

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.

C. Patent Owner Refused To Make Dr. Malhotra Available for Deposition

Beyond just failing to respond to Petitioner's objections, Patent Owner went further and expressly refused to make Dr. Malhotra available for cross-examination. On December 27, 2017, Petitioner affirmatively requested that Patent Owner make Dr. Malhotra available for cross-examination, among other witnesses. EX1172 (Email from Mike Houston to Adam LaRock). Patent Owner responded on January 4, 2018 that it did not intend to make Dr. Malhotra available. EX1173 (Email from Adam LaRock to Mike Houston). Thus, despite attempting to secure a deposition of Dr. Malhotra, a named inventor on the '620 patent, Petitioner was rebuffed and therefore has had no opportunity to cross-examine Dr. Malhotra in this IPR (or any other proceeding).

Patent Owner's failure to offer Dr. Malhotra for deposition deprived Petitioner of an opportunity to obtain testimony from Dr. Malhotra on issues raised in her declaration. One example is that Petitioner was not given the opportunity to explore with Dr. Malhotra how her recreation of Cramer's Example III had an "undesirable" osmolality. *See* EX1002, 287(C). Nor has Petitioner been given an opportunity to ask Dr. Malhotra how her recreation of Example III was representative of the routine modifications a POSA would have undertaken or why she did not attempt to modify: (i) the HPMC used by assessing multiple commercial grades of HPMC; (ii) the amount of HPMC used, (iii) the amount of

sodium chloride used; or (iv) the type of spray device employed to generate a successful formulation.

Patent Owner's deliberate strategy of relying on Dr. Malhotra's prior prosecution declaration, while refusing to make her available for deposition, deprived Petitioner of an opportunity to explore Dr. Malhotra's bases for her testimony, and/or to confront her with evidence and issues not raised during prosecution.

D. Patent Owner's Attempted Reliance on Dr. Malhotra's Testimony Should Be Precluded

Pursuant to 37 C.F.R. § 42.62(a), the FEDERAL RULES OF EVIDENCE apply in *Inter Partes* Review proceedings. Here, the contents of Dr. Malhotra's declaration are out-of-court statements that Patent Owner is now attempting to rely on for their truth, establishing the declaration as hearsay under FRE 801(c). Dr. Malhotra was never made available for deposition in this IPR (or in any other proceeding to which Petitioner was a party), thus subjecting the declaration to exclusion under FRE 802. Accordingly, Patent Owner should be precluded from relying on Dr. Malhotra's declaration testimony because doing so violates FRE 802 as well as the applicable regulations governing this proceeding, which require that affidavit testimony be subject to cross examination under 37 C.F.R. § 42.51(b)(1)(ii). *Accord* 37 C.F.R. § 42.61(c) (explaining that data in a patent specification or drawing upon which a party intends to rely to prove the truth of the data must be

supported by an affidavit from an individual having first-hand knowledge of how the data was generated, which in turn requires that affiant be made available for cross-examination per § 42.51(b)(1)(ii)).

Petitioner appreciates that because the prosecution history of the '620 patent could be relevant to this proceeding for non-hearsay purposes, it may not be appropriate to “exclude” the Malhotra declaration in Exhibit 1002 from the record altogether. As an alternative, where a party relies on prior testimony without making that witness available for deposition as required by the Board’s rules, the Board has repeatedly held that the testimony is entitled to **no** weight. *See Coalition for Affordable Drugs V LLC v. Biogen MA Inc.*, IPR 2015-01993, Paper 34 at 3 (P.T.A.B. Apr. 19, 2016) (explaining that in order for a declaration submitted during patent prosecution to “be given any weight” in an IPR, the declarant/affiant must be made available for cross-examination in the manner specified in 37 C.F.R. § 42.51(b)(1)(ii)); *Altaire Pharm., Inc. v. Paragon Biotech, Inc.*, PGR2015-00011, Paper 29 at 3 (P.T.A.B. Apr. 1, 2016) (warning that no weight will be given to a declaration if the declarant is not made available for cross-examination).

By relying on Dr. Malhotra’s factual assertions without making her available for cross-examination, Patent Owner has violated the Board’s rules. Therefore, the testimony of Dr. Malhotra on pages 284-287 of Exhibit 1002 should be “excluded”

as to the hearsay purposes for which Patent Owner attempts to rely upon the declaration. Instead, the declaration should be given no weight as to the factual statements therein, and Patent Owner and its experts should likewise be precluded from relying on the Malhotra declaration for the truth of the statements made therein.

III. CONCLUSION

For the foregoing 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.

Respectfully submitted,

Dated: April 10, 2018

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CERTIFICATION OF SERVICE

The undersigned hereby certifies that a copy of the foregoing
PETITIONER'S MOTION TO EXCLUDE EVIDENCE was served on April
10, 2018, on Counsel for Patent Owner via electronic mail to the following:

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