

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 Motion to Exclude Evidence

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(c) and Section II.K of the Trial Practice Guide Update (August 2018), Aptar France SAS and AptarGroup, Inc. (collectively, “Patent Owner”) move to exclude certain exhibits submitted by 3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp. (collectively, “Petitioners”) in the *Inter Partes* Review of U.S. Patent No. 9, 370, 631 (the “’631 Patent”).

II. RELIEF REQUESTED

Patent Owner respectfully requests that the Board exclude the following: Exhibit 1002 ¶¶17, 134, and 135; Exhibit 1032; Exhibit 1033; Exhibit 1055; Exhibit 1056; and Exhibit 1058 ¶¶16, 17-19, 23, 25, and 28. *See* 37 C.F.R. § 42.22(a)(1).

III. PATENT OWNER’S ORIGINAL OBJECTIONS

The Board issued its Decision to Institute *Inter Partes* Review of the “’631 Patent” on November 8, 2018. *See* Paper No. 11. Patent Owner timely served its objections to Petitioners’ Petition evidence on November 26, 2018. *See* Paper 16. At that time, Patent Owner objected to Exhibit 1002 (May 9, 2018 Declaration of S. David Piper), Exhibit 1032 (U.S. Patent No. 7,090,66) (“Wimpenny”), and Exhibit 1033 (International Publication NO.WO 2007/045904) (“Campling”). *Id.*

Petitioners’ served their Reply on May 13, 2019. *See* Paper 28. Patent Owner timely served its objections to Petitioners’ Reply evidence on May 20, 2019, “within five business days of service of evidence to which the objection is

directed.” *See* 7 C.F.R. § 42.64(b)(1). At that time, Patent Owner objected to Exhibit 1055 (May 9, 2018 Declaration of Charles E. Clemens in IPR2018-01159, *West Phar, Svcs., Inc. v. Sanofi-Aventis Deutschland GmbH*), 1056 (Excerpt of Transcript of Video Deposition of Charles E. Clemens, taken October 25, 2007, in *Novo NorDisk v. Sanofi-Aventis U.S. LLC, et al.*, No-3:07-cv-03206), 1057 (Deposition Transcript of Charles E. Clemens, taken April 24, 2019), 1058 (May 13, 2019 Declaration of S. David Piper), 1061 (Jill Matzke, *Chapter 16—Dfe for Engineering Managers: Making it Count—Dfe and the Bottom Line*, GREEN ELECTRONICS/GREEN BOTTOM LINE (2000)), and 1062 (C. Manoharan, et. al., *An Expert System for Design for Robotic Assembly*, 1 J. INTELL. MANUF. 17 (1990)).¹ *See* Paper 30.

IV. PETITIONERS’ RELIANCE ON THE EVIDENCE SOUGHT TO BE EXCLUDED

Petitioners relied upon Exhibit 1002 ¶¶17, 134, and 135 as evidence in the Petition. *See* Paper 1 at 18 (citing to Ex. 1002 ¶17), 52-53 (citing to Ex. 1002 ¶134), 53-54 (citing to Ex. 1002 ¶135). Exhibits 1032 and 1033 were also cited as evidence in the Petition. *See id.* at 4, 54 (citing to Exs. 1032 and 1033).

Petitioners relied upon Exhibit 1058 ¶¶16, 17-19, 23, and 25 as evidence in their Reply. *See* Paper 28 at 9-11 (citing to Ex. 1058 ¶16), 13 (citing to Ex. 1058

¹ On June 4, 2019, Petitioners served supplemental evidence resolving Patent Owner’s objection to Exhibit 1057. *See* 37 C.F.R. § 42.64(b)(2).

¶¶17-19), 15 (citing to ¶¶23 and 25). Exhibits 1055 and 1056 were also cited as evidence in Petitioners' Reply. *See id.* at 16 (citing to Exs. 1055 and 1056).

V. PATENT OWNER'S BASIS AND GROUNDS FOR OBJECTIONS

Patent Owner's objections apply the Federal Rules of Evidence ("F.R.E.") pursuant to 37 C.F.R. § 42.62.

A. Exhibit 1002 ¶¶17, 134, and 135

Exhibit 1002 purports to be the May 9, 2018 Declaration of S. David Piper. Paragraphs 17, 134, and 135 of Exhibit 1002 should be excluded because the opinions expressed therein are not supported by sufficient facts, data, or reliable methodology and constitute improper expert testimony under F.R.E. 702 and 703.²

Mr. Piper testifies in Paragraph 17 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; *see also id.* at ¶135. Mr. Piper further elaborates in Paragraph 135 that he "took apart and examined a mechanical pen more closely to see how the mechanical components worked" and

² Federal Rule of Evidence 702 requires that an expert's opinion be "based on sufficient facts or data" and be "the product of reliable principles and methods" which the expert "reliably applied . . . to the facts of the case." Fed. R. Evid. 702. Relatedly, Federal Rule of Evidence 703 states that an expert "may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 703.

“designed the dose indicator that he was asked to build by using the same type of mechanism that was disclosed inside the mechanical pen.” *Id.* at ¶135. Problematically, however, Mr. Piper does not identify either the dose indicator that he purports to have designed or the mechanical pen on which his apparent design was based. *See id.* at ¶¶17, 135. In other words, Mr. Piper fails to offer any evidence to support his claim that he was, in fact, asked to design such a dose indicator or that he did, in fact, do so. *Id.*

Similarly, Mr. Piper asserts in Paragraph 134 that “[a] POSA would have routinely looked to other small, inexpensive mechanical devices when seeking to improve devices like Bason in such ways.” *Id.* at ¶134. Here too, Mr. Piper offers his conclusion without any accompanying facts or data in support thereof. *Id.* The lack of citation in Paragraph 134 sits in contrast with other paragraphs, in Exhibit 1002, where Mr. Piper does offer ostensible support for his assertions regarding what a POSA would have known or done. *See* Exhibit 1002 at ¶¶132, 138.

“[A]n expert, whether basing testimony upon professional studies or personal experience . . . [must employ] the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, L. Ed. 2d 238 (1999). In this regard, “[e]xpert testimony rooted in subjective belief or unsupported speculation does not

suffice.” *Zuckerman v. Wal-Mart Stores E., L.P.*, 611 Fed.Appx. 138, 138 (4th Cir. 2015) (per curiam) (internal quotation marks omitted). As such, Mr. Piper must provide more than mere conclusory assertions for his testimony to be admissible under F.R.E. 702 and 703. He failed to do so here.

Accordingly, because Paragraphs 17, 134, and 135 of Exhibit 1002 lack the factual basis required under Federal Rules of Evidence 702 and 703, these Paragraphs must be excluded.

B. Exhibits 1032 and 1033

Exhibit 1032 (“Wimpenny”) and Exhibit 1033 (“Campling”) are cited in the Petition for the proposition that “others working on the design and development of counting mechanisms for use in medical devices, including MDIs, looked to simple pen technology.” Petition at 4; *see also id.* at 54. However, 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. The foreign priority date of the ’631 Patent is May 15, 2003. *See* Ex. 1001 at 1. Wimpenny was not filed until March 22, 2004, almost a full year later, and Campling was not filed until April 26, 2007, nearly four years later. Ex. 1032 at 1; Ex. 1033 at 1. Any suggestion about what a POSA could have gleaned from the prior art based upon the disclosure of Wimpenny or Campling would be improper hindsight. Hence, neither Exhibit 1032 nor Exhibit 1033 is probative of what a POSA would have known at the time of the invention

because neither was yet in existence, and both should be excluded from evidence as irrelevant. *See* F.R.E. 402 and 403.

C. Exhibits 1055 and 1056

Exhibit 1055 purports to be an excerpt from the May 9, 2018 Declaration of Charles E. Clemens in IPR2018-01159, *West Phar, Svcs., Inc. v. Sanofi-Aventis Deutschland GmbH*. Exhibit 1056 purports to be an excerpt from the Transcript of the October 25, 2007 Video Deposition of Charles E. Clemens taken in *Novo NorDisk v. Sanofi-Aventis U.S. LLC, et al.*, No-3:07-cv-03206. Simply put, Mr. Clemens's excerpted testimony taken from other actions regarding what a POSA in a separate field of art might have known, done, or believed in the context of different patents with different claim terms and different asserted prior art is completely irrelevant to the Board's determinations here. The inclusion of such unrelated testimony fails to shed any light on the evidentiary questions before the Board and serves only to take Mr. Clemens's words out of context and confuse the issues. Accordingly, both Exhibits 1055 and 1056 should be excluded because they are not relevant and because their inclusion would be more prejudicial than probative. Fed. R. Evid. 402, 403.

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

Exhibit 1058 purports to be the May 13, 2019 Declaration of S. David Piper. Paragraphs 16, 17-20, and 23 of Exhibit 1058 should be excluded because the

opinions expressed therein improperly raise new arguments which should have been presented in a prior filing. *See* 37 C.F.R. § 42.23(b). In addition, Paragraphs 6-10, 16, 17-19, 23, 25, and 28 should be excluded because they are not supported by sufficient facts, data, or reliable methodology and constitute improper expert testimony under F.R.E. 702 and 703.

1. Paragraphs 16, 17-20, and 23 are Untimely

Paragraphs 16, 17-20, and 23 of Exhibit 1058 should be excluded as improperly presenting new arguments which should have been presented in the Petition. *See* 37 C.F.R. § 42.23(b) (providing that a reply “may only respond to arguments raised in the . . . patent owner response”).

With regard to Petitioner’s proposed combination of Bason/Rhoades, Petitioners’ initially asserted obviousness on the basis 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. In Exhibit 1058, however, Mr. Piper belatedly added new modifications to the proposed combination of Bason/Rhoades by suggesting, for the first time, 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. *See* Ex. 1058 ¶¶16, 23.

With regard to Petitioner's proposed combination of Bason/Allsop, Petitioners' initially asserted obviousness on the basis that a POSA would have "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 Exhibit 1058, however, Mr. Piper belatedly added new modifications to the proposed combination of Bason/Allsop by suggesting, for the first time, 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." *See* Ex. 1058 ¶¶17-20, 23.

The PTO has repeatedly explained that "it is improper to present in reply new evidence (including new expert testimony) that could have been presented in a prior filing[.]" *See* Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39989 at 14 (August 13, 2018) (available at <https://go.usa.gov/xU7GP>). Here, Petitioners belatedly introduce new evidence about the structure of their proposed combinations that affect the operability of the device and could have been disclosed in their Petition if such modifications were actually obvious. For

example, if it is true that it would have been obvious for a POSA to extend the diameter of ring 4 so that teeth 7 interact with teeth 2, Petitioners and Mr. Piper should have known when filing their Petition that Bason's cap would have slots in it in their proposed Bason/Allsop combination and that Bason's cap would be widened to fit around the inhaler body in their proposed Bason/Rhoades combination, and they should have disclosed structural details that affect the operability of the device.

All of the above theories and evidence could have been asserted in the Petition, but were instead asserted by Petitioner's expert for the first time in reply. This was plainly improper and merits exclusion of the belatedly introduced theories and evidence. *See, e.g., Acceleration Bay, LLC v. Activision Blizzard Inc.*, 908 F.3d 765, 775 (Fed. Cir. 2018) (upholding the Board's refusal to consider expert's declaration raising "a new obviousness argument . . . that could have been made in the Petition"); *see also The Scotts Company LLC v. Encap, LLC*, No. IPR2013-00110, 2014 WL 2886290, at *4 (P.T.A.B. June 24, 2014) (granting motion to exclude expert's reply declaration because the testimony "related to written description and claim construction" and "described the background of the technology," and should "have been submitted with ... [the] Motion to Amend opening brief").

Accordingly, Paragraphs 16, 17-20, and 23 should be excluded because they

improperly raise new arguments for the first time in reply which could and should have been presented in the Petition. *See* 37 C.F.R. § 42.23(b).

2. Paragraphs 6-10, 16, 17-19, 23, 25, and 28 are Unfounded

In addition to presenting belated evidence, Exhibit 1058 fails to provide sufficient facts, data, or show reliable methodology for the assertions in Paragraphs 6-10, 16, 17-19, 23, 25, and 28. *See* F.R.E. 702 and 703.

Thus, Mr. Piper repeatedly imputes improper hindsight knowledge to a POSA without offering any objective support for his opinions. *See* Ex. 1058 at ¶16 (opining that “it would have been obvious to a POSA” to make the modifications to Bason/Rhoades in Reply Fig. 1), ¶¶17-19 (opining that a POSA would have made the modifications to Bason/Allsop described in Reply Figure 2), ¶23 (opining that a POSA “would have known how to connect teeth 7 and teeth 2 so that they interact”), and ¶25 (opining that a POSA would have known how to modify Bason/Allsop “so that the dose values are visible to a user”). Elsewhere, Mr. Piper tries to supplement disclosure of claim elements that are not expressly or inherently present in the prior art and/or proposed obviousness combination. *See id.* at ¶¶6-10 (reading axial movement into Allsop’s push-button cap) and ¶20 (reading “snap-fit” into the combination of Bason/Allsop). And in Paragraph 28, Mr. Piper again repeats the uncorroborated assertion from Exhibit 1002 that he was “called upon to build a dose counter around 1998,” without providing any evidence

that such actually occurred. Ex. 1058 at ¶28.

As explained above in Section V(A), Mr. Piper must offer more than mere conclusory assertions in order for his testimony to be admissible. *See 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”). Accordingly, Mr. Piper’s opinions in Paragraphs 6-10, 16, 17-19, 23, 25, and 28 must be excluded as improper expert testimony under F.R.E. 702 and 703.

VI. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that this motion be granted and that Exhibit 1002 ¶¶17, 134, and 135; Exhibit 1032; Exhibit 1033; Exhibit 1055; Exhibit 1056; and Exhibit 1058 ¶¶6-10, 16, 17-20, 23, 25, and 28 be excluded from evidence in this proceeding.

Respectfully submitted,

Dated: July 15, 2019

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CERTIFICATE OF SERVICE

A copy of the **Patent Owner's Motion to Exclude** has been served on
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