

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC

Petitioner

v.

CIPLA LIMITED

Patent Owner

Case No. IPR2017-00807

U.S. Patent No. 8,168,620

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

Mail Stop "PATENT BOARD"

Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

I. INTRODUCTION

Petitioner’s motion to exclude (Paper 41) a portion of the prosecution history of the ’620 patent is meritless. Patent Owner used the subject evidence—the prosecution declaration of Geena Malhotra (EX1002, 284-87, hereinafter “Malhotra Declaration”)—to support Patent Owner’s arguments made during prosecution, and to show the consistency between Ms. Malhotra’s statements and later-conducted testing by two independent experts, both of whom attempted recreations of the prior art that fall well outside the proper scope of the claim terms “nasal spray” and “suitable for nasal administration.”

As explained below, neither of these uses constitutes hearsay, as Petitioner wrongly contends. But, even if they did, each of these uses is excepted from the hearsay rule under either: (i) Fed. R. Evid. 803(15) (statements pertaining to property); or (ii) the residual exception of Fed. R. Evid. 807. And in any event, Petitioner’s request to preclude Patent Owner’s experts from relying on the Malhotra Declaration is misplaced because experts may rely on hearsay evidence in formulating their opinions. Accordingly, the Board should deny Petitioner’s motion to exclude definitive evidence confirming that Cramer (EX1011), and thus Segal (EX1012)—Petitioner’s primary obviousness reference—does not teach a “nasal spray” that is “suitable for nasal administration” within the meaning of the challenged claims.

II. THE MALHOTRA DECLARATION SHOULD NOT BE EXCLUDED.

Contrary to Petitioner's unsupported assertion, Patent Owner never "attempted to rely on the Malhotra declaration ... for the truth of the statements" made therein. Paper 41, 1. Rather, Patent Owner has used the Malhotra Declaration for two purposes only: (i) for purposes of claim construction based on the arguments Patent Owner made during prosecution; and (ii) for comparison to the testing of Drs. Govindarajan and Herpin, both of which confirmed the problems with the prior art described in the Malhotra Declaration. Petitioner's motion to exclude should be denied because (A) the Malhotra Declaration is not hearsay; (B) even if it was, it falls within exceptions to the hearsay rule and thus should not be excluded.

A. The Malhotra Declaration is not hearsay.

Neither Patent Owner's Response nor Patent Owner's experts rely on the Malhotra Declaration for the truth of the matters asserted therein. The Malhotra Declaration is cited four times in Patent Owner's Response, none for its truth.

The first two citations to the Malhotra Declaration in the Response appear in the claim construction section (Paper 21, 8) explaining that the applicant during prosecution had amended the claims to explicitly require a dosage form "suitable for nasal administration" and a "nasal spray" based on the findings described in the Malhotra Declaration. Ms. Malhotra had recreated the formulation described in

what the Examiner deemed to be the “closest prior art”—Cramer Example III—and demonstrated it to be unacceptable as a formulation suitable for nasal administration, within the meaning of the claims, because it exhibited (1) unacceptable settling and difficulty re-suspending the active ingredients (2) an unacceptable jet rather than a mist spray, and (3) an unacceptable osmolality. EX1002, 286-87.

Patent Owner relies on the findings in the Malhotra Declaration in conjunction with the Applicant’s claim amendments and arguments made during prosecution as intrinsic evidence of the meaning of the “suitable for nasal administration” and “nasal spray” claim terms. Paper 21, 7-10. This is no different than relying on any office action or response thereto made during prosecution to support a claim construction position. The Malhotra Declaration, submitted during prosecution, is a part of the permanent prosecution history of the ’620 patent and a public record. 37 C.F.R. § 1.132. Petitioner has provided no support for its remarkable proposition that the Board should exclude relevant intrinsic evidence, such as the Malhotra Declaration, from its claim construction determination.

The third citation, at page 33 of the POR, explains that Cramer Example III “was shown not to be ‘suitable for nasal administration’ both during original prosecution and again in litigation.” This statement, again, does not rely on the truth of the Malhotra Declaration. Rather, it highlights that this argument was

made by the Applicant, and accepted by the Examiner, during prosecution. Patent Owner's comparison of the statements in the Malhotra Declaration to later testing and findings by Drs. Govindarajan and Herpin—neither of which are subject to a motion to exclude—does not require Ms. Malhotra's statements to be true; it merely requires them to exist. That is not hearsay.

The fourth citation to the Malhotra Declaration in the POR appears in a discussion of the testing conducted by Dr. Govindarajan, the scientist whose testing was recommended by Dr. Donovan—Petitioner's formulation expert in this IPR as well as Apotex's formulation expert in the related district court case—and relied upon by Apotex in the related district court litigation. *See id.*, 34; EX2178, 167:12-22. The sentence which the Malhotra Declaration is cited to support describes Dr. Govindarajan's testing, which was intended to reproduce the testing process described in the Malhotra Declaration. *Id.*

The purpose here was to highlight that Dr. Govindarajan sought to recreate the experiment described in the Malhotra Declaration; not to establish the truth of the statements in the Malhotra Declaration itself. Rather, what matters is that Dr. Govindarajan recreated the testing described therein and his testing confirmed the deficiencies described in the Malhotra Declaration. This is not hearsay.

Patent Owner's experts likewise did not rely on the Malhotra Declaration for the truth of the matter. The sole citation to the Malhotra Declaration in Dr. Carr's

Second Declaration is for purposes of claim construction and thus does not rely on the declaration for its truth. *See* CIP2147, ¶27. Similarly, Dr. Smyth cites to the Malhotra Declaration for: (1) intrinsic supporting evidence for claim construction (CIP2150, ¶23); (2) for what Ms. Malhotra *said* in her declaration (*id.*, ¶¶31, 36); or (3) discussions of the Govindarajan and Herpin testing, which recreated and confirmed what was stated in the Malhotra Declaration. *See id.*, ¶¶36-38, 42. None of these discussions rely on the facts underlying the Malhotra Declaration, and thus they do not constitute hearsay.¹

1. Even Petitioner’s cited authority confirms that the Malhotra Declaration is admissible for claim construction purposes.

First and foremost, Petitioner cannot credibly argue that the Malhotra

¹ Even assuming the Malhotra Declaration was hearsay, it is well settled that experts may rely on hearsay evidence provided that the evidence is of a type reasonably relied on by experts in the field. Fed. R. Evid. 703. Notably, the Malhotra Declaration contains substantial formulation information, including manufacturing steps, ingredient concentrations, and formulation details—precisely the kind of information that an expert would rely on to ascertain how a formulation was made and to determine whether or not a given formulation is suitable for administration to a patient.

Declaration is inadmissible for claim construction because it is a part of the permanent part of the prosecution history, and where the Applicant made both claim amendments and arguments for patentability expressly citing to it. The Malhotra Declaration is highly relevant to claim construction because it illustrates how Patent Owner and the Examiner understood the terms of the patent claims confirming their patentability and leading to their issuance. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc) (“the prosecution history provides evidence of how the PTO and the inventor understood the patent.”).

In this regard, Patent Owner’s reliance on the Malhotra Declaration is analogous to the evidence discussed in *REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954 (Fed. Cir. 2016), upon which Petitioner relies. *See* Paper 41, 2. In that case, the Federal Circuit found that the Board erred by excluding evidence relevant to what the inventor believed he had invented. *Id.* at 964. The Federal Circuit explained that “a statement was not hearsay if the communication (as opposed to the truth) had legal significance.” *Id.* (internal quotations and amendments omitted). That case is dispositive, and compels denial of Petitioner’s motion to exclude. Here, Patent Owner’s arguments during prosecution, which were premised on the Malhotra Declaration, have legal significance for claim construction without regard to the truth of the matter because they evidence how both the inventor (Ms. Malhotra) and the Examiner understood the claims.

2. Petitioner's cited authority also confirms that the Malhotra Declaration is admissible for purposes of comparing unopposed testimony to Ms. Malhotra's findings.

Second, Petitioner cannot plausibly argue that a comparison of later-conducted testing of Cramer Example III, conducted by Drs. Govindarajan and Herpin and not subject to a motion to exclude, to Ms. Malhotra's statements during prosecution in any way relies on the truth of Ms. Malhotra's statements. Here, the relevant facts are (1) the unopposed data from Drs. Herpin and Govindarajan; (2) the statements in the Malhotra Declaration, as opposed to their truth; and (3) the consistency between the data derived from Drs. Herpin and Govindarajan on the one hand, and Ms. Malhotra's statements on the other. The truth of Ms. Malhotra's statements is not the focus of this comparison.

Patent Owner's reliance on the Malhotra Declaration here once again satisfies *Neste Oil's* "legal significance" test. The comparisons between Ms. Malhotra's statements and the data of Drs. Govindarajan and Herpin do not require proof of the truth of Ms. Malhotra's statements. Rather, they evidence (1) that the Malhotra Declaration attempts to demonstrate that the formulations claimed in the '620 patent were "nasal spray" formulations that were "suitable for nasal administration" while the prior art formulations were not; and (2) later-conducted testing by two separate scientists confirmed that the formulations disclosed in the prior art did not satisfy the "nasal spray" or "suitable for nasal administration"

limitations of the '620 patent's claims. In other words, Patent Owner relied on Ms. Malhotra's statements only to show the meaning of the claims and to compare unopposed testing to her statements to show that none of the testing met the meaning she ascribed to the terms "nasal spray" and "suitable for nasal administration."

B. Even if the Malhotra Declaration is Hearsay, it is admissible under the Fed. R. Evid. 803(15) and 807 Exceptions.

Even assuming the Malhotra Declaration qualifies as hearsay, the declaration is admissible under at least two exceptions: Fed. R. Evid. 803 and Fed. R. Evid. 807(a). First, Rule 803(15) excepts from hearsay statements in documents that purport to establish or affect a property interest "if the matter stated was relevant to the document's purpose." The Malhotra Declaration falls squarely within this exception. First, it is well-established that patents are property. *See, e.g.,* 35 U.S.C. § 261 ("patents shall have the attributes of personal property."); *Transparent-Wrap Mach. Corp. v. Stokes & Smith Co.*, 329 U.S. 637, 643 (1947) (patents are "of the same dignity as any other property."); *see also Oil States Energy Servs., LLC v. Greene's Energy Group, LLC*, 584 U.S. ___, slip op. at 17 (Apr. 24, 2018). And here, Ms. Malhotra's statements were made in a document (the prosecution history, EX1002) that affects an interest in property, namely, the scope of Patent Owner's patent (property) right. There are no dealings inconsistent

with the truth of the statement; in fact, all of the relevant later statements (i.e., the testing by Drs. Herpin and Govindarajan) confirm Ms. Malhotra's statements. Accordingly, the Malhotra Declaration satisfies each requirement of Rule 803(15).

Second, the so-called residual exception, Fed. R. Evid. 807, also excepts from hearsay any statement which: (1) has circumstantial guarantees of trustworthiness; (2) is offered as evidence of a material fact; (3) is more probative on the point than any other evidence that can be obtained; and (4) the admission of which will best serve the purposes of the rules and the interests of justice.

Subsection (b) further provides that the statement is admissible "only if, before the trial or hearing, the proponent gives an adverse party reasonable notice of the intent to offer the statement and its particulars, including the declarant's name and address, so that the party has a fair opportunity to meet it."

The Malhotra Declaration meets each of these requirements. First, it has three separate circumstantial guarantees of trustworthiness. Ms. Malhotra's declaration contains an oath and was submitted to a federal agency, *see, e.g.*, EX1002, 287, and the substance of her statement was later confirmed by the testing of each of Drs. Govindarajan and Herpin. *See* CIP2030, CIP2029. Second, the Malhotra Declaration, along with the prosecution arguments based on it, are evidence of a material fact in this case: that the inventors defined the claim terms "nasal spray" and "suitable for nasal administration" to require operability—a

characteristic missing from the prior-art Cramer Example III and Segal references.

Third, the Malhotra Declaration is the most probative evidence on the claim construction point because Patent Owner's arguments during prosecution were based upon the statements in that declaration. Finally, the admission of this evidence will serve both the purpose of the Federal Rules of Evidence and the interests of justice by ensuring that the Board has a complete record and also by ensuring that Petitioner cannot escape the fact that its cited prior art *does not* teach the "nasal spray" or "suitable for nasal administration" limitations of each challenged claim. And finally, the notice provision of subsection (b) is satisfied because Petitioner itself brought the Malhotra Declaration into the case, and moreover because Ms. Malhotra's address appears on the very next page of the prosecution history. *See* EX1002, 288. Notably, Patent Owner also relied on the Malhotra Declaration in its Patent Owner's Preliminary Response *before* trial was instituted, so Petitioner cannot legitimately claim any surprise at this stage.

III. CONCLUSION

The Board should deny Petitioner's motion to exclude the Malhotra Declaration. Petitioner has no legitimate basis to seek its exclusion, but instead hopes to remove a key piece of claim construction evidence from this case because it has not shown in the Petition or Reply that the art taught how to achieve a fixed-dose antihistamine/steroid "nasal spray" combination formulation that is "suitable

for nasal administration.”

Respectfully submitted,
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Date: April 24, 2018
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

Dennies Varughese
Lead Attorney for Patent Owner
Registration No. 61,868

CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

The undersigned hereby certifies that the above-captioned “Patent Owner’s Opposition to Petitioner’s Motion to Exclude Evidence” was served in its entirety on April 24, 2018, upon the following parties via electronic mail upon the following counsel of record for the Petitioner:

Michael R. Houston: mhouston@foley.com

Joseph P. Meara: jmeara@foley.com

James P. McParland: jmcparland@foley.com

ARG-dymista@foley.com

FOLEY & LARDNER LLP

321 North Clark Street

Suite 2800

Chicago, IL 60654

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Date: April 24, 2018
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

Dennies Varughese
Lead Attorney for Patent Owner
Registration No. 61,868