UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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**NOVEN PHARMACEUTICALS, INC.,**
Petitioner

v.

**NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG,**
Patent Owners

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***Inter Partes* Review No.: 2014-00549**

**U.S. Patent 6,316,023**

# PETITIONER'S OBJECTIONS TO EVIDENCE SUBMITTED BY PATENT OWNERS

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Noven Pharmaceuticals, Inc. ("Noven") objects to the admissibility of the following exhibits filed by Patent Owners Novartis AG and LTS Lohmann Therapie-Systeme AG ("Patent Owners").

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 "'023 patent" means U.S. Patent No. 6,316,023. All objections under F.R.E. 802 (hearsay) apply to the extent that Patent Owners rely on the exhibits identified in connection with that objection for the truth of the matters asserted therein.

Noven's objections are as follows:

**Exhibit 2012**

Noven objects to Exhibit 2012 under F.R.E. 802 (hearsay), F.R.E. 702 (improper expert testimony) and F.R.E. 703 (bases for expert opinion) 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.

Noven objects to Exhibit 2012 under 37 C.F.R. § 42.65(a) and 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, as Exhibit 2012 ¶¶ 1 n 1, 14-16, 18-22, 24-25, 27-

28, 30-32, 34, 37, 50, 52, 56, 58, 60, 74, 105-106, 112, 120-123, 132, 139, 149, 156, 160-168, and 175 fail to cite any support at all, or include statements that do not cite any support.

Noven also objects to Exhibit 2012 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), as Exhibit 2012 ¶¶ 33, 38-48, 53, 57, 61, 77, 79-85, 88-96, 111-18, 121, 129-30, 133-37, 140-43, 150-51, 154, 157, 162, 163-67, and 174 include expert opinion based on documents that are inadmissible based on the manner that the documents are used by the declarant, 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), and not the type of document upon which a person of ordinary skill in the art at the time of invention would rely.

Noven objects to Exhibit 2012 ¶¶ 27, 159, 166, pursuant to 37 C.F.R. § 42.65(b), as Exhibit 2012 relies on technical test(s) or data from such test(s) without an accompanying affidavit.

Noven objects to Exhibit 2012 ¶¶ 27, 159, 166, pursuant to 37 C.F.R. § 42.61(c), as Exhibit 2012 refers to data in the ’023 patent (Exhibit 1001, 2011) specification, without an accompanying affidavit.

Noven further objects to Exhibit 2012 ¶¶ 162-67 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, and further as Patent Owners are relying on Exhibit 2053, a trial transcript from a trial to which Noven was not a party, which is a not admissible under F.R.E. 802 (hearsay) and F.R.E. 702 (improper expert testimony), and which is not the type of document upon which an expert in the field would reasonably reply (F.R.E. 703).

Noven further objects to Exhibit 2012 ¶¶ 162-67 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, and further as Patent Owners are relying on Exhibit 2015, a compilation of Patent Owners' internal documents which are not admissible under F.R.E. 802 (hearsay), F.R.E. 901 (lacking authentication), F.R.E. 402 (relevance), F.R.E. 403 (unduly prejudicial, confusing, misleading or cumulative), and F.R.E. 702 (improper expert testimony), and which are not the type of document upon which an expert in the field would reasonably rely (F.R.E. 703).

Noven objects to Exhibit 2012 ¶¶ A1 and 49 under 37 C.F.R. § 42.63 for improperly citing to evidence.

**Exhibit 2013**

Noven objects to Exhibit 2013 under F.R.E. 802 (hearsay), F.R.E. 402 (relevance), and F.R.E. 403 (unduly prejudicial, confusing, misleading or cumulative).

**Exhibit 2014**

Noven objects to Exhibit 2014 under F.R.E. 901 (lacking authentication), F.R.E. 802 (hearsay), F.R.E. 402 (relevance), and F.R.E. 403 (unduly prejudicial, confusing, misleading or cumulative). Noven also objects to Exhibit 2014 under F.R.E. 106 (completeness) and F.R.E. 403 (confusing, misleading) as the document is incomplete and includes only a select portion of a larger document.

**Exhibit 2015**

Noven objects to Exhibit 2015 under F.R.E. 901 (lacking authentication), F.R.E. 802 (hearsay), F.R.E. 402 (relevance), and F.R.E. 403 (unduly prejudicial, confusing, misleading or cumulative) because it is not relevant to any issue in this IPR proceeding at least because the purported date of at least portions of the

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