Served On Behalf Of:
Novartis AG

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL INC.,
Petitioner

v.

NOVARTIS AG,
Patent Owner

Case IPR2016-00084
U.S. Patent 5,665,772

PATENT OWNER'S OBJECTIONS UNDER 37 C.F.R. § 42.64 TO EVIDENCE SUBMITTED BY PAR PHARMACEUTICAL INC. WITH ITS PETITION FOR *INTER PARTES* REVIEW

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Novartis AG ("Novartis") objects to the admissibility of the following exhibits filed prior to institution of the trial by Petitioner Par Pharmaceutical Inc. ("Par") 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 "'772 Patent" means U.S. Patent No. 5,665,772. All objections under F.R.E. 802 (hearsay) apply to the extent Par relies on the exhibits identified in connection with that objection for the truth of the matters asserted therein.

Novartis's objections are as follows:

Exhibit 1001

Novartis objects to Exhibit 1001 under F.R.E. 802 (hearsay), 37 C.F.R § 42.61(c) (hearsay), and F.R.E. 106 (completeness), as the document is incomplete because it does not contain the Certificates of Correction dated June 2, 2015 or February 9, 2016.

Exhibit 1002

Novartis objects to Exhibit 1002 under F.R.E. 802 (hearsay), 37 C.F.R § 42.61(c) (hearsay), and F.R.E. 106 (completeness), as the document is incomplete because it does not contain the Certificate of Correction dated February 9, 2016.

Exhibit 1003

Novartis objects to Exhibit 1003 under F.R.E. 802 (hearsay), F.R.E. 702 (improper expert testimony), F.R.E. 703 (bases for expert opinion), and 37 C.F.R. § 42.65 as 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 the case.

Novartis objects to Exhibit 1003 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 1003 ¶¶ 21, 40-43, 53, 54, 55, 57, 58, 61, 63, 69, 71, 74, 75, 76, 78, 79, 83, 85, 86, 87, 100, 103, 105, 107, 108, 109, 110, 111, 113, 114, 115, 116, 117, 118, 119, 120, 122, 127, 128, 134, 139, 140, 142, 146, 149, 150, 151, 152, 165, 168, 169, 174, 179, 182, 198, and 200 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 1003 ¶¶ 56, 57, 77, 89, 108, 115, 125, 129, 141, and 179 cite to entire articles, book chapters or other references without identifying which aspects of those references are relied upon. Novartis also objects to Exhibit 1003 ¶¶ 107-111, 114-120, 174-79, and 182 under F.R.E. 702 and 37 C.F.R. § 42.65 as those paragraphs rely on software without identifying, disclosing, or providing the

underlying data and software used; without providing or disclosing how the software and underlying data was used to generate the opinions provided in these paragraphs; without providing or disclosing how the underlying data was obtained or generated; or without identifying whether the software used was publicly available as of the priority date of the '772 Patent.

Novartis also objects to Exhibit 1003 ¶¶ 10, 11, 14, 20, 31, 40, 41, 42, 43, 48, 56, 57, 58, 75, 78, 83, 85, 86, 87, 89, 99, 115, 116, 117, 118, 119, 129, 136, 139, 140, 142, 149, 153, 174, and 182 under F.R.E. 402 (relevance) and F.R.E. 403 (confusing, waste of time), as these paragraphs are not cited in Par's Petition. Novartis also objects to Exhibit 1003 ¶¶ 113-120 and 173-204 under FRE 402 (relevance) and FRE 403 (confusing, waste of time) as these paragraphs are cited in Par's Petition only with respect to grounds for which *inter partes* review was not authorized.

Novartis also objects to Exhibit 1003 ¶¶ 10, 11, 19, 40, 41, 42, 43, 53, 54, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 86, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 125, 126, 128, 129, 132, 133, 134, 135, 138, 139, 141, 143, 144, 146, 147, 148, 149, 153, 156, 166, 167, 168, 169, 170, 171, 174, 175, 176, 177, 179, 180, 182, 183, 185, 198, 199, 200, 201, 202, and 203 under F.R.E. 702 (improper

expert testimony), F.R.E. 703 (bases for expert opinion), F.R.E. 402 (relevance) and F.R.E. 403 (confusing, waste of time); these paragraphs include expert opinion based on documents that are inadmissible under at least 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. 702 (improper expert testimony), F.R.E. 703 (bases of an expert opinion), 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 1003 ¶¶ 53, 54, 57, 64, 65, 68, 72, 73, 74, 75, 76, 89, 92, 97, 98, 99, 100, 125, 126, 131, 132, 133, 134, 138, 139, 140, 146, 150, 153, 156, 165, 166, 167, 169, 170, 171, 180, 183, 197, 198, 199, 201, 202, and 203 under F.R.E. 702 (improper expert testimony), F.R.E. 703 (bases of an expert opinion), 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 pharmacology, immunosuppression, or transplant rejection.

Novartis also objects to Exhibit 1003 ¶¶ 40-43 under F.R.E. 602 (lack of personal knowledge), F.R.E. 702 (improper expert testimony), F.R.E. 703 (bases of an expert opinion), F.R.E. 402 (relevance) and F.R.E. 403 (confusing, waste of time), as the declarant is testifying regarding factual matters for which he does not have personal knowledge.

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