

Paper No. ____
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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.

AptarFrance S.A.S.,

Patent Owner.

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

**PETITIONERS' OPPOSITION TO
PATENT OWNER'S MOTION TO EXCLUDE**

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I. INTRODUCTION

Aptar's Motion to Exclude should be denied. Aptar seeks to exclude Exhibits 1032, 1033, 1055, and 1056, as well as part of Exhibits 1002 and 1058. Aptar failed to meet its burden that this evidence is inadmissible.

II. ARGUMENT**A. Exhibit 1002 ¶¶ 17, 134, and 135**

Aptar's challenges to Mr. Piper's opening declaration should fail as Mr. Piper provided more than sufficient facts to support his testimony. Moreover, even if Aptar's challenges had any merit, which they do not, they are directed to the weight that should be accorded to the testimony, not its admissibility. *See Wavemarket Inc. v. LocationNet Sys. Ltd.*, IPR2014-00199, Paper 56, at 20-21 (PTAB May 7, 2015).

In paragraphs 17 and 135 of his opening declaration (Ex. 1002), Mr. Piper points to several prior art devices (including Rhoades) that convert axial to rotational motion and would have been known to a POSA. Mr. Piper then describes a project he worked on related to designing a dose counter for an inhaler, explaining that he understood he would need to convert axial to rotational motion. He described how he looked to a mechanical pen, which is small and inexpensive, and explained how that same approach would have been common to other POSAs at the time. Aptar cross examined Mr. Piper about this point extensively. *See Ex. 2019 at 53:7-59:15.* Mr. Piper explained that this project was a feasibility study for Vortran Medical

relating to Vortran's GentleHaler, *id.* at 54:4-16, and he provided all of the information he had about the project, *id.* at 161:2-162:18. Mr. Piper did not suggest that he developed a commercialized dose counter—his testimony indicated only that he was presented with this problem and he looked to a mechanical pen for design ideas. Aptar's motion seeking to exclude Mr. Piper's testimony in paragraphs 17 and 135 of Exhibit 1002 about a project he was personally involved in fails to establish that this testimony is inadmissible, and accordingly should be denied.

Aptar oddly objects to paragraph 134 apparently based only on the final sentence of that paragraph. The support for that sentence is the preceding eleven sentences in that paragraph, which contain citations to a number of exhibits that support Mr. Piper's opinions. Aptar's argument that paragraph 134 is not sufficiently supported ignores these preceding sentences, and therefore, is entirely without merit.

B. Exhibits 1032 and 1033

Aptar argues that Exhibits 1032 and 1033 should be excluded as irrelevant under Federal Rules of Evidence 402 and 403. Aptar's argument is based on a misunderstanding of the point for which these exhibits are offered. Exhibits 1032 and 1033 provide evidence of the state of the art, which is often relevant to the obviousness analysis. *See Randall Mfg. v. Rea*, 733 F.3d 1355, 1362-63 (Fed. Cir. 2013).

Aptar argues that, “a POSA could not have looked to Wimpenny or Campling at the time of the invention because neither of those patents had yet been filed.” Paper 39 (“Mot. to Excl.”) at 5. But Petitioners never suggested that a POSA would have looked to Wimpenny or Campling at the time of the invention. Petitioners argued that a POSA would have looked to *Rhoades* at the time of the invention. Wimpenny and Campling are references that disclose medical devices and each refers to the mechanism of a mechanical pen. These exhibits are cited to show the state of the art—as examples of situations where engineers developing medical devices were aware of and looked to mechanical pen art—both before and after the ’631 Patent’s priority date.

Second, Wimpenny (Exhibit 1032) is a United States patent listing a foreign priority date of March 22, 2003. In other words, Wimpenny’s foreign priority date is approximately two months *before* the ’631 Patent’s foreign priority date of May 15, 2003. And Aptar ignores the fact that the passage Petitioners cite from Wimpenny is describing an even older prior art reference, DE3814023, which, according to the face of Wimpenny, is a German reference from January 1989. Even if Wimpenny was found to post-date the ’631 Patent’s priority date, it is cited for its information about the state of the art prior to the ’631 Patent’s priority date. Post-priority date references can be used to show the state of that art at the time of the

invention. *See Teva Pharms. USA, Inc. v. Sandoz Inc.*, 906 F.3d 1013, 1020, 1025 (Fed. Cir. 2018).

In its Patent Owner Response, Aptar argues that Rhoades is not analogous art. Paper 23 (“Response”) at 39-40. Wimpenny and Campling show that skilled engineers often considered the design of a small plastic device—like the mechanical pen taught by Rhoades—when designing medical devices. Aptar has not attempted to argue that these references are in any way prejudicial or that any prejudice outweighs their probative value. These references are clearly relevant and should not be excluded under Federal Rule of Evidence 403.

C. Exhibits 1055 and 1056

Aptar argues that Exhibits 1055 and 1056 should be excluded as irrelevant and as more prejudicial than probative under Federal Rules of Evidence 402 and 403. According to Aptar, Mr. Clemens’s prior testimony is in another field of art and irrelevant to his testimony here. Mr. Clemens’s prior testimony, however, is directly relevant here as it confirms an important point—that a POSA in this field would have known of the basic mechanism of a mechanical pen and would have looked to mechanical pen technology to develop a medical device like an MDI.

Relevant evidence is admissible unless its probative value is substantially outweighed by, *inter alia*, the danger of unfair prejudice or confusion. Fed. R. Evid. 401, 403. The Board has consistently declined to exclude relevant evidence under

Rule 403 in an IPR where there is no jury. *See Cellco P'ship v. Bridge & Post, Inc.*, IPR2018-00055, Paper 40, at 80 (PTAB Apr. 15, 2019) (collecting cases).

As noted above, Aptar and Mr. Clemens both took the position that Rhoades is not analogous art and stressed that a POSA would not have looked to Rhoades to develop a medical device like an MDI because Rhoades discloses a mechanical pen. Response at 39-40; Ex. 2021 ¶¶ 65-73; Ex. 1057 at 164:2-6 (“[T]he 177 Patent is directed towards . . . [a] highly tuned medical device . . . and in the other case the field of endeavor is, you know, a pen . . .”). Exhibit 1055 is a declaration submitted by Mr. Clemens on May 9, 2018 in a different IPR. *See* Ex. 1057 at 170:19-171:12. That case was about a different medical device, a safety device for a needle. *Id.* There, Mr. Clemens stated that the mechanism of the safety device for the needle “can be found in an age-old mechanisms [*sic*] of a retractable ball point pen.” Ex. 1055 at ¶ 47; *see* Ex. 1057 at 172:23-173:4.

When confronted with Exhibit 1055, Mr. Clemens explained that a mechanical pen has a similar extending and retracting mechanism as the needle safety devices at issue in that exhibit. *See* Ex. 1057 at 172:23-173:24. Mr. Clemens also agreed that it was known that both pens and dose counters could use a mechanism that converts axial to rotational motion. *See* Ex. 1057 at 166:2-9; 173:25-174:10. Petitioners have taken the position that a POSA designing a dose counter that converts linear to rotational motion would have looked to Rhoades

because of its mechanism of converting linear to rotational motion and because it is a small, inexpensive device. Mr. Clemens's prior testimony on behalf of a petitioner in a different IPR describing the mechanism of a medical device as having the mechanism of a mechanical pen is directly relevant to his credibility here, where he contends that a reference teaching the mechanism of a mechanical pen would not be analogous art for a POSA designing a medical device. *See id.* at 182:24-183:12.

Exhibit 1056 is an excerpt from a deposition in which Mr. Clemens testified about an insulin injector. Ex. 1057 at 183:13-184:10. Specifically, Exhibit 1056 relates to Mr. Clemens's prior testimony about a POSA's knowledge of mechanisms for converting linear to rotational motion. *See id.* at 186:25-187:3 ("And so I was admitting, yes, there are other ways of converting rotational motion into linear motion."). In Exhibit 1056, Mr. Clemens goes on to state that "engineers take these basic mechanisms and they apply it to whatever the product or whatever they are trying to achieve in a product." *See* Ex. 1056 at 100:10-12; Ex. 1057 at 187:18-24. As explained in detail above, that is directly relevant to the parties' dispute in this proceeding.

Aptar does not point to any cogent prejudice that it would suffer if this evidence is not excluded. Aptar's only allegation of prejudice is a vague statement that these exhibits take Mr. Clemens's words out of context and confuse the issues. That is incorrect and, in any event, cannot be sufficient to outweigh the probative

value of these exhibits on Mr. Clemens's credibility in this proceeding. *See Cellco P'ship*, IPR2018-00055, Paper 40, at 80 ("As the factfinder, we are able to consider the evidence and the parties' arguments, and give it the proper weight.").

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

1. Paragraphs 16-20 and 23 Are Not Untimely

Aptar argues that paragraphs 16-20 and 23 present new arguments that should have been presented in the Petition. Aptar is wrong.

First, a motion to exclude is not the appropriate vehicle to address this issue. Aptar cites 37 C.F.R. § 42.23(b), a rule related to arguments raised in reply, and an issue Aptar has already raised in the context of a motion to strike, which it filed on June 18 in response to strict limitations set by the Board. *See* Paper 32 at 1-2. The admissibility of evidence, like Exhibit 1058, is properly addressed by a motion to exclude, which is governed by the Federal Rules of Evidence. *See* 37 C.F.R. § 42.62. Despite claiming that its objections apply the Federal Rules of Evidence pursuant to 37 C.F.R. § 42.62, Mot. to Excl. at 3, Aptar does not cite any Federal Rule in support of its timeliness argument. In light of the August 13, 2018 revisions to the Trial Practice Guide that Aptar cites, Mot. to Excl. at 8, which officially provided the mechanism of a motion to strike, Aptar's argument that Exhibit 1058 contains new evidence is a misuse of the motion to exclude and an attempt to circumvent the limitations the Board placed on Aptar's motion to strike.

In any event, Aptar's argument is infected with the fundamental error that plagues the majority of its responses in this matter. The Petition and Mr. Piper's first declaration explained how a POSA would have combined the teachings of two references, and why he or she would have been motivated to do so. The Petition, and Mr. Piper, also stressed, several times, the abilities of the skilled artisan in this case. Mr. Piper relied on numerous references to support his understanding of the abilities of the POSA, including the patentee's statements to the examiner and the Board during prosecution. Petitioner was not required to create an actual prototype. *See Permobil Inc. v. Pride Mobility Prods. Corp.*, IPR2013-00407, Paper 53, at 18 (PTAB Dec. 31, 2014). Petitioner was not required to present more detail on how components were connected than the amount of detail Aptar's specification provides. *See In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994). Petitioner was not required to explain how a POSA would solve every technical challenge. *See Arctic Cat, Inc. v. Polaris Indus.*, IPR2014-01427, Paper 58, at 22-23 (PTAB Feb. 4, 2016). Petitioners' description of how the references would have been combined was more than sufficient in light of the admitted abilities of a POSA in this case.

Nonetheless, in its response, Aptar ignored all of the Petition's references to the skill of a POSA, as well as the above case law. Aptar chose to base its defense around pointing to small technical challenges (which, according to the parent '177 Patent's prosecution history, were well within the skill of a POSA, *see, e.g.*, Pet. at

10-11 (and cites to Exhibit 1004 therein)) that Petitioners and Mr. Piper allegedly failed to address. In reply, Petitioners and Mr. Piper addressed those discrete issues that Aptar raised. That is the purpose of a reply brief/declaration, and none of the statements Aptar points to are new arguments.

Paragraphs 16-20 and 23 each respond to Aptar's claims that it identified problems with the operation of a device resulting from a combination of Bason/Rhoades or Bason/Allsop. But Mr. Piper described exactly how the Bason inhaler would have been modified in view of Rhoades or Allsop. Specifically, in an effort to reduce costs and increase reliability of manufacturing, the stationary gears of Bason would have been molded directly onto the body, either above (Bason/Rhoades) or below (Bason/Allsop) the canister. Mr. Piper also described the abilities of a POSA, including the abilities Aptar made clear that a POSA possessed during prosecution of the '177 Patent (the '631 Patent's parent). *See, e.g.*, Ex. 1058 ¶¶ 16, 23 (citing Ex. 1004). Finally, Mr. Piper explained that the rest of the components could be connected by the POSA using other ways well understood in the art, Ex. 1002 ¶ 137, and that they would be designed so the rest of the components could maintain their interactions, Ex. 1058 ¶ 21; Ex. 1002 ¶¶ 138, 175. As explained above, Mr. Piper was not required to set forth every technical challenge that a POSA would face and overcome when combining the teachings of the references in ways well understood by a POSA.

Nothing in paragraphs 16-20 or 23 is a new argument, nor was this the appropriate vehicle to address such an issue, and accordingly, Aptar's motion should be denied.

2. Paragraphs 6-10, 16-19, 23, 25, and 28 Are Properly Supported

In challenging several paragraphs from Mr. Piper's declaration (Ex. 1058) submitted in support of Petitioners' reply, Aptar provides no analysis, merely quoting excerpts of those paragraphs and alleging the paragraphs have no support. That is insufficient for Aptar to carry its burden to exclude evidence, and accordingly, Aptar's motion to exclude these paragraphs should be denied on this basis alone. *See* 37 C.F.R. §§ 42.20(c), 64(c).

In any event, Aptar ignores Mr. Piper's testimony and the exhibits he cites in support of those paragraphs. For example, paragraphs 16-19, 23, and 25 each rely on the skill and knowledge of a POSA to make the described modifications. Contrary to Aptar's argument, Mr. Piper did explain how and why a POSA might have made the proposed adjustments to a product resulting from the teachings of Bason/Rhoades or Bason/Allsop. Mr. Piper cited to Aptar's thorough explanation of the POSA's abilities during prosecution of the '631 Patent's parent (the '177 Patent), and to other references that disclose the use of various different caps that were cited in that same prosecution history. *See, e.g.,* Ex. 1058 ¶¶ 16, 23 (citing Ex.

1004); *see also*, *id.* ¶ 19 (citing Ex. 1036 to show conformation known in the art), *id.* ¶ 23 (citing Mr. Clemens's testimony that a POSA would understand how to use springs); *id.* ¶ 25 (citing Ex. 1036 as evidence of number and window arrangement). While criticizing Mr. Piper's statements as unsupported, Aptar ignores the ample support present in these very same paragraphs. Aptar's criticisms are unwarranted and, in any event, go to the weight of Mr. Piper's testimony, not its admissibility.

Aptar also attacks ¶¶ 6-10 as allegedly "reading axial movement into Allsop's push-button cap." Mot. to Exc. at 10. As Mr. Piper explains, axial movement *is* a feature of a "push-button cap." Moving axially is what the component does. Ex. 1058 ¶¶ 8-9. Aptar and its expert, on the other hand, depict the "push-button cap" as a cap with no push-button. Response at 14-15. That cannot be correct, nor is it appropriate to ignore the description of that element because "push-button cap" is just a name the inventor gave it, which, according to Aptar's expert, means nothing. *See* Ex. 1057 at 216:14-218:24, 219:23-220:8. It is not clear what Aptar means in its criticism that Mr. Piper reads "snap-fit" into the combination of Bason/Allsop. A snap-fit is not an element of these claims; it is simply a technique that POSAs used to manufacture these types of small components, which Mr. Piper explains and cites to references to support. *See* Ex. 1058 ¶ 20 (citing Exs. 1061, 1062). Finally, Aptar again criticizes Mr. Piper's explanation in paragraph 28 of his work developing a

certain dose counter sometime between 1998 and 2001. That challenge fails for the same reasons described in § II.A above.

Mr. Piper's testimony in Ex. 1058 is neither untimely nor unsupported, and accordingly, Aptar's motion to exclude it should be denied.

III. CONCLUSION

Aptar's motion should be denied.

Respectfully submitted,

Dated: July 22, 2019

/Steven D. Maslowski/

Steven D. Maslowski, Reg. No. 46,905

Ruben H. Munoz, Reg. No. 66,998

Jason Weil, Reg. No. 73,123

Caitlin E. Olwell, Reg. No. 74,084

AKIN GUMP STRAUSS HAUER & FELD
LLP

Two Commerce Square

2001 Market St., Suite 4100

Philadelphia, PA 19103-7013

Telephone: (215) 965-1200

Facsimile: (215) 965-1210

Gregory A. Morris, Ph.D., Reg. No.
53,349

Ron N. Sklar (admitted *pro hac vice*)

HONIGMAN MILLER SCHWARTZ &
COHN LLP

155 North Upper Wacker Drive, Suite 3100

Chicago, IL 60606-1734

Telephone: (312) 701-9300

Facsimile: (312) 701-9335

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned hereby certifies that a copy of the foregoing Petitioners' Opposition to Patent Owner's Motion to Exclude was served on counsel of record on July 22, 2019 by filing this document through the End-to-End System, as well as delivering a copy via electronic mail to counsel of record for the Patent Owner at the following addresses:

Ashely N. Moore - amoore@mckoolsmith.com
Robert M. Manley - rmanley@mckoolsmith.com
Ryan Hargrave - rhargrave@mckoolsmith.com
Benjamin G. Murray - bmurry@mckoolsmith.com

Date: July 22, 2019

Respectfully submitted,

/Steven D. Maslowski/

Steven D. Maslowski, Reg. No. 46,905
Ruben H. Munoz, Reg. No. 66,998
Jason Weil, Reg. No. 73,123
Caitlin E. Olwell, Reg. No. 74,084
AKIN GUMP STRAUSS HAUER & FELD
LLP
Two Commerce Square
2001 Market St., Suite 4100
Philadelphia, PA 19103-7013
Telephone: (215) 965-1200
Facsimile: (215) 965-1210

Gregory A. Morris, Ph.D., Reg. No.
53,349
Ron N. Sklar (admitted *pro hac vice*)
HONIGMAN MILLER SCHWARTZ &
COHN LLP

155 North Upper Wacker Drive, Suite 3100
Chicago, IL 60606-1734
Telephone: (312) 701-9300
Facsimile: (312) 701-9335

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