

Case No. IPR2018-01055

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 Sur-Reply in the
***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 in Support of Patent Owner's Preliminary Response
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
2012	Declaration of Ryan A. Hargrave in Support of Corrected Motion for <i>Pro Hac Vice</i> Admission
2013	Declaration of Robert M. Manley in Support of Corrected Motion for <i>Pro Hac Vice</i> Admission
2014	Declaration of Benjamin G. Murray in Support of Motion for <i>Pro Hac Vice</i> Admission
2015	<i>Curriculum Vitae</i> of Benjamin G. Murray
2016	RESERVED
2017	Newman, S., <i>Principles of Metered-Dose Inhaler Design</i> , 50 Respiratory Care 1177 (2005)
2018	Malloy, R., <i>Plastic Part Design for Injection Molding</i> , , pgs. 88, 99, Hanser Pub. (1994)
2019	Deposition Transcript of Samuel David Piper, taken January

	25, 2019
2020	The Kids Should See This, available at https://thekidshouldseethis.com/post/how-does-a-retractable-ballpoint-click-pen-work
2021	Declaration of Charles E. Clemens in Support of Patent Owner's Response
2022	Supplemental Declaration of Charles E. Clemens in Support of Patent Owner's Response
2023	Declaration of Charles E. Clemens in Support of Patent Owner's Sur-Reply

I. INTRODUCTION

Rather than attempt to defend the arguments set forth in their Petition, Petitioners advance wholly new theories of anticipation and obviousness in their Reply. Petitioners' belated arguments nevertheless fail to prove any of the asserted art discloses the Asserted Claims, and so the patentability of claims 1-4 of the '631 Patent should be confirmed.

II. PETITIONERS IMPROPERLY INTRODUCE NEW THEORIES IN THEIR REPLY

Unable to find support in their original Petition to support their Reply, Petitioners advance new theories of anticipation and add new modifications to their proposed obviousness combinations for the first time in their Reply. This directly contradicts 35 U.S.C. § 312(a).

“It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify ‘with particularity’ the ‘evidence that supports the grounds for the challenge to each claim.’” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (citing 35 U.S.C. §312(a)). Namely, once a petition is instituted, the challenges set forth in the petition are crystalized, and the scope of a petitioner's argument thereafter is expressly limited to “explaining how its original petition was correct.” *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1286 (Fed. Cir. 2017). Thus, for these same reasons, a petitioner on reply “may not submit any new evidence,

issues, or argument that it could have presented earlier, e.g. to make out a prima facie case of unpatentability.” *Allsteel Inc. v. Dirtt Environmental Solutions, LTD.*, 2018 WL 4488938 *1 (Patent Tr. & App. Bd., Sept. 17, 2018); Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39989 (Aug. 2018).

Yet that is precisely what Petitioners do here, adding a total of 8 brand-new modifications to their combinations and switching proof on one anticipation argument. With respect to Bason/Rhoades, Petitioners argue for the first time on reply that (1) the cap would be “slightly widen[ed] . . . so that its outer edge fits over the outside of the housing,” (2) “a rib . . . would [be] added to the outside of the housing . . . to prevent unintentional removal of the cap,” and (3) “the diameter of ring 4 [would be extended] so that teeth 7 interact with teeth 2.” Reply at 10-11, 15.

With respect to Bason/Allsop, Petitioners argue for the first time on reply that (1) Bason’s “cap would [be] designed with slots through which teeth 2 [] would protrude,” (2) the slots would be “slightly taller than the height of the teeth, allowing the cap to move up and down upon operation of the MDI,” (3) “a POSA would have . . . taper[ed] teeth 2 (narrower at the top, wider at the bottom), to allow the cap to slide into position,” (4) “the diameter of ring 4 [would be extended] so that teeth 7 interact with teeth 2,” and (5) window 13 would “be made on the side of the device.” Reply at 12-13, 15.

With respect to Marelli, Petitioners now argue that the flexible legs 16—and not the previously identified rotating element 9—are the portion of the second member that moves axially. Reply at 5-6. However, the Petition repeatedly and specifically identifies only the “rotating element 9” as the second member that moves axially. See Petition at 46 (Axial movement of ring nut 4 “causes axial movement of the counter [rotating] element 9.”) (emphasis added). Similarly, where the Petition includes annotated Figures depicting element 9 in relation to other components, “rotating element 9” is specifically highlighted in yellow while legs 16 are not. See Petition at 26-27, 44, 46-47. In sum, the Petition does not state that legs 16 are part of the “second member” or that legs 16 move axially, and legs 16 are never depicted as such. See Petition at 46.

Petitioners cannot use their Reply to belatedly “craft a new obviousness challenge by piggybacking on the one that was clearly wanting.” *Yamaha Golf Car Co. v. Club Car, LLC*, 2019 WL 1473077 *13 (Patent Tr. & App. Bd. April 2, 2019). Nor is it permissible for Petitioners to retroactively “fill in the gaps of the Petition by showing, for the very first time, how the prior art of record describes a claim element that was not accounted for previously.” *Allsteel*, 2018 WL 4488938 *2 (Patent Tr. & App. Bd.). “Shifting arguments in this fashion is foreclosed by statute, our precedent, and Board guidelines.” *Wasica*, 853 F.3d at 1286–87.

Accordingly, because none of the aforementioned new allegations in Petitioners' Reply are found in the original Petition, these arguments must be excluded.

III. ALLSOP'S PUSH-BUTTON CAP IS NOT ENABLED

Petitioners dispute as "misguided" Aptar's argument that Allsop's push-button cap cannot be the "first member" because it is not enabled. Reply at 1-3. However, Petitioners' contrary assertion in their Reply that Allsop's push-button cap is adequately enabled and "axially displaceable" is premised entirely on extraneous description that is altogether absent from Allsop itself.

An enabled disclosure is one which a POSA could practice the full scope of without "undue experimentation." *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013). "When there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required." *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1283-84 (Fed. Cir. 2007) (internal citation omitted). Here, Allsop's description of the "push-button cap" is limited to the following:

"A push-button cap (not shown) may be provided as part of the main housing 10 to cover the upper portion of the pressurized dispensing container 15. Advantageously, this prevents the ingress of dust, contaminants and moisture into the apparatus."

Ex. 1006 at 10. Upon reading the above two sentences, Petitioners assert that it would have been "clear" to a POSA that Allsop's push-button cap: (1) is located on the "top rim" of the outer housing; and (2) includes a "top portion" that "moves

axially [and] interact[s] directly with the reservoir and/or directly with the very top of the inner housing.” Reply at 2. But none of this description is found anywhere in Allsop. Such features have simply been built into Allsop’s push-button cap by Petitioners themselves.¹ This is improper. *Auto. Techs*, 501 F.3d at 1283-84; *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). Accordingly, Petitioners cannot supplement Allsop with Petitioners’ preferred description of the push-button cap. Only Allsop can enable the push-button cap,

¹ Petitioners also wrongly assume that “push-button cap” has a clear and specific definition, i.e., a cap that is capable of being pushed. Reply at 3 (“If the push-button of the cap did not move axially (i.e., if it could not be pushed), it would not be a push-button cap.”). But “push-button cap” is a generic and ambiguous term with no clear meaning in this context. For example, a “push-button cap” could refer to a cap that covers a “push-button” (e.g., that covers the canister of an MDI to prevent debris from getting into the device) but which is itself not axially displaceable. Indeed, such a reading of “push-button cap” garners more support from the text than the definition offered by Petitioners. *See* Ex. 1006 at 10 (“A push-button cap . . . may be provided . . . to cover the upper portion of the pressurized dispensing container 15. Advantageously, this prevents the ingress of dust, contaminants and moisture into the apparatus.”).

and it fails to do so. Petitioners' assertion that Allsop anticipates the Asserted Claims must therefore be rejected.

IV. PETITIONER'S REVISED COMBINATIONS FAIL TO RENDER THE '631 PATENT OBVIOUS

Even if the Board considers Petitioners' belated obviousness rationales, Petitioners have not shown that a POSA would have been motivated to combine the prior art so as to create a viable device that discloses both a second member that is displaceable axially and in rotation relative to a stationary body and changing a displayed dose value from among the plurality of displayable dose values, as claimed in the '631 Patent.

A. Bason/Rhoades does not disclose a second member that is displaceable axially and in rotation relative to a stationary body or changing a displayed dose value from among the plurality of displayable dose values.

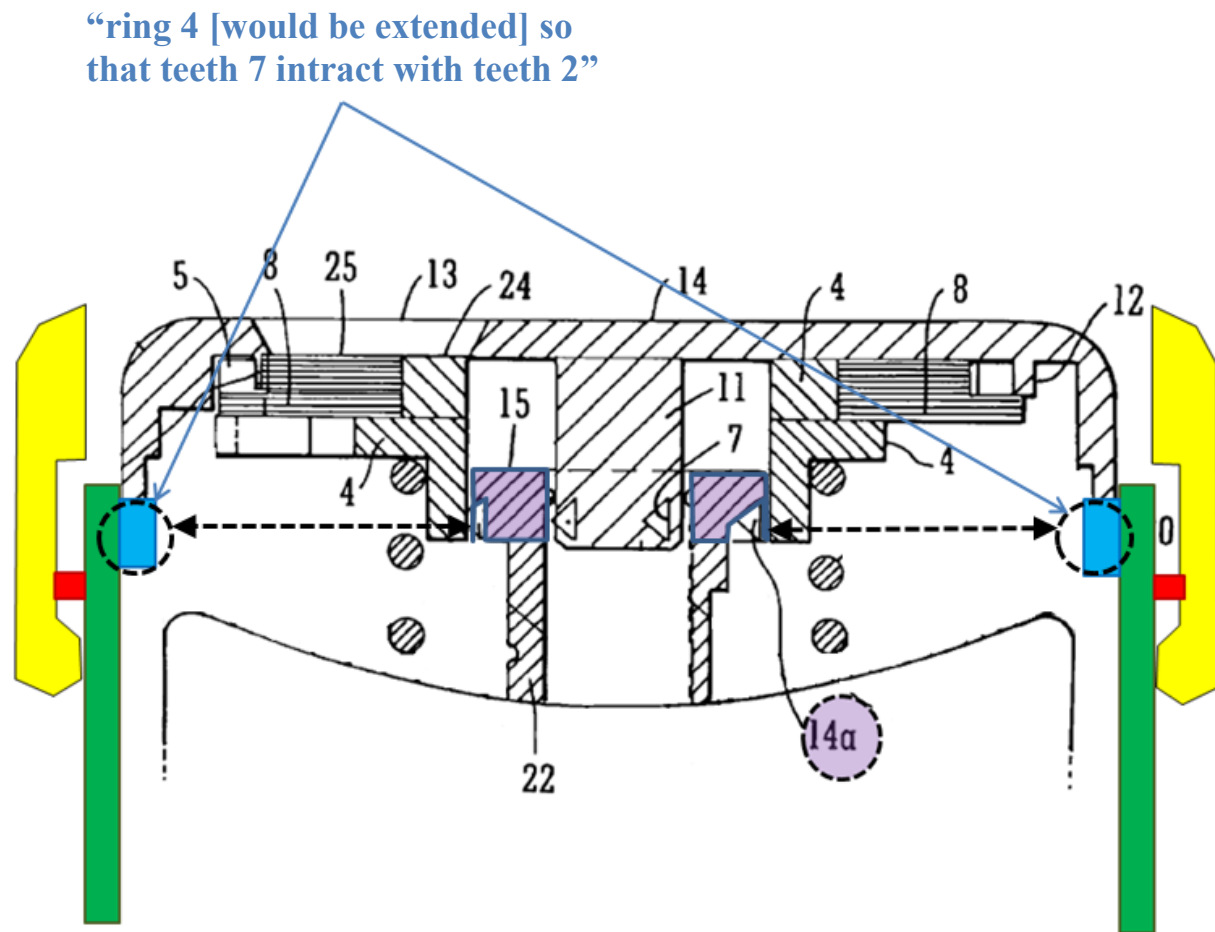
On Ground 3, Petitioners initially asserted that a POSA would have "slightly extend[ed] Bason's inhaler body" and "integrat[ed] the stationary gear (tooth 2)" directly thereon. Petition at 55-56, 60-61. Aptar argued in response that Bason/Rhoades would be inoperable for its intended purpose and also that it fails to disclose either a "first member" or a "second member."

Drawing on the benefit of hindsight, Petitioners now assert, for the first time in their Reply, several new arguments as to how Bason/Rhoades would be combined. Specifically they allege that:

- Bason’s cap would be “slightly widen[ed] . . . so that its outer edge fits over the outside of the housing”;
- “a rib . . . would [be] added to the outside of the housing . . . to prevent unintentional removal of the cap”; and,
- “the diameter of ring 4 [would be extended] so that teeth 7 interact with teeth 2.” Reply at 10-11, 15.

Whether or not the above is new or merely responsive, all of Petitioners’ arguments still fail.

For example, one major issue with Bason/Rhoades raised in Aptar’s Response is that teeth 7 (located on ring 4) and teeth 2 (located on the inhaler body) never come into contact as required for ring 4 (the alleged second member) to move in rotation. Response at 37-39. In their Reply, Petitioners assert, for the very first time, that “a POSA would have extended the diameter of ring 4 so that teeth 7 interact with teeth 2.” Reply at 13. However, teeth 7 must also engage upper teeth 14a for rotation of ring 4 to be successful. Ex. 2021 at ¶24; Ex. 2023 at ¶4; Ex. 1007 at 3:18-22. Thus, the trouble with Petitioners’ answer is that it leaves Petitioners with the exact same problem that they started with: ring 4 will not rotate.



Ex. 1007 at Fig. 2 (annotated); Ex. 2023 at ¶4.

As shown above, if ring 4 is expanded so that teeth 7 “interact with” with teeth 2 (shown in blue), teeth 7 will then no longer contact teeth 14a (shown in purple), which sit on the underside of bush 15 within the circumference of the spring. Ex. 2023 at ¶4. If ring 4 does not rotate, the dose numbers will not advance, and the patient will not know how many doses of medication are in the inhaler. *Id.* Thus, in addition to failing to disclose rotation of the alleged “second member,” Petitioners’ revised Bason/Rhoades combination would also be

inoperable for its intended purpose. Ex. 1007 at 1:15-17 (stating its purpose as “indicat[ing] the number of times the pressurized canister is depressed to dispense a dose of the drug”).

This type of vacuum-logic is pervasive to Petitioners arguments. Indeed, Petitioners rarely account for how their proposed modifications of one component or another impact the device as a whole. As another example, ring 4 will not rotate in Petitioners’ proposed combination because bush 15 is no longer mounted in a “non-moveable” position. The “non-movable” position of bush 15 relative to ring 4 allows teeth 7 to properly engage with teeth 2 and teeth 14a and permits ring 4 itself to rotate. Ex. 2023 at ¶5; Ex. 2021 at ¶24; Ex. 1007 at 2:16-25, 35-57; However, base 1 is eliminated in Petitioners’ proposed Bason/Rhoades combination,² so there is no longer anything holding bush 15 in a fixed position relative the other components as is necessary to accomplish the relative rotation of ring 4. Ex. 2023 at 5; Ex. 2021 at ¶81. Accordingly, with bush 15 permitted to rotate freely, the counting mechanism ceases to function. Ex. 2023 at ¶5.

² See Petition at 55. (“Such a modification is a simple variation known in the prior art and would allow one to injection mold the actuator *with the stationary gear already included*, decreasing the number of parts that must be assembled and tested.”). Petition at 55. (emphasis added).

Finally, Petitioners belated assertion that ring 4 should be “expanded” has still further collateral consequences which Petitioners fail to account for, including that the dose values will no longer be visible to a user through window 13. Bason’s dose values are located on top surfaces 24 and 25 of rings 4 and 8, respectively, and are visible through window 13. Ex. 2023 at ¶6; Ex. 1007 at 2:66-3:5. However, ring 8 is arranged concentrically above and around the outer circumference of ring 4. Ex. 2023 at ¶6; Ex. 2021 at ¶23; Ex. 1007 at 2:43-48. Accordingly, by expanding the diameter of ring 4 to the outer circumferences of the cap and thus making it greater than or equal to the diameter of ring 8, Petitioners’ proposed design disrupts the concentric organization of top surfaces 24 and 25 and necessarily displaces the dose values that would otherwise appear in window 13. Ex. 2023 at ¶6.

B. Bason/Allsop does not disclose a second member that is displaceable axially and in rotation relative to a stationary body or changing a displayed dose value from among the plurality of displayable dose values.

On Ground 4, Petitioners initially argued that a POSA would have simply “move[d] the Bason dose counter below the Bason canister,” and “molded the base 1 with stationary gear teeth 2 . . . directly into the wall of the Bason inhaler.” Petition at 66-68. In response, Aptar pointed out that Bason/Allsop would be inoperable for its intended purpose, that it fails to disclose either a “first member” or a “second member,” and that it fails to disclose a “displayed dose value.”

Now, in reply, Petitioners again attempt to cover the holes in their proof by way of revision, newly arguing that:

- Bason's cap would be designed "with slots through which teeth 2 [] would protrude"
- the slots would be "slightly taller than the height of the teeth, allowing the cap to move up and down upon operation of the MDI,"
- teeth 2 would be tapered "narrower at the top, wider at the bottom," to allow the cap to "slide into position,"
- "the diameter of ring 4 [would be extended] so that teeth 7 interact with teeth 2," and
- window 13 would "be made on the side of the device." Reply at 12-13, 15.

But here too, Petitioners arguments are led by their conclusions, rather than the facts. And being built on the same myopic reasoning, Petitioners' proposed Bason/Allsop combination fails for many of the same reasons.

Thus, Petitioners attempt to correct for Bason/Allsop's failure to disclose the requisite rotation of ring 4 (the alleged "second member") by asserting for the first time in their Reply that the diameter of ring 4 would be extended "so that teeth 7 interact with teeth 2." Reply at 13. But as Bason itself explains, ring 4 cannot rotate unless teeth 7 engage upper teeth 14a. Ex. 2023 at ¶8; Ex. 2021 at 24; Ex. 1007 at 3:18-22. Hence, just as in Bason/Rhoades, extending ring 4 in Bason/Allsop eliminates one defect and creates another, because even if teeth 7

engage with teeth 2, they will no longer engage with teeth 14a as required for ring 4's rotation. Ex. 2023 at ¶ 8; Ex. 2021 at ¶98.

Similarly, ring 4 will not rotate in Bason/Allsop because bush 15 is no longer mounted in a "non-moveable" position to permit the relative rotation of ring 4. Rather, base 1 with teeth 2, on which bush 15 would otherwise have been mounted, has been "molded directly into the wall of the *Bason* inhaler." Petition at 68. While Petitioners seek to permit the rotation of ring 4 by introducing "slots through which teeth 2 [] would protrude" to Bason's cap, the elimination of base 1 defeats this purpose. This is because bush 15, unaffixed, prevents teeth 7 and teeth 2/14a from engaging to permit ring 4's relative rotation. Ex. 2023 at ¶9; Ex. 2021 at ¶24. As such, Petitioners' proposed Bason/Allsop combination is both inoperable for its intended purpose and fails to disclose a "second member" that displaces axially and in rotation relative to a stationary body. Ex. 2023 at ¶9.

In addition, Petitioners' newly proposed Bason/Allsop combination fails to disclose "chang[ing] a displayed dose value from among the plurality of displayable dose values." Ex. 1001 at 10: 12-17, 38-42. Aptar explained in its Response that the effect of moving Bason's dose counter beneath the canister was that window 13 was no longer visible. Response at 55. In reply, Petitioners state simply that window 13 would "be made on the side of the device." Reply at 15. Notwithstanding the purely conclusory nature of this assertion, such a modification

would require, at a minimum, “redesigning the structure of the rings 4 and 8, central bush 15, curved arm 6, pawl 5, downwardly directed wall 12, and radially inwardly directed kink 26.”³ Ex. 2023 at ¶10; Ex. 2021 at ¶99; Response at 55-56. Petitioners offer no explanation for how this would occur. Regardless, it would not be possible to relocate window 13 to the side of the device given Petitioners’ other proposed modifications to Bason/Allsop. Namely, the “side of the device” (i.e.,

³ Bason’s dose values are on the top surfaces of rings 4 and 8. Ex. 1007 at 2:66-3:5. Consequently, relocating window 13 to the side of the device would require that rings 4 and 8 would need to be rotated ninety degrees in orientation and stacked on top of one another so that the dose values appearing on the top surfaces of rings 4 and 8 could be viewed out of window 13, as displayed from a horizontal perspective rather than a vertical perspective. Ex. 2023 at ¶10. In addition, curved arm 6 and upwardly directed pawl 5, which act to rotate ring 8, would similarly need to be redesigned as they currently are placed on the outer extremity of the cap (where window 13 would apparently be moved, and where teeth 7 and teeth 2 would purportedly interact). *Id.* Redesign would also be required for central bush 15, which is loose and unmounted in the Petitioners combination, and would require at least a new bonding process step contradicting the motivation for fewer manufacturing steps. *Id.* Lastly, downwardly directed wall 12 with kink 26 would physically interfere with newly re-located rings 4 and 8 and be required to be operationally moved and reconfigured to interact with pawl 5. *Id.*

the outer extremity of the cap) is now consumed by the alleged interaction between teeth 7 on “expanded” ring 4 with teeth 2 integrally molded “directly into the inhaler body.” Reply at 14-15; Petition at 66-68; Ex. 2023 at ¶10. Accordingly, Petitioners’ proposed Bason/Allsop combination also fails to disclose “chang[ing] a displayed dose value” as required by the Asserted Claims.

V. CONCLUSION

The Patent Owner respectfully requests that the Board find claims 1-4 of the ’631 Patent to be patentable over the cited prior art, as each of the grounds in the Petition fail for the reasons noted above and in the Response.

Respectfully submitted,

Dated: June 13, 2019

by: Ashley N. Moore
Ashley N. Moore
Registration No. 51,667
McKool Smith, P.C.
300 Crescent Court, Suite 1500
Dallas, TX 75201
Telephone: (214) 978-4000
Facsimile: (214) 978-4044
amoore@mckoolsmith.com

Counsel for Aptar France S.A.S.

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 Sur-Reply to Petition for *Inter Partes* Review of U.S. Patent No. 9,370,631** contains 3,203 words, excluding the parts exempted by 37 C.F.R. § 42.24(a)(1).

Respectfully submitted,

Dated: June 13, 2019

by: /Ashley N. Moore/
Ashley N. Moore
Registration No. 51,667

Counsel for Aptar France S.A.S. and
AptarGroup, Inc.

CERTIFICATE OF SERVICE

A copy of the **Patent Owner's Sur-Reply 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:

Steven D. Maslowski
AKIN GUMP STRAUSS HAUER & FELD LLP
Gregory A. Morris
Ron N. Sklar (to be admitted *pro hac vice*)
HONIGMAN MILLER SCHWARTZ AND COHN LLP
Rubén H. Muñoz
Jason Weil
Caitlin Olwell
AKIN GUMP STRAUSS HAUER & FELD LLP
AG-3M-APTARIPR@akingump.com

Respectfully submitted,

Dated: June 13, 2019

by: /Ashley N. Moore/
Ashley N. Moore
Registration No. 51,667

Counsel for Aptar France S.A.S. and
AptarGroup, Inc.