick and cost effective *alternative*[] to litigation”. H.R. Rep. No. 112–98, pt. 1, at 48 (2011) (emphasis

added). Petitioner was fully aware of the District Court case timing and elected to file its Petition at the eleventh hour, despite having asserted invalidity contentions in the District Court case based on the same prior art at least as early as January 25, 2018. *See, e.g., Ex. 2007* at 266-267. In these circumstances, Sanofi respectfully submits that the Board should exercise its discretion to deny institution.

D. General Plastic Industrial Co. v. Canon Kabushiki Kaisha, IPR2016-01357

NHK Spring cites to *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (P.T.A.B. Sept. 6, 2017) (precedential as to § II.B.4.i) (“*Gen. Plastic*”). In *General Plastic*, the Board developed a set of non-exclusive factors to determine whether discretionary denial is appropriate. *Gen. Plastic*, Paper 19 at 9-10. These factors likewise support denial of institution, as explained below.

While the *General Plastic* factors were articulated in the context of denying a follow-on petition, the Board has recognized that the logic underlying these factors is applicable in other contexts. *See NetApp, Inc. v. Realtime Data LLC*, IPR2017-01195, Paper 9 at 10 (P.T.A.B. Oct. 12, 2017) (applying the *General Plastic* factors where different petitioners filed petitions on the same patent); *see also* August 2018 Trial Practice Guide Update at 10 (“The *General Plastic* factors are also not exclusive and are not intended to represent all situations where it may be appropriate to deny a petition.”).

1. ***General Plastic* Factors 1, 2, 4, and 5: Whether the same petitioner previously filed a petition directed to the same claims of the same patent; whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it; the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition; whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent**

The logic of factors 1, 2, 4, and 5 is applicable to the present situation even though the factors were articulated in the context of a follow-on petition. Here, rather than a follow-on petition, Petitioner is duplicating invalidity arguments in the District Court case and the IPRs. Factors 1, 2, 4, and 5 favor denying institution.

First, Petitioner asserts invalidity challenges to the same claims of the 069 Patent using the art it identified both here and in the District Court case. *See* Sections II.A. and II.C.2., *supra*.

Second, Petitioner was aware of the prior art asserted in the Petition at least as early as January 25, 2018, when it served its invalidity contentions in the District Court case, and indeed much earlier when it filed its Paragraph IV notice asserting invalidity of the 069 Patent.³ Ex. 2007. Yet Petitioner waited to file its

³ The prior art asserted in the Petition is also listed on the face of the 069 Patent.

Petition until the eve of the one-year deadline under § 315(b), approximately a month after it received Sanofi's response to Petitioner's amended invalidity contentions. *See* Ex. 2011. As a result, a final written decision is not due until June 2020, well after the requested October 2019 trial on the same prior art.⁴ Instituting trial therefore will not "limit unnecessary and counterproductive litigation costs" (H.R. Rep. No. 112-98, pt. 1, at 40), but will instead unfairly subject Sanofi to defending "repeated attacks on patents." *Gen. Plastic*, Paper 19 at 16-17.

Third, Petitioner's late filing after receiving Sanofi's response to Petitioner's invalidity contentions in the District Court case provides an unfair tactical advantage to Petitioner, to Sanofi's prejudice, by providing Petitioner two bites at the apple. *See* Sections II.A. and II.C.2., *supra*.

Because Petitioner is asserting invalidity against the same claims here as in the District Court case using the same art identified in the District Court case and was aware of the art but chose to delay filing this Petition for a tactical advantage, these factors favor denial.

⁴ Notwithstanding the parties' trial date request, the District Court has indicated that it will render a judgment on validity before the 30-month stay on Petitioner's FDA application expires – *i.e.*, before March 18, 2020. *See* Section II.C.3, *supra*.

2. General Plastic Factor 3: whether at the time of filing of the second petition the petitioner already received the patent owner’s preliminary response to the first petition or received the Board’s decision on whether to institute review in the first petition

The Board has recognized that “Factor 3 is directed to situations in which a petitioner delays filing a subsequent petition so that it can tailor its arguments to address issues identified by the patent owner and/or the Board during a prior proceeding.” *NetApp*, Paper 9 at 11 n.12. This focus is equally applicable here. Petitioner delayed filing its Petition until it had Sanofi’s responses to Petitioner’s invalidity positions in the District Court case. Indeed, Petitioner was able to tailor the Petition to address issues identified by Sanofi in its responses. This factor thus also favors denial.

3. General Plastic Factors 6 and 7: the finite resources of the Board; and the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review

These final two factors also favor denial, because Petitioner asks the Board to institute and conduct a proceeding on validity issues that will be decided in the District Court case well before a final written decision is due. The parties jointly requested an October 2019 trial, but even if the trial does not take place in October 2019, validity will very likely be decided no later than March 18, 2020 (*i.e.*, before the 30-month stay on Petitioner’s FDA application ends). By contrast, the final written decision for the Petition would not be due until June 2020, after the District

Court has tried and decided validity with respect to the art identified in both proceedings. Moreover, this Petition is one of *nine petitions* that Petitioner has filed asserting substantially the same arguments that are currently being litigated in the District Court case on four device patents. *See* IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-1696, IPR2019-00122. Thus, this factor weighs in favor of denial because the Board’s finite resources should not be spent on proceedings that will ultimately be moot.

* * *

All of the *General Plastic* factors favor denial. This Petition is the antithesis of the “effective and efficient alternative to district court litigation” contemplated by the AIA and the Board. It is nothing more than a duplicative effort to test the same invalidity theories in two forums. Institution should be denied.

E. Petitioner’s Arguments Against Discretionary Denial Are Inapposite

In IPR2018-01675, Petitioner submitted a reply brief to Sanofi’s Preliminary Response setting forth Petitioner’s arguments against the Board exercising its discretion to deny institution. *See* IPR2018-01675, Paper 16 (“Reply”). Petitioner’s reply arguments misstate and misapply the law and consistently fail to analyze the appropriate factors as set forth in Sections II.C and D above. For these

reasons and those discussed below, Petitioner’s reply arguments fail to show that denial under § 314(a) would be inappropriate here.

1. The Board Has Discretion To Deny A Timely Filed Petition

a) *Click-to-Call* Does Not Limit The Board’s Discretion In This Case

Relying on the Federal Circuit’s decision in *Click-to-Call Tech., LP. v. Ingenio, Inc.*, 899 F.3d 1321 (2018), Petitioner asserts that the Board lacks discretion to deny IPR petitions that are timely filed within the one-year statutory time period after service of a complaint. Reply at 4-7. This argument fails for several reasons.

First, it is beyond dispute that “the agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.” *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016). Indeed, Petitioner admits that the Director has such discretion under § 314(a). Reply at 5.

Second, Petitioner’s reliance on *Click-to-Call* is misplaced. *Click-to-Call* did not address the Board denying a timely-filed IPR petition. Rather, in *Click-to-Call* a petition was filed *after* the one-year statutory bar, but the Board nonetheless *instituted* review because the complaint had been voluntarily dismissed without prejudice. *Click-to-Call*, 899 F.3d at 1326-27. The Federal Circuit reversed, finding that the Board exceeded its authority. *Id.* at 1325. *Click-to-Call* merely stands for the proposition that the Board cannot use its discretion to *institute*

review on a petition that was filed *after* the expiration of the one-year statutory period and not that compliance with the one-year bar is *sufficient* to compel institution.

b) The Legislative History Relating to “Workload” Denials Is Irrelevant

Petitioner also cites legislative history concerning a “safety valve” provision that “allows the Office to decline to institute further proceedings if a high volume of pending proceedings threaten the Office’s ability to timely complete all proceedings.” 157 Cong. Rec. S1360, 1377 (Mar. 11, 2018); Reply at 10-12. According to Petitioner, because the Director has not implemented a regulation establishing such a safety valve, the requested discretionary denial in this case exceeds the Director’s authority. Reply at 10-12. Sanofi, however, has not asked the Board to deny institution on the ground that the Board would be overwhelmed by its workload. As set forth in Sections II.C and D, Sanofi seeks discretionary denial based on the timing of the petition and the duplicative grounds before the Board and the District Court. This provides Petitioner with an unfair strategic advantage while also rendering it unlikely that the Board will rule on the proposed grounds before the District Court. The result is inefficient and duplicative abuse of the Board’s and the District Court’s resources, *regardless of whether the Board is*

*overwhelmed by its current workload.*⁵ Petitioner’s arguments based on the “safety valve” legislative history are therefore irrelevant.

2. Discretionary Denial Would Not Violate the APA

Petitioner argues that discretionary denials under § 314(a) would invite “procedural shenanigans” by violating the Administrative Procedure Act’s (“APA”) notice requirements. Reply at 8-10. Petitioner relies on 5 U.S.C. § 552(a), which requires administrative agencies to publish in the Federal Register certain information, including rules of procedure, substantive rules of general applicability, and statements of general policy or interpretations of substantive rules of general applicability formulated by the agency. 5 U.S.C. § 552(a)(1). It also requires agencies to make all final opinions and orders available for public inspection in electronic format. 5 U.S.C. § 552(a)(2). Here, the Board has complied with these requirements and a denial would not violate the APA.

⁵ Petitioner cites no authority suggesting that the delegation of authority to the Director to establish a “safety valve” for circumstances in which there is a high volume of proceedings otherwise eliminates the Board’s discretion, recognized by the Supreme Court, to deny a petition for other reasons. *Cuozzo*, 136 S. Ct. at 2140.

As Petitioner admits, the 2018 Update to the Office Trial Practice Guide sets forth the *General Plastic* factors discussed in Section II.D, above, and informs parties that “[t]here may be other reasons besides the ‘follow-on’ petition context,” such as “events in other proceedings related to the same patent, either at the Office, in the district courts, or the ITC,” that “favors denying a petition even though some claims meet the threshold standards for institution under 35 U.S.C. §§ 314(a), 324(a).” 2018 Update at 10. The Board complied with § 552(a)(1)’s requirements by publishing a notice in the Federal Register on August 13, 2018 announcing the release of the 2018 Update and providing the URL at which the update could be obtained. 83 Fed. Reg. 39,989-01 (Aug. 13, 2018).

Similarly, the Board complied with § 552(a)(2) by making its *General Plastic* and *NHK Spring* decisions – as well its other non-confidential decisions – available online. See PTAB Standard Operating Procedure 2 (Revision 10) at 2-3.

Petitioner also complains that the 2018 Update “does not elaborate on what those other considerations [for discretionary denial] may be, imposes no actual requirement, and does not account for *Click-to-Call*,” and that both the 2018 Update and *NHK Spring* are not binding. Reply at 8. Petitioner cites no authority, however, requiring further elaboration beyond the guidance provided in the 2018 Update. Moreover, the 2018 Update cites *NetApp, Inc. v. Realtime Data LLC*, Case IPR2017-01195, Paper 9 at 12-13 (P.T.A.B. Oct. 12, 2017) as an example of

the Board denying institution under § 314(a) “where, due to petitioner’s delay, the Board likely would not have been able to rule on patentability until after the district court trial date.” 2018 Update at 10-11. Thus, Petitioner clearly had notice that the interplay between the time limit for issuing a final written decision under 35 U.S.C. § 316 and the district court trial date is one of the “other considerations” relevant to the Board’s discretion under § 314(a).

Petitioner’s reliance on *Click-to-Call* is similarly misplaced. As discussed in Section E.1, *Click-to-Call* does not address the Board’s discretion in these circumstances, and therefore there was no reason for the 2018 Update to “account for” the decision. And, in asserting that the 2018 Update and *NHK Spring* are not binding and that Petitioner “complied with all then-applicable statutes and rules,” Petitioner again confuses a necessary condition with a sufficient one. Clearly, compliance with all applicable statutes and rules is necessary for instituting an IPR. It is equally clearly not *sufficient* to secure institution; if it were, it would not be the case that “the agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.” *Cuozzo*, 136 S. Ct. at 2140.

For the reasons discussed above, Petitioner’s contention that discretionary denial would violate the APA fails.

3. The District Court Case Will Be Tried By March 2020

As discussed in Section II.C.3, *supra*, the District Court is committed to resolving the District Court case, including Petitioner’s invalidity defenses, well before the BPCIA transition date and the expiration of the 30-month stay in March 2020. Petitioner’s assertion that the “district-court timeline is speculative” can therefore be rejected, especially given that Petitioner has consistently urged a trial before March 2020. From the outset of the District Court case in October 2017, Petitioner has demanded an expeditious trial of validity and infringement well in advance of March 2020, when the 30-month stay expires and the “transition date” occurs. Indeed, Petitioner has repeatedly asserted that “the transition date makes the timeline in this case *more urgent than in a typical Hatch-Waxman case.*” Ex. 2019 at 1 (emphasis added); *see also* Ex. 2020 at 19 (“[i]n view of the unique issues in this case relating to regulatory approval and the BPCIA, the timeline in this case is more urgent than in a typical Hatch-Waxman case.”); Ex. 2021 at 1 (“[T]his case presents a unique timing issue that requires diligent adherence to litigation timelines sufficient to allow the Court plenty of time to issue a decision prior to the expiration of the FDA’s 30-month stay.”).

Thus, Petitioner initially sought to have the case resolved in West Virginia rather than New Jersey, asserting that “[i]t is vital to Defendants’ interests that this case proceed as quickly as possible.” Ex. 2022 at 1; Ex. 2023 at 7-8 (“[T]here is a

heightened need to efficiently litigate this case to allow the Court sufficient time to issue a decision prior to the expiration of the stay in this matter.”); *id.* at 12 (“[T]he timeline in this case is more urgent than in a typical Hatch-Waxman case”).

In deciding to stay the West Virginia action and allow the case to proceed in New Jersey, the West Virginia District Court Judge specifically recognized that the District of New Jersey and Judge Chesler were known to resolve Hatch-Waxman cases expeditiously and in advance of stay expiration:

I really would be out of my league to suggest that the judges—the district judges in New Jersey can’t efficiently handle a pharmaceutical patent case like this and in my years on the Bench, I have bowed to their knowledge and experience in patent work generally. . . . [T]he court has a long standing history of experience trying these cases. ***I have no reason to believe that the District Judge in New Jersey, Judge Chesler, will not make a decision on this as quickly as is reasonable.***

Ex. 2024 at 31:15-32:3 (emphasis added). Petitioner agreed to proceed in New Jersey on the condition that the parties jointly propose an October 2019 trial date.

Ex. 2005, ¶ 8. As discussed in Section II.C.3, Sanofi agreed to the proposed October 2019 trial date, and regardless of the ultimate trial date, the District Court has recognized the importance of resolving the case before the 30-month stay ends in March 2020. Thus, there is no basis to suggest that the District Court case will not resolve the validity issues here before March 2020.

4. Exercising Discretion in This Case Will Not Broadly Impact Hatch-Waxman Litigants

Petitioner claims that Sanofi's arguments for denial would create a "sector-specific nullification of § 315(b) for ANDA suits" by purportedly preventing all ANDA defendants from using the full one-year statutory period to file an IPR. This argument fails because it completely mischaracterizes Sanofi's argument. Sanofi is not advocating a *per se* denial of any IPR where a final written decision would not issue until after the conclusion of an accompanying district court trial. Rather, Sanofi requests the Board to exercise its discretion to deny institution on the unique and specific facts present here.

Petitioner's argument is refuted by Petitioner's own repeated assertions in District Court that "the unique issues in this case relating to regulatory approval and the BPCIA, the timeline in this case is more urgent than in a typical Hatch-Waxman case." Ex. 2020 at 19. These "unique issues" include the transition date, discussed above, and the commitment by the parties and the court to resolve the case in advance of the March 2020 30-month stay expiration and the transition date. In addition, Petitioner asserts the same invalidity grounds in the Petition and the District Court, which results in unnecessary, duplicative litigation in two forums. *See NHK Spring*, IPR2018-00752, Paper 8. These case-specific circumstances arise from Petitioner's selection of invalidity grounds and the timing of the petitions relative to the District Court case.

These facts warranting discretionary denial are specific to this case and are not unique to Hatch-Waxman cases. Indeed, *NHK Spring* did not concern Hatch-Waxman. Thus, it is Petitioner that improperly seeks “sector-specific” treatment for Hatch-Waxman cases by asking the Board to exempt such cases from the Board’s discretion under § 314 and *NHK Spring*.

5. Petitioner Asserts The Same Prior Art Grounds Before The Board And The District Court

Perplexingly, Petitioner argues that because its invalidity contentions in the District Court litigation assert obviousness based on the grounds asserted in the Petition in addition to numerous *other* combinations and grounds, it is not asserting the “same” prior art grounds as in the Petition. Reply at 1-2. The dispute turns on whether the additional asserted grounds in the District Court case render *NHK Spring* inapplicable. They do not.

Petitioner’s unduly narrow reading of *NHK Spring* to require total identity of the asserted prior art grounds is undermined by the facts of *NHK Spring* itself. In *NHK Spring*, the petition asserted anticipation by U.S. Patent No. 5,689,389 (“Braunheim”), obviousness based on Braunheim alone, and obviousness based on Braunheim and Applicant Admitted Prior Art. *NHK Spring*, Paper 8 at 5. NHK’s district court invalidity contentions also included prior art grounds based on “an IPT base plate product (IPT Swage Mount Model No. 15030-02) that they discovered by ordering and searching the file history of a patent different from the

Patent-in-Suit,” and invalidity grounds based on “certain subject matter derived from ‘HTI.’” *Intri-Plex Techs., Inc. v. NHK Int’l. Corp.*, Case No. 17-cv-01097-EMC (EDL), Dkt. No. 167 at 4 (N.D. Cal. Jan. 15, 2019). NHK also asserted invalidity based on indefiniteness before the district court. *Intri-Plex*, 17-cv-01097-EMC (EDL), Dkt. No. 123 (N.D. Cal. June 18, 2018). Thus, the factors the Board analyzed in *NHK Spring* do not require exact identity of invalidity grounds between the Board and the District Court case. Because there is no dispute that Petitioner is asserting obviousness based on grounds that are in both the Petition and the District Court case, Petitioner’s argument regarding the same prior art grounds fails.

Petitioner also contends that because its District Court invalidity positions have not “been developed” to the same degree as its IPR arguments, it is not clear that the District Court ultimately will decide the same issues. Ex. 2025 at 13:10-14:3. But the degree to which the corresponding District Court argument had “been developed” was not a factor in *NHK Spring*. Moreover, Petitioner has never affirmed to the Board, in any of the nine proceedings that it filed, that it will *not* continue to assert the same grounds against the challenged claims in the District Court case. Nor has Petitioner affirmed that it will ultimately present a *different* obviousness theory based on the same prior art to the District Court, or even suggested how it *could* present different, non-overlapping obviousness theories to

the Board and the District Court based on the same prior art. Thus, even accepting *arguendo* Petitioner’s claim that the invalidity arguments in the District Court case are not fully developed, Petitioner has provided no assurances that it will not invite the District Court to adjudicate the same invalidity grounds after receiving an institution decision in this proceeding.⁶ It therefore remains that the invalidity grounds asserted in the Petition are still asserted in the District Court case, and instituting a trial would result in duplicative litigation over the same grounds, with the District Court case resolving before the Board’s final written decision.

6. Petitioner’s Arguments Regarding Multiple Petitions Are Inapposite

Petitioner also argues that a discretionary denial in this case “for timely filing multiple petitions within the AIA timeframe would penalize Mylan for Sanofi’s litigation decision to assert multiple patents against Mylan in district court.” Reply at 3. This argument misses the mark. It is not the volume of the petitions that merits denial, but the fact that each petition seeks a second bite at duplicative invalidity grounds and provides a tactical advantage to Petitioner

⁶ Given that Petitioner can still tailor its District Court invalidity grounds to address weaknesses identified in Sanofi’s Preliminary Response or the institution decision, the potential for further tactical advantage also merits denial.

resulting from being filed after Petitioner had received Sanofi's validity contentions in the District Court case. *See* Section II.C, *supra*.

III. THE 069 PATENT

The 069 Patent describes improved pen-type injectors for medications. Ex. 1001, 1:13-17. The figures below depict an embodiment of an improved injection pen. Additionally, an animation of the embodiment's operation is submitted as Ex. 2012.

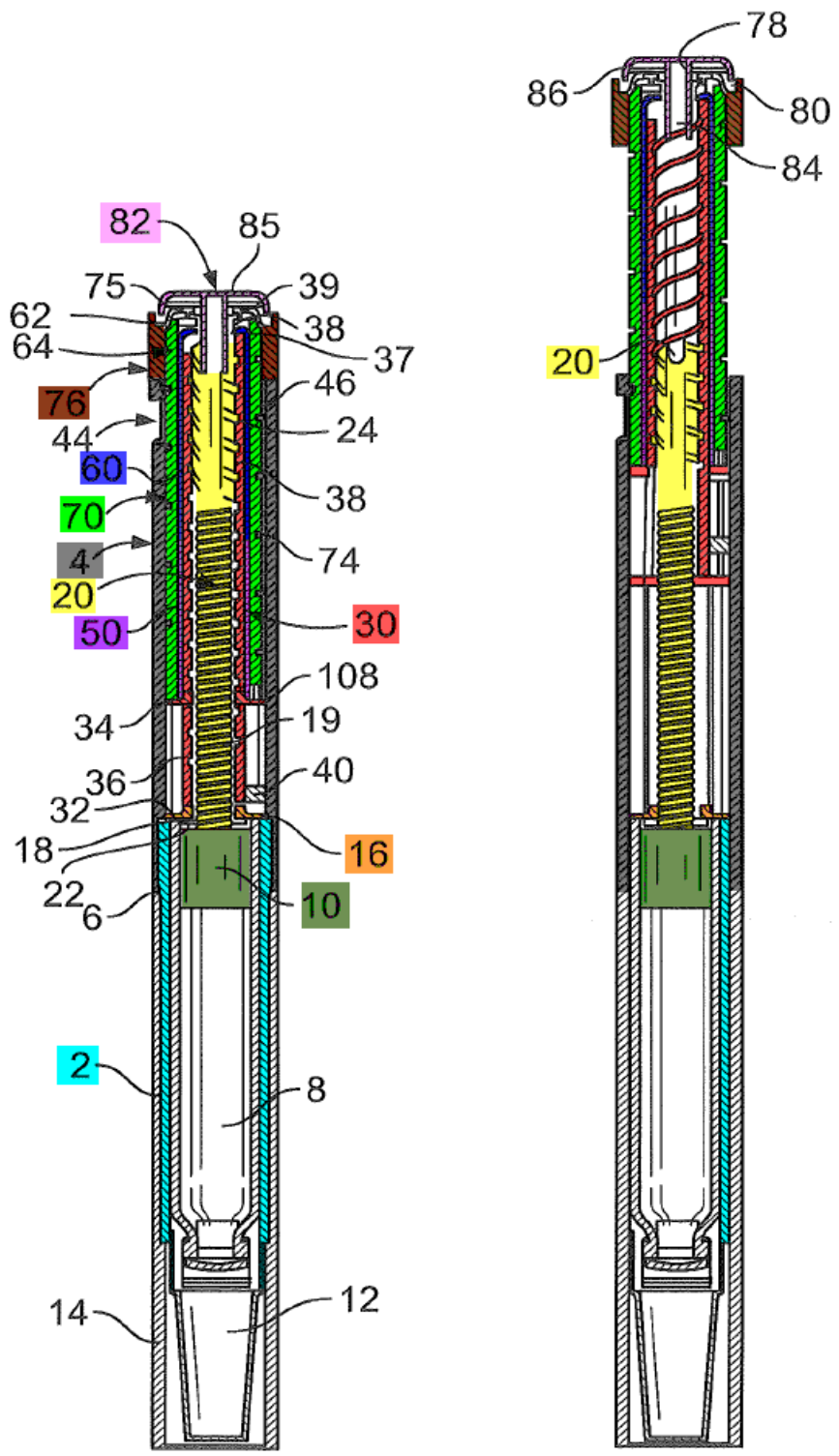


FIG. 1

FIG. 2

Ex. 1001, Figs. 1 and 2 (highlighted).

The injection pen of the above shown embodiment comprises a cartridge retaining part 2 (light blue), an internally threaded main housing 4 (grey), a medicament cartridge 8, a cartridge piston 10 (dark green), an insert 16 (orange), a piston rod 20 (yellow), a drive sleeve 30 (red), a clicker 50 (purple), and clutch 60 (dark blue), an externally-grooved dose dial sleeve 70 (light green), a dose dial grip 76 (brown), and a button 82 (pink). The injection pen includes a window 44 in the main housing 4 that indicates the selected dosage to the user.

IV. CLAIM CONSTRUCTION

Petitioner alleges that “claim terms should be given their ordinary and customary meaning, consistent with the specification and how they would have been understood by the POSA.” Petition at 15. Yet Petitioner does not articulate what the plain and ordinary meaning is for any terms. Petitioner also states that, “Patent Owner Sanofi has taken positions regarding the meaning of certain claim terms, which it cannot now argue are unreasonable,” and lists constructions from a preliminary claim construction disclosure in the District Court case (Ex. 1019). Petition at 15-16. It is unclear, however, whether Petitioner has adopted the preliminary claim constructions from the District Court case for purposes of the Petition. In any event, for purposes of this Preliminary Response, Sanofi believes it is only necessary to address the construction of “helical groove.”

Petitioner additionally addresses the “clutch” limitation as a means-plus-function limitation. Petition at 16-17. Sanofi disputes Petitioner’s contention that this terms should be construed as a means-plus-function term.⁷

A. “helical groove” (claim 1)

Challenged claim 1 requires a “helical groove” provided along an outer surface of the claimed dose dial sleeve. A POSA reading the claims in light of the specification, and applying a POSA’s knowledge, would have understood the phrase “helical groove” to mean a groove formed in the shape of a spiral. Petitioner proffers no construction for this term.

The 069 Patent specification supports this understanding. Specifically, the 069 Patent identifies the helical groove by reference numeral 74. Ex. 1001, 4:51-52. As shown in Figures 12-14 below, the helical groove 74 (in red) is depicted as a spiral-shaped groove in the outer surface of the dose dial sleeve 70.

⁷ Sanofi reserves the right to address the construction of all other terms should the Petition be instituted.

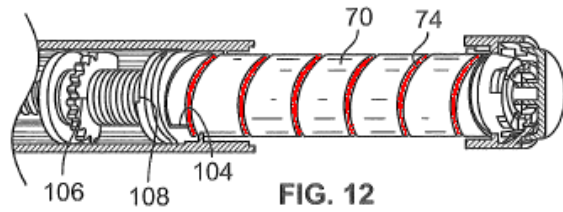


FIG. 12

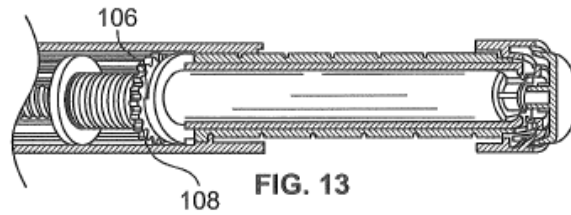


FIG. 13

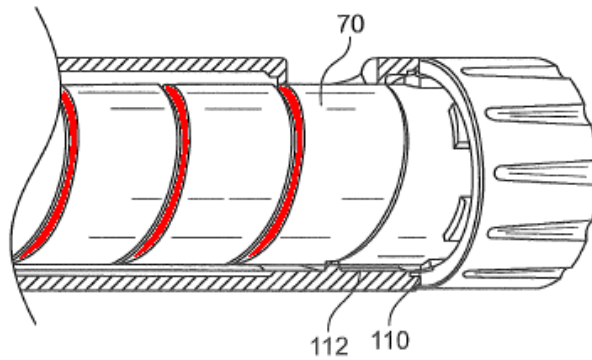


FIG. 14

Ex. 1001, Figs. 12 – 14 (highlighted).

This understanding is further demonstrated by contemporaneous technical and general purpose dictionaries, which consistently define “helical” as connoting a structure formed in the shape of a spiral. The 2003 McGraw-Hill Dictionary of Scientific and Technical Terms, for example, defines “helical” as “pertaining to a *cylindrical spiral*, for example, a screw thread.” Ex. 2013 at 10 (emphasis added).

It further provides the following illustration of a screw thread, clearly depicting a spiral-shaped ridge formed on a cylindrical core:

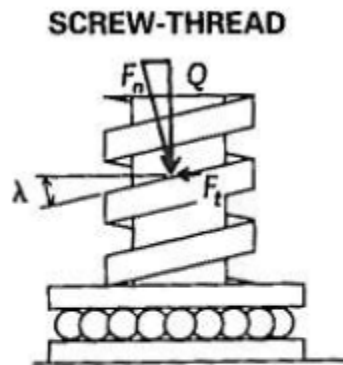
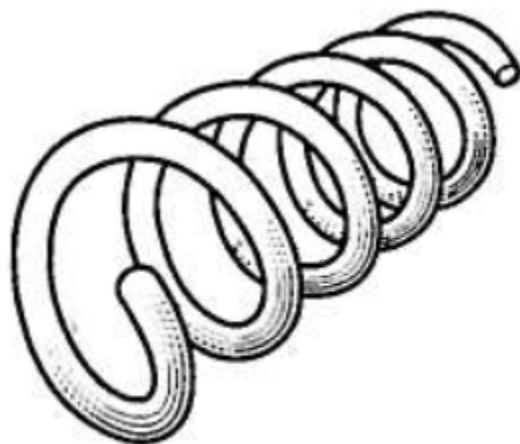


Diagram of a frictionless screw with square threads mounted on a ball thrust bearing, used to raise load Q . Here λ = screw lead angle, F_t = tangential force required to turn screw, F_n = normal force.

Ex. 2013 at 11.

The 2001 Merriam-Webster’s Collegiate Dictionary defines “helical” as “of, relating to, or *having the form of a helix*; broadly: *spiral*,” and defines “helix” as “something *spiral* in form.” Ex. 2014 (emphasis added). Likewise, the 2001 New Oxford American Dictionary defines “helical” as “having the *shape or form of a helix; spiral*,” and defines “helix” as “an object having a three-dimensional shape like that of *a wire wound uniformly in a single layer around a cylinder or cone*, as in a corkscrew or spiral staircase,” (see Ex. 2015 at 4, 5) (emphasis added) offering the following illustration:



helix

Ex. 2015 at 5.

Thus, the intrinsic and extrinsic evidence uniformly demonstrates that the term “helical groove,” in light of the specification and a POSA’s knowledge, is a groove formed in the shape of a spiral. The Board should therefore adopt Sanofi’s proposed construction.

Construing “helical groove” as set forth above is dispositive of the Petition because Petitioner’s prior art does not disclose or render obvious a groove formed in the shape of a spiral on the outer surface of a dose dial sleeve, for the reasons discussed in Section VI.A below.

B. “clutch”/“tubular clutch” (claim 1)

Petitioner asserts that the term “clutch,” which is not written in means-plus-function format, may be a means-plus-function limitation. *See* Petition at 16-17. Petitioner is incorrect, and has not included any support to overcome the

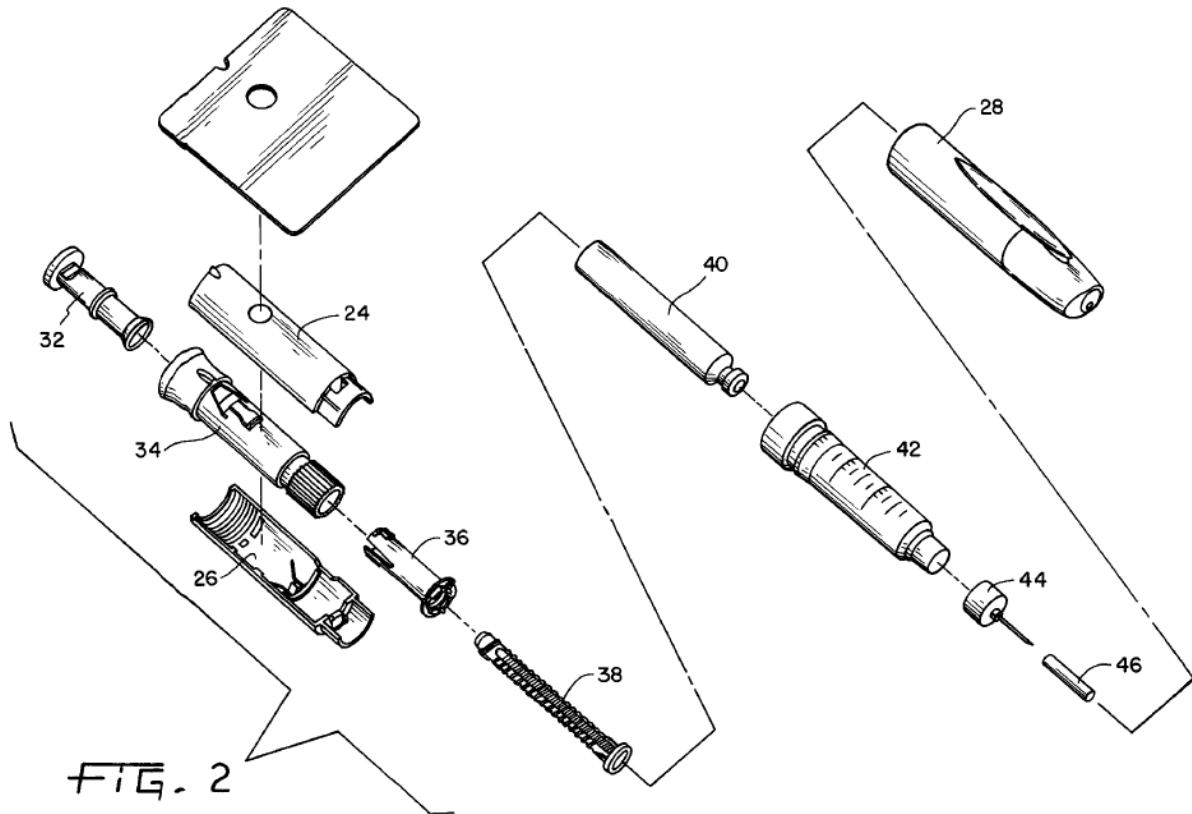
presumption against applying means-plus-function. See *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015).

V. THE PRIOR ART

A. Burroughs

Burroughs relates to a multi-use medication dispensing pen. Ex. 1013, Abstract. According to Burroughs, patients such as diabetics conventionally used syringes to inject themselves with medication, such as insulin. *Id.*, 1:18-24. Patients, however, had difficulty controlling the syringe and the quantity of medication injected. *Id.*, 1:24-25. Burroughs further explained that injector pens were developed to permit diabetics to measure and administer more accurate and controlled dosages. *Id.*, 1:26-29. Burroughs was disclosed to the Examiner during prosecution of the 069 Patent, and is cited on the face of the 069 Patent. Ex. 1001, p. 2; Ex. 1006 at 0148.

The main components of Burroughs' injector pen are shown in Figure 2.

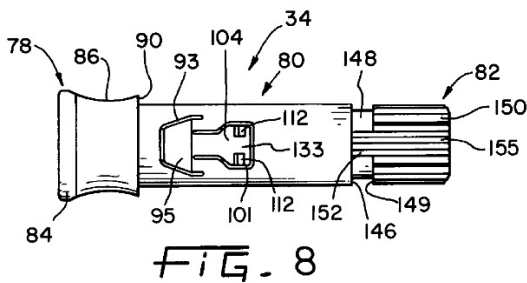
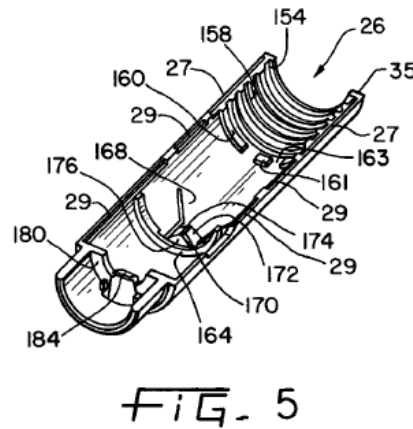
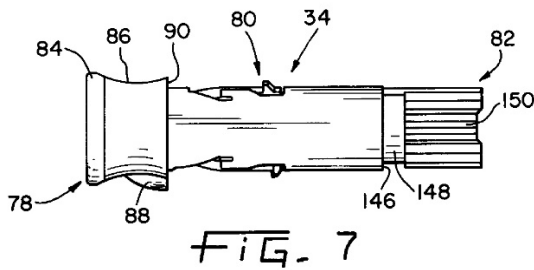


Ex. 1013, Fig. 2.

The main housing is comprised of first part 24 and second part 26. Ex. 1013, 7:16-26. Cap 28 attaches to the distal end of the main housing. *Id.*, 7:27-30. The main housing contains dial mechanism 34, into the proximal end of which button 32 inserts. *Id.*, 7:31-33. Nut 36 interfaces with the distal end of dial mechanism 34, and a drive stem (leadscrew 38) inserts into dial mechanism 34 through nut 36. *Id.* Medication cartridge 40 inserts into distal body 42, which has needle 44 and needle cover 46. *Id.*, 7:34-35.

To use Burroughs' injector pen, a user sets the injection dose. This requires turning dial mechanism 34 to the zero position, which is indicated by a clicking

sound generated when splines 152 (shown in Figure 8) of dial mechanism 34 engage with finger 170 (shown in Figure 5) of second housing part 26. *Id.*, 9:47-64. This engagement also creates a tangible vibration in the device. *Id.*, 9:64-66. Protrusion 153 in first housing part 24 also aligns with protrusion 88 (shown in Figure 7) of the dial mechanism to visually indicate the zero position. *Id.*, 9:66-10:4.



Ex. 1013, Fig. 5, 7, and 8.

From the zero position, the user retracts dial mechanism 34 a predetermined distance to place it into a dose-setting position. *Id.*, 10:15-18. From this position, the user sets the dosage by rotating dial mechanism 34. *Id.*, 10:42-52.

Dial mechanism 34 has threads 110 and 112 on its outer surface, which move within groove 158 on the inner surface of housing parts 24 and 26 to guide and restrict the rotational movement of the dial mechanism. *Id.*, 10:28-38, 10:60-63. Groove 158 is sized such that when the dial mechanism reaches the predetermined maximum dosage, threads 110 and 112 reach the proximal end of the groove. *Id.*, 10:63-65. A ledge at the end of the groove prevents the dial mechanism from turning past this maximum dosage. *Id.*, 10:65-11:1.

Once the dosage is set, the user can dispense the dose by pressing button 32, which causes the button and dial mechanism to move forward until the dial mechanism reaches the end-of-injection position. *Id.*, 11:13-23. At this position, click finger 97 located on the surface of dial mechanism 34 engages with groove 154 on the inner surface of housing parts 24 and 26 (shown in Figures 3 and 5), providing an audible “click” sound to indicate that the dosage has been injected. *Id.*, 11:23-26.

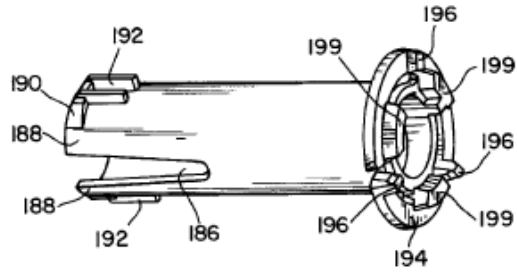


FIG. 10

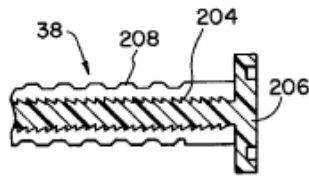


FIG. 13

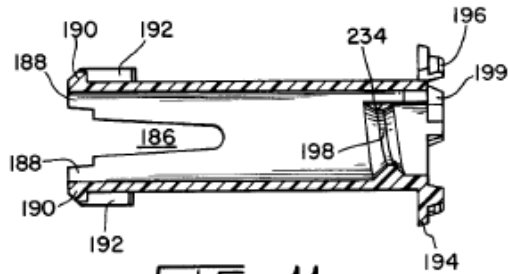


FIG. 11

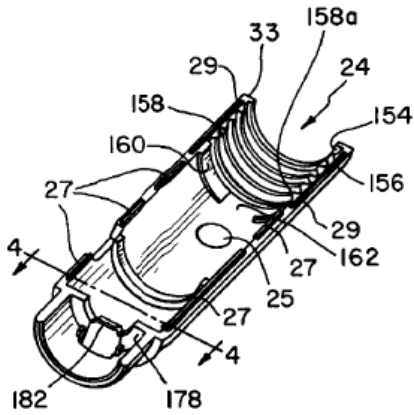


FIG. 3

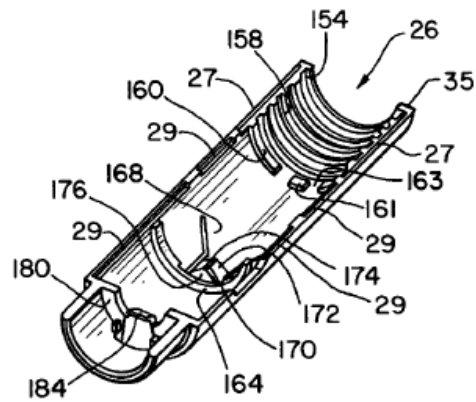


FIG. 5

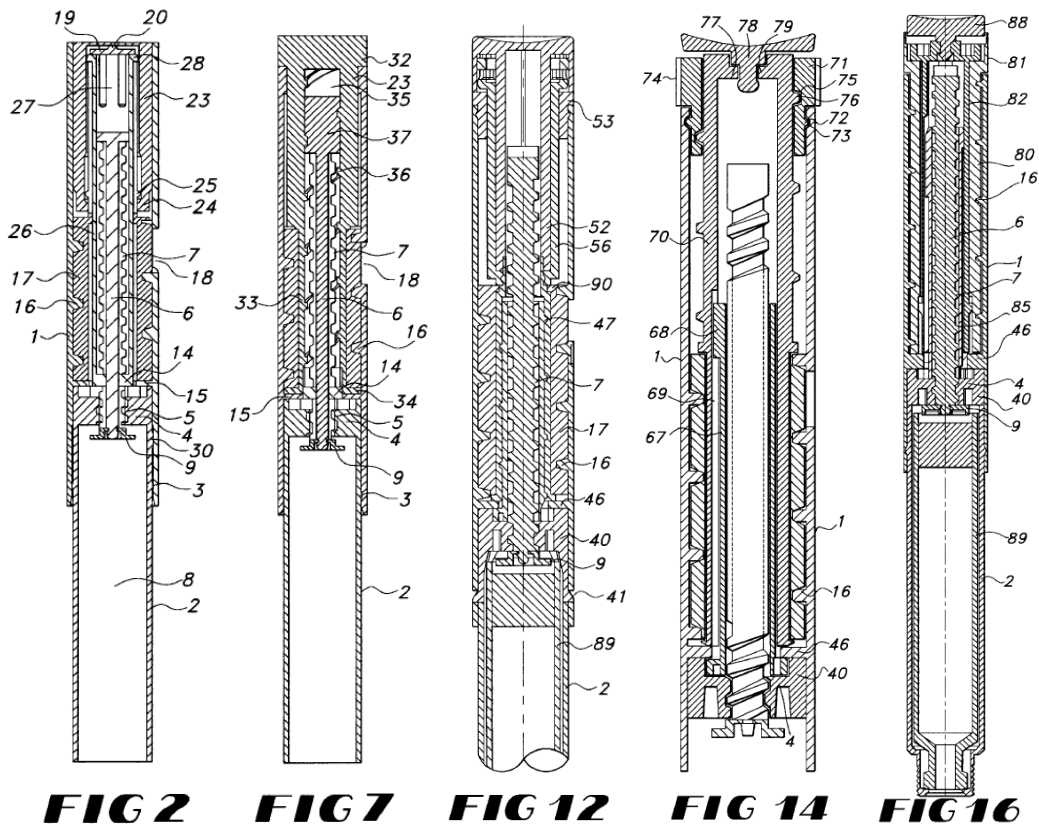
Ex. 1013, Fig. 3, 5, 10, 11, and 13.

B. Steinfeldt-Jensen

Steenfeldt-Jensen is a U.S. patent. Its PCT counterpart application, WO 99/38554 (Ex. 2026), was disclosed during prosecution of the 069 Patent and is

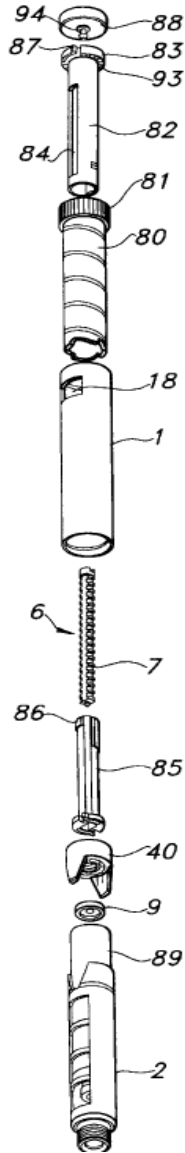
cited on the face of the 069 Patent. *See* Ex. 1014 (claiming priority to DK 1998 00130), Ex. 2026 (same), Ex. 1006 at 0149 (listing WO 99/38554).

Steenfeldt-Jensen discloses five distinct pen injector embodiments comprising different components and arrangements, and which operate differently, as shown below.



Ex. 1014, Figs. 2, 7, 12, 14, and 16.

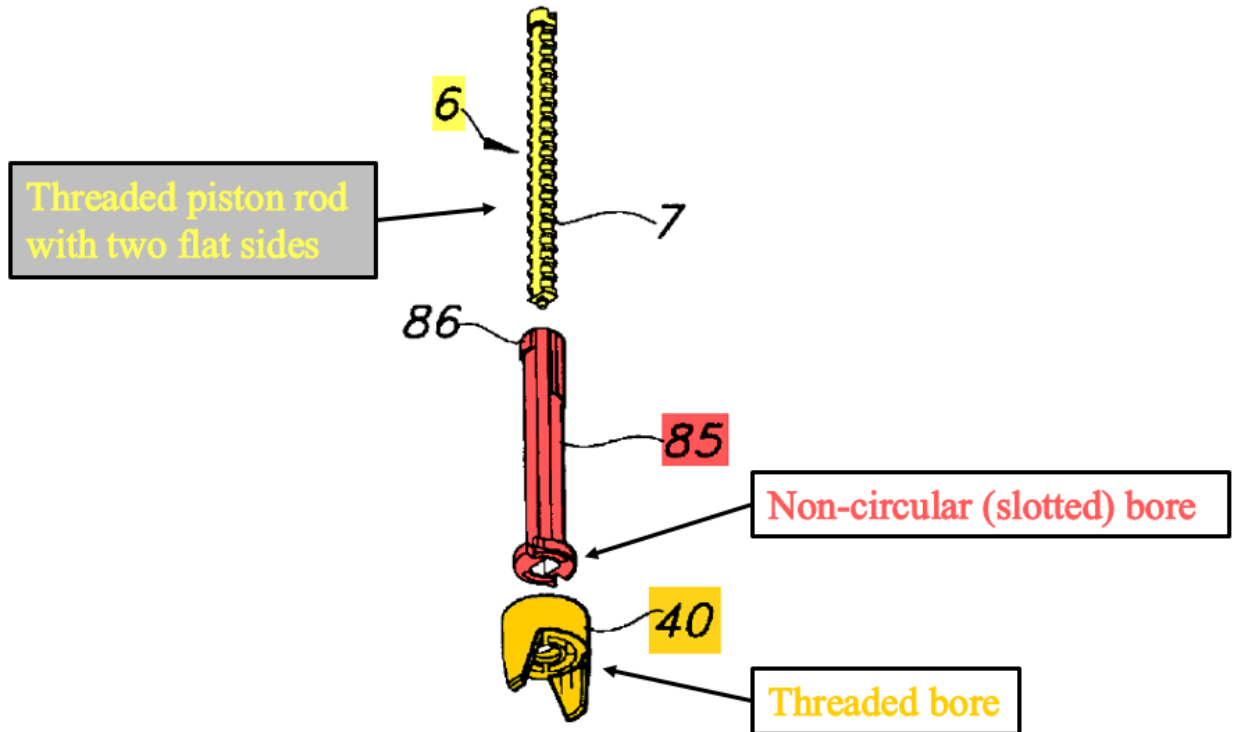
Petitioner primarily relies on the fifth embodiment (Ex. 1014 at 11:6-12:16, Figs. 15-17) to argue that Steenfeldt-Jensen discloses or renders obvious the challenged claims. *See* Petition at 43-62, 68-71. The fifth embodiment is depicted in exploded view, below:



Ex. 1014, Fig. 17.

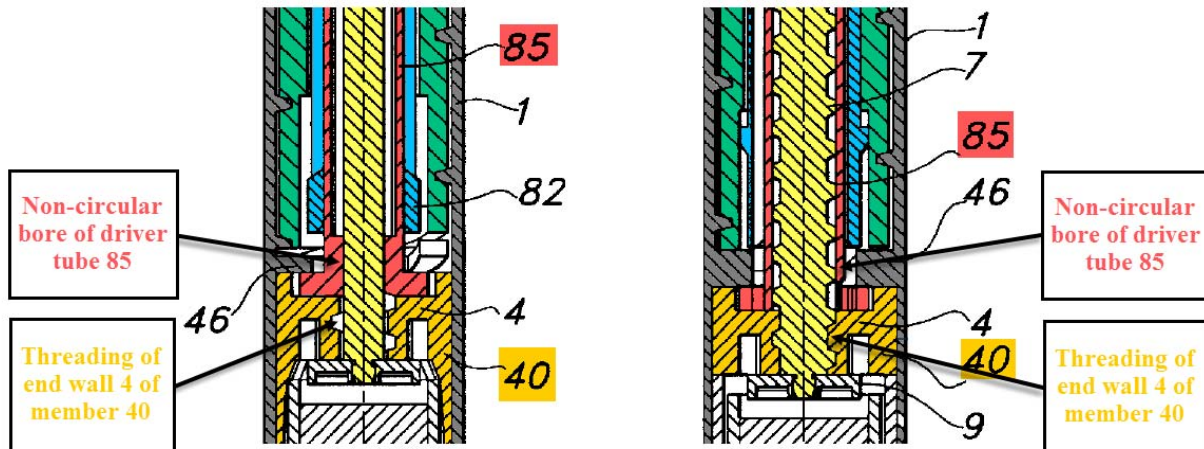
Significant to this Preliminary Response, Steinfeldt-Jensen's fifth embodiment includes a threaded piston rod 6 having two flat sides – *i.e.*, a non-circular threaded piston. The non-circular shape of piston rod 6 fits within the same non-circular bore of driver tube 85, thus rotationally coupling the

components while allowing them to move axially relative to one another. Note that while piston rod 6 is threaded, driver tube 85 is not threaded.



Ex. 1014, Fig. 17 (cropped and annotated).

Piston rod 6 extends from driver tube 85 and the threading of piston rod 6 interfaces with the threaded bore of member 40, which is fixed relative to housing 1. During the dose dispensing phase, rotation of the driver tube causes the piston rod to rotate and screw into member 40. Cross-sections from two different angles of the fifth embodiment are depicted below.



Ex. 1014, Figs. 15 and 16 (cropped and annotated).

C. Møller

Møller is a U.S. patent application. Møller was submitted in an IDS and is cited on the face of the 069 Patent. Ex. 1006 at 0129. Møller provides an injection pen where the mechanical advantage (*i.e.*, “gearing”) is generated between an injection button and an ampoule piston via a rack and gear. *See* Ex. 1015, [0006]. Møller explains that this gearing reduces the force necessary to deliver an injection. *Id.*

Møller specifically teaches away from using Steinfeldt-Jensen’s high-pitch helical thread. Specifically, Møller notes that WO 99/38554, Steinfeldt-Jensen’s

PCT counterpart,⁸ discloses a dose-setting drum having an exterior high-pitch thread that engages with a thread on the inner surface of a housing. *See* Ex. 1015, [0008]. Møller further notes that “by this [Steenfeldt-Jensen] kind of gearing [Steenfeldt-Jensen’s] relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces.” *Id.* As a result, “a traditional gearing using mutual engaging gear wheels and racks is preferred.” *Id.* Møller then explains that it is “an objective of the invention to provide an injection device, which combines the advantages of the devices according to the prior art *without adopting their disadvantages*” *Id.*, [0011] (emphasis added). Møller’s device accounts for these advantages and disadvantages, and notably, does not include the dose setting drum with the exterior high-pitched thread taught by WO 99/38554.

VI. REASONS WHY THE PETITION SHOULD BE DENIED

A. Ground 1 Should Be Denied Because Burroughs Does Not Disclose Or Render Obvious “A Helical Groove Provided Along An Outer Surface Of Said Dose Dial Sleeve”

⁸ *See* Ex. 1014 (claiming priority to DK 1998 00130), Ex. 2026 (same); *see also* Ex. 1011, ¶ 356 (“In discussing the background for this invention, I note that Møller discusses the device disclosed in Steenfeldt-Jensen.”).

Ground 1 should be denied because Petitioner fails to show that Burroughs, in view of a POSA's knowledge, discloses or renders obvious all of the elements of the challenged claims. In particular, Burroughs does not disclose a "helical groove provided along an outer surface of said dose dial sleeve," as recited in independent claim 1, and Petitioner fails to prove that such a helical groove would have been obvious.

1. Burroughs Does Not Disclose A Helical Groove Provided Along An Outer Surface Of Said Dose Dial Sleeve

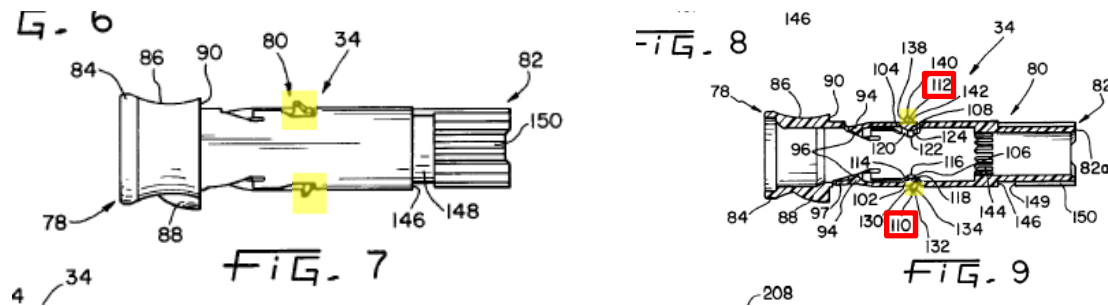
Petitioner admits that Burroughs does not disclose a helical groove on the outer surface of the dose dial sleeve. Petition at 30. Thus, there is no dispute that Burroughs fails to disclose this limitation.

2. Burroughs In View Of The Knowledge Of A POSA Does Not Render Obvious A Helical Groove Provided Along An Outer Surface Of Said Dose Dial Sleeve

Petitioner contends that it would have been obvious to provide threads 110 and 112 as a "helical groove, formed by two, parallel threads 110, 112 on the outer surface of the dial mechanism 34 of Burroughs," Petition at 42. This contention, however, fails to carry Petitioner's burden because the proposed modification does not result in a "helical groove" as properly construed.

Petitioner contends that threads 110 and 112 on Burroughs' dial mechanism form a "helical" rib. Petitioner adds a groove to each of these "helical" ribs 110 and 112, asserting that this yields "helically" grooved ribs. Petition at 40-42.

Petitioner’s modification does not create a helical groove. The term “helical” refers to a structure formed in the shape of a spiral. *See* Section IV. As shown in Figures 7 and 9 of Burroughs, threads 110 and 112 are *discrete, tooth-like protrusions* on the surface of dial mechanism 34, and *not* a spiral-shaped.



Ex. 1013, Figs. 7 and 9 (highlighted).

Petitioner offers nothing but Dr. Leinsing’s own conclusory opinion that these discrete, tooth-like protrusions 110 and 112, that Burroughs calls “threads”, constitute a “discontinuous ‘helical rib.’” Ex. 1011, ¶ 165. This unsupported testimony should be given no weight. 37 C.F.R. § 42.65(a); *Compass Bank, Commerce Bankshares, Inc. v. Intellectual Ventures II, LLC*, IPR2014-00786, Paper 46 at 31 (P.T.A.B. Sept. 23, 2015); *see also Corning Inc. v. DSM IP Assets*, IPR2013-00050, Paper 77 at 22-23, 25 (P.T.A.B. May 1, 2014).

Petitioner also cites Exhibit 1001 at 3:42-44, but this nonetheless does not support Petitioner’s position that Burroughs’ threads 110 and 112 are “helical.” Specifically, Exhibit 1001 at 3:42-44 discusses an embodiment of the 069 Patent’s

injector pen in which helical thread 24 includes discrete interruptions. This is illustrated in Figures 1 and 2 of the 069 Patent:

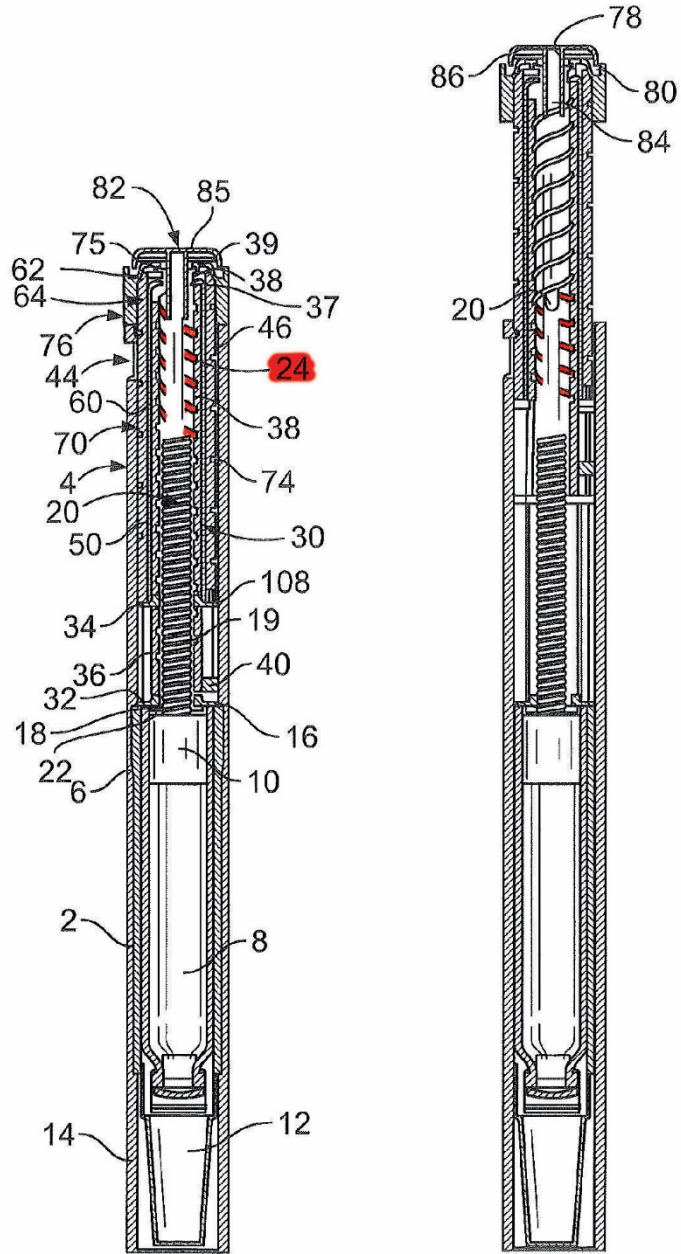
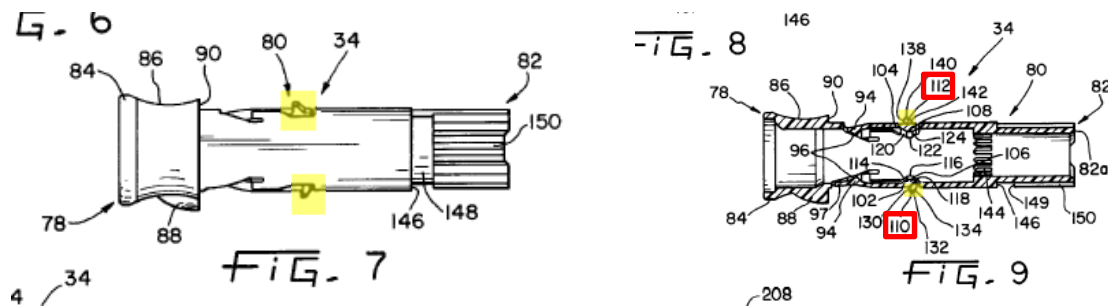


FIG. 1

FIG. 2

Ex. 1001, Figs. 1 and 2 (highlighted).

As shown in the figures, there is no question that thread 24 is a thread formed in the shape of a spiral, even though it may have discontinuities. This, however, does not support Petitioner’s contention that *Burroughs’ threads 110 and 112 are a helical rib*. As discussed below, Burroughs’ threads 110 and 112, which are only small, tooth-like structures, are clearly *not* formed in the shape of a spiral.



Ex. 1013, Figs. 7 and 9 (highlighted).

Dr. Leinsing’s testimony is unreliable because it fails to apply an appropriate construction of “helical,” as set forth in Section IV, which requires a structure formed in the shape of a spiral. Dr. Leinsing admits that threads 110 and 112 are formed in the shape of “rib-like protrusions,” but *not* in the shape of a spiral. Ex. 1011, ¶ 165. Rather than evaluating the shape of threads 110 and 112 themselves, Dr. Leinsing erroneously bases his opinion on the alleged relative position between the two threads. *Id.* In other words, Dr. Leinsing’s opinion is based on his contention that one could trace an imaginary, spiral-shaped path between the threads, rather than the threads themselves being formed in the shape of a spiral. Neither Dr. Leinsing nor Petitioner provide any evidence showing that it would

have been obvious to a POSA to further modify threads 110 and 112 such that the threads, and not some imaginary, arbitrary line, are formed in the shape of a spiral.

Dr. Leinsing's unsupported and unreliable opinion and an inapposite citation to the 069 Patent are all that Petitioner provides to assert that Burroughs' threads 110 and 112 are "helical" such that forming a groove in each rib would result in a "helical" groove. Petitioner thus failed to show that a "helical groove" on the outer surface of the dose dial sleeve would have been obvious based on Burroughs in view of a POSA's knowledge.

* * *

Because Burroughs neither discloses nor renders obvious a "helical groove" on the outer surface of the dose dial sleeve, as required by claim 1, Petitioner has failed to carry its burden and the Petition should be denied.

3. Petitioner Does Not Establish A Motivation To Modify Burroughs' Threads To Include A Groove

Assuming *arguendo* that Burroughs' threads 110 and 112 formed a "helical" rib, Petitioner fails to establish a motivation to modify Burroughs to include a groove in each of threads 110 and 112 and a corresponding thread in the inner surface of housing parts 24 and 26 to engage those grooves. It is Petitioner's burden to show "that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so."

Kinetic Concepts, Inc. v. Smith & Nephew, Inc., 688 F.3d 1342, 1360 (Fed. Cir. 2012) (internal citation and quotations omitted). Petitioner does not even purport to provide a motivation, asserting only that such a modification would have been “interchangeable” with the structure disclosed in Burroughs and that the modified elements would have still performed the same functions. Petition at 40-42.

As the Federal Circuit has cautioned, merely asserting that a particular placement of elements was a “design choice” does not make it obvious. *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 n. 4 (Fed. Cir. 2018) (citing *Cutsforth, Inc. v. MotivePower, Inc.*, 636 F. App’x 575, 578 (Fed. Cir. 2016)). Rather, Petitioner must show “why a person of ordinary skill in the art would have selected these components for combination in the manner claimed.” *Id.* (internal quotation marks omitted). Here, Petitioner makes no such showing. Petitioner identifies neither any problem that would be solved by the proposed modification, nor any other improvement to Burroughs that would have resulted therefrom. Indeed, Petitioner does not explain why a POSA would have been motivated to increase the complexity of manufacturing Burroughs’ injector pen by removing or adding material from threads 110 and 112 to form a groove in each thread, only to provide a structure that, according to Petitioner, would simply perform the same function as the structure already disclosed in Burroughs. Petition at 42. Thus, Ground 1 fails and should be denied.

B. Ground 2 Should Be Denied Because Steinfeldt-Jensen Does Not Disclose Or Render Obvious A “Drive Sleeve Comprising An Internal Threading . . . Adapted To Engage An External Thread Of Said Piston Rod”

Claim 1 requires “a drive sleeve extending along a portion of said piston rod, *said drive sleeve comprising an internal threading* near a distal portion of said drive sleeve, *said internal threading adapted to engage an external thread of said piston rod.*” (emphasis added). Petitioner and its expert concede that Steinfeldt-Jensen’s fifth embodiment, the embodiment relied upon by Petitioner, does not disclose this limitation. *See* Petition at 55 (admitting that the driver tube “engages with the rod through *[a] non-circular bore, rather than ‘an internal threading’*”); Ex. 1011, ¶ 274.

Petitioner argues that it would have been obvious to apply a teaching from Steinfeldt-Jensen’s first embodiment to Steinfeldt-Jensen’s fifth embodiment to swap member 40’s internal threading in the fifth embodiment with driver tube 85’s non-circular bore in the fifth embodiment to arrive at a “drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod.” *See* Petition at 55, 60-62; Ex. 1011, ¶¶274-278.

This argument fails for at least three reasons. First, the teaching Petitioner relies upon is strictly related to the *first* embodiment, not the *fifth* embodiment. Petitioner points to no disclosures that teach modifying the fifth embodiment in the

manner proposed. Second, the motivations to modify the first embodiment are not applicable to the fifth embodiment because the problems addressed in the first embodiment are not present in the fifth embodiment. Third, modifying the fifth embodiment in the manner proposed creates a substantial risk that the resulting device would not work for its intended purpose. *See Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F. App'x 755, 758-60 (Fed. Cir. 2015) (rejecting obviousness of the prior art modification because the modification would render the prior art “inoperable for its intended purpose”) (citing *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984)).

1. Steinfeldt-Jensen’s Disclosure on Switching the Piston Rod Guide and Nut Element Is Made for a Different Embodiment That Is Not the Basis for the Ground

Petitioner argues that a POSA would have known to modify the fifth embodiment (shown in Figures 15-17 and described at 11:6-12:16) based on the following passage from Steinfeldt-Jensen’s discussion of its first embodiment (shown in Figures 1-5 and described at 5:33-7:47):

In the *shown embodiment* [embodiment 1] the end wall 4 with its threaded bore forms a nut member relative to which the piston rod is rotated by the piston rod guide 14 and the driver tube 26. Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention.

Ex. 1014, 7:41-47 (emphasis added).

The “shown embodiment” is the first embodiment—*i.e.*, an embodiment that is not the basis for Ground 2. Moreover, the passage suggests interchanging the non-circular opening (*i.e.*, piston rod guide 14) of driver tube 26 in the first embodiment with the threaded opening in end wall 4 of ampoule holder 2 in the first embodiment. The passage does not teach, as Petitioner suggests, interchanging member 40’s internal threading in the fifth embodiment with driver tube 85’s non-circular bore in the fifth embodiment.

Nor could the passage be applicable to the fifth embodiment. The fifth embodiment does not include the features interchanged in the passage. Specifically, the fifth embodiment does not include a driver tube 26 nor a rotatable ampoule holder 2 with threaded end wall 4. And where the specification discusses the fifth embodiment, it does not include a similar passage. *See* Ex. 1014, 11:6-12:16 (describing the fifth embodiment). This is not surprising. As discussed below, the first and the fifth embodiment operate differently and such a modification would not have a commensurate benefit in the fifth embodiment.

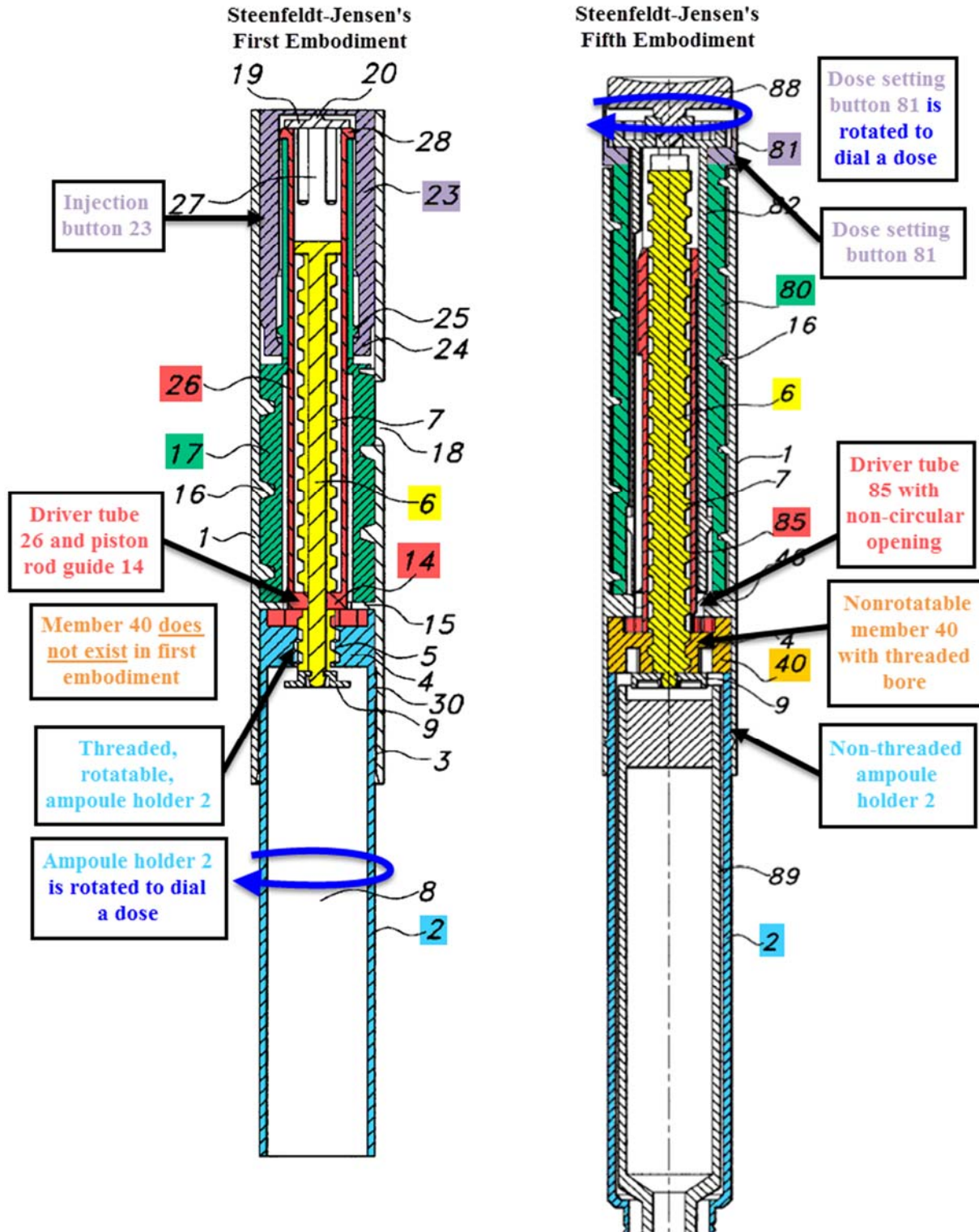
Petitioner argues that Steinfeldt-Jensen discloses a threaded drive tube because it discloses alternative ways to drive a piston rod; namely, (1) “[w]hen the injection button is pressed the movement of this button is transformed into a rotation of the piston rod (or the nut member) relative to the nut member (or the piston rod)”; or (2) “the dose scale drum may be ‘coupled to a driver rotating the

piston rod (or the nut member) relative to the nut member (or the piston rod) when the injection button is pressed.” See Petition at 60 (citing Ex. 1014, 3:15-20, 3:44-47). These disclosures, however, only teach rotating either a piston rod or a nut member; they do not contemplate or teach a threaded drive tube with internal threading. Thus, these disclosures in Steinfeldt-Jensen cannot support Petitioner’s obviousness argument to modify the driver tube in the fifth embodiment to include threading when it did not otherwise include threading.

Accordingly, contrary to Petitioner’s assertions, Steinfeldt-Jensen does not provide any teachings with respect to the fifth embodiment to support Petitioner’s modifications.

2. A POSA Would Not Have Been Motivated to Make Petitioner’s Proposed Modification to the Fifth Embodiment Because the Fifth Embodiment Does Not Suffer the Same Drawbacks as the First Embodiment

Notwithstanding that the teachings that Petitioner cites are unrelated to the fifth embodiment, a POSA would not have been motivated to make the proposed modifications to the fifth embodiment. For context, it is important to understand why Steinfeldt-Jensen proposes modifying the first embodiment, which is explained in the context of the figures below.



Ex. 1014, Figs. 2 and 16 (annotated).

In the first embodiment (above, left), piston rod 6 (yellow) directly engages ampoule holder 2 (blue). To dial a dose, the user grasps ampoule holder 2 and rotates it relative to housing 1. *See* Ex. 1014, 6:42-43. When ampoule holder 2 is rotated, piston rod 6 rotates along with ampoule holder 2 due in part to a high-friction interface between piston rod 6 and ampoule holder 2. *See Id.*, 6:54-59 (“The rotation of the ampoule holder is due to the friction in the engaging threads 5 and 7 transmitted to the piston rod 6”). Piston rod 6 in turn rotates with piston rod guide 14, and piston rod guide 14 then rotates dose scale drum 17.

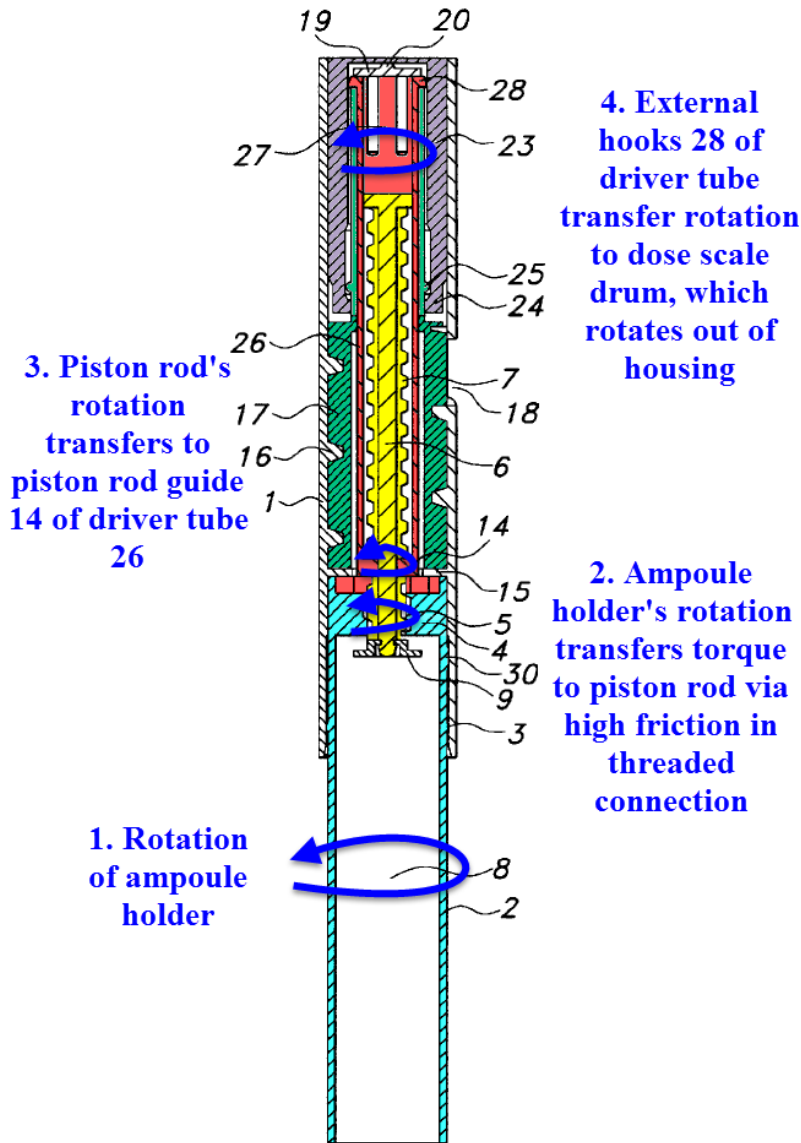


FIG 2

Ex. 1014, Fig. 2 (annotated).

The disadvantage of this arrangement, however, is that administering a dose requires pushing injection button 28 with sufficient force to overcome the high friction between piston rod 6 and ampoule holder 2 so that piston rod 6 no longer rotates with ampoule holder 2 but instead rotates relative to ampoule holder 2.

Once piston rod 6 rotates relative to ampoule holder 2, it moves axially and pushes medicament out of the ampoule. *See* Ex. 1014, 7:17-40. Pushing the injection button with great force, however, is difficult for some users or may cause unwanted pen movement during injection. This is a significant issue in view of the potentially elderly and impaired population using pen injectors.

Steenfeldt-Jensen at 7:30-47 (which encompasses the passage relied on by Petitioner) suggests a solution for this problem in the first embodiment. Namely, interchanging the threaded connection between piston rod 6 and ampoule holder 2 in the first embodiment for the non-circular bore of piston rod guide 14 in driver tube 26 of the first embodiment eliminates the high-friction threaded interface between piston rod 6 and ampoule holder 2 in the first embodiment.

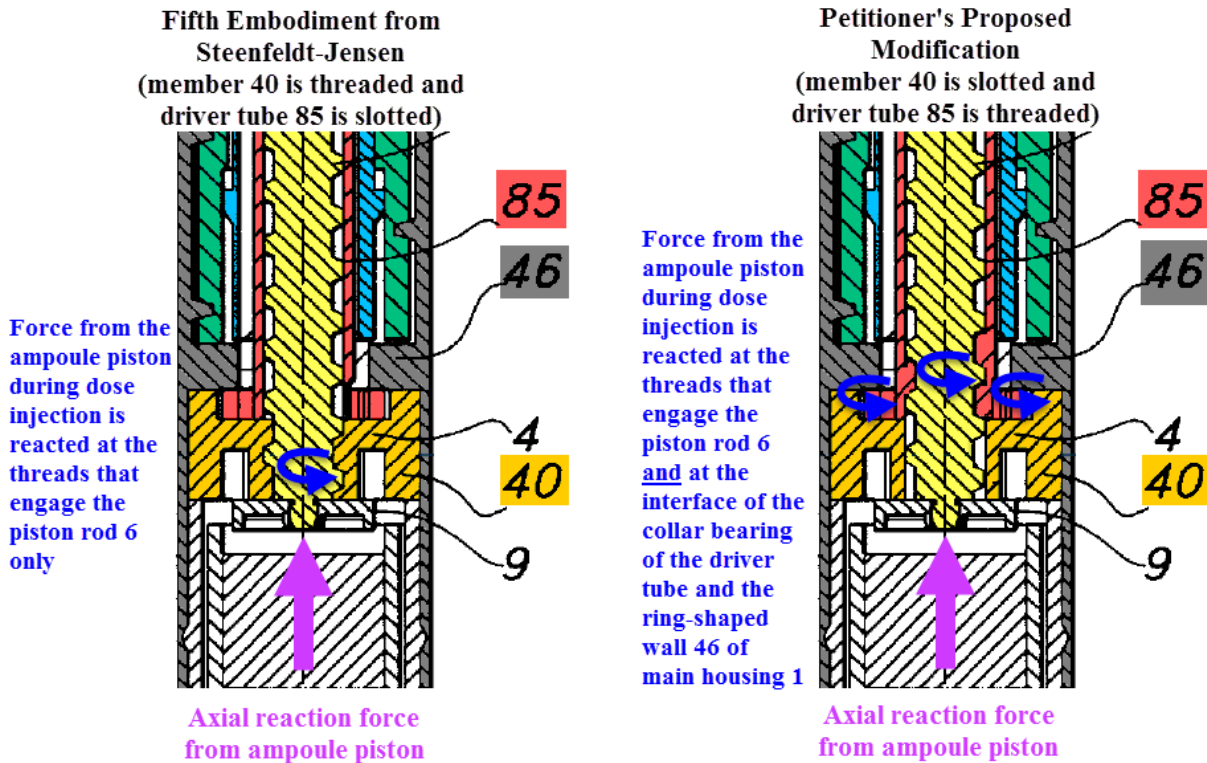
In contrast, in the fifth embodiment, piston rod 6 does not directly engage an ampoule holder 2 that rotates in order to dial a dose. As seen in Figure 16, above – piston rod 6 (yellow) does not engage ampoule holder 2 (blue) but instead engages *non-rotatable* member 40 (orange), which does not exist in the first embodiment. Further, dose setting button 81, not ampoule holder 2, is rotated to dial a dose. *See* Ex. 1014, 11:52-12:3. Thus, *there is no high-friction interface* in the fifth embodiment, which makes the teachings of the first embodiment inapplicable to the fifth embodiment.

Accordingly, a POSA would not have been motivated to make the modifications to the first embodiment suggested by Steinfeldt-Jensen to the fifth embodiment.

3. Petitioner's Modification to Switch the Piston Rod Guide and Nut Element to the Fifth Embodiment Results in an Inferior Pen Injector

In the first embodiment, the teaching to interchange the threaded connection between piston rod 6 and ampoule holder 2 in the first embodiment for the non-circular bore of piston rod guide 14 in driver tube 26 of the first embodiment eliminates the high-friction interface between piston rod 6 and ampoule holder 2. The fifth embodiment, however, is mechanically different from the first embodiment. If the same modification were made to the fifth embodiment, it would *introduce* a major new friction source, making it harder to use.

A fundamental purpose of these pen injector mechanisms is to permit users to perform difficult injections using low injection force. *See, e.g.*, Ex. 1015, [0004-0006] (discussing the need for pen injectors to require only low injection forces). Adding a major friction source substantially diminishes the utility of the pen injector.



Ex. 1014, Fig. 16 (left) (annotated).

During dose injection, piston rod 6 delivers an axial force to the ampoule piston. In the fifth embodiment, as depicted in the leftmost embodiment above, this axial force causes a reaction force (purple arrow) against piston rod 6 that translates to the internal threads of non-rotatable member 40 as an upward force.⁹ Thus, in the fifth embodiment, all of the reaction force needed to drive the ampoule piston during dose injection is borne by member 40, which is axially and *rotationally fixed* within housing 1 (denoted in grey), and not by driver tube 85. Importantly, the friction from rotating piston rod 6's threads through those of

⁹ For every action, there is an equal and opposite reaction.

member 40 acts at a small radius and thus introduces only minor frictional torque ($\tau = r \times F$) (blue arrow).

In Petitioner's modified device (rightmost figure, above), however, the reaction force is no longer borne by member 40, but is instead borne by now-threaded driver tube 85 (red). Unlike member 40, driver tube 85 *is not rotationally fixed* with respect to housing 1 (and its ring-shaped wall 46) because driver tube 85 must also rotate as piston rod 6 is driven axially during dose injection. *See Ex. 1014, 12:10-13.* Accordingly, driver tube 85 in the modified device must bear the reaction force *at the same time that it is rotating*.

Thus, in addition to the friction between the threads of piston rod 6 and those of driver tube 85, a significant friction source is introduced during dose injection at the flanges on driver tube 85 as it is being driven upward into the ring-shaped wall 46 of housing 1 (grey). Moreover, because this new friction interface is at a greater radius than the friction interface between piston rod 6 and member 40 in the fifth embodiment, the resulting frictional torque (blue arrows) is much greater ($\tau = r \times F$).

A user of Petitioner's modified embodiment would need to exert considerably more effort to overcome these larger friction losses, which is contrary to the objectives in this art to create pen injectors with low injection forces. *See Ex. 1002, 1:31-35* ("The injector must be ... easy to use ... in terms of the

manipulation of parts In the case of those with diabetes, many users will be physically infirm”), Ex. 1015, [0004-0006] (discussing the need for pen injectors to require only low injection forces). While the teaching is beneficial to the first embodiment (*i.e.*, eliminating the high-friction interface between the threads of piston rod 6 and those of ampoule holder 2, as described above), there is no corresponding benefit in the fifth embodiment because there is no high-friction interface between the threads of piston rod 6 and those of member 40 in the fifth embodiment. Modifying the fifth embodiment as Petitioner proposes only impairs the device.

In sum, a POSA would not have been motivated to modify the fifth embodiment in the manner suggested by Petitioner because it would have made the device much more difficult to use. *See Plas-Pak Indus.*, 600 F. App’x at 758-60 (rejecting obviousness of the prior art modification because the modification would render the prior art “inoperable for its intended purpose”) (citing *In re Gordon*, 733 F.2d at 902 (“The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.”)).

C. Ground 3 Should Be Denied Because Møller, Alone or in Combination with Steinfeldt-Jensen, Does Not Render Obvious the Challenged Claims

1. The Combination of Møller and Steinfeldt-Jensen Does Not Teach or Render Obvious “a drive sleeve extending along a portion of said piston rod”

Petitioner argues that Møller’s connection bars 12 having nut 13 teach the claimed “drive sleeve.” Petition at 74-77. As shown with red shading in both the side and top-down cross-sectional views, connection bars 12 and nut 13 do not form a sleeve:

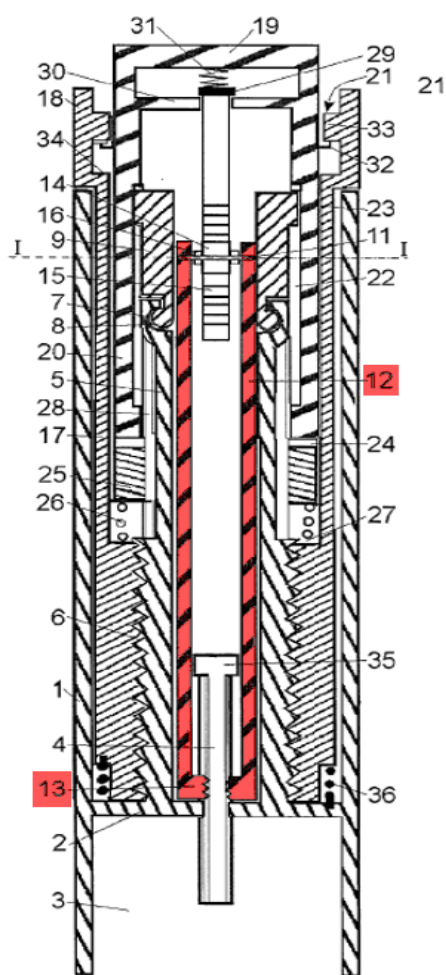


Fig. 1

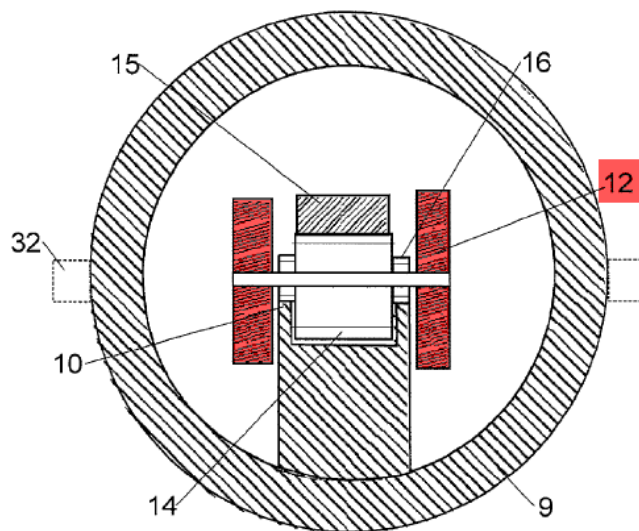


Fig. 2

Ex. 1015, Figs. 1 and 2 (red shading added).

Rather, the connection bars constitute two parallel bars.

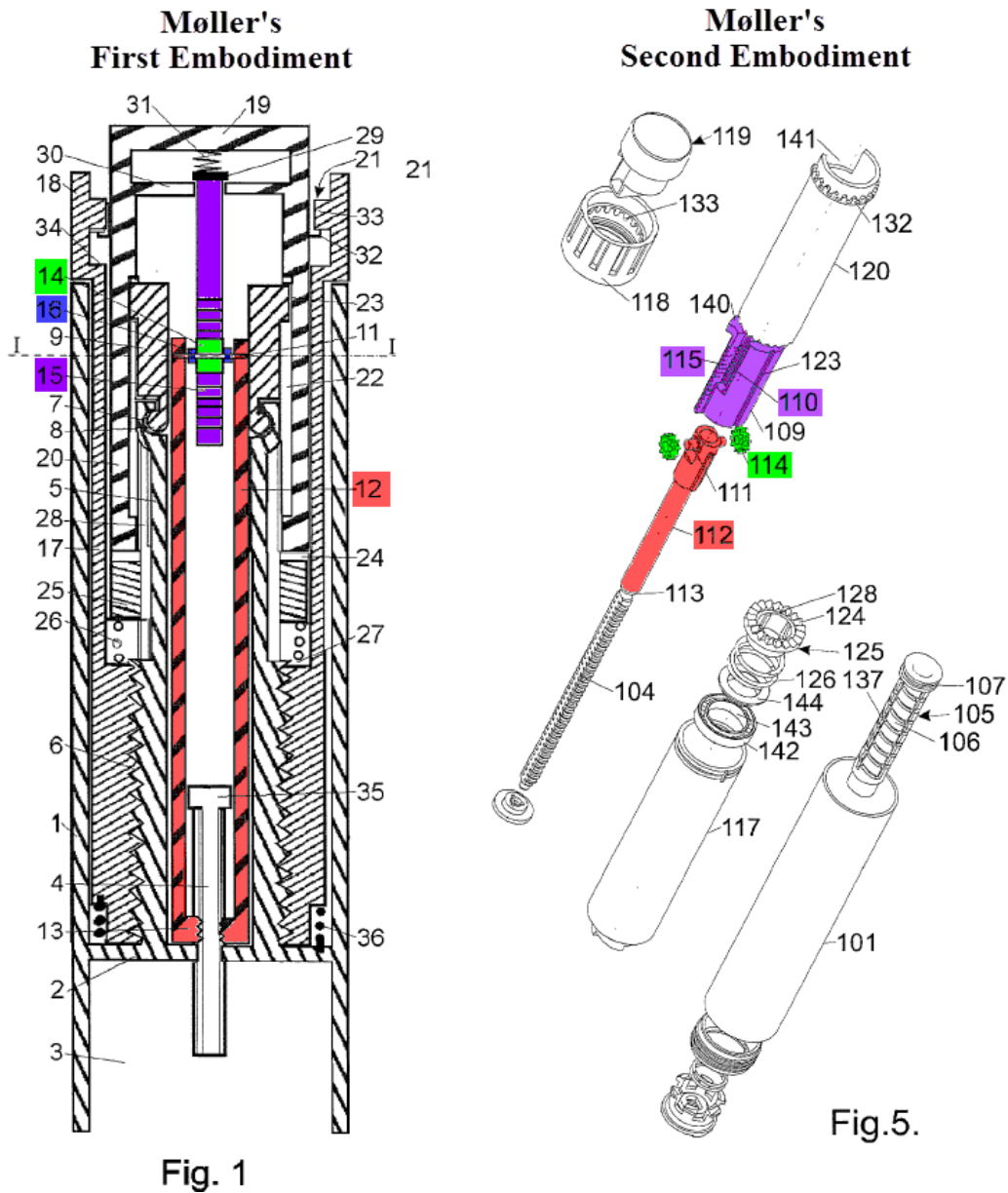
Tacitly admitting that connection bars 12 and nut 13 do not comprise the claimed “drive *sleeve*,”¹⁰ Petitioner also points to tubular connection element 112 and nut 113 in Møller’s *second embodiment* to try to overcome this deficiency. Petition at 77. Petitioner contends that “a POSA would have understood [connection bars 12 and nut 13 in the first embodiment and connection element 112 and nut 113 in the second embodiment] to be structurally and functionally equivalent.” *Id.* Based on this assertion, Petitioner concludes that a POSA “would have expected connection bars 12 with nut 13 could readily be formed as a tubular structure that encompasses piston rod 4, without affecting the device’s operation.” *Id.*

Connection bars 12 and nut 13 in Møller’s first embodiment, however, are *not* structurally and functionally equivalent to connection element 112 and nut 113 in the second embodiment. Nor would a POSA would have expected that connection bars 12 and nut 13 in Møller’s first embodiment could be formed as a tubular structure without affecting the device’s operation.

¹⁰ Note that in the District Court case, Sanofi and Petitioner agree that the claimed “drive sleeve” is at least “an essentially tubular component.” *See Ex. 2016.*

a) **A POSA Would Not Have Considered Connection Bars 12 and Nut 13 Functionally and Structurally Equivalent to Connection Element 112 and Nut 113**

The figure below makes clear that connection bars 12 in the first embodiment are not structurally equivalent to connection element 112 in the second embodiment:



Ex. 1015, Figs. 1 and 5 (annotated).

Connection bars 12 and connection element 112 are differently shaped, engage with components in different ways, and operate in different manners. To better visualize this complexity, Sanofi has animated Møller's embodiments. *See* Ex. 2027 (animation depicting Møller's first embodiment), Ex. 2028 (animation depicting Møller's second embodiment). As can be seen, Møller's second embodiment is structurally and functionally more complicated than the first embodiment.

Specifically, as shown below, in Møller's first embodiment, connection bars 12 have an open shape that allows gear wheel 14 (green), gear wheel 16 (blue), and rack 15 (purple) to be mounted in between connection bars 12; and more importantly, allows gear wheel 16 (blue) to engage rack 10 (yellow), which is connected to gearbox 9 as shown below. *See* Ex.1015, [0024].

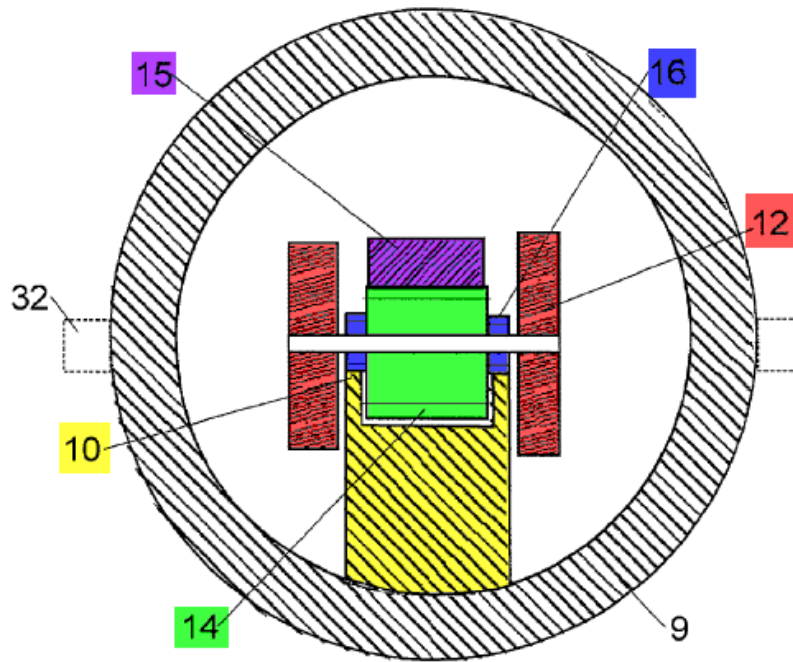


Fig. 2

Ex. 1015, Fig. 2 (annotated).

In contrast, in Møller's second embodiment, connection element 112 (see Fig. 5, above) has a closed tubular shape with gear wheel 114 (green) *mounted on its exterior* and is engaged with racks 110 and 115 (both purple), which are also *exterior* to connection element 112.

Mounting the gear and rack components *within* a tubular element such as the second embodiment's connection element 112, as urged by Petitioner, requires a substantial redesign. For example, a second pair of gear wheels 14 and 16 is necessary, which means racks 10 and 15 need to be duplicated. Because the four racks (two of rack 10 and two of rack 15) and the four gear wheels (two of gear

wheel 14 and two of gear wheel 16) are mounted externally, the racks and gear wheels would need to be structurally redesigned to leave room for the new tubular structure. The gearbox would also need to be redesigned to drive additional components. In effect, the device becomes substantially more complicated with the introduction of these additional components.

In sum, a POSA would not have considered connection bars 12 and nut 13 in Møller's first embodiment functionally and structurally equivalent to connection element 112 and nut 113 in Møller's second embodiment. Petitioner's contention otherwise is conclusory without any meaningful analysis between the components. Because Petitioner's obviousness argument is predicated on this purported equivalency, the argument fails. Accordingly, Møller does not teach or render obvious claim limitation [1.5], and thus does not render obvious claim 1.

b) A POSA Would Not Have Expected Connection Bars 12 with Nut 13 Could Be Formed as a Tubular Structure That Encompasses Piston Rod 4 Without Affecting the Device's Operation

Assuming *arguendo* that Petitioner was correct that the components are equivalent, neither Petitioner nor its expert explains how to implement the tubular shape of connection element 112 in the first embodiment without interfering with the internally mounted gears and racks, and thus the device's operation.

The non-tubular, open shape of connection bars 12 in the first embodiment provides sufficient space for the *internal* gear wheels and racks, and importantly

permits gear wheels 16 (blue) to engage rack 10 (yellow). The first embodiment at minimum would require a significant reconstruction and redesign of elements to accommodate a tubular structure that avoids interfering with the engagement of rack 10 and gear wheel 16.

Given the significant differences and the advantage provided by the open (not tubular) shape of connection bars 12, a POSA would not have been motivated to implement a sleeve shaped connection element in Møller's first embodiment.

Accordingly, Møller does not teach or render obvious claim limitation [1.5], and thus does not render obvious claim 1.

2. A POSA Would Not Have Been Motivated to Combine the Teachings of Møller and Steinfeldt-Jensen as Petitioner Contends

Petitioner fails to demonstrate that a POSA would have been motivated to combine Møller and Steinfeldt-Jensen. Petitioner asserts that a POSA would be motivated to modify the inner threads of dose setting drum 17 and outer thread 6 of tubular element 5 in Møller such that dose setting drum 17 instead comprised “a high-pitch helical groove as taught by Steinfeldt-Jensen on the outer surface” that engaged with a helical rib on the inner surface of housing 1. Petition at 87; *see also id.* at 70-71, 85-87. A POSA, however, would not have been motivated to modify Møller as proposed for at least the reasons set forth below.

a) Møller Teaches Away From Steinfeldt-Jensen's Externally-Grooved Dose Scale Drum

A POSA would not have been motivated to combine Møller with Steinfeldt-Jensen's externally-grooved dose scale drum 80, because Møller teaches away from doing so. Møller explains that an objective of his invention is “to provide an injection device, which combines the advantages of the devices according to the prior art *without adopting their disadvantages*” Ex. 1015, [0011] (emphasis added). Møller expressly cites the very dose scale drum from Steinfeldt-Jensen that Petitioner seeks to use in its obviousness combination as an example of a disadvantageous prior art teaching (due to its undesirable friction losses), and thus Møller proposes an embodiment with a completely different configuration. Specifically, Møller criticizes Steinfeldt-Jensen as follows:

A similar gearing is provided in WO 99/38554 [Steenfeldt-Jensen's PCT counterpart] wherein the thread with the high pitch is cut in the outer surface of a dose setting drum and is engaged by a mating thread on the inner side of the cylindrical housing. *However, by this kind of gearing relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces.* Therefore a traditional gearing using mutual engaging gear wheels and racks is preferred.

Ex. 1015, [0008] (emphasis added).¹¹ Møller’s injection device specifically lacks the disadvantageous high-pitch and externally-grooved dose scale drum described by Steinfeldt-Jensen (*see* Ex.1015, [0011] (“It is an objective of the invention to provide an injection device, which combines the advantages of the devices according to the prior art *without adopting their disadvantages* ...”)), and neither Petitioner nor its expert have demonstrated that a POSA would be motivated to disregard Møller’s teaching against using it. *See Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1366-67 (Fed. Cir. 2017).

b) A POSA Would Not Have Been Motivated to Make the Relied-Upon Combination Due to a Purported Benefit Alleged by Petitioner

Despite this teaching-away, Petitioner argues that a POSA would have been motivated to modify the internal threading on Møller’s dose setting drum 17 due to a purported advantage. Specifically, Petitioner states: “Because the threaded engagement in Steinfeldt-Jensen is configured to reduce the friction between the sliding surfaces of the drum and housing, a POSA would have understood that this configuration would reduce the force needed to rotate the drum back into the housing during injection.” Petition at 87. This argument fails for at least three reasons.

¹¹ WO 99/38554 is the related PCT publication to Steinfeldt-Jensen. *See* Ex. 2026.

First, as explained above, Møller's inventors expressly considered the friction involved in Steendfeldt-Jensen's externally-grooved dose scale drum and rejected using it for their injector pen. *See* Ex.1015, [0008], [0011], Fig. 1.

Second, while Møller teaches an internal thread on dose setting drum 17 that has a higher-pitch than that of nut 13, a POSA would not implement Steenfeldt-Jensen's high-pitch thread because, as explained below, it would impair the ability to dial a precise dosage. As illustrated below in Møller Figure 1, the internal thread on tubular dose setting drum 17 is sufficiently low pitch that dialing out the maximum dose advantageously requires multiple turns of the dose setting drum. Maximum axial displacement of injection button 19 and dose setting drum 17 corresponds to the sum of the length of rack 15 below gear wheel 14 and the length of rack 10 (on gearbox 9) above gear wheel 16 when a dosage has not been dialed. *See* Ex. 1015, [0024]. To dial out injection button 19 this distance requires at least seven rotations (by counting dose setting drum 17's threads over the same distance). Requiring more rotations to dial out the maximum dosage allows a user to finely adjust the dosage to avoid over-dialing or under-dialing the intended dosage.

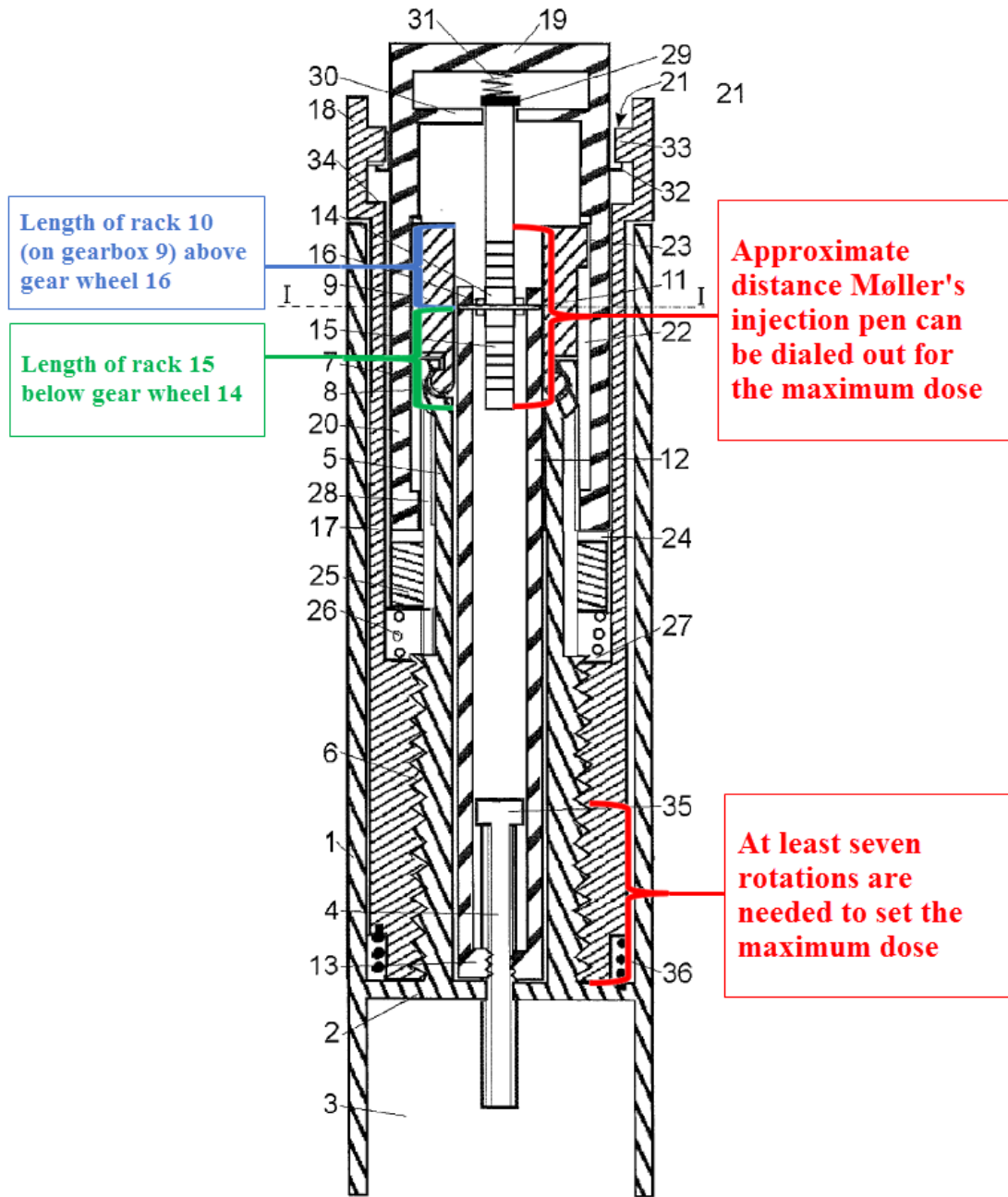


Fig. 1

Ex. 1015, Fig. 1 (annotated).

In contrast, implementing the high-pitch groove of Steinfeldt-Jensen's dose scale drum in Møller would result in the maximum dosage being dialed out in approximately a single rotation. It would have been much more difficult for a user

to dial any dosage less than a maximum dosage, or to make any fine adjustments, using the high-pitch taught by Steinfeldt-Jensen's injector pen in Møller's device. Because the modification lacks any ability to finely tune the dosage, a POSA would not have made such a combination. The illustration below demonstrates that Steinfeldt-Jensen's dose scale drum groove is much higher pitch than Møller's.

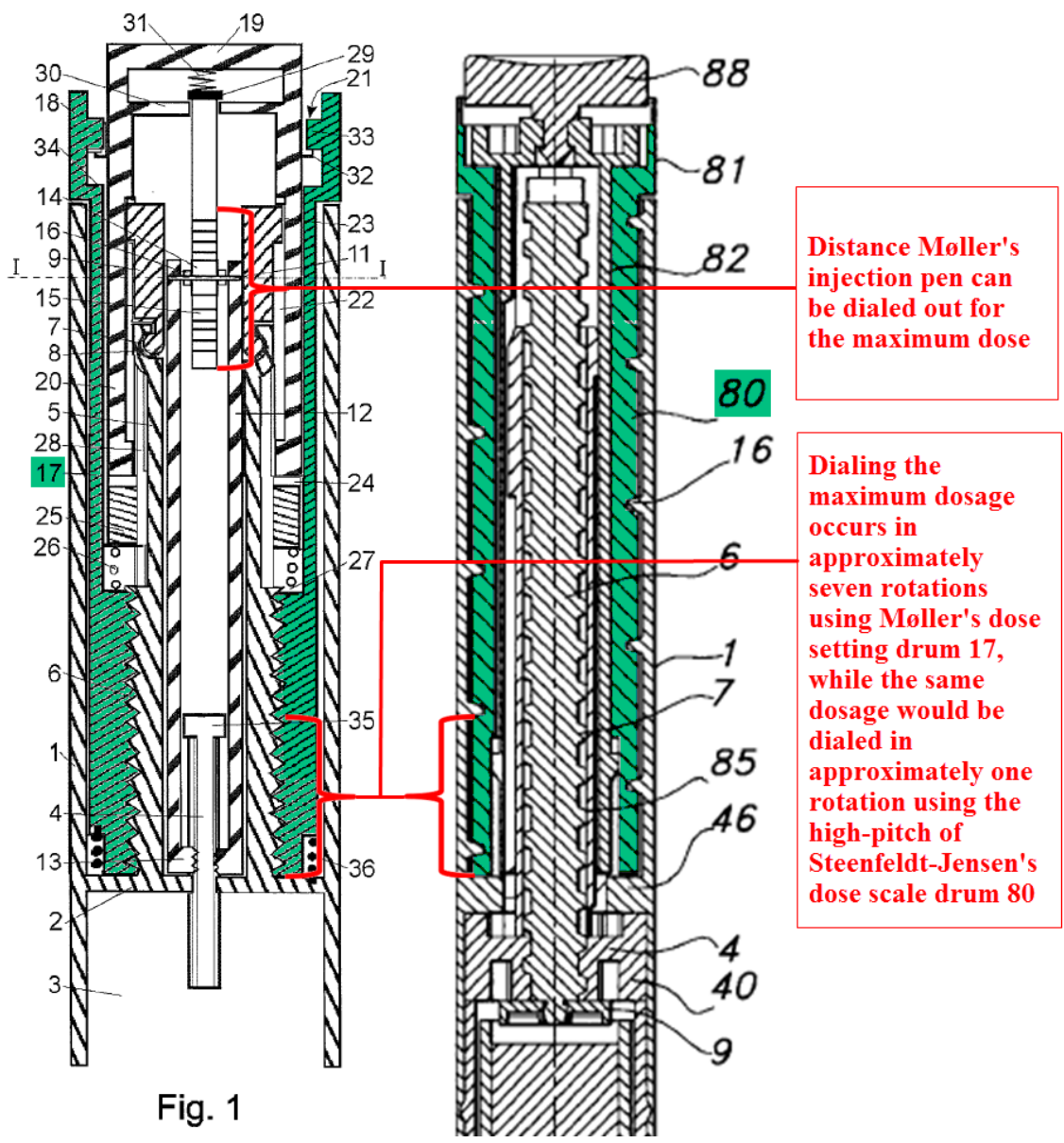


Fig. 1

Ex. 1015, Fig. 1 (annotated) and Ex. 1014, Fig. 16 (cropped & annotated).

Third, Petitioner and its expert did not point to any evidence suggesting that a POSA would look beyond Møller’s teachings for addressing undesirable thread friction in the dose setting drum. Nor would a POSA do so, because Møller teaches its own solution: a “helical reset spring 36” that “exerts a torque

approximately corresponding to the torque necessary to overcome the friction in the movement of the dose setting drum along the thread 6 so that the force which the user have to exert on the injection button is only the force necessary to drive the piston rod into the ampoule to inject the set dose.” Ex. 1015, [0033]. Petitioner does not address why a POSA would ignore this express teaching of a different solution.

In sum, Møller expressly considered Steinfeldt-Jensen’s teachings and rejected them, and Møller proposes a different solution to the purported “problem.” Petitioner is incorrect that “[a] POSA would have had reason to incorporate a high-pitch helical groove as taught by Steinfeldt-Jensen,” let alone one that is “on the outer surface of Møller’s drum.”

VII. CONCLUSION

For the reasons set forth above, Sanofi respectfully requests that the Board deny institution of the Petition on all grounds.

Dated: March 4, 2019

Respectfully submitted,

/Elizabeth Stotland Weiswasser/

Elizabeth Stotland Weiswasser

(Reg. No. 55,721)

Anish R. Desai (Reg. No. 73,760)

Sudip K. Kundu (Reg. No. 74,193)

Kathryn M. Kantha (Reg. No. 70,371)

Weil, Gotshal & Manges LLP

767 Fifth Avenue

New York, NY 10153

Phone: 212-310-8000

elizabeth.weiswasser@weil.com

anish.desai@weil.com

sudip.kundu@weil.com

kathryn.kantha@weil.com

William S. Ansley (Reg. No. 67,828)

Matthew D. Sieger (Reg. No. 76,051)

Weil, Gotshal & Manges LLP

2001 M Street NW, Ste. 600

Washington, D.C. 20036

Phone: 202-682-7000

sutton.ansley@weil.com

matthew.sieger@weil.com

Adrian C. Percer (Reg. No. 46,986)

Brian C. Chang (Reg. No. 74,301)

Weil, Gotshal & Manges LLP

201 Redwood Shores Parkway

Redwood Shores, CA 94065

Phone: 650-802-3000

adrian.percer@weil.com

brian.chang@weil.com

Sanofi.IPR.Service@weil.com

CERTIFICATE OF COMPLIANCE

1. The undersigned certifies that this brief complies with the type volume limitations of 37 CFR § 42.24(a)(1)(i). This brief contains 13,646 words (excluding the table of contents, the table of authorities, mandatory notices under 37 CFR § 42.8, the certificate of service, certificate of compliance, and appendix of exhibits), as calculated by the “Word Count” feature of Microsoft Word 2016, the word processing program used to create it.

2. The undersigned further certifies that this brief complies with the typeface requirements of 37 CFR § 42.6(a)(2)(ii) and typestyle requirements of 37 CFR § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman 14 point font.

Dated: March 4, 2019

Respectfully submitted,

/Elizabeth Stotland Weiswasser/

Elizabeth Stotland Weiswasser

Reg. No. 55,721

Weil, Gotshal & Manges LLP

767 Fifth Avenue

New York, NY 10153

Phone: 212-310-8000

elizabeth.weiswasser@weil.com

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 4, 2019, the foregoing Patent Owner's Preliminary Response and accompanying exhibits were served via electronic mail upon the following:

Richard Torczon
Wesley Derryberry
Tasha Thomas
Wilson Sonsini Goodrich & Rosati
1700 K Street NW, 5th Floor
Washington, D.C. 20006-3817
rtorczon@wsgr.com
wderryberry@wsgr.com
tthomas@wsgr.com

Douglas Carsten
Jeffrey W. Guise
Arthur Dykhuis
Wilson Sonsini Goodrich & Rosati
12235 El Camino Real
San Diego, CA 92130
dcarsten@wsgr.com
jguise@wsgr.com
adykhuis@wsgr.com

Franklin Chu
Wilson Sonsini Goodrich & Rosati
701 Fifth Avenue, Ste. 5100
Seattle, WA 98104
ychu@wsgr.com

Lorelei Westin
Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
lwestin@wsgr.com

Nicole W. Stafford
Wilson Sonsini Goodrich & Rosati
900 South Capital of Texas Highway
Las Cimas, IV Fifth Floor
Austin, TX 78746-5546
nstafford@wsgr.com

/Timothy J. Andersen/
Timothy J. Andersen
Case Manager
Weil, Gotshal & Manges LLP
2001 M Street NW, Ste. 600
Washington, D.C. 20036
Phone: 202-682-7000
timothy.andersen@weil.com