

Filed On Behalf Of:
Novartis Pharmaceuticals Corporation

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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 PETITIONER WITH ITS REPLY**

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Novartis Pharmaceuticals Corporation (“Novartis”) objects to the following exhibits filed with Petitioner’s Breckenridge Pharmaceutical, Inc. (Petitioner) Reply 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) and 37 C.F.R § 42.61(c) (hearsay) apply to the extent Petitioner relies on the exhibits identified in connection with that objection for the truth of the matters asserted therein. Novartis’s objections to Petitioner’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:

Ex. No.	Description	Patent Owner's Objections
1121	Shrinkage table showing results of the Weckbecker in vivo assay	<ul style="list-style-type: none"> • F.R.E. 802 (hearsay). • F.R.E. 402 (relevance). • F.R.E. 403 (confusing, waste of time). • F.R.E. 106 (incomplete). • F.R.E. 901 (authentication). Petitioner has not provided sufficient evidence to establish that the exhibit is authentic or that the exhibit is self-authenticating under F.R.E. 901. • Improper and untimely to the extent they are cited in support of Petitioner's case as they should have been included in the evidence served with the petition as required by 35 U.S.C. § 312(a)(3) and 37 C.F.R. §§ 42.22(a)(2), (b)(2). • F.R.E. 402 (relevance), F.R.E. 403 (confusing, waste of time), F.R.E. 702 (expert testimony), F.R.E. 703 (bases for expert opinion), as it is not relevant to the IPR proceeding, and is not the type of document upon which a person

Ex. No.	Description	Patent Owner's Objections
		<p>the art at the time of invention would rely.</p> <ul style="list-style-type: none"> 37 C.F.R. §§ 42.22(a)(2), 42.104(b)(2) and (b)(5), 35 U.S.C. § 311 (relevance), F.R.E. 403 (confusing, waste of time), F.R.E. 702 (imp) and F.R.E. 703 (bases for expert opinion) as this document was not February 19, 2001 priority date of the '131 Patent, the October 17, '131 Patent, or the February 18, 2002 application date of the '131 Patent of document upon which a person of ordinary skill in the art at the rely. 35 U.S.C. § 312(a)(3), 37 C.F.R. §§ 42.22(a)(2), 42.24(a), 42.104(b) document is not cited in the Reply, and therefore any attempt by Pet Exhibit to establish unpatentability (either directly by citing this Ex citing paragraphs of Petitioner's expert declaration that discusses th and untimely and will constitute an improper incorporation by refer

Ex. No.	Description	Patent Owner's Objections
		<p>42.6(a)(3). <i>See</i> Ex. 1126 (Burriss Deposition Transcript) at 25:23-2</p> <ul style="list-style-type: none"> • 37 C.F.R. § 42.104(b)(5) (failure to identify specific portions of evi
1122	O'Donnell	<ul style="list-style-type: none"> • F.R.E. 802 (hearsay). • F.R.E. 402 (relevance). • F.R.E. 403 (confusing, waste of time). • Improper and untimely to the extent they are cited in support of Pet case as they should have been included in the evidence served with as required by 35 U.S.C. § 312(a)(3) and 37 C.F.R. §§ 42.22(a)(2), • 37 C.F.R. §§ 42.22(a)(2), 42.104(b)(2) and (b)(5), 35 U.S.C. § 311 (relevance), F.R.E. 403 (confusing, waste of time), F.R.E. 702 (imp and F.R.E. 703 (bases for expert opinion) as this document was not February 19, 2001 priority date of the '131 Patent, the October 17,

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