

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.

Petitioner

v.

NEURELIS, INC.

Patent Owner

Case: IPR2019-00451

U.S. Patent No. 9,763,876

**PETITIONER'S REPLY IN SUPPORT OF ITS
MOTION TO EXCLUDE EVIDENCE**

I. INTRODUCTION

In its Opposition to Petitioner’s Motion to Exclude (Paper 39, “PO’s Opp.”), Patent Owner’s (“PO’s”) arguments attempting to support admissibility can be divided into three main categories: (a) exhibits that are not being relied on for the truth of the matter, but rather for what those exhibits allegedly describe to one skilled in the art; (b) exhibits that purportedly satisfy the “residual exception” because they are cited by PO’s expert; and (c) arguments relating to excerpts of testimony proffered in the declaration of PO’s expert (Exhibit 2012).

A. Exhibits 2001-2004, 2013, 2018, 2023-2024

Patent Owner urges that each of these exhibits is admissible because they are “not relied on for the truth of the matter asserted but rather for what [the exhibit] described to an ordinary artisan.” *See, e.g.*, PO’s Opp., 2-4, 10-12, 14. In making its arguments in support of the admissibility of these exhibits, PO conveniently loses sight of the effective filing date of the ‘876 patent (*i.e.*, March 27, 2009), and that each of these exhibits was published after that date. In fact, some of these exhibits (*i.e.*, Exhibits 2001, 2018, 2021 and 2023-2024) are even dated after the ‘876 patent issued in 2017. Based on an effective filing date of March 27, 2009, what each of these post-critical date exhibits purportedly describe to a POSITA or the exhibits’ effect on a POSA’s state of mind is simply not relevant. Exhibits 2001-2004, 2013, 2018, 2021 and 2023-2024 are hearsay and should be excluded.

B. Exhibits 2007-2010, 2013-2024

PO argues that Exhibits 2007-2010 and 2013-2024 is not hearsay and “meet the ‘residual exception’ under FRE 807” because PO’s expert cites them in his declaration. PO’s Opp., pp. 6-7, 13. PO also asserts that Exhibits 2015, 2018, 2021 and 2023-2024 are “not relied on for the truth of the matter asserted but rather for what [it exhibit] described to an ordinary artisan,” and are therefore admissible.¹

While an expert may rely on hearsay, that does not make the underlying exhibit and evidence admissible. Even if PO’s expert could rely on such hearsay to form his opinions, PO cannot itself directly rely on them. Committee Note to 2000 Amendment to Rule 703 (“[W]hen an expert reasonably relies on inadmissible information to form an opinion or inference, the underlying information is not admissible simply because the opinion or inference is admitted.”); *Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 666 (S.D.N.Y. 2007) (“[A] party cannot call an expert simply as a conduit for introducing hearsay under the guise that the testifying expert used the hearsay. . .”).

Additionally, the residual exception of Federal Rule of Evidence 807(a) was “meant to be reserved for exceptional cases [and was] not intended to confer ‘a broad license’” to admit hearsay. *Conoco Inc. v. Dept. of Energy*, 99 F.3d 387,

¹ These post-critical date publications are inadmissible. *See supra*, p. 1.

392 (Fed. Cir. 1996). PO's hearsay exhibits present no such "exceptional case." Also, for hearsay statement not to be excluded, PO must satisfy several criteria, including, that the exhibit is "more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts." Fed. R. Evid. 807(a)(2); *see* Committee Note to 2019 Amendments ("proponent must show that the hearsay statement is more probative than any other evidence the proponent can obtain"). PO failed to meet the requirements needed to satisfy the "residual exception." Exhibits 2007-2010 and 2013-2024 should be excluded.

C. Exhibit 2012

1. Relevance

Contrary to PO's assertion, the narratives provided by PO's expert in paragraphs 2, 5, 7 and 67 of his declaration is not relevant to the subject recited in the challenged claims of the '876 patent.

2. Personal Knowledge

In a failed attempt to support admissibility, PO proclaims that paragraphs 2-3, 5, 28-33, 36, 44, 48 and 50-51 "are replete with citations" to supporting printed publications. PO's Opp., 8. However, PO's expert does not cite any documentary evidence in paragraphs 2-3, 28-33, 36, 48 and 50-51. Nor does he otherwise provide the underlying basis for the statements contained in those paragraphs. Additionally, PO's lack of personal knowledge regarding the statements in

paragraphs 2, 28-33, 36, 48 and 50-51 is germane in evaluating his credibility.

Fed. R. Evid. 702. For example, PO's expert opines, with insufficient personal knowledge, regarding the appropriate level of skill possessed by a POSA as of the invention date of the subject matter recited in the '876 patent (*e.g.*, ¶¶ 28-33), and the alleged secondary considerations PO attempts points to in an attempt to support patentability (*e.g.*, ¶¶ 36, 48, 50-51). Paragraphs 2-3, 5, 28-33, 36, 44, 48 and 50-51 should be excluded.

3. Expert Testimony

Paragraphs 35, 77-80, 100-109, and 115-116 offers improper testimony on the ultimate legal conclusion of obviousness. 37 C.F.R § 42.65(a) (prohibiting expert testimony on patent law or patent examination practice).

PO's expert, in paragraphs 34, 68-70, 75 and 114, offers his views on an ultimate question of law -- what constitutes sufficient incorporation by reference. This is impermissible and the paragraphs should be excluded. 37 C.F.R § 42.65(a); *see Advanced Display v. Kent State Univ.*, 212 F.3d 1272, 1283 (Fed. Cir. 2000).

Paragraphs 16-26, 28, 31, 34-36, 41-43, 48, 68-70, 75, 77-79, 85, 87, 89, 95, 100-109 and 111-116 contain nothing more than improper attorney argument and testimony regarding United States patent law shrouded in an expert report, and constitutes improper and unqualified expert testimony. *See* 37 C.F.R § 42.65(a).

PO's expert failed to provide information relating to his methodology and

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