

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**

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U.S. Patent and Trademark Office
P.O. Box 1450
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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

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