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. IPR2018-01680
U.S. Patent No. 9,526,844

PATENT OWNER'S PRELIMINARY RESPONSE

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CASES

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EXHIBIT LIST

Exhibit #	Description
2001	Press Release, "Mylan Enhances Partnership with Biocon through Strategic Collaboration for Insulin Products," Feb. 13, 2013 (PR Newswire), available at http://newsroom.mylan.com/pressreleases?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	First Amended and Supplemental 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. 58.
2005	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
2006	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
2007	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.)
2008	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.)
2009	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.)

I. INTRODUCTION

The Board should decline to institute a trial on the Petition. The Petition identifies the same art that Petitioner also identifies against the 844 Patent in a co-pending district court litigation, where the validity of claims 21-30 will be decided before a final written decision is due here. In addition, each ground on which the Petition is based relies on Giambattista (U.S. Patent No. 6,932,794), either as an anticipatory reference or a primary reference for obviousness. But Giambattista is not prior art, and thus cannot be relied on to invalidate the 844 Patent.

More specifically, the Board should exercise its discretion to deny institution under 35 U.S.C. §§ 314(a) and 324(a), because Petitioner identifies the same art here as it did nearly a year ago in a co-pending district court case that is requested 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 844 Patent was submitted for listing in the FDA's Orange Book as covering Patent Owner's insulin glargine prefilled pen drug product on December 27, 2016 and Petitioner identified the 844 Patent in its Paragraph IV notice served approximately a year ago prior to filing this Petition. Moreover, Patent Owner had previously asserted the 844 Patent in a related lawsuit against Merck. Thus, Petitioner has long had notice of the 844 Patent but waited until the eve of the one-year statutory bar to file the instant Petition. Because of Petitioner's delay, the validity of the 844 Patent will be tried in the co-

pending District Court case, where Petitioner has identified the same art as it does here, *before* a final written decision on this Petition will be due.

Instituting an IPR trial would not serve as a "quick and cost effective alternative[] to litigation," but would rather subject Patent Owner to defending against the same art in different forums. 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 such attacks, which would result in wasting 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 Giambattista is not prior art. The application leading to Giambattista was filed on April 3, 2003, whereas the 844 Patent claims the benefit of the filing date of Great Britain Application No. 03 04822.0 ("GB Application"), filed a month before, on March 3, 2003. Ex. 1026 at 1. To try and overcome this fact, Petitioner argues that the GB Application does not provide written description support for claims 21-30, because it does not explicitly disclose "an internally threaded piston rod." Petition at 16. This argument, however, fails to account for the full scope of the GB Application.

For example, the GB Application broadly describes a drive sleeve being connected to a piston rod for rotation along a threaded portion of the piston rod. Ex.

1026 at 8 (2:7-9). This disclosure is more than sufficient for a person of ordinary skill in the art to understand that the drive sleeve can be threaded internally or externally, especially when Petitioner's expert argues that such information was not just well-known to a skilled artisan, but "routine" and "predictable," Ex. 1011 at ¶ 120; *see Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d 1357, 1362 (Fed. Cir. 2018); *Hynix Semiconductor v. Rambus Inc.*, 645 F.3d 1336, 1352 (Fed. Cir. 2011).

Moreover, it is well established that a claim does not lack written description "simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language." *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2005) (citation omitted). This is because "the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification." *Id*. And indeed, Petitioner's own expert contends that "[p]roviding threading, splines, clutches, or other features on these types of concentric components to achieve the desired relative movements during dose setting and injection was routine, predictable, and well within the abilities of a person of ordinary skill." Ex. 1011 at ¶ 120.

Petitioner's written description argument is thus inconsistent with its position on the knowledge of a person of ordinary skill as set forth by its expert. The Board

has previously rejected written description arguments under these circumstances. *See, e.g.*, *Celltrion, Inc. v. Biogen, Inc.*, IPR2017-01229, Paper 10 at 14 (P.T.A.B. Oct. 23, 2017) ("Petitioner's priority date contentions are inconsistent with its position that the combination of cyclophosphamide and fludarabine was itself already a well-known chemotherapeutic regimen for treating CLL."). The Board should also reject Petitioner's written description argument here.

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 litigation, but does not state whether these

are the plain and ordinary meanings applied in the Petition.[1] Second, where the 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" as the corresponding structure. In contrast, when discussing the prior art, the Petition identifies a "flexible arm 52" with "toothed member 54" and "splines 42" as the corresponding clicker structure. *See, e.g.*, Petition at 60. 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 TO DENY INSTITUTION PURSUANT TO §§ 314(A) AND 324(A)

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

[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.

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 Petitioner's invalidity 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 a trial on the validity of the 844 Patent takes place in the District Court case, where Petitioner identifies the same art it asserts here. *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 844 Patent not as "an effective and efficient

alternative to district court litigation," *id*., but instead in an inefficient and intentionally staggered attempt at multiple invalidity challenges to claims 21-30 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 this time in 2017, Patent Owner had already asserted the 844 Patent against another competitor seeking approval of follow-on glargine products. *See* Ex. 2004 at 4.

Relatedly, the 844 Patent was submitted for listing in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") on December 27, 2016 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 844 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 a so-called "Paragraph IV" certification alleging that Petitioner's proposed glargine product would not infringe the claims of the 844 Patent, which Petitioner alleged to be invalid and 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 844 Patent, among others. As part of that patent infringement case, Petitioner served its invalidity contentions on Patent Owner on January 25, 2018 (amended April 25, 2018), which identified the same art advanced in the Petition. *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, which responded to Petitioner's invalidity contentions. Despite long having notice of the 844 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, which is among nine petitions asserting similar invalidity grounds it alleges in the District Court case. IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01678, IPR2018-01679, 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 March 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. 2005, ¶ 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 system, the efficient administration of the Office, and the ability of the Office to

[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 in Mylan's favor. *See* 21 U.S.C. § 355(c)(3)(C).

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 identified the same 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 similarities[3] with *NHK Spring* and in view of *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*"), to which *NHK Spring* extensively cites, 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 844 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. 2006.

[3] Because the *NHK Spring* patent was expired, both the Board and District Court applied the *Phillips* standard for claim construction. Here, however, the 844 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 18-19.

2. Petitioner identifies the same 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 three grounds of unpatentability as to the 844 Patent: (1) claims 21-29 are anticipated by Giambattista; (2) claims 24-29 are obvious over Giambattista in combination with U.S. Patent No. 6,235,004 ("Steenfeldt-Jensen"); and (3) claim 30 is obvious over Giambattista in combination with U.S. Patent No. 6,582,404 ("Klitgaard"). Petition at 3. In the co-pending District Court case, Petitioner served invalidity contentions alleging that Giambattista and Steenfeldt-Jensen, either by themselves or in combination rendered claims 21-30 of the 844 Patent invalid. Ex. 2007, Inv. Contentions at 2, 26-27, 437-38 (identifying asserted claims of the 844 Patent as claims 21-30, and stating "Defendants further identify the following combinations as rendering the asserted claims obvious…Giambattista '794, alone or in combination with…Steenfeldt-Jensen"); *see also* Ex. 2008, Am. Inv. Contentions at 2, 40-41, 622. In addition, Petitioner's invalidity contentions also incorporated by reference "any art listed on the face of the patents-in-suit," including the 844 patent. Ex. 2007 at 4; Ex. 2008 at 4. Klitgaard is one of the cited references in the 844 patent. *See* Ex. 1004. Thus Klitgaard was identified both here and in the District Court case.

3. The District Court trial 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 here 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]). Even if the 844 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 844 Patent in an IPR proceeding before the Board on the same art identified in both proceedings.

This gamesmanship is highly prejudicial to Patent Owner, and antithetical to the purpose of the statute, which is to provide "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 identifying the same art at least as early as January 25, 2018. *See, e.g.*, Ex. 2007 at 414-417. 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

Noted above, *NHK Spring* cites extensively to *General Plastic*, where 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 attempting multiple

invalidity challenges here and in the District Court. Factors 1, 2, 4, and 5 favor denying institution.

First, Petitioner asserts invalidity challenges to the same claims of the 844 Patent using the art it identified in both here and in the District Court proceedings. *See* Section [II.C.2], *supra.*

Second, Petitioner was aware of the 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 844 Patent. Ex. 2007. 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. 2009. As a result, the final written decision is not due until April 2020, well after the conclusion of the requested October 2019 trial.[4] Institution of trial therefore will not "limit unnecessary and counterproductive litigation costs" (H.R. Rep. No. 112-98, pt. 1, at 40), but will

[4] 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.

instead unfairly subject Patent Owner to having to defend "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. *See* Section [II.C.2], *supra.*

Because Petitioner is asserting the same art here that it identified in the District Court case and was aware of the art but chose to delay filing this Petition for a tactical advantage, these factors 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,* IPR2017-01195, 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. 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 of claims 21-30 based on art that Petitioner identified in the District Court case, where the validity of these claims will be decided 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 validity with respect to art identified in both proceedings. Moreover, this Petition is one of ***three petitions*** that Petitioner filed on the 844 patent—all on the eve of the statutory bar—and 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. IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01678, IPR2018-01679, IPR2018-01682 (844 patent), IPR2018-01696 (844 patent), IPR2019-00122. Thus, this factor

weighs in favor of denial because the Board's finite resources should not be spent on proceedings that will ultimately be moot.

* * *

All of the *General Plastic* factors 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 an effort to test the validity of claims 21-30 in two forums, where the same art has been identified. Institution should therefore be denied.

III. THE 844 PATENT

A. Overview of the 844 Patent

The 844 Patent is directed to a pen-type injector for medications such as insulin and insulin glargine. Ex. 1004, 1:25-29. Such injectors are regularly used by patients without formal medical training, such as diabetic patients who manage their condition through self-treatment. *Id*., 1:30-34. The 844 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*., 1:34-40.

The 844 Patent teaches improved pen injectors that meet these criteria. For example, according to an embodiment the 844 Patent provides a pen-type injector comprising:

> a housing;
>
> a piston rod adapted to operate through the housing;
>
> a dose dial sleeve located between the housing and the piston rod, the dose dial sleeve having a helical thread of first lead;
>
> a drive sleeve located between the dose dial sleeve and the piston rod, the drive sleeve having a helical groove of second lead;
>
> characterized in that the first lead of the helical thread and the second lead of the helical groove are the same.

Ex. 1004 at 1:47-60. The patent continues, "[p]referably, the piston rod has a first threaded portion at a first end and a second threaded portion at a second end," with "the drive sleeve being releasably connected to the dose dial sleeve and connected to the piston rod for rotation with respect thereto along the second threaded portion of the piston rod." *Id*. at 1:61-2:4. Described in more detail below, the 844 Patent claims the benefit of the filing date of the GB Application, which includes the same quoted disclosures above. *Compare* Ex. 1003 at 1:47-2:4 *with* Ex. 1026 at 1, 7-8 (1:26-2:9).

Returning to the 844 Patent, the figures below depict a further embodiment of an improved injection pen.

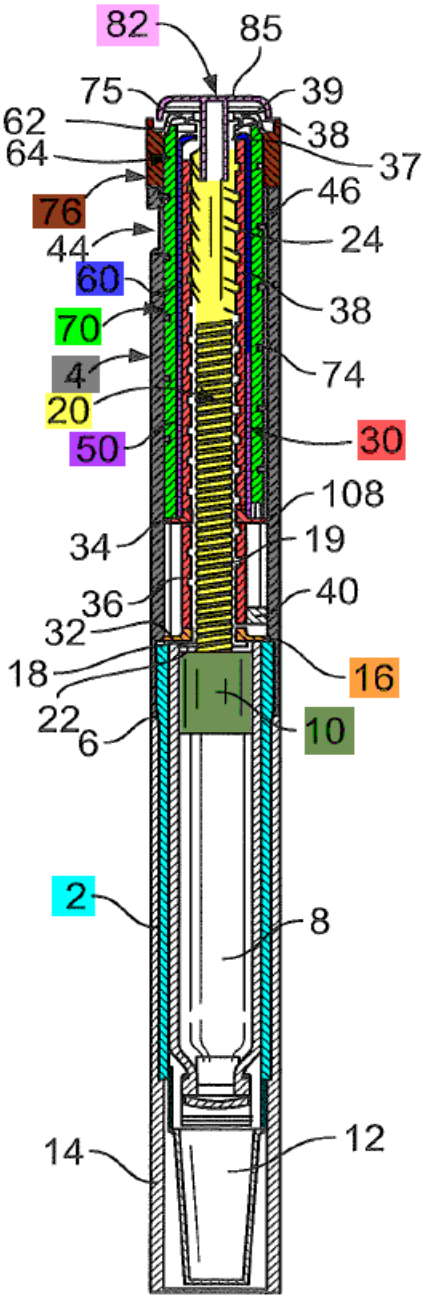


FIG. 1

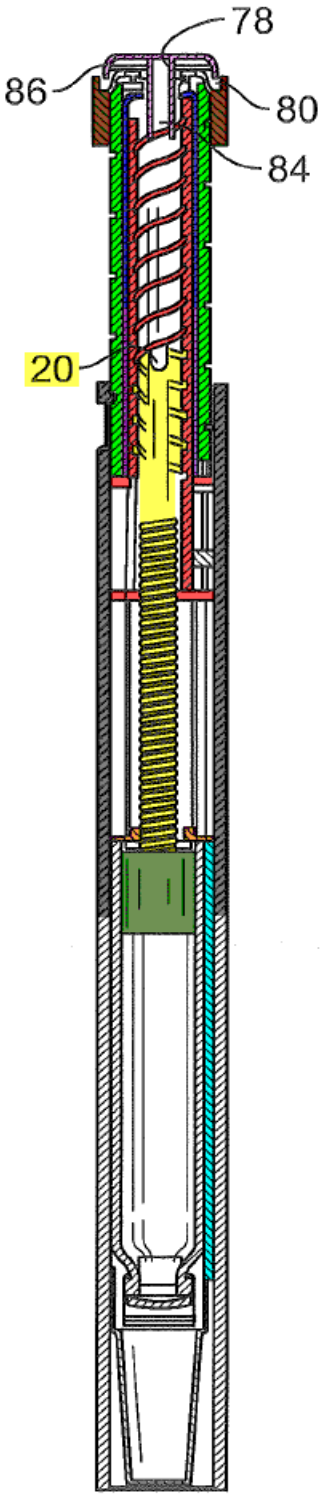


FIG. 2

Ex. 1004, 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 cartridge 8, a 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.*, 5:60-6:13; Figs. 9-10.

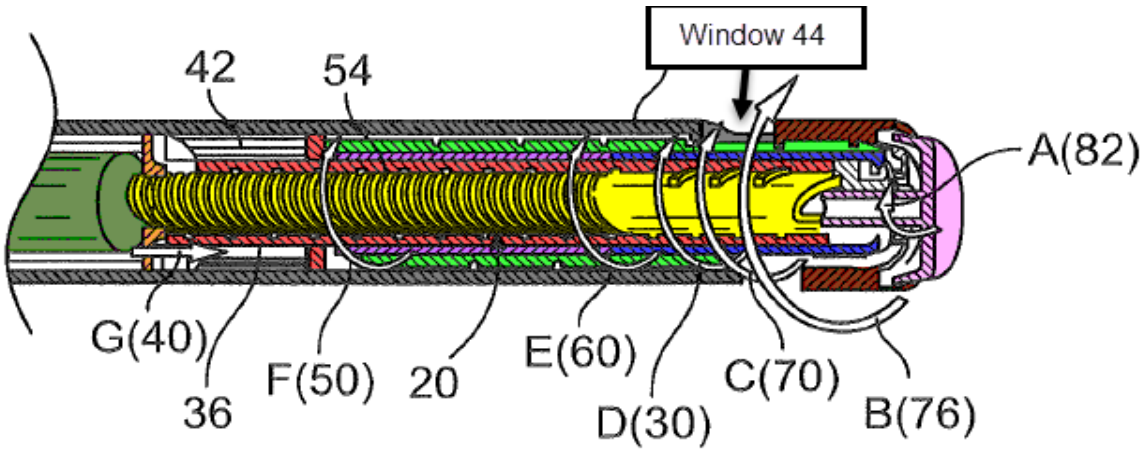


FIG. 9

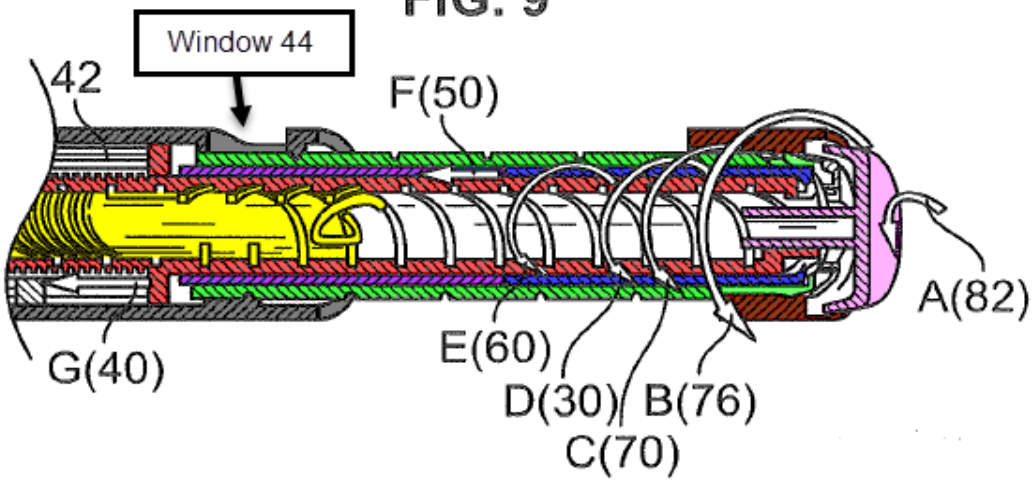


FIG. 10

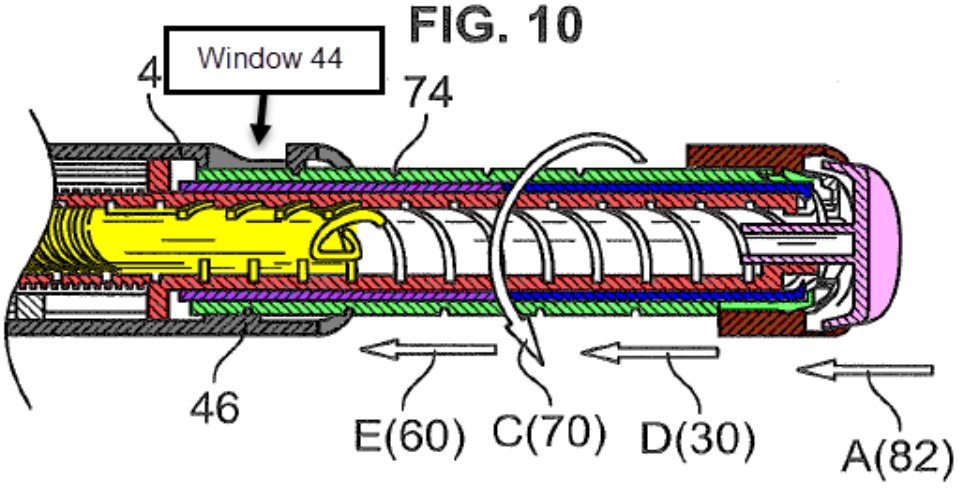


FIG. 11

Ex. 1004, Figs. 9 – 11

Dose markings (numbers) printed on an external surface of the dose dial sleeve 70 indicate the dosage. *Id*., 5:27-31. 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*., 4:42-53, 5:64-6:3.

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*., 6:38-39. 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*., 6:55-58. 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*., 6:38-45; 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*., 6:59-62. The user then releases the dose button, which returns the internal mechanism of the device into the dose dialing state. *Id*., 6:50-54.

B. 844 Patent Family

The issue of whether Giambattista is prior art, which is discussed further below, involves an analysis of the GB Application. For completeness, Patent Owner sets forth the 844 patent's patent family.

The application leading to the 844 Patent (Application No. 15/156,616) was filed on May 17, 2016. Ex. 1004 at Cover. The '616 Application "is a continuation of U.S. Application No. 14/946,203, filed Nov. 19, 2015, now U.S. Patent No. 9,408,979, which is a continuation of U.S. Application No. 14/635,573, filed Mar. 2, 2015, now U.S. Patent No. 9,233,211, which is a continuation of U.S. Patent Application No. 13/919,251, filed Jun. 17, 2013, now U.S. Patent No. 9,011,391, which is a divisional of U.S. Application No. 13/040,198, filed Mar. 3, 2011, now U.S. Patent No. 8,512,297, which is a continuation of U.S. Application No. 11/483,546, filed Jul. 11, 2006, now U.S. Patent No. 7,918,833, which is a continuation of U.S. Application No. 10/790,225, filed Mar. 2, 2004, which claims priority to GB 0304822.0 (the "GB Application") filed Mar. 3, 2003, the entire contents of which are incorporated herein by reference." Ex. 1004 at 1:6-21.

IV. CLAIM CONSTRUCTION

As an initial matter, Patent Owner's positions that (i) the Board should exercise its discretion to deny institution under 35 U.S.C. §§ 314(a) and 324(a); and (ii) Giambattista is not prior art, do not depend on the positions Petitioner set forth

in its claim construction section. *See* Petition at 18-22. Nonetheless, Patent Owner addresses certain issues raised in the Petition regarding claim construction. Petitioner alleges that the grounds presented in the Petition "rely on the ordinary and customary meaning of the claim terms as they would be understood by a POSA." Petition at 21. Yet, the Petition does not articulate a plain and ordinary meaning for any terms. Petitioner also states that, "Patent Owner Sanofi has taken positions regarding the meaning of certain claim terms, which it cannot now argue are unreasonable" and proceeds to list constructions from a preliminary claim construction disclosure in the District Court case. Petition at 19-20. It is unclear, however, whether Petitioner has adopted the preliminary claim constructions from the District Court case for purposes of the Petition. Moreover, the Petition lists a construction for "main housing," but this term does not appear in claims 21-30

Petitioner additionally addresses "the 'clutch,' 'clicker,' and 'holder' limitations…as "means-plus-function limitations." Petition at 20-22. Patent Owner disputes this contention.

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

V. REASONS WHY THE PETITION SHOULD BE DENIED

A. Ground 1 Should Be Denied Because Giambattista Is Not Prior Art

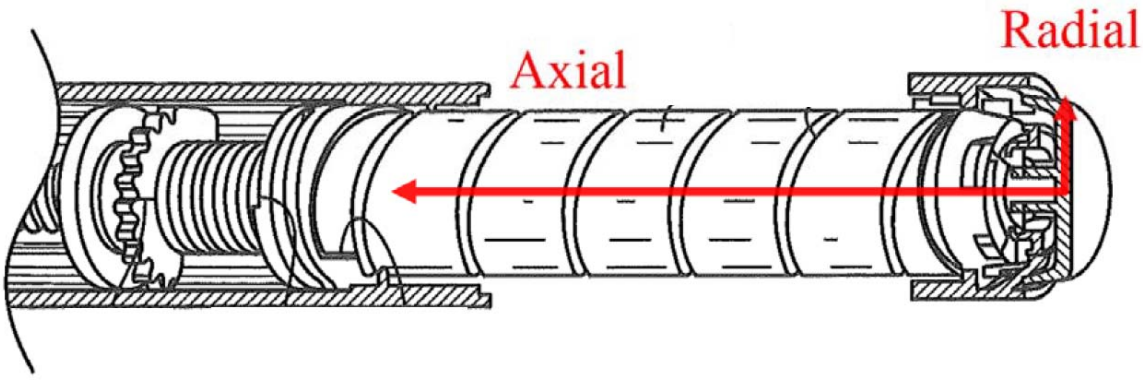
Ground 1 of the Petition should be denied because Giambattista is not prior art, and therefore cannot anticipate any claim of the 844 Patent. The application leading to Giambattista was filed on April 3, 2003. Ex. 1016 at Cover. The 844 Patent, however, claims the benefit of the filing date of the GB Application, which was filed on March 3, 2003, a month before the Giambattista application. Ex. 1026 at 1. Thus, Giambattista post-dates the 844 Patent.

1. The GB Application Provides Written Description Support for Claims 21-30 of the 844 Patent

Petitioner argues that the 844 Patent is not entitled to the GB Application because, according to Petitioner's argument, the GB Application does not specifically disclose an internally threaded piston rod. Yet Petitioner's argument fails because the GB Application's specification broadly discloses a piston rod having a threaded portion and a person of ordinary skill in the art would have recognized that the inventor was in possession of both internal and external threading. Specifically, the GB Application provides "[p]referably, the piston rod has a first threaded portion at a first end and a second threaded portion at a second end," with "the drive sleeve being releasably connected to the dose dial sleeve and connected to the piston rod for rotation with respect thereto along the second threaded portion of the piston rod." *Id*. at 8 (2:1-9).

Petitioner attempts to dismiss the GB Application's broad disclosure (*i.e.*, "the piston rod has a first threaded portion at a first end and a second threaded portion at a second end") by arguing that its disclosure ***only*** refers to external threading. Petition at 17. Petitioner reaches this conclusion because this disclosure is made in the context of a "drive sleeve located ***between*** dose dial sleeve and piston rod". *Id.* Thus, the threading, according to Petitioner, must be on the outside of the piston rod.

Petitioner's conclusion, however, is falsely predicated on "between" being restricted to the radial direction – *i.e.*, from the center out. But that is not the case. Importantly, the GB Application uses "between" to also refer to the relationship of components in the axial direction (*i.e.*, lengthwise). *See, e.g.*, Ex. 1026 at 12 (6:8-12) (using "between" in the axial direction when discussing threading "extending between the first flange 32 and the second flange 34."). The figure below illustrates the difference between the axial and radial directions:



Accordingly, Petitioner's argument that the GB Application is limited to a piston rod with an external thread because it discloses the drive sleeve being "between" the piston rod and the dose dial sleeve, is not consistent with the GB Application and improperly limits the disclosure. Indeed, when "between" is considered in the axial direction (which the Petition does not do), this spatial relationship does not confine a piston rod to having external threads, but allows for an internally threaded piston rod—a feature the GB Application supports by its broad disclosure of a threaded piston rod. Put differently, an arrangement where a drive sleeve is between a piston rod and dose dial sleeve in the axial direction, does not restrict the piston rod to having only external threads. The GB Application should be taken on its face – it discloses a "piston rod has a first threaded portion at a first end and a second threaded portion at a second end". Ex. 1026 at 8 (2:1-9).

Further, Petitioner does not argue, and did not argue in the District Court case, that the construction of "piston rod" should carry an additional limitation of having only external threads. The only construction set forth in the Petition is from the District Court case where the Petitioner argued that "piston rod" should be define as "[a] rod that engages with the driving member to advance the piston during dose dispensing." Petition at 19. Accordingly, under this construction, when the GB Application discloses a piston rod, it is not limited to a piston rod ***only*** having external threads as Petitioner contends.

In view that the GB Application discloses broadly a threaded piston rod, it is well established that a claim does not lack written description "simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language." *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2005) (quoting *LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (citing *Union Oil Co. v. Atl. Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000))). This is because "the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification." *Id*. Relevant here, Petitioner's own expert explains that "[p]roviding ***threading***, splines, clutches, or other features on these types of concentric components to achieve the desired relative movements during dose setting and injection ***was routine, predictable,*** and well within the abilities of a person of ordinary skill." Ex. 1011 at ¶ 120 (emphasis added). The "routine, predictable" nature of threading necessarily leads a person of ordinary skill in the art to conclude that the inventor possessed the full scope of the invention.

1. Even Accepting Petitioner's Arguments, the GB Application Includes Written Description Support For the Full Scope of The Claims

Even if we disregard the disclosure of the GB Application and accept for the moment Petitioner's argument that the express disclosure of the GB Application is

limited to an externally threaded piston rod, the claims remain supported by the specification. The proper question is whether the disclosure of a species (*i.e.*, an externally threaded piston) is sufficient to put a person of ordinary skill on notice that the inventor had possession of the genus (*i.e.*, the claimed "piston rod comprising either an internal or an external fourth thread").

The Federal Circuit recently addressed exactly this question. In *Hologic*, the parties disputed whether the original filed specification, which only disclosed "a fibre optics bundle," provided sufficient written description support for the claim term "light guide." *Hologic*, 884 F.3d at 1360-61. The Federal Circuit, in reaching its determination, considered two factors. First, the Federal Circuit noted that neither party disputed that a "fibre optic bundle" is a type of light guide – *i.e.*, that a fiber optic bundle is a species of the light guide genus. *Id*. at 1362. The Federal Circuit further noted that neither party disputed that various types of light guides were well-known in the prior art. *Id*. The Federal Circuit concluded that these two factors were sufficient to conclude that substantial evidence supported a finding that the original filed application reasonably conveyed to a person of ordinary skill that the inventor had possession of the genus "light guide." *Id*. at 1362.

The facts here are similar. First, neither party disputes that an externally threaded piston rod is a type of piston rod. Indeed, the genus recited by the claims requires a "piston rod comprising either an ***internal or an external fourth thread***".

Second, neither party disputes that various types of threaded piston rods were well-known in the prior art. Petitioner's own expert confirms that "[p]roviding ***threading***, splines, clutches, or other features on these types of concentric components to achieve the desired relative movements during dose setting and injection was ***routine, predictable***, and well within the abilities of a person of ordinary skill." Ex. 1011 at ¶ 120. Thus the same conclusion should be reached as in *Hologic* – the GB application provides written description support for the claims. This is the correct result. Petitioner cannot argue that threading is so mundane as to be "routine, predictable" and then argue that a person of ordinary skill in the art would not have considered the inventor in possession of both internal and external threading – *i.e.,* the genus.

Notably, the Board has previously rejected a petitioner's written description arguments when, as here, they were inconsistent with the petitioner's position on the knowledge of a person of ordinary skill. *See, e.g.*, *Celltrion, Inc. v. Biogen, Inc.*, IPR2017-01229, Paper 10 at 14 (2017) ("Petitioner's priority date contentions are inconsistent with its position that the combination of cyclophosphamide and fludarabine was itself already a well-known chemotherapeutic regimen for treating CLL."). Similar to *Celltrion*, the Board should reject Petitioner's written description argument given the inconsistency with positions espoused by Petitioner's expert.

B. Grounds 2-3 Should Be Denied Because They Rely on Giambattista

Grounds 2 and 3 of the Petition should also be denied because they rely on Giambattista as a primary reference for purposes of obviousness. Specifically, ground 2 alleges that claims 24-29 of the 844 Patent are invalid as obvious over Giambattista in combination with Steenfeldt-Jensen, and ground 3 alleges that claim 30 is obvious over Giambattista in combination with Klitgaard. Petition at 3. Because Giambattista is not prior art, the Board should deny grounds 2 and 3.

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 should 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:

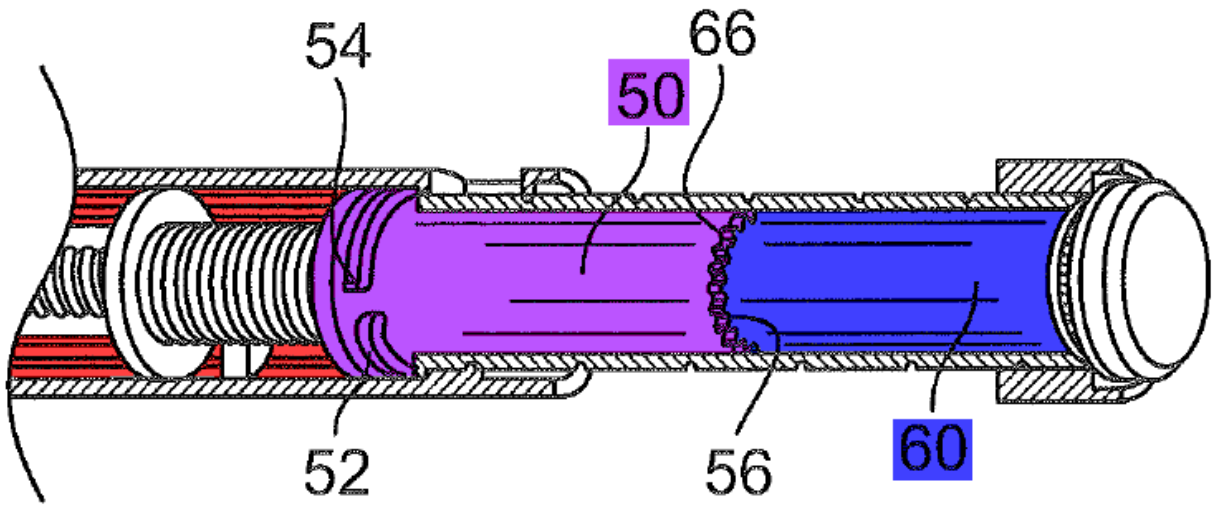
> (3) How the challenged claim is to be construed. Where the claim to be construed contains a means-plus-function or step-plus-function limitation as permitted under 35 U.S.C. 112(f), the construction of the claim must identify the specific portions of the specification that describe the structure, material, 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 they would be understood by a POSA." (Petition at 21), 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, or whether and how the ordinary and customary meanings are different. *See* Petition at 19 ("Patent Owner Sanofi has taken positions regarding the meaning of certain claim terms, which it cannot now argue are unreasonable.").

Second, the Petition additionally requests specific means-plus-function constructions for the terms "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 844 Patent. *See* Petition at 21. As shown below in purple, this is a tubular element.



Ex. 1004, Fig. 6 (annotated).

When analyzing the grounds, however, the Petition instead identifies different corresponding structure: "[t]he '844 patent teaches that in dialing a dose, 'flexible arm 52' with 'toothed member 54' is dragged over 'splines 42' to produce a click." Petition at 60. Petitioner makes no attempt to compare the prior art to the tubular structure of component 50, the original structure identified in Petitioner's construction. This internal inconsistency fails to put Patent Owner on notice of how the claims are being construed in the Petition.

Similarly, for "clutch," the Petition identifies "component 60" (shown in blue, above) of the 844 Patent (Petition at 20), but again fails to compare the prior art to this structure in its analysis of the grounds. See Petition at 55-56

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 22, 2019

Respectfully submitted,

Elizabeth Stotland Weiswasser
Elizabeth Stotland Weiswasser
Reg. No. 55,721
Anish R. Desai
Reg. No. 73,760
Sudip K. Kundu
Reg. No. 74,193
Weil, Gotshal & Manges LLP
767 Fifth Avenue
New York, NY 10153
Phone: 212-310-8000
elizabeth.weiswasser@weil.com
anish.desai@weil.com
sudip.kundu@weil.com

Adrian C. Percer
Reg. No. 46,986
Brian C. Chang
Reg. No. 74,301
Weil, Gotshal & Manges LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
Phone: 650-802-3124
adrian.percer@weil.com
brian.chang@weil.com

William S. Ansley
Reg. No. 67,828
Weil, Gotshal & Manges LLP
2001 M Street NW, Ste. 600
Washington, D.C. 20036
Phone: 202-682-7000
sutton.ansley@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 7,687 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 22, 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 22, 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