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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 Exhibit 1159 (Second Declaration of Allan J. Pantuck, M.D. in support of *Inter Partes* Review of U.S. Patent 8,410,131), filed with Petitioner's Breckenridge Pharmaceutical, Inc. (Petitioner) Reply on June 21, 2018, 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 exhibit identified in connection with that objection for the truth of the matters asserted therein. Novartis's objections to Petitioner's Exhibit 1159 are without prejudice to Novartis's reliance on or discussion of that exhibit in Novartis's papers in this proceeding.

Novartis's objections are as follows:

Novartis objects to Exhibit 1159 under F.R.E. 802 (hearsay), F.R.E. 402 (relevance), F.R.E. 403 (confusing, waste of time), F.R.E. 702 (improper expert testimony), F.R.E. 703 (bases for expert opinion), and 37 C.F.R. § 42.65, as Dr. Pantuck's scientific, technical, or other specialized knowledge will not help the trier of fact to understand the evidence or to determine a fact in issue, the testimony is not based on sufficient facts or data, is not the product of reliable

principles and methods, and the principles and methods have not been reliably applied to the facts of this case.

Novartis objects to Exhibit 1159 under F.R.E. 802 (hearsay), F.R.E. 402 (relevance), F.R.E. 403 (confusing, waste of time), F.R.E. 702 (improper expert testimony), F.R.E. 703 (bases for expert opinion), and 37 C.F.R. § 42.65, as Dr. Pantuck's testimony is not based on an analysis of the prior art as a whole. Exhibit 1159 ¶¶ 72-75, 185, 214, 240, 261, and 302 rely on a review of SciFinder® search results and references identified from that search that do not reflect the prior art as a whole.

Novartis objects to Exhibit 1159 under 35 U.S.C. § 312(a)(3), 37 C.F.R. §§ 42.65 and 42.104(b)(5), F.R.E. 702 (improper expert testimony), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, waste of time) for failing to identify with particularity the underlying facts and data on which the opinion is based. Exhibit 1159 ¶¶ 72-73, 75, 83, 101-103, 131-146, 226-249, 259-262, 273-276, 278, 282-287, 299, 326-382 fail to cite any support at all, include statements that do not cite any support, or include statements that are not supported by the cite(s) provided; and Exhibit 1159 ¶¶ 4, 70, 73, 81, 82, 85, 86, 87, 88, 100, 117, 215, 240, 261, 277, 302 cite to entire articles, book chapters or other references without identifying which aspects of those references are relied upon.

Novartis objects to Exhibit 1159 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 1159 ¶¶ 1-71, 74, 76-82, 84-100, 104-130, 147-225, 250-258, 263-272, 277, 279-281, 288, 300-325, and 283 are not cited in Petitioner's Reply; and Exhibit 1159 ¶¶ 134-146, 226-249, 326-333, 334-340, 341-376, 377-382 are not specifically identified or discussed in detail in whole or in part in Petitioner's Reply. Any attempt by Petitioner to rely on these paragraphs 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 also objects to Exhibit 1159 ¶¶ 131-133, 136-138, 140-145, 146, 226-249, 261-262, 273-275, 276 to the extent that these paragraphs recite arguments that have not been made in any detail in Petitioner's Reply. Any attempt by Petitioner to rely on the arguments in these paragraphs 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). In particular, Exhibit 1159 contains arguments that are not made in any detail in Petitioner's Reply: ¶¶ 131-133 (citing references in support of opinion that the immunosuppressive activity of temsirolimus was comparable with rapamycin); ¶¶

136-138 (discussion of the experimental protocol in Weckbecker); ¶¶ 140-145 (arguments and citing references in support of opinion that Novartis's statements support Dr. Pantuck's opinions); ¶ 146 (arguments that the '131 Patent supports Pantuck's opinions); ¶¶ 226-249 (arguments and citing references, including reliance on Schuler (Exhibit 1008), Sedrani (Exhibit 1020) and Cottens WO '010 (Exhibit 1026), regarding a class of rapamycin derivatives; details of the Wasik experiments; arguments and citing references in support of opinion regarding the distinction between the properties of everolimus, cyclosporin, and tacrolimus; argument against using Majewski to support Dr. Burris's opinion; and reliance on other various parts of Wasik (Exhibit 1002)); ¶¶ 261-262 (arguments regarding Beirer (Exhibit 1133) and arguments that POSA need not understand the mechanism of action of mTOR inhibitors given development of mTOR inhibitors); ¶ 273 (arguments and citing references in support of opinion that a POSA would have understood the immunosuppressive activity of temsirolimus to be comparable to the immunosuppressive activity of rapamycin); ¶¶ 274-275 (arguments and citing references in support of opinion that the immunosuppressive effect of temsirolimus disappears based on the dosing schedule); and ¶ 276 (argument regarding the distinction between the properties of everolimus, cyclosporin, and tacrolimus).

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