

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner

v.

CIPLA LTD.,
Patent Owner.

Patent No. 8,168,620

Issue Date: May 1, 2012

Title: COMBINATION OF AZELASTINE AND STEROIDS

Inter Partes Review No.: IPR2017-00807

**PETITIONER'S REPLY TO PATENT OWNER'S OPPOSITION TO
PETITIONER'S MOTION TO EXCLUDE**

I. Reliance On The Malhotra Declaration For Its Truth Should Be Precluded

Petitioner's motion made clear that it does not seek to entirely exclude the Malhotra Declaration, but rather only to preclude Patent Owner and its experts from relying on it—as they have—for hearsay purposes. *See* Mot, 7-8. Patent Owner's attempts to recharacterize those uses now cannot avoid the hearsay rule.

A. The Malhotra Declaration Is Hearsay As Used By Patent Owner And Its Experts

Referring to the Malhotra Declaration as part of what the Examiner was told during prosecution may have some nonhearsay relevance to this proceeding, and therefore is not a hearsay use of the document. What is hearsay, however, is Patent Owner's repeated attempts to refer to the Malhotra Declaration for its truth—*i.e.*, that Dr. Malhotra actually did test Cramer's Example III and actually did encounter problems with it. *See* POR, 9 (“However, attempts to recreate, and testing of, Cramer Example III revealed that the formulation exhibited: (1) unacceptable osmolality, which would have caused irritation to patients.... These problems rendered Cramer Example III unsuitable for use” (citing EX1002, 284-87)). These representations are necessarily premised on Dr. Malhotra's out-of-court statements being true.

While the declaration, as a part of the prosecution history, need not be excluded from the record altogether, Patent Owner misstates its relevance in this context when arguing that it was part of the Examiner's reasoning for allowing the

claims. Opp., 3-4 (“...and accepted by the Examiner”). There is zero evidence in the prosecution history that the Examiner relied in any way on the declaration. *See* EX1002, 137-47 (Not. of Allowance). Instead, the Examiner relied on three other declarations relating to other secondary considerations, but, significantly, the Examiner did **not** rely the Malhotra Declaration. *Id.*

Patent Owner also ignores its own arguments in the POR, where the results of Dr. Malhotra’s alleged efforts were stated as ***truthful*** definitive evidence concerning reasonable expectations of success. *See* POR, 28 (“[A] POSA following the prior art guidance of Cramer and Segal would not have arrived at a formulation that was ‘suitable for nasal administration.’ Multiple formulators, acting as a POSA in 2002, all failed....”). While the Malhotra Declaration is not directly cited, the mention of “Multiple formulators, acting as a POSA in 2002” certainly suggests reliance on the Malhotra Declaration, especially since Dr. Govindarajan’s report decidedly does not support this allegation. *See* CIP2030, ¶¶11-15; EX1145, ¶¶34-40.

This same section of the POR later makes the disjunctive statement that “Example III of Cramer ... was not shown to be ‘suitable for nasal administration’ both ***during original prosecution*** and again in litigation” (POR, 33 (citing EX1002, 286) (emphasis added)), which cannot be read as anything other than relying on the contents of the Malhotra Declaration for its substantive truth.

Additionally, the comparison testing of Drs. Govindarajan and Herpin that Patent Owner asserts found the **same results** as Dr. Malhotra also require the Malhotra Declaration to be truthful.^{1,2} While it may be a nonhearsay purpose for Dr. Herpin to say that he attempted to reproduce the experiment that Dr. Malhotra said she carried out, such reliance crosses over into an impermissible hearsay use where Patent Owner tries to claim that other experts “confirmed” Dr. Malhotra’s results, as here (*see, e.g.*, CIP2176, ¶38 (citing EX1002, 286-87)). Such alleged “confirmation” is only relevant if the results in the Malhotra Declaration are taken as true, which is what makes Patent Owner’s reliance a prohibited hearsay use.

As for Patent Owner’s experts, their declarations mimic the content of the POR, and similarly rely on the Malhotra Declaration for its truth. *See* CIP2147,

¹ Patent Owner’s assertion that Dr. Govindarajan arrived at the same results as Dr. Malhotra is completely incorrect. *See* CIP2030, ¶¶11-15; EX1145, ¶¶34-40 (discussing physical stability recreations). Nevertheless, for purposes of the hearsay analysis, what is relevant is Patent Owner’s considerations and how those are advanced for a hearsay purpose, as the Malhotra Declaration is here.

² Patent Owner’s claim that “Dr. Govindarajan sought to recreate the experiment described in the Malhotra Declaration” (Opp., 4.) is also wrong, as Dr. Govindarajan sought to and did reproduce Cramer’s Example 3, not Dr. Malhotra’s experiments. *See* CIP2030, ¶¶7-10.

¶27 (Carr); CIP2176, ¶¶ 23, 31, 36, 38, 40-43 (Smyth (public)). Their attempt to use the Malhotra Declaration to allegedly show a lack of expectation of success (*see, e.g.*, CIP2176, ¶36) can only be relying on the declaration for its truth.

B. Hearsay Uses Of The Malhotra Declaration Can And Should Be Precluded

Patent Owner claims that *REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954 (Fed. Cir. 2016), is dispositive, and compels denial of Petitioner’s motion to exclude. Opp., 6. Patent Owner is wrong. The relevance of *REG Synthetic Fuels*, and the reason Petitioner cited this case in its motion, was to show that evidence can be “admitted” into the proceeding for one purpose (*i.e.*, a nonhearsay use), even while other uses (*i.e.*, hearsay) remain prohibited. 841 F.3d at 963-65. Thus, it is not that the Malhotra Declaration should be stricken from the proceeding altogether, but rather that the parties’ and the Board’s reliance on it should be restricted to nonhearsay purposes.

C. Patent Owner And Its Experts’ Reliance Does Not Fit Within A Hearsay Exception

The exceptions to the hearsay rule Patent Owner identifies are not applicable to their and their expert’s reliance on the Malhotra Declaration. Specifically, FRE 803(15) states that “unless later dealings with the property are inconsistent with the truth of the statement or the purport of the document,” which directly implicates that fact that Dr. Govindarajan’s testing efforts directly contract those of Dr.

Malhotra, as explained above. *See supra*, FN 1. Patent Owner has not cited any authority to show how FRE 803(15) is even applicable to a declaration submitted during prosecution.

As for the alleged FRE 807 exception, Patent Owner pays lip service to the “including the declarant’s name and address” portion of the residual exception, without actually addressing the “so that the party has a fair opportunity to meet it” portion of the same rule. Here, Patent Owner is conveniently forgetting that a cross-examination deposition was requested and denied by Patent Owner. *See* Mot., 5-6. As such, Patent Owner’s reliance on the Malhotra Declaration does not fit within the residual exception—otherwise, virtually any sworn declaration would be admissible without cross-examination, which is certainly not the Board’s practice. *US Endodontics, LLC v. Gold Standard Instruments, LLC*, PGR2015-00019 (Paper 54), at *38-42 (P.T.A.B. Dec. 28, 2016) (refusing to admit a declaration under FRE 807 (residual exception)).

II. Conclusion

For these reasons, Petitioner respectfully requests that the Board preclude Patent Owner from relying on the factual assertions in Dr. Malhotra’s declaration contained in Exhibit 1002 at pages 284-287 as if true.

Respectfully submitted,

Dated: April 30, 2018

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CERTIFICATION OF SERVICE

The undersigned hereby certifies that a copy of the foregoing
**PETITIONER'S REPLY TO PATENT OWNER'S OPPOSITION TO
PETITIONER'S MOTION TO EXCLUDE** was served on April 30, 2018, on
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