

Filed On Behalf Of:
Novartis Pharmaceuticals Corporation

By:
Nicholas N. Kallas
NKallas@fchs.com
ZortressAfinitorIPR@fchs.com
(212) 218-2100

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BRECKENRIDGE PHARMACEUTICAL, INC.,

Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Patent Owner.

Case IPR2017-01592

Patent No. 8,410,131

**PATENT OWNER'S OBJECTIONS UNDER
37 C.F.R. § 42.64 TO EVIDENCE SUBMITTED
BY BRECKENRIDGE PHARMACEUTICAL, INC.**

In its January 3, 2018 decision instituting *inter partes* review in this proceeding (Paper 12, “Institution Decision”), the Board authorized Petitioner Breckenridge Pharmaceutical, Inc. (“Breckenridge”) “to file one or more declarations explaining the relevance of the documents appended to the Luan abstract....” Institution Decision at 22-23 (discussing Exhibit 1005, Luan). On January 18, 2018, Breckenridge filed Exhibits 1112 – 1118. In its January 23, 2018 Order Regarding the Conduct of the Proceeding Under 37 C.F.R. § 42.5 (Paper 16, “Order”), the Board authorized Breckenridge to file a Declaration of Fu L. Luan, M.D. on the basis of Breckenridge’s representation to the Board that “the proposed ‘declaration specifically addresses the publication date issue of the Luan Abstract.’” Order at 2. On January 23, 2018, Breckenridge filed Exhibit 1119.

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Novartis Pharmaceuticals Corporation (“Novartis”) objects to the admissibility of the following exhibits filed on January 18, 2018 and January 23, 2018 by Breckenridge on the grounds set forth below.

In this paper, a reference to “F.R.E.” means the Federal Rules of Evidence, a reference to “C.F.R.” means the Code of Federal Regulations, and “the ’131 Patent” means U.S. Patent No. 8,410,131. All objections under F.R.E. 802 (hearsay) apply to the extent Breckenridge relies on the exhibits identified in connection with that objection for the truth of the matters asserted therein.

Novartis's objections to Breckenridge's exhibits are without prejudice to Novartis's reliance on or discussion of those exhibits in Novartis's papers in this proceeding.

Novartis's objections are as follows:

Exhibit 1112

Novartis objects to Exhibit 1112 under F.R.E. 802 (hearsay), F.R.E. 402 (relevance), F.R.E. 403 (confusing, waste of time), and F.R.E. 701 (improper testimony by lay witness), as Dr. Evans's testimony is not rationally based on his perceptions and not helpful to clearly understanding his testimony or determining a fact in issue in this proceeding.

Novartis also objects to Exhibit 1112 under F.R.E. 402 (relevance), F.R.E. 403 (confusing, waste of time), 35 U.S.C. § 312(a)(3), and 37 C.F.R. §§ 42.22(a)(2), 42.24(a), 42.104(b), and 42.105; Exhibit 1112 was not cited in Breckenridge's Petition. Any attempt by Breckenridge to rely on this document to establish unpatentability is improper and untimely and will constitute an improper incorporation by reference under 37 C.F.R. § 42.6(a)(3) or attempt to circumvent the word count limits for petitions under 37 C.F.R. § 42.24(a).

Novartis further objects to Exhibit 1112 as improper and untimely to the extent this document is cited in support of Breckenridge's *prima facie* case as this document should have been included in the evidence served with Breckenridge's

Petition as required by 35 U.S.C. § 312(a)(3) and 37 C.F.R. §§ 42.22(a)(2), 42.104(b), and 42.105.

Novartis also objects to Exhibit 1112 ¶¶ 2-7 and 9-12 under F.R.E. 701 (improper testimony by lay witness), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, waste of time); these paragraphs include statements based on documents that are inadmissible under at least 37 C.F.R. §§ 42.22(a)(2), 42.104(b)(2) and (b)(5), F.R.E. 802 (hearsay), F.R.E. 402 (relevance), F.R.E. 403 (confusing, waste of time, needlessly presenting cumulative evidence), F.R.E. 701 (improper testimony by lay witness), and F.R.E. 901 (authentication), documents that are stamped with dates after the February 19, 2001 priority date of the '131 Patent, the October 17, 2001 priority date of the '131 Patent, or the February 18, 2002 application date of the '131 Patent, documents that were not published until after the February 19, 2001 priority date of the '131 Patent, the October 17, 2001 priority date of the '131 Patent, or the February 18, 2002 application date of the '131 Patent, and/or documents for which Breckenridge has not provided evidence to prove were published before the February 19, 2001 priority date of the '131 Patent, the October 17, 2001 priority date of the '131 Patent, or the February 18, 2002 application date of the '131 Patent, as not relevant to any issue in this IPR proceeding and not the type of document upon which a person of ordinary skill in the art at the time of invention would rely.

Novartis also objects to Exhibit 1112 ¶ 5 under F.R.E. 701 (improper testimony by lay witness), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, waste of time), as the declarant has provided no information to support his testimony that Exhibit 1114 was located “[f]rom online research” or is “available online.” Exhibit 1112 ¶ 5.

Novartis also objects to Exhibit 1112 ¶¶ 3-7, 9, and 10 under 37 C.F.R. § 42.123 and as beyond the scope of the Board’s order in its Institution Decision, as these paragraphs do not “explain[] the relevance of the documents appended to the Luan abstract” and/or rely on documents that are not “declarations explaining the relevance of the documents appended to the Luan abstract.”

Novartis also objects to Exhibit 1112 ¶¶ 2-12 under F.R.E. 701 (improper testimony by lay witness), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, waste of time), as they are not relevant to any issue in this IPR proceeding because they relate to the field of immunosuppression and/or transplantation and/or are in a separate field of endeavor and/or are not pertinent to the entire problem solved by the ’131 Patent.

Novartis also objects to Exhibit 1112 ¶¶ 4, 5, and 10 under F.R.E. 701 (improper testimony by lay witness), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, waste of time). The declarant is not stated to have expertise with respect to renal cell carcinoma, transplantation, library science, or related fields

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