

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 MOTION TO EXCLUDE EVIDENCE

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(c), Petitioner Argentum Pharmaceuticals LLC (“Petitioner”) moves to preclude Patent Owner, Cipla Ltd. (“Patent Owner”) or its experts from relying on the factual assertions made by Dr. Geena Malhotra in her declaration (*see* EX1002, 284-87) that was submitted during the prosecution of U.S. Patent No. 8,168,620 (“the ’620 patent”) as inadmissible hearsay under Federal Rule of Evidence (“FRE”) 802.

The prosecution history file for the ’620 patent was submitted by Petitioner as Exhibit 1002. This exhibit contained the declaration of Dr. Geena Malhotra submitted by Patent Owner during the prosecution of the ’620 patent. EX1002, 284-87. The Petition cited to Exhibit 1002 to illustrate, for example, the reasons given by the Examiner for allowing the claims, and to discuss various allegations made by Patent Owner during prosecution. *See, e.g.*, Pet. at 6-7, 40-41, 55, 59. These were non-hearsay uses of Exhibit 1002.

However, in its Preliminary Response (and again in its formal Response), Patent Owner and its experts attempted to rely on the Malhotra declaration submitted during prosecution for the truth of the statements made by Ms. Malhotra therein reporting certain experiments she allegedly conducted. *See, e.g.*, POPR, 10, 14, 25, 41; EX2001 ¶¶27-28; EX2007 ¶¶25, 31, 37, 42, 44, 47. That is, beyond reporting what arguments were made to the Examiner during prosecution as

Petitioner has done for a non-hearsay purpose, Patent Owner and its experts attempted to affirmatively rely on the Malhotra declaration for the truth of the matters asserted therein, thereby going beyond non-hearsay uses of Exhibit 1002. *REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F. 3d 954, 963-965 (Fed. Cir. 2016) (recognizing distinction between admissibility of out-of-court statements for non-hearsay purposes, versus inadmissibility for hearsay purposes); *Minemyer v. B-Roc Representatives, Inc.*, 678 F. Supp. 2d 691, 709-710 (N.D. Ill. 2009) (noting that the hearsay rule is not a bar to admissibility as to a relevant, non-hearsay purpose).

Shortly after trial was instituted in this proceeding, Petitioner objected to Patent Owner's attempt to rely on Exhibit 1002 in this manner. Paper No. 16, Pet. Obj. at 2. Patent Owner failed to address or cure Petitioner's objection. As explained below, Patent Owner should be precluded from relying on the testimony by Dr. Malhotra in Exhibit 1002, as this hearsay use of Exhibit 1002 is precluded by FRE 802 (the hearsay rule) and improperly circumvents the right to cross-examination in violation of the Board's rules under 37 C.F.R. § 42.51(b)(1)(ii). Patent Owner's attempted reliance on this declaration evidence without making Ms. Malhotra available for cross-examination also violates at least the spirit if not the letter of 37 C.F.R. § 42.61(c).

II. ARGUMENT

A. Patent Owner's Attempted Reliance on Dr. Malhotra's Declaration Testimony Renders Such Testimony Hearsay and Subjection to Exclusion under FRE 802.

During prosecution, Patent Owner submitted a declaration by Dr. Malhotra, who allegedly tested Cramer's Example III formulation and, based on that alleged testing, found it to be "unsuitable for nasal administration." EX1002, 284-287. In this proceeding, Patent Owner goes beyond simply reciting the events that occurred during prosecution, and now attempts to rely on Dr. Malhotra's declaration to argue that Dr. Malhotra's testing of Cramer affirmatively establishes a lack of reasonable expectation of success to combine azelastine and fluticasone into a combination formulation. *See* POPR, 10, 14, 25, 41; EX2001 ¶¶27-28; EX2007 ¶¶25, 31, 37, 42, 44, 47; *see also* POR, 9, 28, 32-36, EX2147 ¶¶27-28; EX2176 ¶¶23, 31, 36, 38, 40-43.

In attempting to rely on Dr. Malhotra's out-of-court statements for their truthfulness, *i.e.*, trying to show a lack of expectation of success by assuming Dr. Malhotra's statements/tests to in fact be true, Dr. Malhotra's declaration testimony falls squarely within the hearsay definition under FRE 801(c), and therefore is subject to exclusion for hearsay purposes, per FRE 802. *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))

that was submitted during *ex parte* prosecution and noting that “a declaration from [declarant] in this proceeding would have been more probative than the declaration [from the *ex parte* proceeding] because a declaration in this proceeding would have subjected [declarant] to cross-examination by Petitioner as a matter of routine discovery under the rules governing this proceeding”).

B. Petitioner Timely Objected to Patent Owner’s Attempted Hearsay Use of Dr. Malhotra’s Declaration Testimony

On September 5, 2017, Petitioner timely objected to Patent Owner’s attempt to rely on Exhibit 1002 in a hearsay manner. *See* Paper 16, Pet. Obj. at 2.

Specifically, Petitioner’s objections called out Exhibit 1002, and recited numerous places where Patent Owner was attempting to rely on the exhibit in a hearsay manner, in violation of FRE 802. *Id.* Petitioner’s objections further pointed out that Petitioner has not had the opportunity to subject the declarant to cross examination. *Id.*

Petitioner’s objections were timely, having been served within ten business days of institution. 37 C.F.R. 42.64(b)(1). In response to Petitioner’s September 5, 2017 objections, Patent Owner made no attempt to submit supplemental evidence or to otherwise address Petitioner’s objection.

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