

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3M Company, Merck & Co., Inc. and Merck Sharp & Dohme Corp.,
Petitioners

v.

Aptar France S.A.S.,
Patent Owner

Case IPR2018-01055
Patent No. 9,370,631

**Patent Owner's Preliminary Response to Petition for
Inter Partes Review of U.S. Patent No. 9,370,631**

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TABLE OF EXHIBITS

Exhibit #	Reference Name
2001	Affidavit of Ryan A. Hargrave in Support of Motion for <i>Pro Hac Vice</i> Admission
2002	<i>Curriculum Vitae</i> of Ryan A. Hargrave
2003	Affidavit of Robert M. Manley in Support of Motion for <i>Pro Hac Vice</i> Admission
2004	<i>Curriculum Vitae</i> of Robert M. Manley
2005	Declaration of Charles E. Clemens
2006	<i>Curriculum Vitae</i> of Charles E. Clemens
2007	Petition for <i>Inter Partes</i> Review, Paper 1, IPR2018-01054 (May 10, 2018)
2008	Stein, S., <i>Advances in Metered Dose Inhaler Technology: Hardware Development</i> , 15 AAPS PHARMSCITECH 326, 330 (2014)
2009	Sander, N., et al., <i>Dose counting and the use of pressurized metered-dose inhalers: running on empty</i> , 97 ANNALS OF ALLERGY, ASTHMA & IMMUNOLOGY 34 (2006)
2010	Stuart, A., <i>More Than Just a Dose Counter</i> , 46 INNOVATIONS IN PHARMACEUTICAL TECHNOLOGY 40
2011	Henry, A.R., <i>The Role of Statistical Tolerance Analysis Tools in Dose Counter Optimization</i> , available at http://multimedia.3m.com/mws/media/1159495O/statistical-tolerance-analysis-tools-in-dose-counters.pdf

Aptar France S.A.S. and AptarGroup, Inc. (collectively, “Aptar” or “Patent Owner”) respectfully submits this Preliminary Response, timely filed under 37 C.F.R. 42.107(b), to the petition seeking *inter partes* review (“Petition” or “IPR”) of claims 1-4 (“Asserted Claims”) of U.S. Patent No. 9,370,631 (“the ’631 Patent”) (Ex. 1001). As explained in detail below, the Board should deny 3M Company, Merck & Co., Inc, and Merck Sharp & Dohme Corp.’s (collectively, “Petitioners”) Petition.

I. INTRODUCTION

To institute an IPR, Petitioners must show a reasonable likelihood of prevailing on unpatentability. Petitioners advance four grounds for institution: *first*, that the Asserted Claims are anticipated by International Publication WO 00/59806 (“Allsop”); *second*, that the Asserted Claims are anticipated by EP 0480488 (“Marelli”); *third*, that the Asserted Claims are obvious over U.S. Patent No. 6,283,365 (“Bason”) in view of U.S. Patent No. 3,205,863 (“Rhoades”); and *fourth*, that the Asserted Claims are obvious over Bason in view of Allsop. Petitioners fail to establish a reasonable likelihood of success on any ground, and their Petition should therefore be rejected.

First, the Petition suffers from lack of proof. Petitioners generally fail to disclose in adequate detail *how* Bason would be modified in view of Rhoades or Allsop. And for many claim elements, Petitioners point to (1) components of the

unmodified secondary references that were not incorporated in the modified device or (2) components of Bason that are changed or removed in the alleged combination. Petitioners cannot show that their asserted obviousness combinations disclose each element of the Asserted Claims.

Second, Petitioners ask the Board to revisit prior art that was considered during prosecution. Allsop, Marelli, and Bason were expressly considered by the Examiner. The Board should exercise its discretion to deny institution on this basis.

Third, Petitioners have not established that a person of ordinary skill in the art (“POSA”) would have been motivated to modify Bason in view of Rhoades. Rhoades is not analogous art, and Petitioners ignore significant impracticalities and limitations that would result from any attempt to combine a metered dose inhaler with an ink pen. Given the disparity in ultimate purpose and functionality of an inhaler and a pen, a POSA would not have been motivated to combine the two.

Fourth, the asserted modification of Bason in view of Allsop would have rendered the resulting product inoperable for its intended purpose; Petitioners cannot show that a POSA would have been motivated to combine these references.

Finally, objective indicia support nonobviousness of the Asserted Claims. This evidence is an important part of the overall obviousness analysis, and includes the long-felt, unsolved need for the technology claimed in the ’631 Patent. Metered

dose inhalers had been available for nearly 50 years when the FDA issued a request for more accurate dose counting technology. Shortly thereafter, Aptar filed a French application disclosing the '631 Patent's technology, which solves the problems identified by the FDA. For all of these reasons, the Petition should be denied.

II. BACKGROUND OF THE INVENTION

As Petitioners concede, the Food and Drug Administration ("FDA") issued a call to action for accurate dose counting in metered dose inhalers ("MDIs") as early as 2001. Petition at 2-3. The FDA expressed that "[d]ose counters should be engineered to reliably track actuations and should be designed to be as close to 100 percent reliable as possible." Petition, Ex. 1013 at 3. And if error was unavoidable, the FDA cautioned that "the device should be designed to specifically avoid undercounting (i.e., the MDI sprays, but the counter does not advance)." *Id.* As the FDA emphasized, "[u]ndercounting could result in patients assuming they have medication left in their MDI when they do not, a circumstance that is potentially dangerous." *Id.*

Aptar set out to answer the FDA's call. Aptar developed a "fluid dispenser including a dose indicator device that prevents any risk of under-counting, i.e. that guarantees that the indicator device is actuated each time fluid is dispensed by the fluid dispenser." '631 Patent at 1:67-2:3. The Examiner considered the

patentability of Aptar's technology and ultimately allowed the claims. Petitioners now implore the Board to engage in another review of the '631 Patent using some of the same prior art considered at length during prosecution. The Board should deny this request.

III. PROCEDURAL HISTORY

Aptar first filed a French patent application describing its innovative technology on May 15, 2003 as Application No. 03/05858. A corresponding PCT application was filed on May 14, 2004 as Application No. PCT/FR2004/001189, which entered National Stage on November 9, 2005. The corresponding United States Application No. 10/556,432 issued as U.S. Patent No. 8,936,177 ("the '177 Patent") on Jan. 20, 2015. Aptar filed a continuation of the '177 Patent on October 9, 2014. That continuation ultimately issued as the '631 Patent on June 21, 2016.

On June 7, 2018, Aptar asserted the '631 Patent in federal court against Petitioners. *AptarGroup, Inc. v. Aptar France S.A.S. v. 3M Co. et al.*, No. 17-CV-4295 (N.D. Ill.) ("the 4295 Action"). On August 30, 2017, the 4295 Action was dismissed, and the case was refiled as Civil Action No. 17-CV-6294 ("the 6294 Action"). Approximately nine months later, Petitioners filed this Petition seeking institution on the Asserted Claims.

IV. PERSON OF ORDINARY SKILL IN THE ART

Petitioner asserts that a POSA would have had “a bachelor’s degree in industrial design, mechanical engineering or a related discipline and at least three to five years of industry experience in the design or manufacture of mechanical devices, or equivalent experience, education, or both.” Petition at 15. Aptar disagrees that Petitioners’ proposed level of skill in the art reflects the education, training, and experience required to qualify as a POSA. However, for purposes of this Preliminary Response, the Board need not resolve this dispute to find that institution should be denied.¹

V. RESPONSE TO CLAIM CONSTRUCTIONS OF THE ’631 PATENT CLAIM TERMS

In an *inter partes* review, “[a] claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.” 37 C.F.R. § 42.100(b); *see also* *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2144–45 (2016). Claim terms are therefore presumed to have their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Here, there are no claim terms that require construction for purposes of the Board’s decision on institution. *See Wellman, Inc.*

¹ Aptar reserves the right to later propose an alternate level of skill to the extent that the Board institutes review.

v. Eastman Chem. Co., 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed to the extent necessary to resolve the controversy.”).

Petitioners propose constructions for the terms “a stationary body comprising at least one stationary multi-toothed gear” and “disposed on.” Petition at 12-15. Aptar disagrees that Petitioners’ proposed construction for these terms reflects their broadest reasonable constructions. Again, however, the Board need not resolve these disputes to determine that it should deny institution.²

VI. PETITIONER HAS FAILED TO SHOW THAT THE CHALLENGED CLAIMS ARE MORE LIKELY THAN NOT UNPATENTABLE

Aptar respectfully requests that the Board deny the Petition because Petitioners have failed to show a reasonable likelihood that they will prevail. 35 U.S.C. § 314(a).

A. All Grounds: Petitioners Raise the Same or Substantially the Same Prior Art Previously Submitted to the Patent Office

As explained herein, the Board should exercise its discretion to reject the Petition because it relies on prior art or arguments that are the same or substantially

² Aptar reserves the right to later propose its own proposed constructions for these terms to the extent that the Board institutes review.

the same as prior art or arguments that were already considered and rejected by the Patent Office and the Board during the prosecution of the '631 Patent.³

Section 325(d) authorizes the Patent Office to reject petitions that seek to reargue positions previously lost:

In determining whether to institute or order a proceeding under this chapter, . . . the Director may take into account whether, and reject the Petition or request because, the same or substantially the same prior art or arguments were presented to the Office.

35 U.S.C. § 325(d). In determining whether to deny institution on the basis of § 325(d), the Board has considered certain non-exclusive factors, including, for example, the extent to which the asserted art was evaluated during examination and the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments. *See Becton Dickinson & Co. v. B. Braun Melsungen AG*, Case IPR2017-01586, 2017 WL 6405100, at *6 (Patent Tr. & App. Bd. Dec. 15, 2017) (Paper 8) (identifying six non-exclusive factors). Here,

³ *See, e.g., Prism Pharma v. Choongwae*, IPR2014-00315 (Patent Tr. & App. Bd. July 8, 2014) (denying institution when the same prior art and substantially the same arguments were presented to the Office previously); *Hosp. Core Servs. LLC v. Nomadix, Inc.*, IPR2016-00052, 2016 WL 2909164, at *6–8 (Patent Tr. & App. Bd. Apr. 27, 2016) (Paper 8) (declining to institute *inter partes* review “in view of [the Board’s] discretion under 35 U.S.C. § 325(d)).

Allsop, Marelli, and Bason were considered by the Examiner during prosecution. The Board need not expend resources to consider them again.

1. Allsop and Marelli Were Considered During Prosecution

Both Allsop and Marelli were cited in an information disclosure statement during prosecution of the '631 Patent on October 9, 2014. Ex. 1005 (Information Disclosure Statement, Oct. 9, 2014) at 5-6. On August 22, 2015, the Examiner signed the IDS and stated that "ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH." Ex. 1005 (Information Disclosure Statement, annotated by Examiner, Aug. 22, 2015) at 74-75. As neither Allsop nor Marelli was lined through by the Examiner, they were considered. *Id.* Both Allsop and Marelli are also cited on the face of the '631 Patent. '631 Patent at References Cited. Petitioners present no compelling reasons why the Board should retread old ground. *See Becton Dickinson*, 2017 WL 6405100, at *10 ("Petitioner has not pointed to error by the Examiner, or for that matter addressed the evidence and argument presented by Patent Owner, during the underlying prosecution of the '762 patent.").

The Board's analysis in *Microsoft Corporation v. Koninklijke Philips N.V.* is expressly on point. IPR2018-00279, 2018 WL 2943417 (Patent Tr. & App. Bd. June 8, 2018). In that case, as here, the petitioner relied on certain references that had been considered by the examiner during prosecution of the patent at issue.

Microsoft, 2018 WL 2943417, at *5. In exercising its discretion to deny the petition under § 325(d), the Board reasoned that because the examiner signed an IDS listing the asserted references and included language *identical to the Examiner's language* in the '631 Patent prosecution, the references had already been presented to and considered by the Office. *Id.* (“Specifically, we note that the Examiner signed an Information Disclosure Statement listing Willey as a reference. . . . The bottom of each page of the signed Information Disclosure Statement reads, “ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /DS/.” . . . Willey is not lined through. . . . Thus, we find that Willey was previously presented to, and considered by, the Office.”).

The facts here are identical to those in *Microsoft*. The Examiner expressly indicated that Allsop and Marelli had been considered during prosecution. Ex. 1005 (Information Disclosure Statement, annotated by Examiner, Aug. 22, 2015) at 74-75. Both Allsop and Marelli were cited on the face of the '631 Patent. '631 Patent at References Cited. Petitioners do not attempt to establish that the PTO's prior review of these references was improper or incomplete. Nor do Petitioners assert any novel interpretation of these references to justify a second review. As in *Microsoft*, the Board should exercise its discretion to deny the Petition under § 325(d).

2. Petitioners Have Not Established that the Board Should Expend Resources to Review Bason Again

As with Allsop and Marelli, the Patent Office has already considered and rejected Bason. First, related EP 0949584A2 (“Bason EP Application”) was cited and considered at length by the Examiner and the Board during the prosecution of the ’177 Patent. Petition, Ex. 1017. Aptar cited the Bason EP Application in an information disclosure statement on December 6, 2010. Ex. 1004 (Information Disclosure Statement, Dec. 6, 2010) at 400. In an Office Action dated February 18, 2011, the Examiner rejected the claims of the ’177 Patent over the Bason EP Application. Ex. 1004 (Office Action, Feb. 14, 2011) at 1111-12; *see also id.* at Information Disclosure Statement (annotated by Examiner to indicate that all references were considered except where lined through). On appeal, the Board ultimately found that the Examiner did not establish by a preponderance of the evidence that the Bason EP Application disclosed each and every limitation of the claims, and so it did not sustain the anticipation rejections over the Bason EP Application. Ex. 1004 (Decision on Appeal, July 20, 2014) at 1272-73. The claims were allowed, and the ’177 Patent issued on January 20, 2015.

During prosecution of the ’631 Patent, the Examiner rejected the claims over Bason under § 102(b) in an August 27, 2015 Office Action. *See* Ex. 1005 (Office

Action, Aug. 27, 2015) at 70-71.⁴ In response, Aptar noted that Bason discloses that the canister (C) is bonded to the base (1) and, thus, does not teach the claimed stationary body because the canister (C) cannot be axially displaced with respect to the stationary body. Ex. 1005 (Amendment Under 37 C.F.R. § 1.111, Jan. 27, 2016) at 85. The claims were subsequently allowed.

The Patent Office has already considered whether Bason discloses the elements of the claims of the '631 Patent and found that it does not. *See* Ex. 1004 (Decision on Appeal, July 2, 2014) at 1272-73. And as described in detail below, Rhoades is not analogous art, so a POSA would not have been motivated to modify Bason in view of Rhoades or Allsop, and Petitioners' proof for these combinations are fundamentally deficient. *See infra* Sections VI.B.1 and VI.C.1. As a result, the modification presents no compelling reason to retread old ground; considering these arguments again here would waste the Board's resources. *See* 37 C.F.R. § 42.1(b) (stating the Board's policy of securing the "just, speedy, and inexpensive resolution of every proceeding"); *Becton Dickinson*, 2018 WL 6405100, at *8

⁴ The Bason EP Application was also cited in an Information Disclosure Statement, and the Examiner expressly indicated that it had been considered; *see* Ex. 1004 (Office Action, Aug. 27, 2015) at Information Disclosure Statement (annotated by Examiner to indicate that all references were considered except where lined through).

(“Based on the Petitioner’s explanation as to how and why a person of skill in the art would have combined the references, and here, considering the same and similar references as applied during examination, we find little if any, different argument than that considered previously by the Office.”). The Board should therefore deny institution on this basis.

B. Ground 3: Claims 1-4 of the ’631 Patent Are Not Obvious Under 35 U.S.C. § 103 over Bason in View of Rhoades

Petitioners also assert that the Asserted Claims are obvious over Bason in view of Rhoades. Petitioners claim that a POSA would have been motivated to combine Bason with Rhoades and that the combination of Bason and Rhoades discloses each and every limitation of the Asserted Claims of the ’631 Patent. Petitioners’ proof of unpatentability fails because it suffers from failure of proof, Rhoades is not analogous art, and a POSA would have no motivation to combine Bason with Rhoades. Moreover, as noted above, the Board has already considered Bason at length, and it should exercise its discretion to deny institution on that basis.

1. The Petition Suffers from a Fundamental Failure of Proof

As an initial matter, the Petition fails because Petitioners do not describe the Bason/Rhoades combination in sufficient detail. A petitioner in an *inter partes* review proceeding cannot “satisfy its burden of proving obviousness” by “employ[ing] mere conclusory statements” and “must instead articulate specific

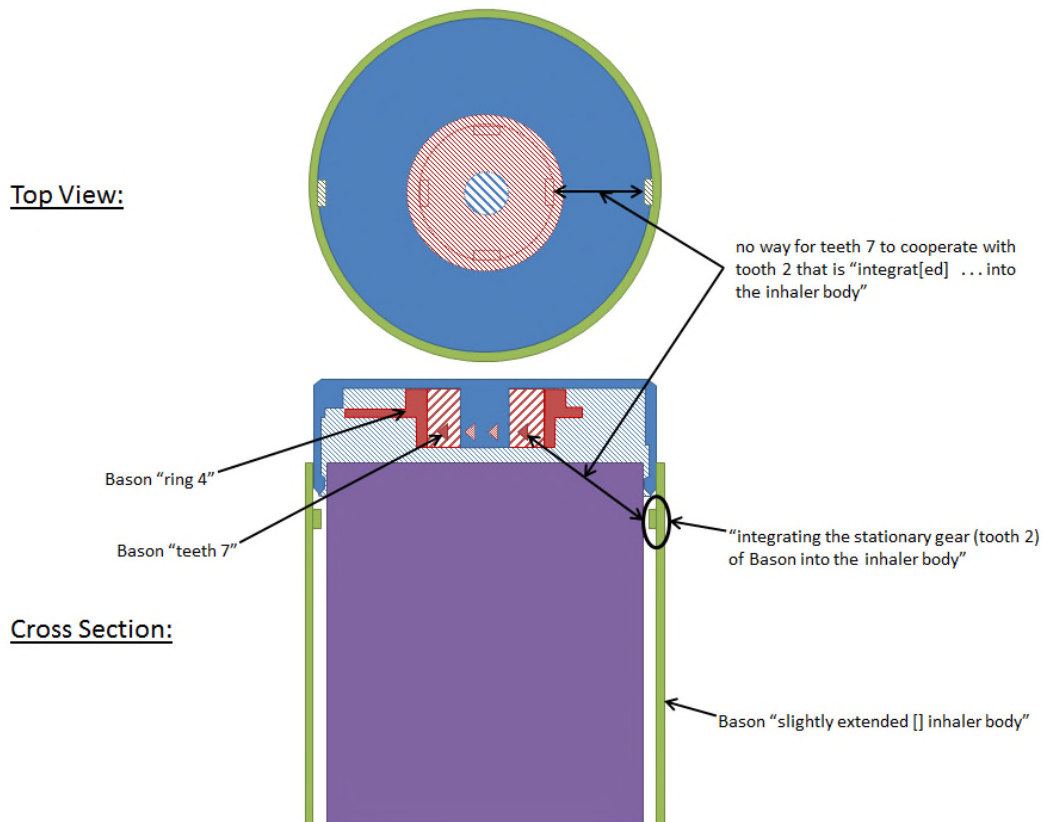
reasoning, based on evidence of record” to support an obviousness determination. *In re Magnum Oil Tools Int’l*, 829 F.3d 1364, 1380–81 (Fed. Cir. 2016). The “factual inquiry” into the reasons for “combin[ing] references must be thorough and searching, and the need for specificity pervades” *In re Nuvasive, Inc.*, 842 F.3d 1376, 1381–82 (Fed. Cir. 2016) (internal quotations and citations omitted) *Magnum Oil*, 829 F.3d at 1380–81.

As described above, Petitioners assert that a POSA would have slightly extended Bason’s inhaler body, integrating the stationary gear (tooth 2) of Bason into the inhaler body. Clemens Decl. (Ex. 2005) at ¶ 22. Petitioners state that the rest of the components would be connected in the same way they are connected in Bason. *Id.* Petitioners include no figures describing how the modification would have been constructed. They also do not describe how the teeth 2, which are disclosed as a component of Bason’s base 1, would be integrated into the inhaler, where the teeth would be located in relation to the remaining components, or how such a modification might affect the efficacy of the dose counting functionality disclosed in Bason. *Id.* Without structural details regarding the proposed combination, merely surmising that these kinds of modifications are ones that a person of skill in the art would have made “is too thin a reed to support a conclusion of obviousness here.” *Acclarent, Inc. v. Ford Albritton, IV*, Case IPR2018–00268, 2018 WL 2553983, at *6 (Patent Tr. & App. Bd. May 31, 2018).

This is especially true since these components have numerous gears, teeth, and other components that act in concert to perform the actions of the device. Petitioners provide no guidance on how to modify these components so that they still interact properly.

Further, in providing their element-by-element analysis, Petitioners frequently point to components that are not included in the asserted combination. For example, Petitioners appear to argue that the second member is either Rhoades cam body 20 or Bason ring 4. *See* Petition at 61-62. However, Petitioner never suggests that the combination of Bason and Rhoades includes Rhoades cam body 20. In fact, the only modifications to Bason are to elongate the inhaler body and move tooth 2 to the inhaler body. Petition at 55; Clemens Decl. at ¶ 22. Rhoades's cam body 20 is never described as being included in the inhaler that allegedly results from the combination of Bason and Rhoades. Petition at 55; Clemens Decl. at ¶ 22. Petitioner says that, other than the inhaler body modifications described above, "the rest of the components could be connected in the same way they are connected in Bason." Petition at 55; Clemens Decl. at ¶ 22. This concept is reinforced by Petitioners' statement that "all of the [Bason] components would retain their same functions." Petition at 56. Thus, the Rhoades cam body 20 is not present in the device resulting from the combination of Bason and Rhoades and cannot form a basis of invalidity under § 103.

In addition, the Bason ring 4 also fails at a basic level to meet the requirements of the “second member” element. This element, present in both independent claims 1 and 3, requires that the second member (1) be displaceable in rotation and (2) be engageable with the stationary body. Petitioners argue that “teeth 7 of rotational ring 4 contact teeth 2 of the stationary body and rotational ring 4 begins to rotate.” Petition at 62. This is incorrect. A graphic showing this modification, both from a top view and a profile cross-section, is below:



As illustrated above, the Bason ring 4 (shown in red) cannot rotate when tooth 2 is moved to the inhaler body (shown in green). Clemens Decl. at ¶ 29.

Depressing the Bason cap will not result in teeth 7 contacting teeth 2, and thus the ring 4 will not rotate. *Id.* Petitioners' proof for this claim element fails.

2. Rhoades Is Not Analogous Art

Rhoades, which discloses an ink pen, is not analogous art. Prior art is only analogous when it is (1) from the same field of endeavor or (2) reasonably pertinent to the particular problem the inventor was trying to solve. *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992) (“A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.”). To determine if art is analogous, the Federal Circuit “looks to the purposes of both the invention and the prior art. If a reference disclosure and the claimed invention have a same purpose, the reference relates to the same problem, which supports an obviousness rejection.” *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1001 (Fed. Cir. 2016).

The stated purpose of the '631 Patent is to “provide a fluid dispenser including a dose indicator device that prevents any risk of under-counting, i.e. that guarantees that the indicator device is actuated each time fluid is dispensed by the fluid dispenser.” '631 Patent at 1:67-2:3. Rhoades is not directed to the same purpose, as it purports to “provide a ball point writing instrument having an

improved push button operated projecting and retracting mechanism.” Rhoades at 1:15-17. Actuation of an MDI and projection/retraction of a pen are entirely different mechanisms, and a POSA would not have looked to an ink pen to ensure more dose accurate counting in an MDI. Clemens Decl. at ¶ 15. Indeed, Rhoades does not count anything, so there is no risk of undercounting that would motivate a POSA to look to Rhoades for guidance. *Id.*; see also *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992) (“The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a prima facie case of obviousness.”).

Because the '631 Patent and Rhoades share no commonality and are not directed to the same purpose, Rhoades is not analogous art. *In re Clay*, 966 F.2d at 658. As a result, Rhoades cannot be “be considered within the prior art for purposes of the obviousness analysis.” *Circuit Check Inc. v. QXQ Inc.*, 795 F.3d 1331, 1335-36 (Fed. Cir. 2015). (“An alleged infringer should not be able to transform all systems and methods within the common knowledge into analogous prior art simply by stating that anyone would have known of such a system or method. The question is not whether simple concepts. . . are within the knowledge of lay people or even within the knowledge of a person of ordinary skill in the art. Rather, the question is whether an inventor would look to this particular art to solve the particular problem at hand.”).

Petitioners cite four references and their expert's uncorroborated testimony to support their assertion that a POSA would have looked to Rhoades's mechanical pen technology to improve the counting mechanism in Bason's MDI. Petition at 53-54. None of Petitioners' references establish that Rhoades is analogous art.

For example, U.S. Patent No. 5,234,970 ("Ambrosio") discloses a dosing device for administering powdered medication. Petition, Ex. 1031. In Ambrosio, the patentee discusses prior art U.K. Patent No. 2,165,159 ("Auvinent"). *Id.* at 2:36-51. As Petitioners point out, Ambrosio explains that Auvinent discloses a device for rotating the rod is an indexing mechanism much like that of a ball-point pen. *Id.* But Ambrosio expressly teaches away from the mechanism disclosed in Auvinent: "However, because of the cup-like arrangement of this patent, adhesion can occur along the walls of each depression, *which is disadvantageous from a delivery viewpoint.*" *Id.* at 2:47-51 (emphasis added). Thus, a POSA with knowledge of Ambrosio and/or Auvinent would not have been motivated to incorporate a ball-point pen mechanism into a dosing device. Clemens Decl. at ¶ 18.

Similarly, U.S. Patent No. 7,090,662 ("Wimpenny") was cited by Petitioners for its discussion of the "ball point pen principle" disclosed in prior art patent DE 3,814,023. Petition, Ex. 1032 at 1:40-48. But Wimpenny makes clear that such mechanism "does not address the problem of incorrect dose setting by the user."

Id. In addition, both Wimpenny and the other references cited by Petitioners either do not relate to dose counting technology and/or were filed long *after* the '631 Patent. *See* Exs. 1033 (filed several years after invention of the '631 Patent); 1034 (filed in 2016, disclosing a suturing device); Clemens Decl. at ¶ 19.⁵ Petitioners, thus, fail to show that Rhoades is analogous art.

3. A POSA Would Not Have Been Motivated to Combine Bason with Rhoades

Petitioners assert that a POSA would have understood the desire to modify Bason to scale up production, maximize efficiency of manufacture and product reliability, and increase commercial viability. Petition at 53. Because Rhoades is “a small, plastic, inexpensive mechanical device that converts axial motion . . . into rotational motion,” Petitioners assert that a POSA would have looked to this type of art when seeking to improve Bason. *Id.* at 53-54.

But the asserted modification of Bason in view of Rhoades does not relate to the mechanism of action disclosed in Rhoades. *Id.* Indeed, Petitioners assert that a POSA “would have slightly extended Bason’s inhaler body (just as guide member

⁵ Petitioners’ expert testifies that he looked to the mechanism of a pen when asked to design a dose indicator prior to 2001. Ex. 1002 at ¶¶ 17, 135. But he cites no evidence or proof, and he fails to provide enough detail regarding the technology and design at issue to evaluate whether his experience at the time is relevant to the Board’s task here.

28 in Rhoades extends beyond the reservoir) . . . integrating the stationary gear (tooth 2) of Bason into the inhaler body, just as the stationary gears (stop members) of Rhoades are integrated directly on the Rhoades body[.]” Petition at 55. However, Petitioners do not describe how the teeth 2, which are disclosed as a component of Bason’s base 1, would be integrated into the inhaler, where the teeth would be located in relation to the remaining components, or how such a modification might affect the efficacy of the dose counting functionality disclosed in Bason. *Id.* Nor do Petitioners describe in sufficient detail how or why a POSA would have been motivated to combine these particular features to attain the claimed functionality. The Petition, thus, suffers from a fundamental deficiency of proof of motivation to combine. *See Purdue Pharma L.P. v. Depomed, Inc.*, 643 Fed. App’x 960, 966 (Fed. Cir. 2016) (“Its expert opined generally on the interrelated teachings of those references, but did not explain in sufficient detail how or why a skilled artisan would have been motivated to combine the ‘swelling’ and ‘substantially intact’ features of the Shell formulation with the Baveja formulation to attain the claimed dosage form.”).

In addition, Petitioners’ essentially suggest that a person seeking to improve the accuracy of an MDI dose counter would have looked to *any* small, mass-produced device regardless of its design or functionality. This is improper as a basis for combining Bason and Rhoades. *See Circuit Check Inc. v. QXQ Inc.*, 795

F.3d 1331, 1335-36 (Fed. Cir. 2015) (“An alleged infringer should not be able to transform all systems and methods within the common knowledge into analogous prior art simply by stating that anyone would have known of such a system or method. The question is not whether simple concepts. . . are within the knowledge of lay people or even within the knowledge of a person of ordinary skill in the art. Rather, the question is whether an inventor would look to this particular art to solve the particular problem at hand.”).

Moreover, the Rhoades ball point pen is not designed to be a precision-engineered plastic device. Clemens Decl. at ¶ 26. It functions simplistically with wide physical tolerances. *Id.* These design characteristics are consistent with the Petitioners’ assertion that an ink pen can be manufactured in higher volumes at a low cost, and the fact that the pen’s writing function is non-critical. *Id.* Indeed, Rhoades expressly teaches away from use of “close manufacturing tolerances”:

The construction of the projecting-retracting mechanism is in both embodiments such that the stop members may be formed integrally with a stationary member and may be *made of substantial size thereby avoiding a common disadvantage of known projecting-retracting mechanisms* employing one or more pins as stop members. . . . *None of the operating parts of the projecting-retracting mechanism in accordance with my invention requires close manufacturing tolerances for dependable operation.*

Rhoades at 8:6-16 (emphasis added). Petitioners fail to explain why a person seeking to improve the accuracy of an MDI would look to non-precision components like those of an ink pen. Clemens Decl. at ¶ 23.

Unlike a pen, a metered dose inhaler must be executed precisely upon every single actuation, and every function of the inhaler must be effectuated in much tighter geometries, usually just a few millimeters. *Id.* at ¶ 25. For example, the distance traveled by the components in Rhoades is substantially greater than the distance traveled by the medication canister of an MDI when pressed by a patient. *Id.* at ¶ 26. Nevertheless, in that smaller range of motion, the travel distance of actuation of the inhaler must permit (1) delivery of the dose of medication; (2) refill of the valve’s metering chamber; and (3) engagement of an accurate counting mechanism so as to allow the count to progress. *Id.* at ¶ 25. Whether or not Rhoades’s cam mechanism is less expensive to manufacture, a POSA would understand that it simply was not designed for the accuracy that is required for an MDI. *Id.* at ¶ 23.

Because the mechanism of action in Rhoades does not translate to the functionality of an MDI, a POSA would not have looked to Rhoades in improving the MDI disclosed in Bason. *Id.* Petitioners point to no known method for combining a pen with an inhaler, and a POSA would have had no reasonable expectation of success in doing so. *Id.* at ¶ 27.

i. The Proposed Modification Would Be Inoperable for Its Intended Purpose

Petitioners propose that a POSA “would have slightly extended Bason’s inhaler body (just as guide member 28 in Rhoades extends beyond the

reservoir) . . . integrating the stationary gear (tooth 2) of Bason into the inhaler body, just as the stationary gears (stop members) of Rhoades are integrated directly on the Rhoades body[].” Petition at 55. As described below, Petitioners provide no further explanation as to how the teeth (2) would be integrated into the inhaler, where the teeth would be located in relation to the remaining components, or how such a modification might affect the efficacy of the dose counting functionality disclosed in Bason, and thus the Petition fails at the outset.

However, even if the combination were described sufficiently, Petitioners’ proposed modification renders Bason inoperable for its intended purpose. As described by Petitioners, the combination of Bason and Rhoades would require a POSA to slightly extend the inhaler body and integrate tooth 2 into the inhaler body. Petition at 55. “The rest of the components could be connected in the same way they are connected in Bason, or other ways well-understood in the art.” *Id.* There is no description that any components of Rhoades are actually incorporated into the Bason inhaler, only that a POSA viewing Rhoades would have extended the inhaler body and moved the tooth 2 onto the inhaler body.

The critical issue with this combination is that if the “tooth 2” is integrated into the inhaler body (shown in green in the graphic above), then it cannot engage with tooth 7 (shown in red). When the cap (shown in blue) is depressed, the teeth 7 (shown in red) do not engage with tooth 2 (shown in green). This is because the

teeth 7 are located near the center of the cap inside of ring 4 compared to tooth 2, which is located on the inhaler body near the outer circumference of the device. As a result, teeth 7 cannot engage with tooth 2 in order to rotate the ring 4. If the ring 4 cannot rotate, then the dose numbers will not advance, and the patient will not know how many doses of medication are in the inhaler. *Id.*; Clemens Decl. at ¶ 29. Without an indication of the number of doses remaining in the inhaler, Bason is rendered inoperable for its intended purpose of “indicat[ing] the number of times the pressurized canister is depressed to dispense a dose of the drug.” Bason at 1:15-17.

Alternatively, if base (1), itself, is made integrally with inhaler body (A), Petitioners do not explain how cap (14) can be depressed sufficiently to actuate the inhaler. Clemens Decl. at ¶ 30. Nor do Petitioners describe how the canister (C) could be placed inside the body (A) if the base (1) is integral to body (A). *Id.* In other words, if the base and inhaler body are formed as one integral piece, there is no longer any access to the interior of the inhaler so that the canister of medicine can be placed inside. The Federal Circuit has made clear that combinations that render the prior art inoperable for its intended purpose likely fail to support a finding of obviousness. *See, e.g.*, MPEP 2143.01(V); *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). Here too, the proposed modifications leave Bason inoperable

for its intended purpose. For this reason, and all the others described above, a POSA would not have been motivated to modify Bason as Petitioners suggest.

ii. The Combination of Bason and Rhoades Does Not Yield Predictable Results

Furthermore, Petitioners argue that the proposed modification of Bason in view of Rhoades would have yielded predictable results. *See, e.g.*, Petition at 56. However, Petitioners also filed a petition for *inter partes* review of related U.S. Patent No. 8,936,177 (“the ’177 Patent”). Petition for *Inter Partes* Review at 52-71, IPR2018-01054 (May 10, 2018) (“the ’177 Petition”) (attached as Ex. 2007). In the ’177 Petition, just as here, Petitioners assert that the ’177 Patent is rendered obvious by Bason in view of Rhoades. But the combination of Bason and Rhoades alleged in the ’177 Petition is structurally and functionally different than the combination disclosed here.

For example, in the ’177 Petition, Petitioners assert that a POSA would have incorporated Rhoades’s cam body 20, bonding it to the base of the canister, and that the outer housing of Bason would correspond to Rhoades’s guide member 28. ’177 Petition at 58. Petitioners assert that a POSA would have modified Rhoades’s cam body to include displayable values and that all of the components incorporated from Rhoades would retain their original function. *Id.* at 58-59. The fact that Petitioners cannot combine Bason and Rhoades in predictable ways belies Petitioners’ argument that a POSA’s combination of Bason and Rhoades would

have yielded predictable results.

C. Ground 4: Claims 1-4 of the '631 Patent Are Not Obvious Under 35 U.S.C. §103 over Bason in View of Allsop

Petitioners assert that a POSA would have been motivated to modify Bason to include “fewer components and tolerances that needed to be modulated.” Petition at 67. As a result, Petitioners allege, a POSA “would have simply moved the Bason dose counter below the Bason canister, where the rotational mechanism (outer housing collar 155 and inner housing flange 142) is located in Allsop, and integrally molded the teeth 2 into the inhaler housing, just as Allsop teaches.” *Id.* at 66-67. Petitioners’ argument fails for three independent reasons as described below.

1. The Petition Suffers from a Failure of Proof

i. Petitioners Do Not Disclose the Asserted Modification in Adequate Detail

First, Petitioners do not disclose how the components of Bason would be modified as Petitioners describe while maintaining operability of the device as described in Bason. For example, Petitioners have not explained how the dose counting components of Bason can be disengaged from the base, moved below the canister, engaged with some stationary component so as to allow the canister to be axially displaceable to such component, and still function in the way described in Bason. Clemens Decl. at ¶ 34. Nor do Petitioners describe how the valve extending from the canister through the counting mechanism would clear the components of

the counting mechanism and still allow the canister to be axially displaceable relative to a stationary component (which must also engage with the counter element) as required by the claim. *Id.* Petitioners also fail to explain how teeth (2) can be integrally formed in the housing if the dose counter is moved to the bottom of the device. *Id.*

“An obviousness determination cannot be reached where the record lacks explanation as to *how* or *why* the references would be combined to produce the claimed invention.” *TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1066 (Fed. Cir. 2016) (internal citations omitted) (emphasis in original); *In re Nuvasive, Inc.*, 842 F.3d at 1381–82. Petitioners’ threadbare arguments and evidence are insufficient to support an obviousness determination. *See Facebook, Inc. v. Uniloc USA, Inc.*, 2017 WL 6034157, at *18 (Patent Tr. & App. Bd. Dec. 4, 2017) (citing *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017)). Petitioners’ failure to adequately describe their proposed combinations in adequate detail supports denial of the Petition.

ii. Petitioners Fail to Show that the Asserted Combination Discloses the Claimed Elements

Petitioners’ proof is deficient on an even more fundamental level, as Petitioners fail to point to evidence that *the asserted combination*, as opposed to Bason and Allsop individually, discloses each element of the Asserted Claims. For example, for claim elements (e) and (f)—the “first member” and “second member”

limitations—Petitioners do not identify any evidence that the asserted combination of Bason and Allsop discloses such elements. Petition at 72. Instead, Petitioners make a generic reference to the evidence proffered in support of their asserted Bason/Rhoades obviousness combination and the Allsop §102 assertion for those elements. *Id.* Petitioners do the same for the “a plurality of displayable dose values” element, despite the fact that the modification fundamentally changes the structure and location of the dose display components as described in detail below. *Id.* at 69.

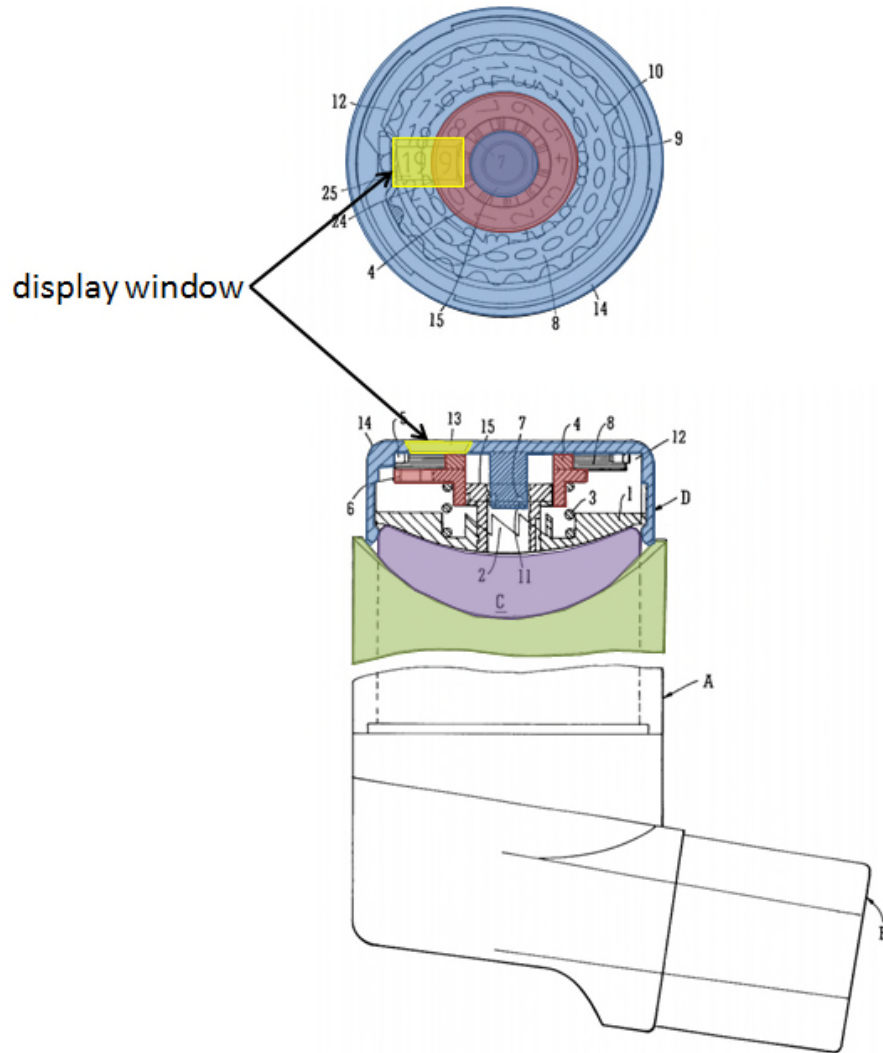
Petitioners cannot simply point to an entirely different combination of Bason with a separate reference or its evidence of Allsop’s purported anticipation as evidence that the particular combination of Bason and Allsop discloses each of the claimed elements. Instead, Petitioners must establish that the *combination* of Bason and Allsop discloses the claimed elements. Because Petitioners have not even attempted to carry their burden, the Board should deny institution.

2. A POSA Would Not Have Been Motivated to Combine Bason with Allsop

Petitioners have failed to explain why a POSA would have been motivated to make the asserted modification to Bason and reasonably expect success in doing so. Petitioners’ most substantial explanation is that “the prior art explained that the fewer components and tolerances that needed to be modulated, the more accurate and reliable a device would be.” Petition at 67; Clemens Decl. at ¶ 35. But Bason

teaches away from the concept of fewer components, expressly teaching that “[p]referably, the entire device with the possible exception of spring 3 is made from individual pieces.” Bason at 3:58-60; Clemens Decl. at ¶ 35. Even if taken as true, Petitioners’ purported motivation to combine reflects no more than the prior art’s identification of a problem, not the solution. *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (“[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.”) (emphasis in original).

In addition, Petitioners’ proposed modification to Bason would render it inoperable for its intended purpose. Specifically, Bason’s display window for viewing the number of doses remaining is on the top of the dose counter. *See* Bason at Abstract (“Within the cap (14) is a pair of independently rotatable rings, each carrying on its upper surface indicia visible through a window (13) in the cap.”). The display window is shown in yellow in the Figures below:



If a POSA were to remove the counter from the top of the canister and place it below the canister, the display window would no longer be a portal for viewing the number of remaining doses. It would instead show the top of the canister. Clemens Decl. at ¶ 36. And there would be no way to view the remaining doses from the side of the inhaler body. *Id.* This is because the dose numbers are on the top of the dial and the counting mechanism allows for rotation of each number based on a rotation viewed from the top of the device rather than the side of the

device. The counting mechanism would be completely useless for its intended purpose, as the patient could not see the number of doses remaining in the inhaler. *See* Bason at 1:15-20 (“Thus there is a need for a dose counter for an MDI to indicate the number of times the pressurised canister is depressed to dispense a dose of the drug. Such a counter must count down, typically from 200 to zero, progressively as doses are administered so that the user can readily see how many doses remain.”).

Petitioners do not attempt to describe how the display of dose values would be achieved when Bason is modified as they assert. Indeed, for the “displayable dose values” element, they merely incorporate their evidence from the asserted combination of Bason and Rhoades, as well as their anticipation evidence for Allsop. Petition at 69 (“Both Bason and Allsop disclose a plurality of displayable dose values for the reasons above. See §§VIII.C.2.b (Bason); VIII.A.1.b (Allsop).”). Thus, not only does the Petition fail for a fundamental lack of proof, it also fails because Petitioners’ asserted combination of Bason and Allsop renders the invention useless for its intended purpose. *In re Gordon*, 733 F.2d at 902. A POSA would not have been motivated to combine Bason and Allsop as Petitioners describe.

VII. PETITIONER IGNORES OBJECTIVE INDICIA OF NONOBVIOUSNESS OF THE CLAIMED INVENTIONS

Objective indicia of nonobviousness are part of the overall obviousness analysis, not just an afterthought. *In re Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation*, 676 F.3d 1063, 1075-76 (Fed. Cir. 2012) (noting that a fact finder “may not defer examination of the objective considerations until after the fact finder makes an obviousness finding”). Objective indicia of nonobviousness play a critical role because they are “not just a cumulative or confirmatory part of the obviousness calculus but constitute[] independent evidence of nonobviousness.” *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008). Objective indicia “can be the most probative evidence of nonobviousness in the record, and enables the . . . court to avert the trap of hindsight.” *Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (objective evidence of nonobviousness “may often be the most probative and cogent evidence in the record”).

Objective evidence of nonobviousness can include copying, long felt but unsolved need, failure of others, commercial success, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans

before the invention. *Power Integrations, Inc. v. Fairchild Semiconductor Intern., Inc.*, 711 F.3d 1348, 1368 (Fed. Cir. 2013).

The '631 Patent met a long felt, but unresolved need. “The existence of an enduring, unmet need is strong evidence that the invention is novel, not obvious, and not anticipated. If people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence—the kind that can’t be bought from a hired expert, the kind that does not depend on fallible memories or doubtful inferences—of the state of knowledge.” *In re Mahurkar Patent Litigation*, 831 F. Supp. 1354, 1378 (N.D. Ill. 1993), *aff’d*, 71 F.3d 1573 (7th Cir. 1995).

The '631 Patent resulted from Aptar’s efforts to respond to the FDA’s call for a more accurate dose counter. For nearly fifty years before the invention of the '631 Patent, there was no method by which a patient could accurately determine how many doses remained in his or her MDI. Petition, Ex. 1013 at 2. As a result, patients were left to guess how many doses were left in their MDIs and had only two practical options: (1) throw away an MDI that still contained medicine or (2) use an MDI that may be empty of medicine and risk not receiving the correct drug dose. As the FDA recognized, “[t]he former is wasteful, and the latter is potentially dangerous.” *Id.* Competitors in the industry at the time of the invention of the '631 Patent were aware of this problem, and yet were unable to create a satisfactory solution. *Id.*

Despite the proliferation of inferior MDIs for many years, drug makers (including Petitioners) failed to create an accurate MDI dose counter. Indeed, although the FDA issued draft guidance in 2001, the FDA's final Guidance for Industry was issued in March 2003, two months before Aptar filed its French application disclosing the groundbreaking technology of the '631 Patent.⁶ And MDIs had been available for nearly fifty years before the final Guidance was issued. Ex. 1013 at 2. The '631 Patent addressed the long-felt need in the industry for an accurate dose counter that avoided undercounting.

In this case, objective indicia point to a conclusion of nonobviousness. These objective indicia are the “most probative evidence of nonobviousness” and should enable the Board “to avert the trap of hindsight.” *Crocs*, 598 F.3d at 1310; *see also Stratoflex*, 713 F.2d at 1538; *Leo Pharm.*, 726 F.3d at 1358. This powerful evidence, in conjunction with the conclusory reasoning provided in the Petition, shows that Aptar's challenged claims are not obvious. The Board should deny Grounds I and II in the Petition.

⁶ Aptar filed its French Application for the '177 Patent, the '631 Patent's parent, in May 2003.

VIII. CONCLUSION

The Patent Owner respectfully requests that the Board deny institution of *inter partes* review of claims 1-4 of the '631 Patent, as each of the grounds in the Petition fail for the reasons noted above.

Respectfully submitted,

Dated: August 15, 2018

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CERTIFICATE OF COMPLIANCE WITH WORD COUNT

Pursuant to 37 C.F.R. § 42.24(a), (b), (d), I hereby certify that the attached **Patent Owner's Preliminary Response to Petition for *Inter Partes* Review of U.S. Patent No. 9,370,631** contains 7,777 words, excluding the parts exempted by 37 C.F.R. § 42.24(a)(1).

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CERTIFICATE OF SERVICE

A copy of the **Patent Owner's Preliminary Response to Petition for *Inter Partes* Review of U.S. Patent No. 9,370,631** has been served on Petitioner via electronic mail at the following correspondence address:

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