

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX, INC.
Petitioner,

v.

UCB BIOPHARMA SPRL,
Patent Owner.

U.S. Patent No. 8,333,194 to Fanara et al.
Issue Date: January 21, 2014
Title: Pharmaceutical Composition of Piperazine Derivatives

Inter Partes Review No.: IPR2019-00400

PETITIONER'S OBJECTIONS TO EVIDENCE

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Pursuant to 37 C.F.R. § 42.64(b)(1), Apotex, Inc. (“Apotex” or “Petitioner”) timely objects under the Federal Rules of Evidence (“FRE”) to the admissibility of Exhibits 2024, 2030, and 2031. In addition, Petitioner objects to the admissibility of paragraphs 6, 71-73, 191-193, and 196-197 of the Declaration of Dr. Sarfaraz K. Niazi, i.e., Exhibit 2034, under FRE 401 and 403. Collectively, these exhibits (“Challenged Evidence”) were served by UCB Biopharma Sprl (“UCB” or “Patent Owner”) with its Patent Owner Complete Response filed on October 15, 2019.

Petitioner’s objections are timely under 37 C.F.R. § 42.64(b)(1) because they are being filed and served within five business days. Petitioner files these objections to provide notice to Patent Owner that Petitioner may move to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c), unless timely cured by Patent Owner.

**IDENTIFICATION OF CHALLENGED EVIDENCE AND GROUNDS FOR
OBJECTIONS**

A. Multiple Exhibits Are Inadmissible as Being Irrelevant, and/or Containing Hearsay, and Are Therefore More Prejudicial Than Probative as to Any Fact of Consequence.

1. Exhibit 2024:

Exhibit 2024 is inadmissible under FRE 401 and 403. Exhibit 2024 purports to be a Pharmaceutical Manufacturing Handbook dated “2008.” Exhibit 2024 is not relevant to any issue in the IPR proceeding because the purported date of the

document is after the filing date of the '194 patent. Therefore, Exhibit 2024 is inadmissible as being irrelevant.

2. Exhibit 2030:

Exhibit 2030 is inadmissible under FRE 401 and 403. Exhibit 2030 purports to be an article by El-Nakeeb et al. dated "March 14, 2011." Exhibit 2030 is not relevant to any issue in the IPR proceeding because the purported date of the document is after the filing date of the '194 patent. Therefore, Exhibit 2030 is inadmissible as being irrelevant.

Exhibit 2030 is also inadmissible under FRE 801 and 802. Patent Owner relies on the March "2011" date in Exhibit 2030, as well as its description on the correlation between antihistaminic and antibacterial properties, for the truth of the matter asserted. Patent Owner cannot rely on the "2011" date shown in Exhibit 2030 or its description on the correlation between antihistaminic and antibacterial properties because there is no evidence that the reference was a printed publication as of a particular date. No hearsay exception applies.

3. Exhibit 2031

Exhibit 2031 is inadmissible under FRE 401 and 403. Exhibit 2031 purports to be an article by Nemes dated "23 July 2018." Exhibit 2031 is not relevant to any issue in the IPR proceeding because the purported date of the document is after the

filing date of the '194 patent. Therefore, Exhibit 2031 is inadmissible as being irrelevant.

Patent Owner relies on the “23 July 2018” date in Exhibit 2031, as well as its description on “the [high] risk of contamination,” for the truth of the matter asserted. Patent Owner cannot rely on the “23 July 2018” date shown in Exhibit 2031 because there is no evidence that the reference was a printed publication as of a particular date. No hearsay exception applies.

C. Any Paragraphs in Declaration of Dr. Sarfaraz K. Niazi (i.e., Exhibit 2034) That Rely on the Exhibits Identified above Should Be Excluded.

Any paragraph of the Declaration of Dr. Sarfaraz K. Niazi (i.e., paragraphs 56, 71-73, 191-193, and 196-197 of Exhibit 2034) that relies on any of the exhibits identified above is objected to for the same reason as Petitioner’s objection to the underlying exhibit.

DATE: 10/21/19

Respectfully submitted,

Katten Muchin Rosenman LLP

By: /Jitendra Malik/
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