

Case No. IPR2018-01055

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

Aptar France S.A.S.,  
Patent Owner

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

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**Patent Owner's Reply in support of its Motion to Exclude Evidence**

## **I. INTRODUCTION**

For the reasons below, Aptar's Motion to Exclude should be granted.

## **II. ARGUMENT**

### **A. Exhibit 1002 ¶¶17 and 135**

Petitioners contend that Mr. Piper sufficiently supported his opinions in ¶¶17 and 135. Not so. Mr. Piper testifies that he “was asked to design and build a dose indicator and . . . looked to the mechanism of a . . . mechanical pen that converted axial motion into rotational motion.” Ex. 1002 at ¶¶17, 135. Petitioners rely on this to show that Rhoades is analogous. Paper No. 1 at 54. Despite the pertinent and specific nature of Mr. Piper's testimony, his declaration is silent as to facts that would render it reliable. Thus, Mr. Piper's declaration casually omits identification or description of the party that asked him to design and build the dose indicator device, the model of pen that he allegedly “took apart and examined,” the structure and components of the dose indicator that he allegedly designed, and most tellingly, what the design itself actually looked like and how it functioned. Rather, Mr. Piper's discussion of events is highly generalized and employs language that conveniently conforms to the claim language at issue here. *See* Ex. 1002 ¶135 (“I was aware that there were many similarities between an MDI having a dose counter, and a mechanical pen. ...both products converted an axial motion ... into a rotational motion ... and contained a fluid reservoir that could be moved axially and rotationally.”). Assuming that Mr. Piper's testimony is in fact true, Mr. Piper must still offer more than vague reminiscences for it to be deemed reliable under Rule 702.

## **B. Exhibits 1032 and 1033**

Petitioners state that Wimpenny and Campling are not analogous prior art at the time of the invention, but rather evidence of the “state of the art” Paper No. 43 at 2. But Petitioners miss the point. Whether cited as analogous art or of the state of the art, Wimpenny and Campling did not exist until almost a year after ’177 was filed and almost four years afterwards, respectively. *See* Paper 39 at 5-6. Thus, neither is relevant to whether a POSA, *at the time of the invention*, would have looked to a pen when designing an MDI. *See, e.g., Licensing v. Ab*, IPR2017-00904, 2017 WL 3841242, at \*14 (Patent Tr. & App. Bd. Aug. 30, 2017) (“Petitioner directs us to a document published in 2003—well after the priority date of the ’122 patent. In an analysis under 35 U.S.C. § 103, the critical inquiry is what the combined disclosures of the prior art would have suggested to an ordinary artisan at the time of the invention. ....We are not persuaded that the document published in 2003 ... bolsters the disclosure ... or otherwise compensates for the lack of disclosure in the combined disclosures of the prior art.”).<sup>1</sup> Accordingly,

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<sup>1</sup> Petitioners cite *Teva Pharms. USA, Inc. v. Sandoz Inc.*, 906 F.3d 1013, 1020, 1025 (Fed. Cir. 2018) for the premise that “post-priority date references can be used to show the state of the art at the time of the invention.” Paper 43 No. at 4. However, the circumstances of *Teva* are distinguishable. The district court there admitted two exhibits. *Teva*, 906 F.3d 1013, 1020. The first was a study published just three weeks after the applicable priority date, but which began two years earlier. *Id.* The second was a trial study conducted by Teva, the party opposing

these exhibits should be excluded as irrelevant under FRE 402 and 403.

**C. Exhibits 1055 and 1056**

As previously explained, Mr. Clemens’s testimony in Exhibits 1055 and 1056 has been plucked from other actions involving different patents and different claim terms, and different asserted prior art is in no way relevant to the Board’s determination here. Exhibits 1055 and 1056 should therefore be excluded.

Petitioners respond that Exhibits 1055 and 1056 go to Mr. Clemens’s “credibility” in this action and are “directly relevant” to whether a POSA would have looked to mechanical pen technology to develop an MDI. Paper No. 43 at 4, 7. Yet, neither of those actions involved MDIs or dose counters; both were concerned with needle-based injector devices. Ex. 1055 ¶¶41; 1057 at 183:13-184:10. The inclusion of cherry-picked soundbites from these wholly unrelated matters serves only to falsely inflate the factual record and create confusion, while taking Petitioners’ argument that a POSA “would have looked to mechanical pen technology to develop a medical device like an MDI” well beyond its logical conclusion. As such, Exhibits 1055 and 1056 should be excluded as irrelevant and prejudicial to the Patent owner under Fed. R. Evid. 402 and 403.

**D. Exhibit 1058 ¶¶6-10, 16, 17-19, 20, 23, 25, and 28**

Petitioners rely on inapposite case law to justify the introduction of new evidence in ¶¶8-9, 11, and 48-52 of their Reply. Namely, Petitioners point to *In re*

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exclusion, which cited to the first study, and which was admitted as an admission by Teva. *Id.*

*Epstein*, 32. F.3d 1559, 1568 (Fed. Cir. 1994) as support for the notion that Petitioners were “not required to present more detail on how components were connected than the amount of detail Aptar’s specification provides.” See Paper No. 43 at 8. *Epstein*, however, was concerned with determining whether a patent was sufficiently enabled under § 35 U.S.C. § 112—not whether a petitioner in an IPR had proposed a sufficiently detailed combination to establish obviousness under § 35 U.S.C. § 103, as here. Importantly, the burden of proof in an IPR lies with the petitioner, and *never* shifts to the patent owner. See *Dynamic Drinkware, LLC v. Natl. Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). As such, Petitioners’ cannot escape that burden by improperly attempting to shift it to Aptar or by introducing new theories of obviousness in their Reply.

Petitioners contend that Mr. Piper supported his opinions in ¶¶6-10, 16-19, 23, 25, and 28 of Ex. 1058 with “sufficient facts or data” to justify inclusion under FRE 702 and 703. They are wrong. For example, Petitioners argue that Mr. Piper’s opinion in ¶¶6-10 (“reading axial movement into Allsop’s push-button cap”) is supported by the apparent fact that “axial movement *is* a feature of a “push-button cap. Moving axially is what the component does.” Paper 43 at 11. But nowhere does Allsop teach that the Push-button cap is axially displaceable. See *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 859 (Fed. Cir. 2015) (“Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness.”). Rather, as previously explained, a “push-button cap” could just as easily refer to a cap that covers a “push-button” but which is itself not axially displaceable. See Paper 31 at 5, n.1;

*see also* 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.”).

With respect to paragraphs 16-19, 23, and 25, Petitioners argue that Mr. Piper’s opinions are supported by “the skill and knowledge of a POSA to make the desired modifications.” Paper 43 at 10. As the party with the burden of proof on obviousness, however, such conjecture about a POSA’s abilities is insufficient to overcome the design flaws identified by Aptar in Petitioners’ proposed combinations, and also fails to explain *why* a POSA would have been motivated to make the specific changes put forth by Petitioners and Mr. Piper. *Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1269 (Fed. Cir. 2012) (“[T]he opinions of [Mr. Krippelz’ expert] are not a substitute for the actual [prior art] disclosure”). Lastly, ¶28 is unfounded for the same reasons as described in section II.A. above.

### **III. CONCLUSION**

Patent Owner respectfully requests that its Motion to Exclude be granted.

Respectfully submitted,

Dated: July 29, 2019

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**CERTIFICATE OF SERVICE**

A copy of the **Patent Owner's Reply in support of its Motion to Exclude** has been served on Petitioner via electronic mail at the following correspondence address:

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