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. IPR2018-01676
U.S. Patent No. 8,603,044

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Rules

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, *Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH v. Eli Lilly and Company*, C.A. No. 1-14-cv-00113-RGA (D. Del), Dkt. No. 1
2005	Complaint for Patent Infringement, *Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie v. Merck Sharp & Dohme Corp.*, C.A. No. 1-16-cv-00812-RGA (D. Del), Dkt. No. 1
2006	Stipulation and Proposed Order, *Sanofi-Aventis U.S. LLC v. Mylan, N.V.,* Civil Action No. 17-9105-SRC-SLW (D.N.J. Feb 5, 2018), Dkt. No. 45
2007	Complaint for Patent Infringement, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J. Oct. 24, 2017), Dkt. No. 1
2008	Excerpts from Defendants' Invalidity Contentions, dated Jan. 25, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2009	Excerpts from Mylan GMBH's Amended Invalidity Contentions, dated April 25, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2010	Excerpts from Mylan GMBH's Exhibit C to Amended Invalidity Contentions, dated April 25, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)

2011	Aug. 13, 2018 Service of Sanofi's Responses to Mylan's Amended Contentions, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2012	MP4 file of Sanofi's Patented Pen animation
2013	Excerpt from Defendants' opening claim construction brief, dated October 12, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2014	Memorandum Opinion, *Sanofi-Aventis U.S. LLC v. Merck Sharp & Corp.*, Case No. 16-cv-812-RGA (D. Del.), Dkt. No. 192
2015	International Patent WO 99/3855
2016	Excerpt from Joint claim construction statement, Ex. A, dated October 8, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2017	Animation depicting Møller's first embodiment
2018	Animation depicting Møller's second embodiment

I. INTRODUCTION

The Board should decline to institute a trial on the Petition. The Petition 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, fails to demonstrate a reasonable likelihood of success that at least one of the challenged claims is unpatentable, and fails to comply with the requirements of 37 C.F.R. § 42.104(b).

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—and continues to assert—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 044 Patent has been listed in the FDA's Orange Book as covering Patent Owner's insulin glargine prefilled pen drug product since 2014 and Petitioner identified the 044 Patent in its Paragraph IV notice served well over a year prior to filing this Petition. Moreover, and Patent Owner had previously asserted the 044 Patent in related lawsuits against Eli Lilly and Merck. Petitioner has thus long had notice of the 044 Patent but waited until the eve of the one-year statutory deadline to file the instant Petition. Because of Petitioner's own delay, the identical invalidity grounds raised in this Petition will 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 repeated and duplicative attacks on the same patent 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, the Petition should be denied because it fails to demonstrate a reasonable likelihood of success that at least one claim is unpatentable. In Ground 1, Petitioner concedes that Steenfeldt-Jensen fails to disclose a drive sleeve that engages with a piston rod via a threaded connection as required by the challenged claims. Petitioner and its expert argue obviousness but a person of ordinary skill in the art ("POSA") would not have been motivated to make the Petition's proposed modification. The proposed modification would result in an inferior (if not inoperable) device without any beneficial tradeoff.

In Ground 2, Petitioner relies on the combination of Steenfeldt-Jensen and Møller. A POSA, however, would not have been motivated to combine Steenfeldt-Jensen's scale drum with Møller's injection pen, because Møller disparages and

rejects Steenfeldt-Jensen's scale drum. Moreover, the Petition does not apply the correct construction for "main housing." When properly construed, Møller fails to disclose or render obvious a "dose dial sleeve … configured to engage a threading provided by said main housing" as required by claim 11. Møller also fails to teach or render obvious a "drive sleeve" as required by claim 11 of the 044 Patent.

Finally, 37 C.F.R. § 42.104(b) requires that a petition identify "[h]ow the challenged claim is to be construed" and "[h]ow the construed claim is unpatentable" so as to put a patent owner sufficiently on notice of the alleged grounds. 37 C.F.R. § 42.104(b)(3)-(4). *See also* Section VI, *infra* (discussing the purpose of the rule from its rulemaking history). The Petition runs afoul of these requirements in two ways. First, the Petition fails to clearly identify what constructions it relies upon. The Petition proffers the "plain and ordinary meaning" generally for all claim terms yet does not articulate a plain and ordinary meaning for those terms. Leading to further confusion, Petitioner identifies the claim constructions proposed by Patent Owner in the co-pending District Court case, but does not state whether these are the plain and ordinary meanings applied in the Petition.[1] Second, where the Petition

[1] In the District Court case Petitioner articulates constructions for various claim terms, but Petitioner does not identify whether it is applying those constructions as the plain and ordinary meaning in this Petition.

does clearly proffer claim constructions (for what it incorrectly contends are means-plus-function limitations), the Petition does not use these constructions consistently in its grounds and thus does not explain how the claims, *as construed*, are unpatentable. For example, the Petition construes "clicker" as a means-plus-function term and identifies "component 50" in Figures 6-8 as the corresponding structure. In contrast, when discussing the prior art, the Petition identifies a "flexible arm 52" and "splines 42," or "saw teeth" 55 and 66 as the corresponding clicker structure. *See, e.g.*, Petition at 43. This internal inconsistency fails to put Patent Owner on notice for "[h]ow the challenged claim is to be construed" and "[h]ow the construed claim is unpatentable …." 37 C.F.R. § 42.104(b)(3)-(4).

For these reasons, as detailed further below, Patent Owner 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 is fundamentally unfair and inefficient to require Patent Owner to expend resources on an IPR trial where the final written decision will issue only after the conclusion and resolution of the identical validity challenge in the related District Court case.

The efficient resolution of patent challenges is foundational to the IPR system and the AIA generally. To this end, 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.*, lIPR2018-00277, 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 until such time that the IPR, if instituted, would result in a final written decision only after the same 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 multiple petitions on the 044 Patent not as "an effective and efficient alternative to district court litigation," *id*., but instead in an inefficient and intentionally staggered attempt to take the same shot at the same patent 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 version of insulin glargine 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 the time of the June 2017 press release, Patent Owner had already asserted the 044 Patent against two other competitors seeking approval of follow-on glargine products. *See* Ex. 2004 at 6-7, Ex. 2005 at 1.

Relatedly, the publication of the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") has listed the 044 Patent since 2014 as covering Patent Owner's Lantus® SoloSTAR® product (*i.e.*, Sanofi's insulin glargine formulation and the injector pen device for administering the formulation). Thus, Petitioner was long on notice of the 044 Patent, and that the Patent Owner was actively enforcing it against competitors.

On April 27, 2017, Petitioner submitted its application to market its follow-on insulin glargine product to the FDA. Thereafter, 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 Patent Owner a letter dated September 15, 2017 that noticed the submission of Petitioner's FDA application and contained so-called "Paragraph IV" certification alleging that Petitioner's proposed glargine product would not infringe the claims of the 044 Patent, which Petitioner alleged to be

amongst a list of patents that are not "not valid, unenforceable, and/or will not be infringed." *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 Patent Owner filed a patent infringement case against Petitioner asserting the 044 Patent, among others. As part of that patent infringement case, Petitioner served its invalidity contentions on Patent Owner on January 25, 2018 that included the exact same prior art advanced in the Petition and amended those contentions on April 25, 2018 to include the exact same prior art grounds now advanced in the Petition—*i.e.*, obviousness of claims 11, 14, 15, 18, and 19 of the 044 Patent over Steenfeldt-Jensen and also over Møller in combination with Steenfeldt-Jensen. *See* Section II.C.2, *infra*.

On August 12, 2018 (approximately a month before filing the Petition), Petitioner received and reviewed Patent Owner's detailed validity contentions responding to those grounds. Despite long having notice of the 044 Patent and its assertion against Petitioner, it was not until September 10, 2018—the eve of the one-year statutory bar under 35 U.S.C. § 315(b)—that Petitioner filed this Petition, along with eight others, asserting substantially the same invalidity grounds it alleged in the District Court case. *See* IPR2018-01670, IPR2018-01675, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01696, IPR2019-00122.

In the meantime, the parties have been actively litigating the District Court case. A *Markman* hearing is likely to occur in early February 2019, and the parties have jointly requested a trial for October 2019 in order to achieve resolution of the issues before the end of the FDA's 30-month stay of regulatory approval of Petitioner's FDA application (March 18, 2020).[2] *See* Ex. 2006, ¶ 8 ("The parties hereby agree to jointly request the Court to schedule trial in the Action in October 2019"). Accordingly, resolution of the District Court case should occur well before the April 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) ("August 2018 Trial Practice Guide 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

[2] As part of the Hatch-Waxman process, Patent Owner's District Court case against Petitioner triggered a 30-month period during which the FDA will not approve Petitioner's follow-on application without resolution of the District Court case. *See* 21 U.S.C. § 355(c)(3)(C).

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 August 2018 Trial Practice Guide 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 under §§ 314(a) and 324(a) 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 circumstances[3] 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. The parties are engaged in district court litigation on the same patent

In *NHK Spring*, the challenged patent was being 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 044 Patent is asserted by Patent Owner 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. 2007.

[3] Because the *NHK Spring* patent was expired, both the Board and District Court applied the *Phillips* standard for claim construction. Here, however, the 044 Patent is not expired and thus the Board will apply the BRI standard and the District Court will apply the *Phillips* standard for claim construction. This is a distinction 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, the Petition cites *Phillips* to support its constructions. Petition at 14.

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

In support of its decision to deny 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 claims 11, 14, 15, 18, and 19 are obvious over Steenfeldt-Jensen and also over the combination of Møller and Steenfeldt-Jensen. Petition at 3. In the co-pending District Court case, Petitioner served invalidity contentions alleging that Steenfeldt-Jensen alone renders these claims obvious, as does the combination of Møller and Steenfeldt-Jensen. *See* Ex. 2008 at 202; Ex. 2009 at 268-269, Ex. 2010 at 10-12, 21, 27, 34-35, 39, 62-63, 65-67, 80-81, 95-97, 111-113, 115-116, 132-136, 154-156, 164-166, 176-177, 188-190, 194-195, 198-199, 221-223, 226 (an invalidity chart applying Steenfeldt-Jensen's and Møller's disclosures against claims 11, 14, 15, 18, and 19). Thus, the same situation exists here as in *NHK* – the same prior art combinations used in the IPR are used in the litigation between the parties.[4] *See NHK Spring,* Paper 8 at19-20.

[4] Moreover, Petitioner has filed ***eight other petitions*** that assert substantially the same arguments being litigated in the District Court case. *See* IPR2018-01670, IPR2018-01696, IPR2018-01675, IPR2018-01678, IPR2018-01680, IPR2018-01679, IPR2018-01682, 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 a little 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 co-pending District Court case, Petitioner and Patent Owner have jointly requested a trial in October 2019. And even if a trial does not take place in October 2019, the District Court is keenly aware that the 30-month stay of regulatory approval of Petitioner's FDA application expires on March 18, 2020, and has indicated that it will decide the issue of validity in advance of that date. A Final Written Decision in an IPR trial on the same prior art and arguments would not issue until April 2020, six months after the likely date of the District Court case trial. 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 the Petitioner a tactical advantage

In *NHK Spring*, the patent owner argued that the petitioner waiting to file the petition until shortly before the expiration of the one-year deadline 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 had obtained Patent Owner's detailed validity positions in response to Petitioner's invalidity contentions (as explained in Section II.A. and II.C.2), and is attempting to get the proverbial two bites at the apple. Even if the 044 Patent is found valid and infringed at trial in the District Court case, Patent Owner will be unfairly required to defend the validity of the 044 Patent in an IPR proceeding before the Board on the same prior art and arguments.

This gamesmanship is highly prejudicial to Patent Owner, and antithetical to the purpose of the statute, which is to provide a "quick and cost effective *alternatives* to litigation". H.R. Rep. No. 112–98, pt. 1, at 48 (2011) (emphasis added). Petitioner was fully aware of the timing of the District Court case 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. 2008 at 202. In these circumstances, Patent Owner respectfully submits that the Board should exercise its discretion to deny the Petition.

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

NHK Spring cites extensively 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 a discretionary denial is appropriate. *Gen. Plastic,* Paper 19 at 9-10. These factors likewise amply support denial of the Petition, as explained below.

While the *General Plastic* factors were articulated in the context of denying a follow-on petition filed by the same petitioner on the same patent, the Board has since 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 are applicable to the present situation even though the factors were articulated in the context of a follow-on petition filed on the

same patent. Here, rather than a follow-on petition, Petitioner is duplicating its invalidity arguments in the District Court case and the IPRs. Factors 1, 2, 4, and 5 favor denying institution.

First, Petitioner has asserted, and continues to assert, the same prior art and arguments directed to the same claims of the same patent in its Petition and in the District Court case. *See discussion in Section II.C.2, above.*

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 044 Patent.[5] Ex. 2008. Yet Petitioner waited almost eight months to file its Petition on the eve of the expiration of the one-year deadline under § 315(b), approximately a month after it received Patent Owner's response to Petitioner's amended invalidity contentions. *See* Ex. 2011. As a result, the final written decision is not due until April 2020, well after the conclusion of the requested October 2019 trial on the same prior art.[6] Institution of trial therefore will not "limit

[5] The prior art assed in the Petition is also listed on the face of the 044 Patent.

[6] Notwithstanding the parties' trial date request, the District Court has indicated that it will render a judgment on patent validity before the expiration of the 30-month stay on Petitioner's FDA application – *i.e.*, before March 18, 2020.

unnecessary and counterproductive litigation costs" (H.R. Rep. No. 112-98, pt. 1, at 40), but will instead unfairly subject Patent Owner to having to defend the same "repeated attacks on patents." *Gen. Plastic,* Paper 19 at 16-17.

Third, Petitioner's late filing after receiving Patent Owner's positions in response to Petitioner's invalidity contentions in the District Court case provides an unfair tactical advantage to Petitioner to the prejudice of Patent Owner by providing Petitioner two bites at the apple. *See* Section II.C.4, *supra.*

Because Petitioner is asserting the same prior art grounds in the District Court case and was aware of the art but chose to delay filing this Petition for a tactical advantage, these factors weigh in favor of denial.

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

Extending the logic of the third factor to the present circumstances, this factor favors denying institution. 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 on tailoring arguments after seeing another party's positions is equally applicable here. Petitioner delayed filing its Petition until it had the benefit of reviewing Patent

Owner's responses to Petitioner's invalidity positions in the co-pending District Court case. Indeed, Petitioner was able to tailor the Petition to address issues identified by Patent Owner 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 weigh in favor of 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 have jointly requested a trial in October 2019, but the validity questions will very likely be decided no later than March 18, 2020 (*i.e.*, before the end of the 30-month stay on Petitioner's FDA application). By contrast, the final written decision for the Petition would not be due until April 2020, after the District Court has conducted a trial and issued a decision on the same invalidity grounds.[7] 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, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01696, IPR2019-00122. Thus, this

[7] Indeed, even before the Board issues an Institution Decision, the District Court will likely have already issued its claim construction order.

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 weigh in favor of denial. This Petition is the antithesis of the "effective and efficient alternative to district court litigation" contemplated by the AIA and the Board. Instead, it is nothing more than a duplicative effort to test the same invalidity theories in two forums. Institution should therefore be denied.

III. THE 044 PATENT

The 044 Patent is directed to a pen-type injector for medications such as insulin and insulin glargine. Ex. 1002, 1:19-24. Such injectors are regularly used by patients without formal medical training, such as diabetic patients who manage their condition through self-treatment. *Id*., 1:25-29. The 044 Patent teaches that pen injectors should meet several criteria, including being robust in construction while being easy to manipulate and understand by the user, who in many cases may be physically infirm and have impaired vision. *Id*., 1:30-35.

The 044 Patent teaches improved pen injectors that meet these criteria. The figures below depict an embodiment of an improved injection pen. Additionally, an animation of the embodiment's operation has been submitted as Ex. 2012.

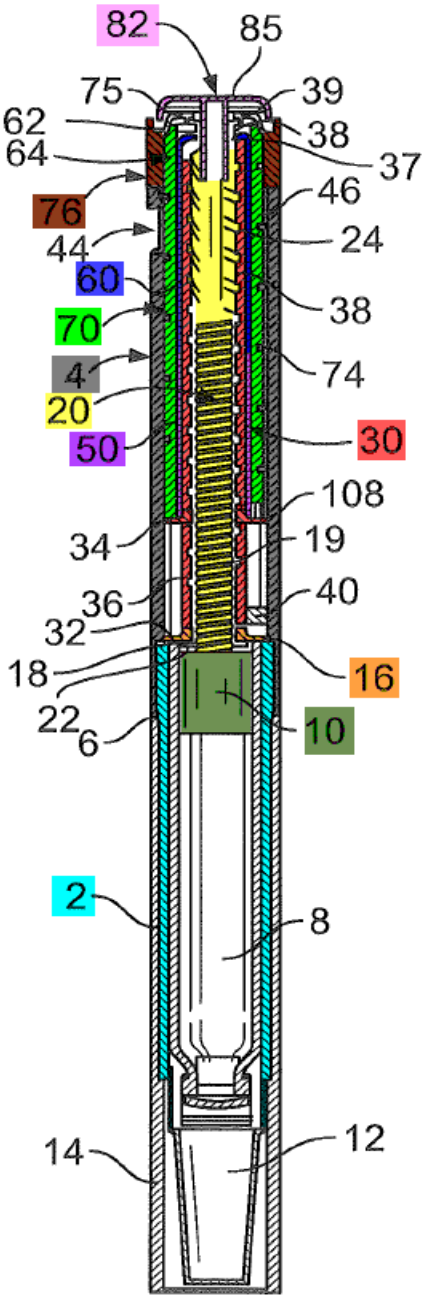


FIG. 1

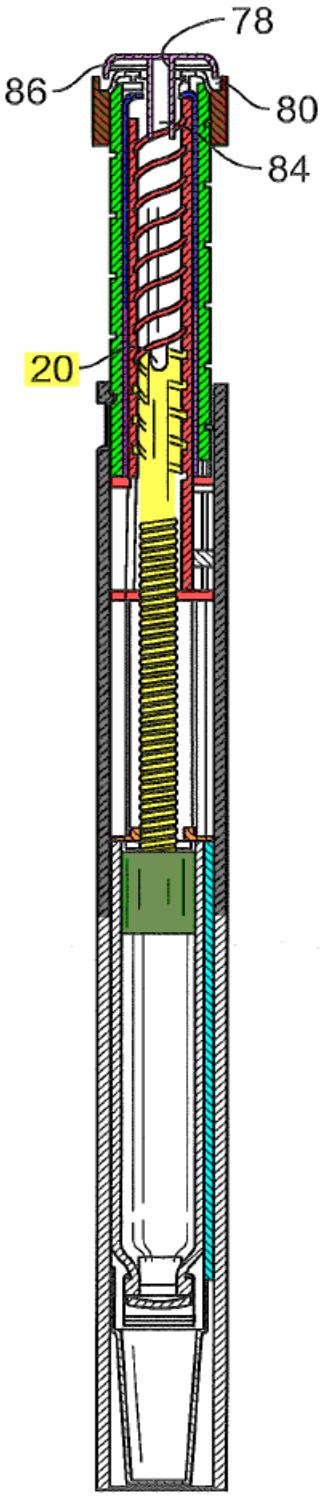


FIG. 2

Ex. 1002, Figs. 1 and 2

The injection pen of the 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.

As seen below, in this embodiment, the dose value is selected by rotating the dial grip portion 76 (brown) of a dose dial sleeve 70 (light green), which winds out of the main housing 4 (grey) on a helical path defined by a threaded engagement between a helical groove on the surface of the dose dial sleeve and a helical rib 46 inside the housing. *Id.*, 5:50-6:3; Figs. 9-10.

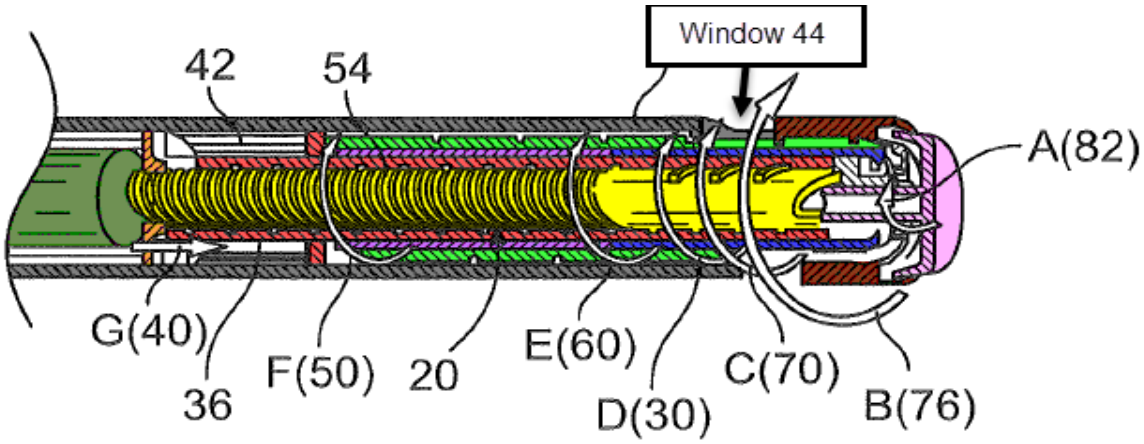


FIG. 9

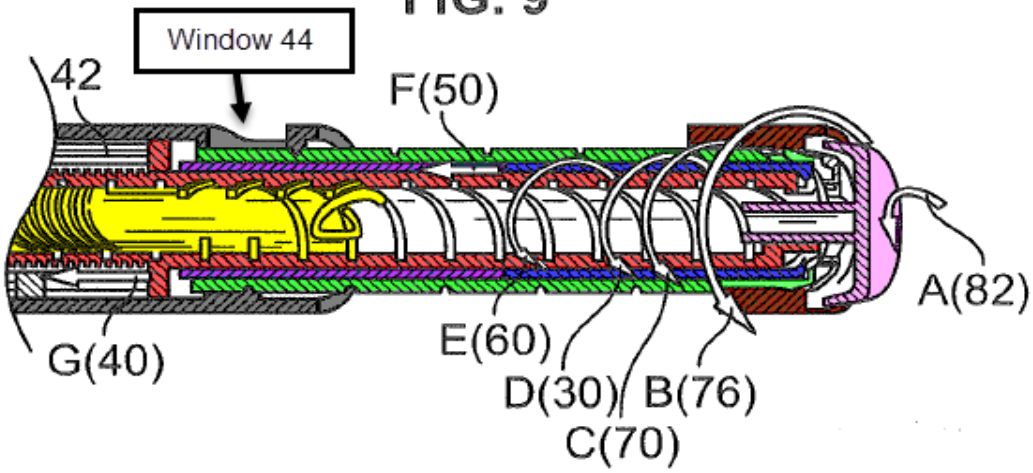


FIG. 10

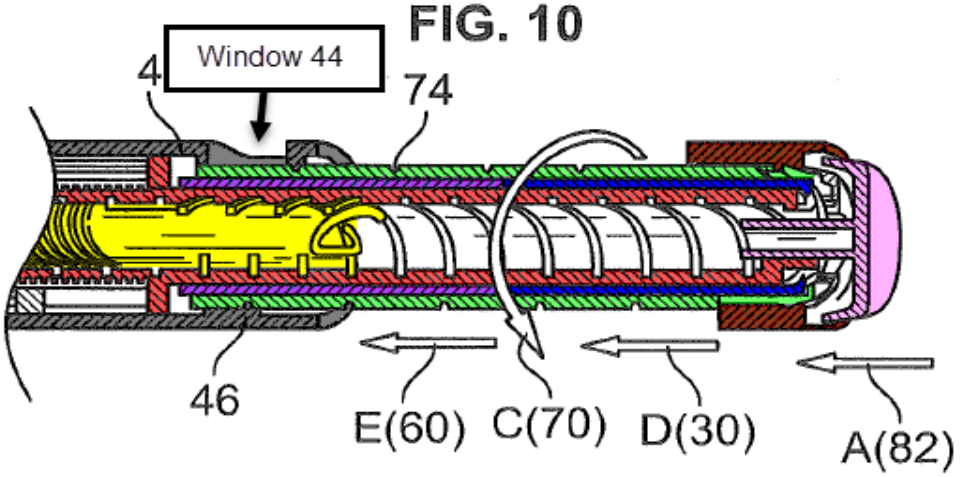


FIG. 11

Ex. 1002, Figs. 9 – 11

Dose markings (numbers) printed on an external surface of the dose dial sleeve 70 indicate the dosage. *Id*., 5:17-21. In this embodiment, a clicker 50 detents the dose dial sleeve relative to the housing at each fixed dosage unit and provides audible feedback (*e.g.*, one click for every unit dialed) to assist in dose selection. *Id*., 4:33-44, 5:54-60.

Once the correct dose is selected, the user delivers a dose by pressing the dose button 82 (pink) with his or her finger or thumb, as shown in Figure 11. *Id*., 6:27-28. This user action returns the dose dial sleeve into the housing and delivers the dose by causing the drive sleeve 30 (red) to move toward the distal end of the pen, as indicated by the arrow D in Figure 11. This in turn causes a piston rod 20 (yellow) to advance a piston 10 (dark green) into the cartridge to dispense the stored medication. *Id*., 6:44-46. During this dose-injection process the dose button and drive sleeve are not rotationally coupled to the dose dial sleeve, allowing the dose dial sleeve to rotate back into the housing along the path defined by the helical groove (arrow C in Figure 11), while the dose button and drive sleeve travel on an axial path without rotating (arrows A and D in Figure 11). *Id*., 6:27-34; Fig. 11.

Once the dose is administered, the dose dial sleeve returns to the starting or "zero dose" position and is prevented from rotating further into the device. *Id*., 6:47-51. The user then releases the dose button, which returns the internal mechanism of the device into the dose dialing state. *Id*., 6:39-43.

IV. CLAIM CONSTRUCTION

The Petition alleges that "[t]he grounds rely on the ordinary and customary meaning of the claim terms as a POSA would have understood them." Petition at 16. Yet the Petition does not articulate what the plain and ordinary meaning is for any terms. Petitioner also states that, "[t]he Patent Owner has defined certain claim terms in related litigations, and cannot now argue its definitions are unreasonable" and proceeds to list constructions from a preliminary claim construction disclosure in the District Court case (Ex. 1019). Petition at 14. 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, Patent Owner believes it is only necessary to address the construction of the term "main housing" in the Preliminary Response.

Petitioner additionally addresses the "tubular clutch" and "clicker" limitations as means-plus-function limitations. Petition at 16. Patent Owner disputes Petitioner's contention that these terms should be construed as means-plus-function terms.[8]

A. "main housing"

[8] Patent Owner reserves the right to address the construction of all other terms should the Petition be instituted.

"Main housing" should be construed to mean, "an exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components". This construction is supported by the inventors' lexicography, which governs the meaning of claim terms in proceedings before the Board. *See Nestle USA, Inc. v. Steuben Foods, Inc.*, 686 F. App'x 917, 918-19 (Fed. Cir. 2017) (where the broadest reasonable construction applied, finding that the Board erred in not adopting the lexicography); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) ("[T]he inventor's lexicography governs."). Specifically, this construction derives from lexicography in related U.S. Patent No. 9,604,008 (the "008 Patent")[9,10], which recites:

---

[9] The same foreign application—GB 0304822—is the ultimate parent of both the 044 Patent and the 008 Patent. The 044 Patent and 008 Patent are therefore related.

[10] The lexicographical statement in the 008 Patent is applicable because the same term in related patents is presumed to have the same construed meaning. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003) ("The disputed term … is the same throughout all five patents in the genealogy …. [W]e presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning."). Further, in the co-pending District

> The term "housing" according to instant invention shall preferably mean any ***exterior housing ("main housing"***, "body", "shell") or interior housing ("insert", "inner body") having a helical thread. The housing may be designed to enable the safe, correct, and comfortable handling of the drug delivery device or any of its mechanism. Usually, it is ***designed to house, fix, protect, guide, and/or engage with any of the inner components*** of the drug delivery device (e.g., the drive mechanism, cartridge, plunger, piston rod) by limiting the exposure to contaminants, such as liquid, dust, dirt etc. In general, ***the housing may be unitary or a multipart component*** of tubular or non-tubular shape. Usually, the exterior housing serves to house a cartridge from which a number of doses of a medicinal product may by dispensed.

Ex. 1005, 2:66-3:12 (emphasis added). Consistent with Patent Owner's construction, this lexicography specifies that a "main housing" is an "exterior housing," "designed to house, fix, protect, guide, and/or engage with any of the inner components," and "may be unitary or a multipart component."

At least one Court has confirmed that this lexicography is controlling for "main housing" in the 044 Patent. In a prior litigation ("*Merck* case"), Patent Owner proffered this same construction and the District Court adopted it, finding that "the

---

Court case, Petitioner agrees that the constructions for terms should be the same for the 044 and 008 Patents. Ex. 2013 at 14 ("… the parties agree the same construction should apply for all five Device Patents.").

lexicography of the . . . '008 patent[]" required this construction. *See* Ex. 2014 at 7-9. While the claim construction standards applied by the PTAB and district courts differ (for petitions filed before November 13, 2018), the District Court's construction of "main housing" in the *Merck* case is consistent with the broadest reasonable interpretation of the term *in view of the lexicography in the specification*. *See Nestle*, 686 F. App'x at 918-19 (where the broadest reasonable construction applied, finding that the Board erred in not adopting the lexicography).

In contrast, Petitioner's "plain and ordinary meaning" for "main housing" (to the extent its construction can be inferred) is so broad as to include an interior housing. *See, e.g.*, Petition at 52-54 (identifying Møller's "housing 1," interior "partitioning wall 2," and interior "tubular element 5" as the claimed "main housing"). Yet as set forth above, the lexicography relied upon by the District Court draws a clear distinction between an "exterior housing ('main housing', 'body', 'shell')" and "interior housing ('insert', 'inner body')." Ex. 1005, 2:66-3:12. A "main housing" is not an interior housing.

B. "tubular clutch" and "clicker"

Petitioner asserts that the terms "tubular clutch" and "clicker," which are not written in means-plus-function format, may be means-plus-function limitations. *See* Petition at 15-16. 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).

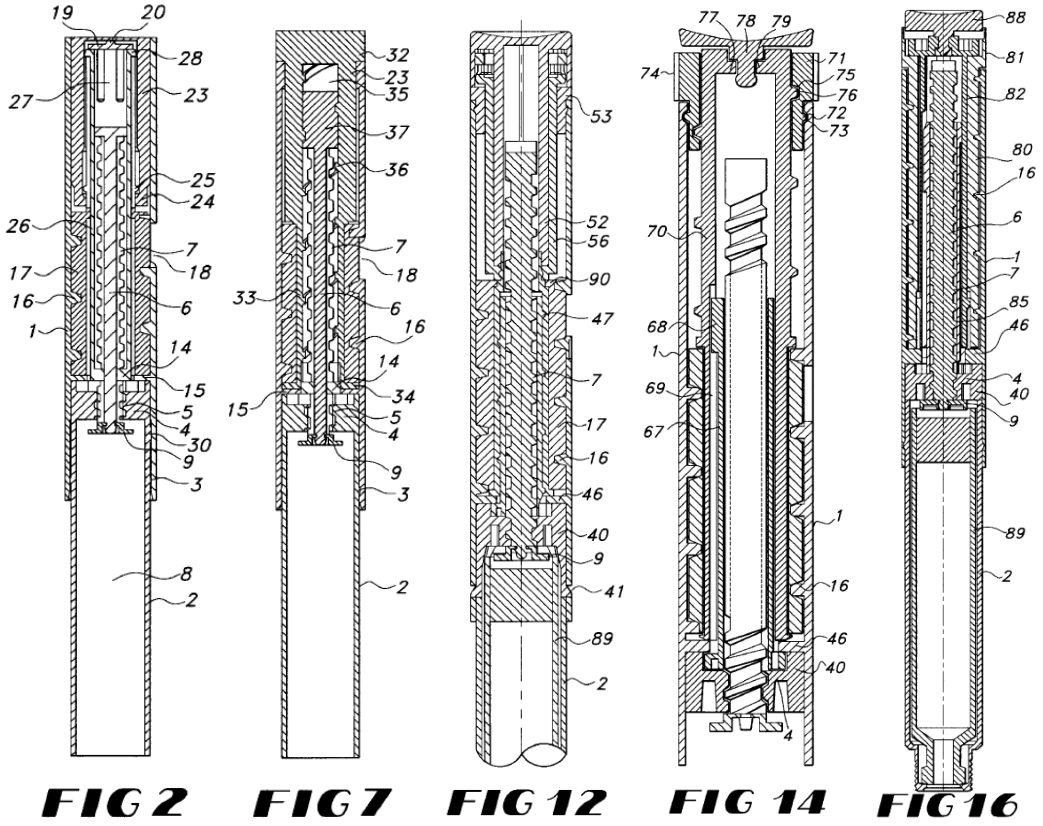
V. PETITIONER HAS FAILED TO DEMONSTRATE A REASONABLE LIKELIHOOD OF SUCCESS ON GROUNDS 1 AND 2

A. Ground 1 Should Be Denied Because Steenfeldt-Jensen Does Not Render Obvious the Challenged Claims

1. Overview of U.S. Patent No. 6,235,004 ("Steenfeldt-Jensen") (Ex. 1014)

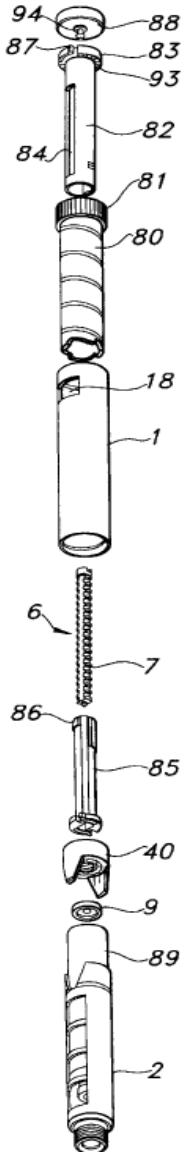
Steenfeldt-Jensen is a U.S. patent. Its PCT counterpart application, WO 99/38554 (Ex. 2015), was included in an IDS during prosecution of the 044 Patent and is cited on the face of the 044 Patent. *See* Ex. 1014 (claiming priority to DK 1998 00130), Ex. 2015 (same), Ex. 1007 at 0234 (listing WO 99/38554).

Steenfeldt-Jensen discloses five distinct pen injector embodiments. *See* Ex. 1014, Figs. 1-17. The first, second, third, fourth, and fifth embodiments are depicted in figures 1-5, figures 6-10, figures 11-13, figure 14, and figures 15-17, respectively. *See* Ex. 1014, 5:33-37, 7:48-49, 8:34-35, 10:14-15, 11:6. These pen injectors comprise different components and arrangements, as shown below, and are configured to operate differently.



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

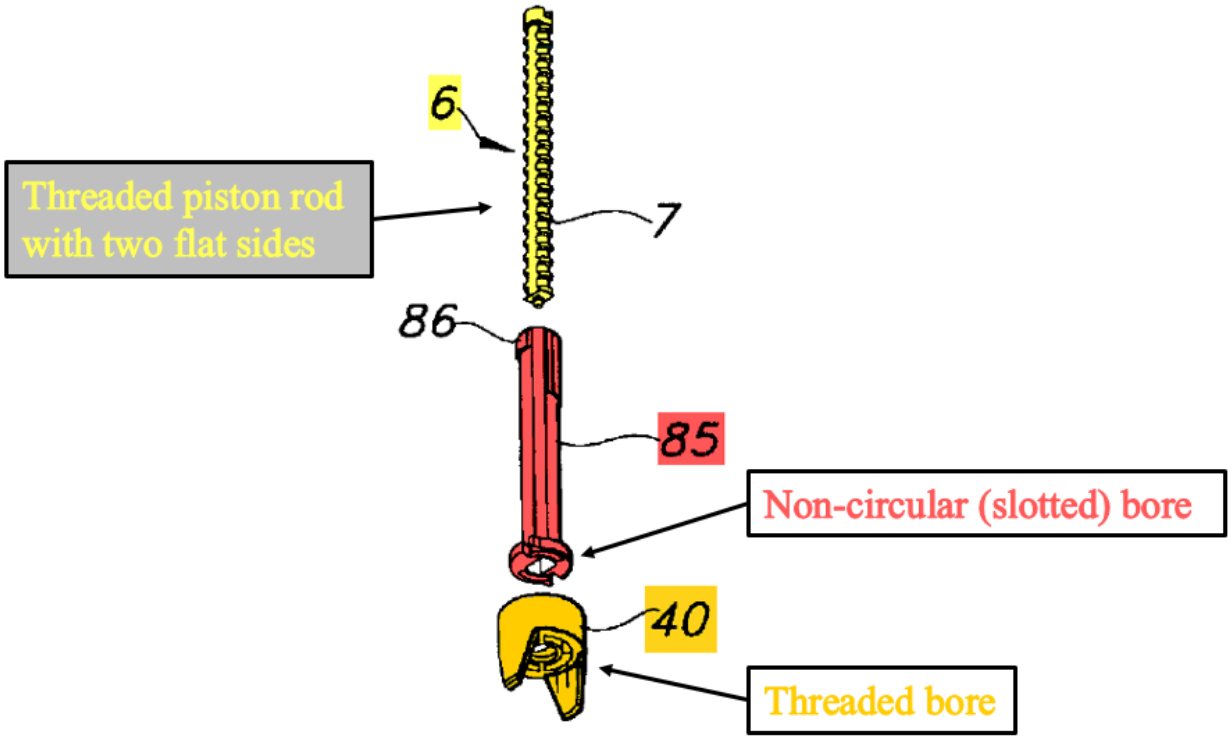
For the grounds asserted in the Petition, Petitioner primarily relies on the fifth embodiment (Ex. 1014 at 11:6-12:16, Figs. 15-17) to argue that Steenfeldt-Jensen discloses or renders obvious the challenged claims. *See* Petition at 21-49. The fifth embodiment, depicted in an exploded view, below, comprises an ampoule holder 2, an ampoule (or cartridge) 89, pressure foot 9, member 40, driver tube 85, piston rod 6, housing 1, scale drum 80, bushing 82, and injection button 88.



Ex. 1014, Fig. 17.

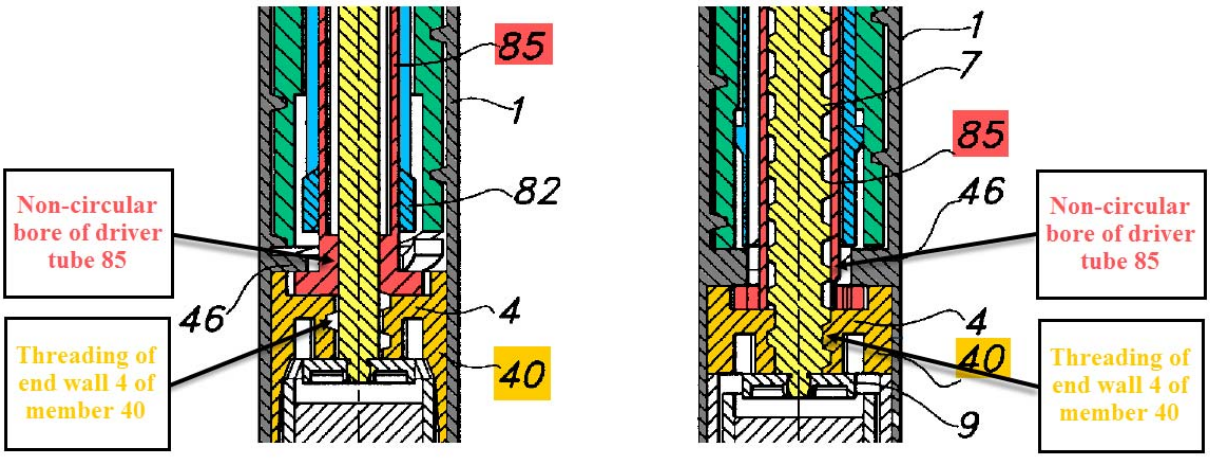
Significant to the issues raised in this Preliminary Response, Steenfeldt-Jensen's fifth embodiment includes a threaded piston rod 6 having two flat sides – *i.e.,* a non-circular threaded piston. This non-circular shape is important in the fifth embodiment because the piston rod 6 rotates with driver tube 85 when driver tube 85 is rotated. Note that while piston rod 6 is threaded, driver tube 85 is not threaded.

The non-circular shape of the piston rod 6 fits within the same non-circular bore of the driver tube 85, thus rotationally coupling the components while allowing them to move axially relative to one another.



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. As further detailed below, when the driver tube is rotated (during the dose dispensing phase), the piston rod 6 is also rotating, causing it to 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).

Referring to Figure 17, depicted above, to set a dose, the user rotates the dose setting button 81 on the proximal end of scale drum 80 in the clockwise direction (viewed from the proximal end). This causes the scale drum 80 to screw out of the housing. Ex. 1014, 11:43-49. The bushing 82, driver tube 85, and piston rod 6 remain stationary during the clockwise rotation of dose setting because the pawls on the distal end of the driver tube 85 engage with the teeth in the member 40 and prevent movement in that direction, and also because the hooks 86 on the driver tube engage with the longitudinal slots 84 on the bushing. *Id.*, 11:52-67.

Once the dose is set, the dose is dispensed by pressing the injection button 88, whereby the teeth on bushing 82 and in dose setting button 81 are "pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 which is induced by the thread engagement between the helical track of the scale drum 80 and the rib 16 in the housing when the scale drum 80 is

pressed back into said housing." Ex. 1014, 12:5-10. There is sufficient counter-clockwise torque applied through these various components that driver tube 85 rotates counter-clockwise with the bushing. This advances the piston rod 6 axially in the distal direction because the piston rod 6 screws into member 40 during this rotation.

2. Steenfeldt-Jensen Does Not Teach or Render Obvious a "drive sleeve comprising an internal threading … adapted to engage an external thread of said piston rod"

Claim 11 of the 044 Patent 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). As noted above, the Petition relies on Steenfeldt-Jensen's fifth embodiment to argue that the challenged claims are obvious. Petitioner and its expert concede, however, that Steenfeldt-Jensen's fifth embodiment does not disclose this limitation. Specifically, Petitioner admits that Steenfeldt-Jensen discloses a driver tube that "engages with the rod through ***[a] non-circular bore, rather than 'an internal threading*** ….'" Petition at 31 (emphasis added); *see also* Ex. 1011, ¶ 274.

In light of this missing limitation, Petitioner argues that based on a teaching in Steenfeldt-Jensen for its first embodiment, it would have been obvious to apply this teaching to Steenfeldt-Jensen's fifth embodiment to swap the internal threading

of member 40 in the fifth embodiment with the non-circular bore of driver tube 85 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 30-31, 40-42; 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. The Petitioner points to no disclosures that teach modifying the fifth embodiment in the manner proposed by the Petitioner. 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 by the Petitioner 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)).

a) Steenfeldt-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 POSA would have known to modify the fifth embodiment (shown in Figures 15-17 and described at col. 11, ln. 6 through col. 12, ln. 16) based on the following passage from Steenfeldt-Jensen's discussion of its first embodiment (shown in Figures 1-5 and described at col. 5, ln. 33 through col. 7, ln. 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 embodiment described with respect to Figures 1-5, which is the first embodiment—*i.e.*, an embodiment that is not the basis for Ground 1. The passage is included in the discussion of the specification that describes only the first embodiment (*id.,* 5:33-7:47). Moreover, the passage suggests interchanging the non-circular opening (*i.e.*, piston rod guide 14) of the driver tube 26 in the first embodiment with the threaded opening in the end wall 4 of ampoule holder 2 in the first embodiment. The passage does not teach, as Petitioner suggests,

interchanging the internal threading of member 40 in the fifth embodiment with the non-circular bore of driver tube 85 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 (the portion of the specification 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.

Note that the Petition cites two other disclosures in Steenfeldt-Jensen's summary of the invention recognizing that in order for a piston rod to move axially through a nut member on dose injection, there must be relative rotation between the piston rod and the nut member (i.e., either the nut member rotates, or the piston rod rotates). *See* Ex. 1014, 3:15-20, 3:44-47. These disclosures only teach rotating one or the other (piston or nut member). These disclosures do not contemplate or instruct modifying a device component to ***create*** a new nut member. That is, none of these passages supports, as the Petition contends, a threaded drive tube created from whole cloth. Thus, these disclosures in Steenfeldt-Jensen cannot serve to support

Petitioner's obviousness argument to modify the driver tube in the fifth embodiment to include threading when it did not otherwise include threading.

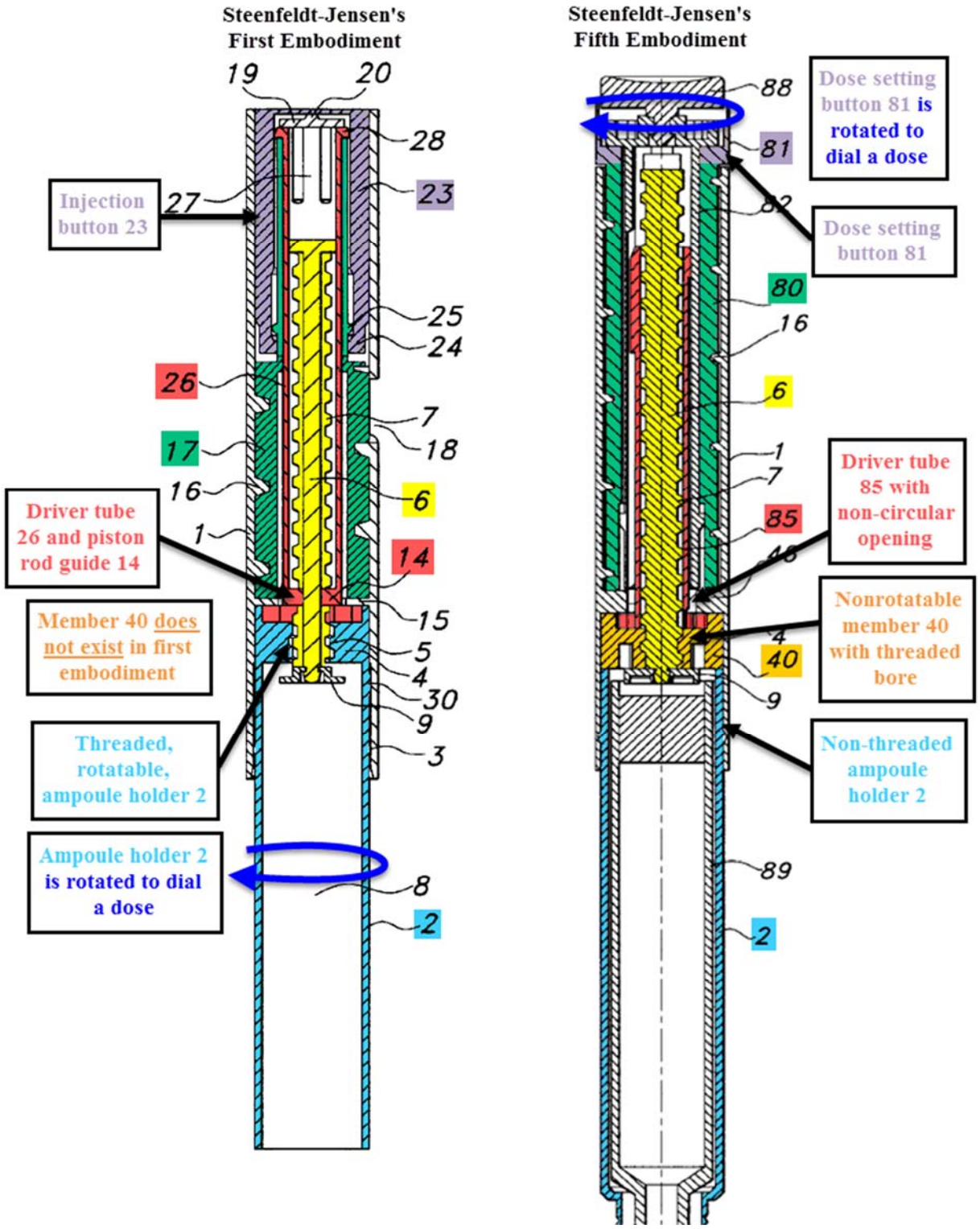
Accordingly, contrary to Petitioner's assertions, Steenfeldt-Jensen does not provide any teachings with respect to the fifth embodiment to support Petitioner's modifications.

b) 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 from Steenfeldt-Jensen that Petitioner relies upon are not related 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 Steenfeldt-Jensen proposes to modify the first embodiment. The first embodiment requires a high-friction threaded engagement between piston rod (yellow, below) and rotatable ampoule holder (blue, below). This high-friction interface is needed for dialing a dose (which is done by grasping and rotating the ampoule holder 2), but the high-friction must also be overcome by a user pressing the injection button with sufficient force to inject the dosage. The modification proposed by Steenfeldt-Jensen eliminates this high-friction interface in the first embodiment.

In contrast, the fifth embodiment does not need or include a high-friction interface. Thus, the passage relied on by the Petitioner, and its teaching to eliminate

the high-friction interface in the first embodiment, is not applicable to the fifth embodiment. This difference between the first and fifth embodiments is discussed more fully in the context of the figures, below.



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

In the first embodiment (above, left), the piston rod 6 (yellow) directly engages the 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 the ampoule holder 2 is rotated, the piston rod 6 rotates along with the ampoule holder 2 due in part to a high-friction interface between the piston rod 6 and the ampoule holder 2. *See Id.*, 6:54-59 ("The rotation of the ampoule holder is due to the friction in engaging threads 5 and 7 transmitted to the piston rod 6 …."). The piston rod 6 in turn rotates with the piston rod guide 14 (the piston rod 6 is inserted into the piston rod guide 14) and the piston rod guide 14 then rotates the dose scale drum 17.

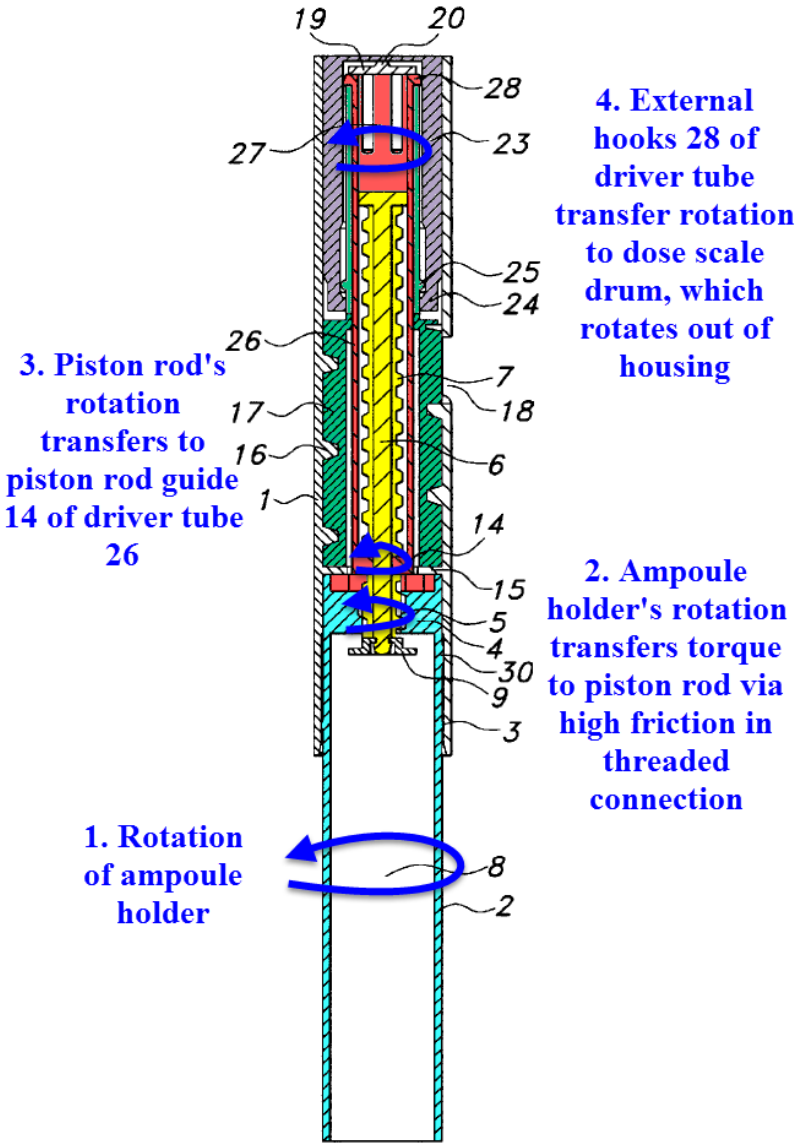


FIG 2

Ex. 1014, Fig. 2 (annotated).

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

relative to the ampoule holder 2. Once the piston rod 6 is rotating relative to the 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 movement in the pen during injection. This is a significant issue in view of the potentially elderly and impaired population using pen injectors.

Steenfeldt-Jensen at column 7, lines 38-44 (the passage relied on by Petitioner), suggests a solution for this problem in the first embodiment. Namely, by interchanging the threaded connection between the piston rod 6 and the 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, the high-friction threaded interface between piston rod 6 and ampoule holder 2 in the first embodiment is eliminated. Now, the ampoule holder 2 can rotate the piston rod 6 via its non-circular bore during the dose dialing phase (which is still done by grasping and rotating the ampoule holder 2), and there is no undesirable thread friction between the ampoule holder 2 and piston rod 6 in the first embodiment during the dose dispensing phase.

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. This is seen in Figure 16, above – the 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

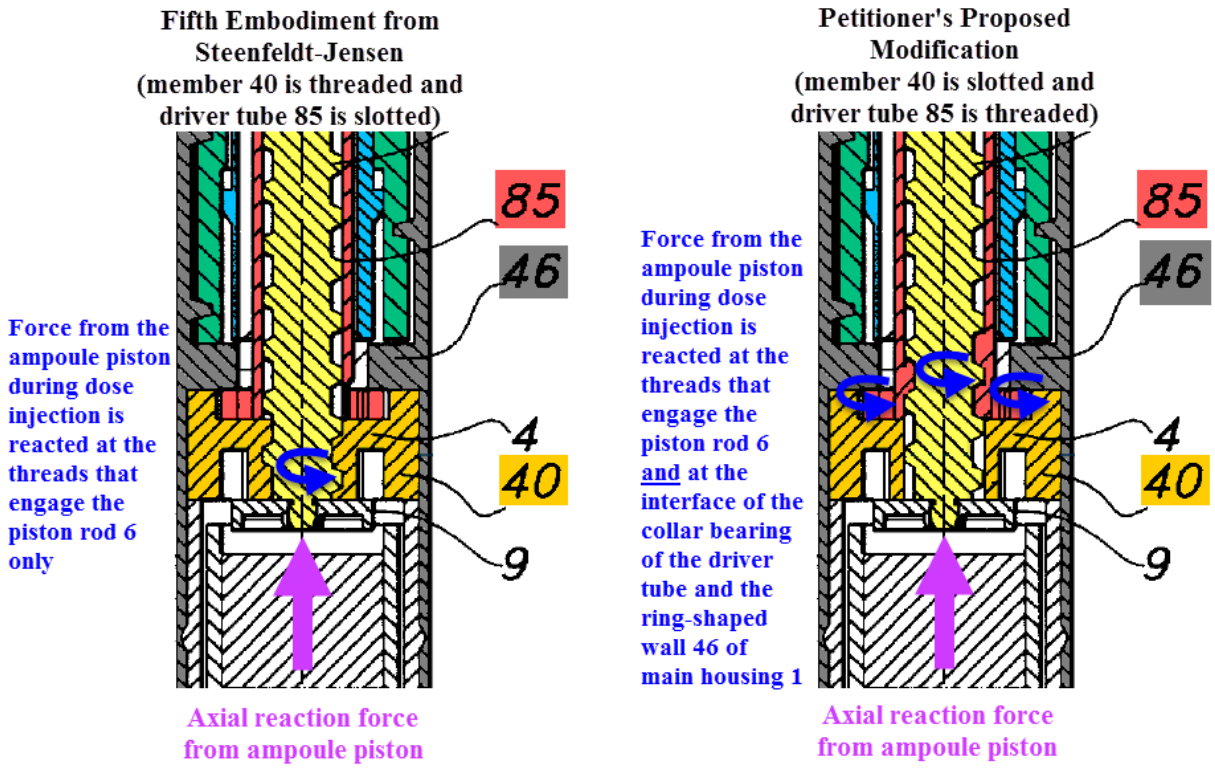
embodiment. Further, dose setting button 81, not the ampoule holder 2, is rotated to dial a dose. *See* Ex. 1014, 11:52-12:3. Thus, ***there is no high-friction interface*** included or needed in the fifth embodiment, which is a significant distinction from the first embodiment.

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

c) The 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, this modification eliminates the high-friction interface between the piston rod 6 and the ampoule holder 2. The fifth embodiment, however, is mechanically very different from the first embodiment. If the same modification were made to the fifth embodiment, the modification ***introduces*** a major new source of friction, which degrades the device by making it harder to use.

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



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

During dose injection, an axial force is delivered from the piston rod 6 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 the piston rod 6 that translates to the internal threads of non-rotatable member 40 as an upward force.[11] 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.

[11] For every action, there is an equal and opposite reaction.

Importantly, the friction from the rotation of piston rod 6's threads through those of member 40 acts at a small radius and thus introduces only minor frictional torque ($\tau = r \times F$) (blue arrow).

In the 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). But unlike member 40, driver tube 85 ***is not rotationally fixed*** with respect to housing 1 (and its ring-shaped wall 46) because the driver tube 85 must also rotate as the 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 source of friction is introduced during dose injection at the flanges on the driver tube 85 as 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). And whereas there is a benefit to modifying the first embodiment in this manner (*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 the 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 the Petition 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.")).

B. Ground 2 Should Be Denied Because Møller, Alone or in Combination with Steenfeldt-Jensen, Does Not Render Obvious the Challenged Claims

1. Overview of U.S. Patent Application Publication No. 2002/0052578 ("Møller")

Møller is a U.S. patent application publication dated May 2, 2002. Møller was submitted in an IDS and is cited on the face of the 044 Patent. Ex. 1007 at 0038. Møller was filed on June 14, 2001. Møller is aimed at providing an injection pen where the mechanical advantage (*i.e.*, "gearing") is provided between an injection button and an ampoule piston via a rack and gear. *See* Ex. 1015, [0006] ("Consequently a wish for a gearing between the injection button and the piston has occurred so that the button has a larger stroke than has the piston."). Møller explains that this gearing reduces the force necessary to deliver an injection. *Id.*

In discussing gearing, Møller considers the teachings of prior art references. Specifically, Møller references and describes WO 99/38554, the PCT counterpart to Steenfeldt-Jensen.[12] Møller states that WO 99/38554 discloses a dose setting drum having an exterior high-pitch thread that engages with a thread on the inner surface of a cylindrical housing. *See* Ex. 1015, [0008]. Møller notes that "by this 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

[12] *See* Ex. 1014 (claiming priority to DK 1998 00130), Ex. 2015 (same); *see also* Ex. 1011, ¶356 ("In discussing the background for this invention, I note that Møller discusses the device disclosed in Steenfeldt-Jensen.").

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]. The invention presented by Møller 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.

The embodiment primarily relied upon by Petitioner (Møller's first embodiment) is configured and described as follows. *See also* Ex. 2017 (animation depicting Møller's first embodiment). To set a dose, "the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 6. Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and will be lifted with this drum up from the end of the housing 1." Ex. 1015, [0029]. "When the dose setting drum is screwed up along the thread 6 on the tubular element 5 the ring 25 will follow the dose setting drum in its axial movement as the spring 26 is supported on the shoulder 27." *Id.* "The spring will keep the V-shaped teeth of the ring 25 and the cup shaped element in engagement and maintain in engagement the coupling 21, which may comprise Δ-shaped protrusions 32 on the cup shaped element engaging Δ-shaped recesses in an inner ring 33 in the dose setting button 18." *Id.*

"The rotation of the dose setting button 18 and the cup shaped element is further transmitted to the gearbox 9 through the protrusions 23 on this gearbox engaging the longitudinal recesses 22 in the inner wall of the tubular part 20 of said cup shaped element." *Id.,* [0030]. "The rotation of the gearbox 25 is through the connection bars 12 transmitted to the nut 13, which is this way screwed up along the thread of the piston rod 4 and lifted away from its abutment with the wall 2 when a dose it set." *Id.*

To dispense a dose, "the injection button is pressed by pressing on the bottom 19." *Id.,* [0032]. The protrusions 32 are drawn out of engagement with recesses in the ring 33, such that the "dose-setting drum 17 can now rotate relative to the injection button and will do so when the Δ-shaped protrusions 32 press against a shoulder 34 at the bottom of the dose setting button 18." *Id.,* [0033]. "Only a force sufficient to make the dose setting drum rotate to screw itself downward along the thread 6 is necessary as the force necessary to make the injection is transmitted to the piston rod 4 through the gearbox 9." *Id.*

2. The Combination of Møller and Steenfeldt-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 a nut 13 teach the claimed "drive sleeve." Petition at 60-63. As shown with red shading in both the side

and top-down cross-sectional views below, the connection bars 12 and the nut 13 do not form a sleeve:

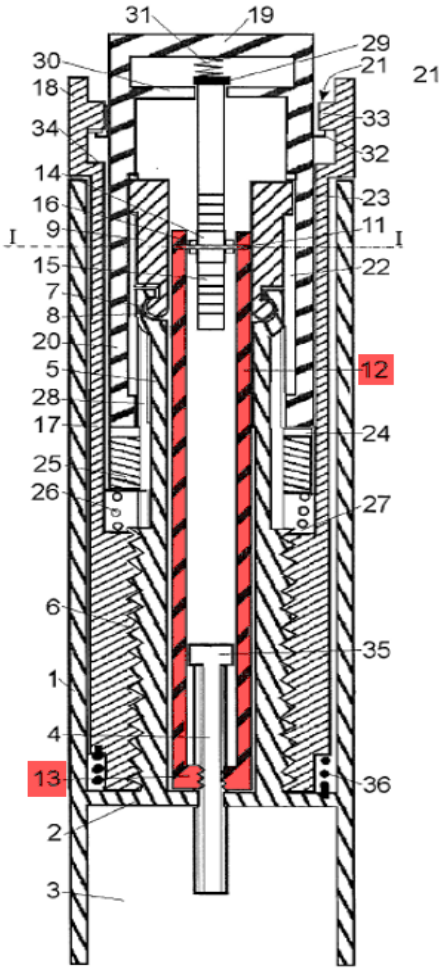


Fig. 1

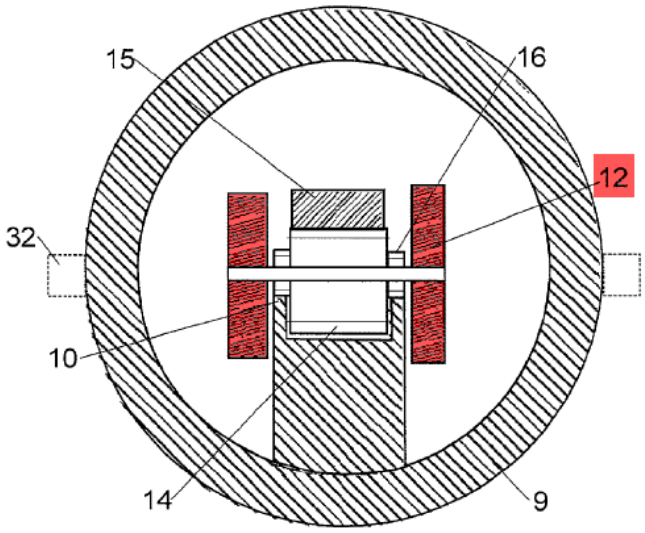


Fig. 2

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***,"[13] Petitioner also points to tubular connection element 112 and nut 113 in Møller's ***second embodiment*** to try to overcome this deficiency. Petition at 63. 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.*,at 63. Based on this purported structural and functional equivalency, the Petition 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.*

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

[13] Note that in the District Court case, Patent Owner 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 Petition contends that connection bars 12 and nut 13 in Møller's first embodiment are structurally and functionally equivalent to connection element 112 and nut 113 in Møller's second embodiment and thus it would have been obvious to form connection bars 12 and nut 13 as a tubular structure. Petition at 63. The figure below, at a minimum, makes clear that connection bars 12 in the first embodiment are not structurally equivalent to the connection element 112 in the second embodiment:

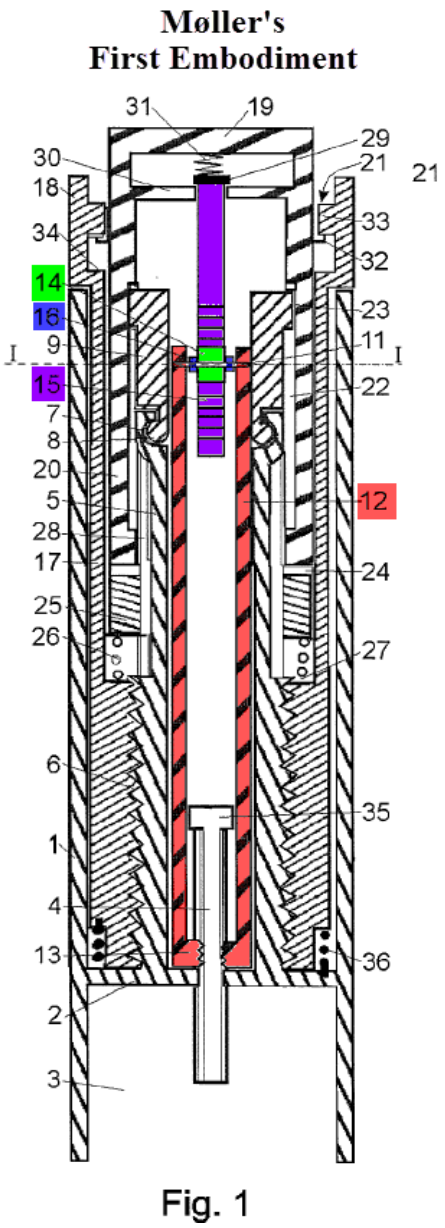


Fig. 1

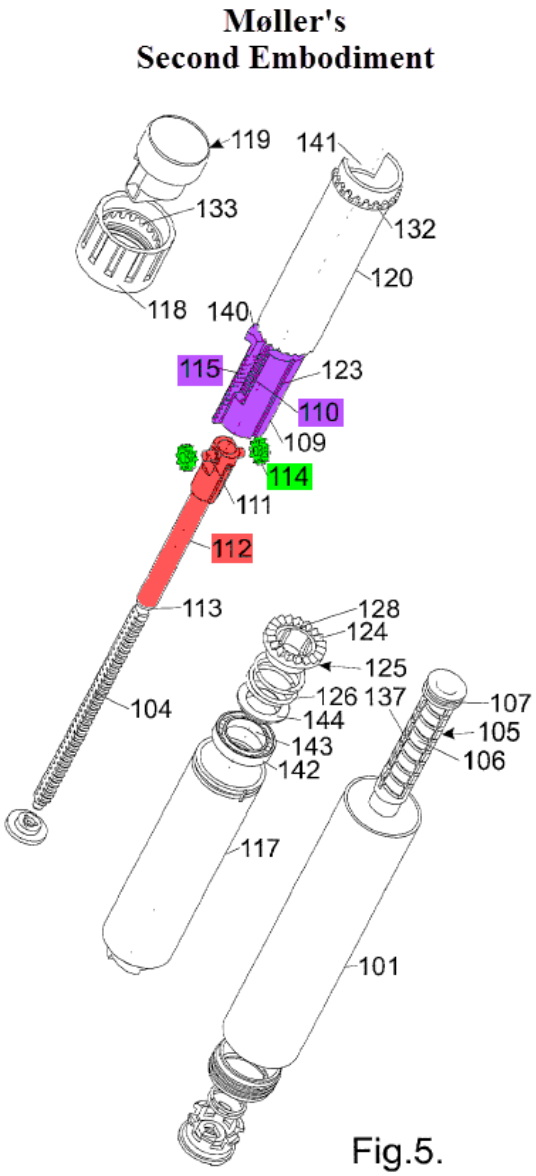


Fig.5.

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

The connection bars 12 and connection element 112 are differently shaped, engage with components in different ways, and operate in different manners. *See* Ex. 2017 (animation depicting Møller's first embodiment), Ex. 2018 (animation depicting Møller's second embodiment).

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

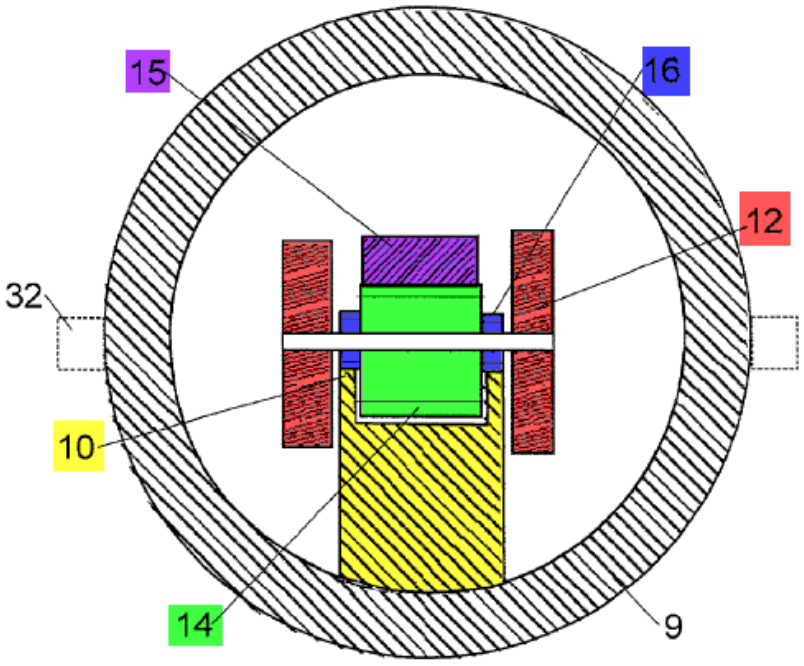


Fig. 2

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 requires a substantial redesign of the device. For example, a second pair of gear wheels 14 and 16 is necessary, which means racks 10 and 15 also 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.

To better visualize this complexity, Patent Owner has animated Møller's embodiments. *See* Ex. 2017 (animation depicting Møller's first embodiment), Ex. 2018 (animation depicting Møller's second embodiment). As can be seen, Møller's second embodiment is, structurally, significantly more complicated than the first embodiment. It is also evident from the animations that the structural differences result in functional differences too.

In sum, a POSA would not have considered the 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. Thus, because Petitioner's obviousness argument is predicated on this purported

equivalency, the argument fails. Accordingly, Møller does not teach or render obvious claim limitation [11.5], and thus does not render obvious claims 11, 14, 15, 18, and 19.

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

Even if the Petitioner were 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 gear wheels 14 and 16, and racks 10 and 15 and thus the device's operation. Petitioner simply concludes:

> Given Møller's teaching that the tubular connection element 112 with nut 113 corresponds to connection bars 12 with nut 13, a POSA would have understood the components to be structurally and functionally equivalent. EX1011, ¶¶370-71. A POSA thus 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.* Møller thus taught the claimed "drive sleeve."

Petition at 63.

But as noted above, 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). As

discussed above, the first embodiment at minimum would require a significant reconstruction and redesign of elements to accommodate a tubular structure because a tubular structure would interfere with the engagement of rack 10 and gear wheel 16, which is only possible due to the open shape of connection bars 12.

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 [11.5], and thus does not render obvious claims 11, 14, 15, 18, and 19.

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

The Petition fails to demonstrate that a POSA would have been motivated to combine Møller and Steenfeldt-Jensen. Petitioner asserts that a POSA would be motivated to modify the inner threads of the tubular dose setting drum 17 and the outer thread 6 of tubular element 5 in Møller such that the tubular dose setting drum 17 instead comprised "a high-pitched helical groove as taught by Steenfeldt-Jensen on the outer surface" that engaged with a helical rib on the inner surface of the housing 1. Petition at 78-79; *see also id.* at 56-57, 76-79. 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 Steenfeldt-Jensen's Externally-Grooved Dose Scale Drum

A POSA would not have been motivated to combine Steenfeldt-Jensen's externally-grooved dose scale drum 80, because Møller teaches away from doing so. Møller explains that it is an objective of his invention "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 exact dose scale drum from Steenfeldt-Jensen that Petitioner is seeking to use in its obviousness combination as 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 Steenfeldt-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).[14] The Møller injection device specifically lacks the disadvantageous high-pitched and externally-grooved dose scale drum described by Steenfeldt-Jensen, and neither Petitioner nor its expert, as explained below, have demonstrated that a POSA would be motivated to disregard Møller's teaching against using it. Møller thus teaches away from Steenfeldt-Jensen. *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 tubular dose setting drum 17 due to a purported advantage. Specifically, the Petition states: "Because Steenfeldt-Jensen's threaded engagement 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 78. This argument fails for at least three reasons.

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] ("However, by this kind of

[14] WO 99/38554 is the related PCT publication to Steenfeldt-Jensen. *See* Ex. 2015.

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.") (emphasis added), [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*** ….") (emphasis added), Fig. 1 (showing a tubular dose setting drum with internal threads).

Second, while Møller teaches an internal thread on tubular 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 depicted and described by Møller (see Figure 1, below), the internal thread on tubular dose setting drum 17 is sufficiently low such that dialing out the maximum dose advantageously requires multiple turns of the dose setting drum.

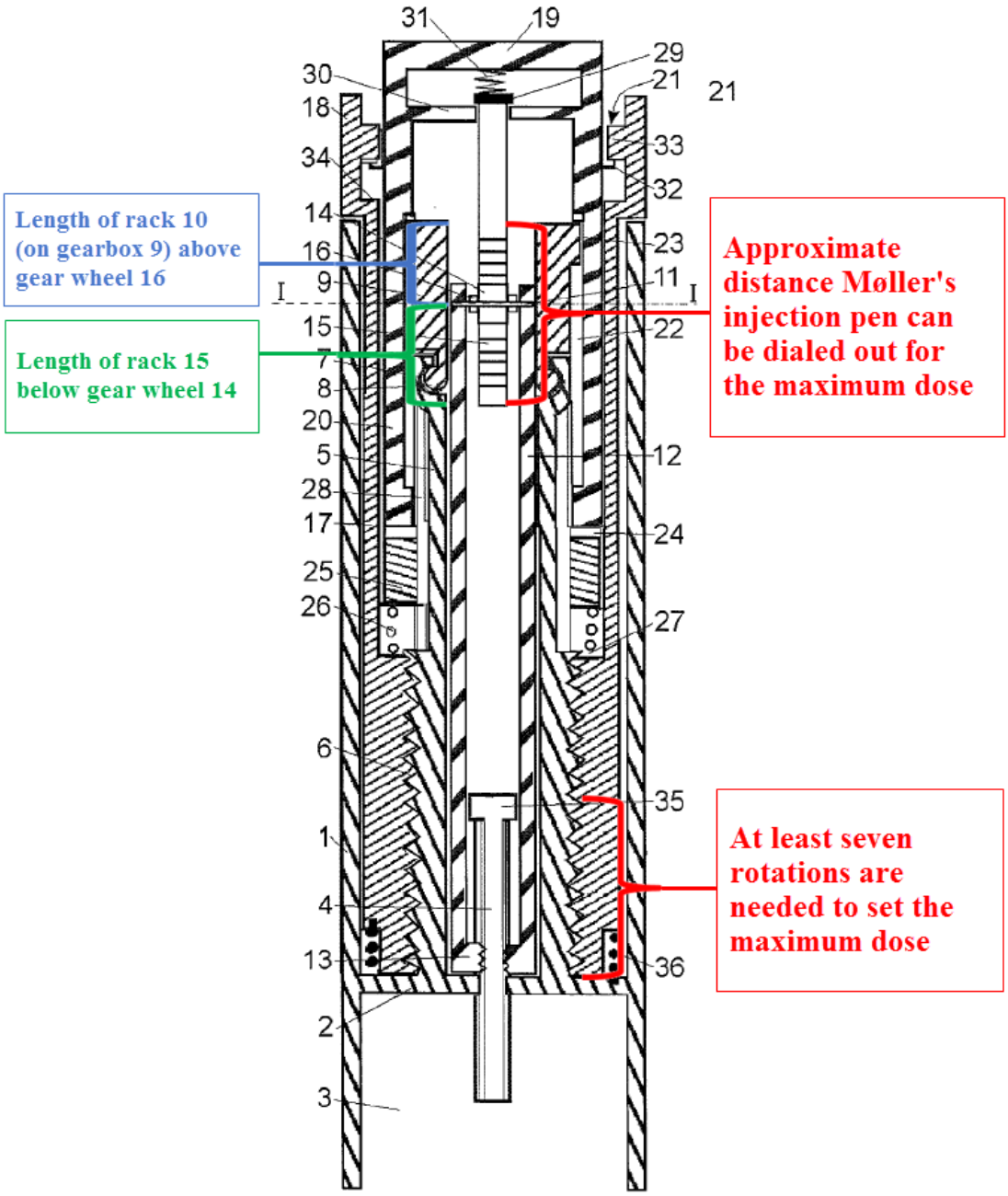


Fig. 1

Ex. 1015, Fig. 1 (annotated).

As illustrated above in Møller Figure 1, the maximum axial displacement of injection button 19 and dose setting drum 17 corresponds to the sum of the length of the rack 15 below the gear wheel 14 and the length of the 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 would require at least seven rotations (by counting the 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.

In contrast to requiring at least seven rotations to dial out the maximum dosage, the high-pitch groove on Steenfeldt-Jensen's dose scale drum dials out the maximum dosage 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 Steenfeldt-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 the groove on Steenfeldt-Jensen's dose scale drum is much higher than that of Moller's.

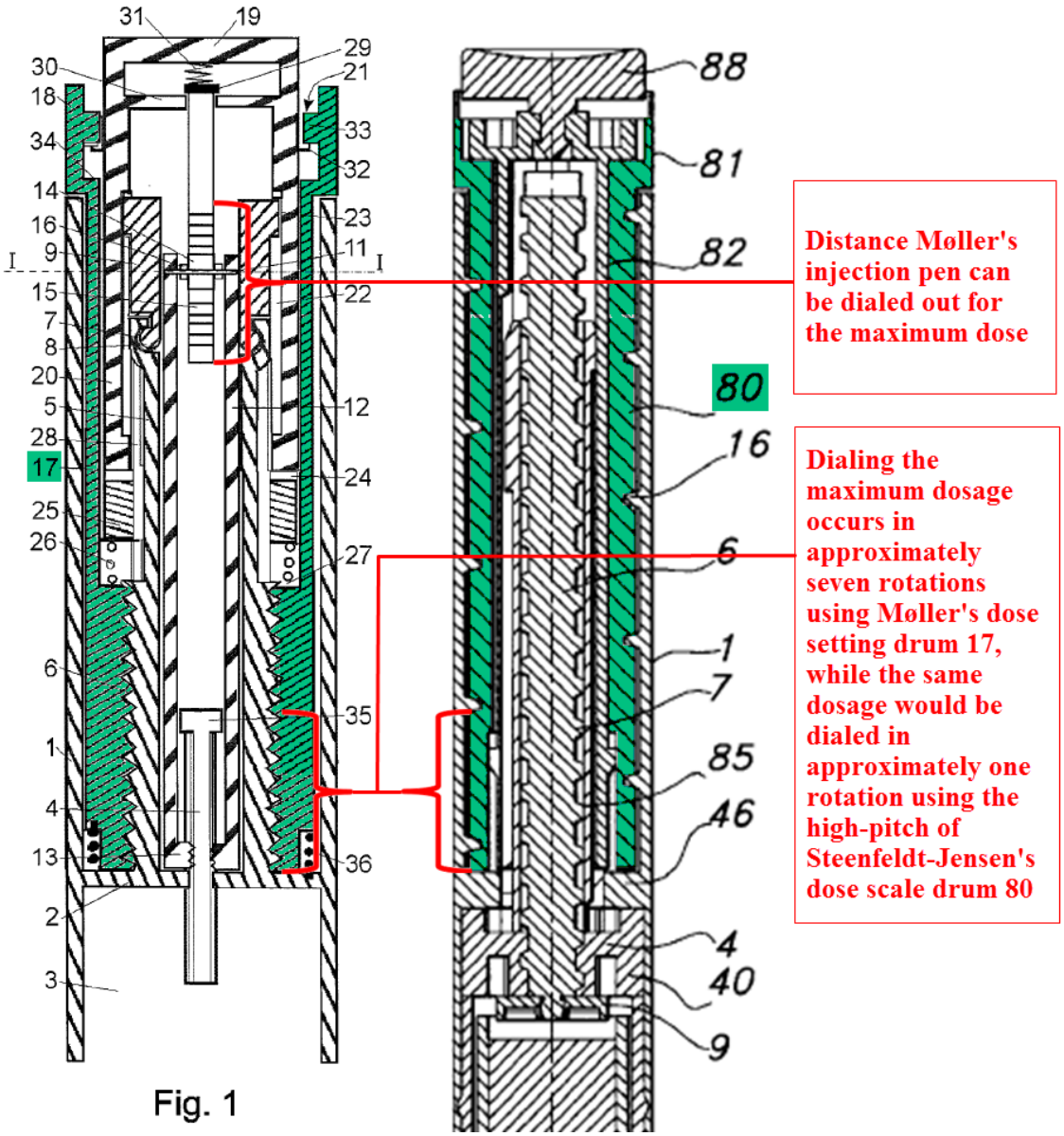


Fig. 1

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

Above, Møller's dose setting drum 17 and Steenfeldt-Jensen's dose scale drum 80 are shown in green. Implementing the high-pitch groove taught by Steenfeldt-Jensen results in a dialing mechanism where the full dosage would be dialed out by approximately a full rotation of the dose setting drum.

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. And nor would an expert because Møller teaches its own solution. Specifically, Møller teaches 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]. The Petition does not address how a POSA would treat this disclosure – *e.g.*, why a POSA would ignore this express teaching of a different solution.

In sum, Møller expressly considered Steenfeldt-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 Steenfeldt-Jensen," let alone one that is "on the outer surface of Møller's drum."

4. The Combination of Møller and Steenfeldt-Jensen Does Not Teach or Render Obvious "said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve"

Møller does not disclose that dose-setting drum 17 is configured to engage a threading provided by said ***main housing*** as the claim requires. Ex. 1002, claim

limitation [11.2] ("said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing"). Instead, the threads of Møller's dose setting drum 17 engage those of tubular element 5, which is not the required "main housing" as explained below.

Properly construed, "main housing" means "an exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components." *See* Section IV.A. Møller's tubular element 5 (depicted in orange, below) is not the "main housing" within the meaning of the 044 Patent, because it is an interior, not an exterior, component. Nor can Møller's tubular element 5 be understood to be part of the housing as Møller's tubular element 5 is identified both in Figure 1 and in the written description as a component separate and distinct from the housing 1 (depicted in grey, below), which is exterior:

> ***Concentrically with the housing 1*** the wall 2 carries on its side turning away from the compartment 3 ***a tubular element 5*** which is at a part of it adjacent to the wall 2 provided with an outer thread 6 and which has at its free end a circumferential recess 7.

Ex. 1015, [0023] (emphasis added).

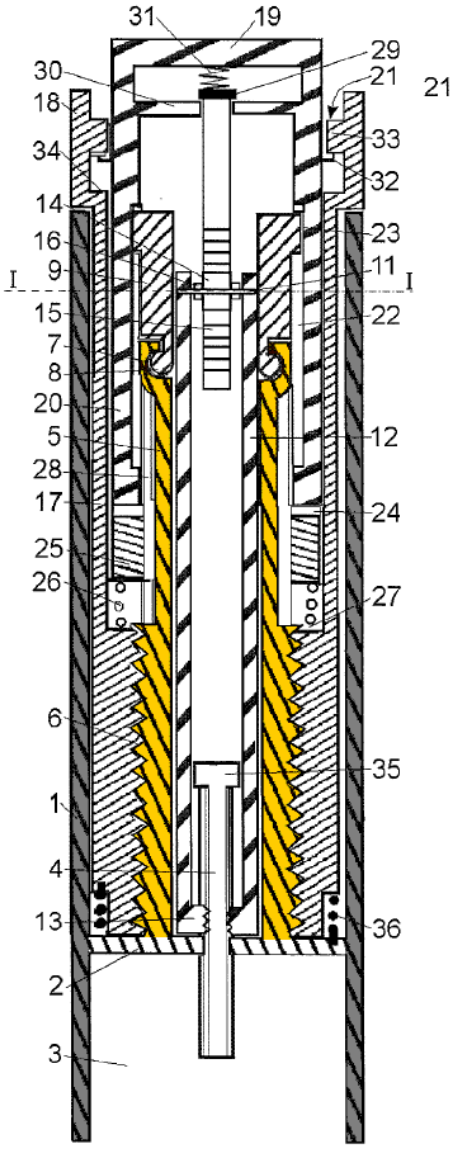


Fig. 1

Ex. 1015,Fig. 1 (annotated).

Tubular element 5 in Møller is insubstantially different from the "insert" described in the 044 Patent. "Insert," in the 044 Patent, is described as a separate interior component. Specifically, the 044 Patent states:

> In the illustrated embodiment, an insert 16 is provided at a first end of the main housing 4. The insert 16 is secured against rotational or

> longitudinal motion. The insert 16 is provided with a threaded circular opening 18 extending therethrough. ***Alternatively, the insert may be formed integrally with the main housing 4*** the form of a radially inwardly directed flange having an internal thread.

Ex. 1002, 3:49-55 (emphasis added). *See also* Ex. 1005, 2:66-3:2 (related patent defining "main housing" as a type of "exterior housing" and "insert" as a type of "interior housing"). Like the "insert" described by the 044 Patent, Møller's tubular element 5 is a separate component from the main housing even though it can be formed integrally with the main housing. *See* 044 Patent at 3:53-55.

Nonetheless, Petitioner argues that it would have been "obvious to modify internal threading of drum 17 as an external threading that engaged the housing for the same rotational movement relative to the housing as disclosed in Steenfeldt-Jensen." Petition at 57, 76-79. As explained above in Section V.B.3, however, a POSA would not have been motivated to combine the teachings of Steenfeldt-Jensen's dose scale drum with Møller's pen injector. Further, neither Petitioner nor its expert have put forth any reasoning for why a POSA would have switched the threading of Møller's dose setting drum from internal to external as described in Steenfeldt-Jensen. Indeed, configuring Møller's housing 1 to have an internal rib that engaged with an external groove of the dose setting drum 17 would interfere with helical reset spring 36. *See* Ex. 1015, Fig. 1 (element 36). This helical reset spring 36 exists between the housing 1 and dose setting drum 17, precisely where

Petitioner proposes to place a threaded connection. Neither Petitioner nor its expert has explained how their proposed modification would avert interference between the threads and the spring, which could cause the device to malfunction.

Thus, the Petition fails to show that the combination of Møller and Steenfeldt-Jensen teaches or renders obvious "said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve" as required by claim limitation [11.2]. Thus, the Petition fails to show that claim 11 and its dependent claims are anticipated or obvious.

VI. THE PETITION FAILS TO PUT PATENT OWNER ON NOTICE OF HOW THE CLAIMS ARE TO BE CONSTRUED IN THE GROUNDS AS REQUIRED BY 37 C.F.R. § 42.104(B)

The Board must reject the Petition because it fails to comply with the requirements for a petition under 37 C.F.R. § 42.104(b) by not clearly identifying how the claims are to be construed for purposes of the petition. 37 C.F.R. § 42.104(b) requires a petition to identify at least the following:

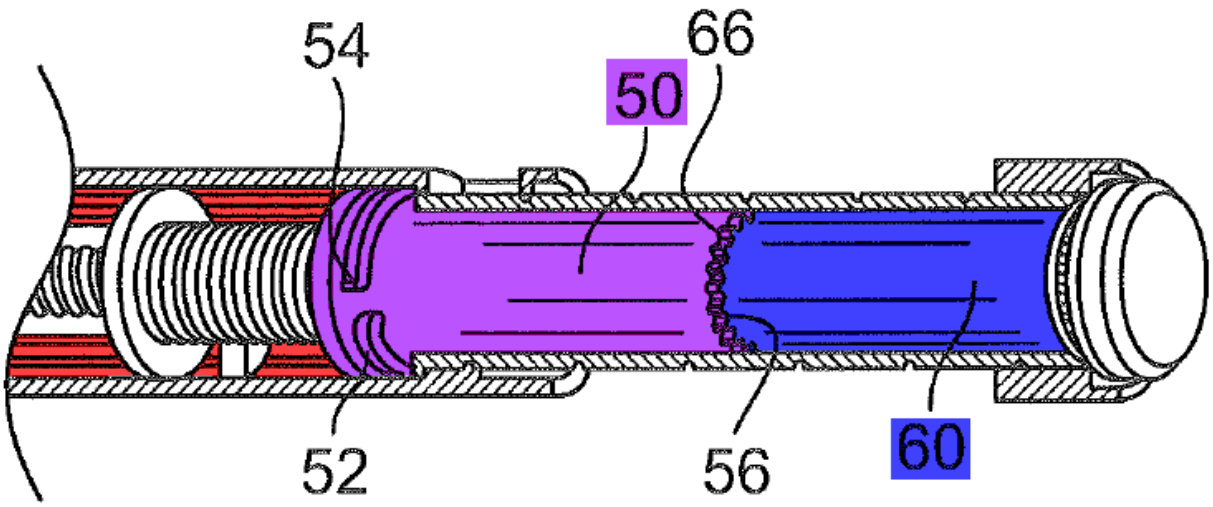
> (3) How the challenged claim is to be construed. Where the claim to be construed contains a means-plus-function or step-plus-function limitation as permitted under 35 U.S.C. 112(f), the construction of the claim must identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function;

> (4) How the construed claim is unpatentable under the statutory grounds ….

37 C.F.R. § 42.104(b)(3),(4). Compliance with § 42.104(b) requires that a petition identify the how the claims are to be construed and how the claims as construed are unpatentable with sufficient clarity to provide the patent owner adequate notice. *See Gen. Electric Co. v. Vestas Wind Systems A/S*, IPR2018-00928, Paper 9 at 13-15 (P.T.A.B. Nov. 5, 2018); 77 Fed. Reg. 48680, 48688 (Aug. 14, 2012) (explaining that the rule "provides the patent owner with notice as to the basis for the challenge to the claim.").

The Petition does not comply with these requirements for several reasons. First, the Petition states that the "grounds rely on the ordinary and customary meaning of the claim terms as a POSA would have understood them" (Petition at 16), but it does not state what those meanings are. Further, Petitioner identifies Patent Owner's constructions from the co-pending District Court case without specifying whether these are in fact the ordinary and customary meanings of the terms that are being applied in the Petition, or whether and how the ordinary and customary meanings are different. *See* Petition at 14-15 ("The Patent Owner (Sanofi) has defined certain claim terms in related litigations, and cannot now argue its definitions are unreasonable.").

Second, the Petition additionally requests specific means-plus-function constructions for the terms ”tubular clutch” and “clicker,” but then applies different means-plus-function constructions, or does not apply a means-plus-function construction at all, in the limitation-by-limitation analysis. Specifically, in the claim construction section the Petition proffers a means-plus-function construction for “clicker” and identifies the corresponding structure as “component 50” from the 044 Patent. *See* Petition at 16. As shown below in purple, this is a tubular element.



Ex. 1002, Fig. 6 (annotated).

When analyzing the grounds, however, the Petition instead identifies different corresponding structure in the ’044 Patent: “the structure the ’044 patent uses to provide an audible click is either a ***flexible arm*** being dragged over ***splines***, or ***saw teeth*** riding over one another.” Petition at 43. Petitioner makes no attempt to compare the prior art to the tubular structure of component 50, the structure it

identified in its construction. *Id.* This internal inconsistency fails to put Patent Owner on notice of how the claims are being construed in the Petition.

Similarly, for "tubular clutch" the Petition identifies "component 60" (shown in blue, above) of the 044 Patent (Petition at 15-16), but again fails to compare the prior art to this same structure in its analysis of the grounds.

Thus, the Petition fails to identify (1) how the claims should be construed, and (2) how the claims as construed are allegedly unpatentable. *See* 37 C.F.R. § 42.104(b)(3)-(4). Instead, Petitioner puts the onus on the Patent Owner to guess what constructions were applied. This unfairly prejudices Patent Owner's ability to defend its patent, and independently warrants denying the Petition under 37 C.F.R. § 42.104(b).

VII. CONCLUSION

For the reasons set forth above, Patent Owner respectfully requests that institution of *inter partes* review should be denied.

Dated: January 3, 2019

Respectfully submitted,

/Elizabeth Stotland Weiswasser/

Elizabeth Stotland Weiswasser
Reg. No. 55,721
Anish R. Desai
Reg. No. 73,760
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
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

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 13,075 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: January 3, 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 January 3, 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