

**On Behalf Of:**

Noven Pharmaceuticals, Inc.  
And Mylan Pharmaceuticals Inc.

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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**NOVEN PHARMACEUTICALS, INC.  
AND MYLAN PHARMACEUTICALS INC.,**  
Petitioners

v.

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

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Inter Partes Review No.: 2014-00549<sup>1</sup>

U.S. Patent No. 6,316,023

**PETITIONER'S OBJECTIONS TO EVIDENCE SUBMITTED BY PATENT  
OWNERS**

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<sup>1</sup> Case IPR2015-00265 has been joined with this proceeding.

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioners Noven Pharmaceuticals, Inc. (“Noven”) and Mylan Pharmaceuticals Inc. (“Mylan” and jointly “Petitioners”) object 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, “’031 patent” means U.S. Patent No. 6,335,031, 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.

Petitioners’ objections are as follows:

### **Exhibit 2058**

Petitioners object to Exhibit 2058 under F.R.E. 901 (lacking authentication) and F.R.E. 802 (hearsay). Petitioners also object to Exhibit 2058 under F.R.E. 106 (completeness), F.R.E. 402 (relevance), and F.R.E. 403 (confusing, misleading) as the document is not, contrary to the assertion in Patent Owners’ Exhibit List 5, a “U.S. Patent No. 4,948,807 Prosecution History,” but instead purports to be a copy of an abandoned application no. 06/835466, to which the ’807 patent claims priority. The application for the ’807 patent (Rosin, Exhibit 1008) was accorded serial number 320,700, according to its face.

To the extent that Patent Owners attempt to rely on Exhibit 2058 or on any testimony from the April 20, 2015 deposition of Dr. Kydonieus relating to Exhibit 2058, Petitioners object under F.R.E. 611 and 37 C.F.R. § 42.53(d)(5)(ii) as being outside the scope of the direct testimony set forth in Dr. Kydonieus' Reply Declaration (Ex. 1031). To the extent that Patent Owners attempt to rely on Exhibit 2058 to rebut any opinions provided by Dr. Kydonieus, Petitioners object to the use of the document as violating the scheduling order (Paper 11), which set forth the timing of Patent Owners' Response and did not provide for a Sur-reply.

### **Exhibit 2059**

Petitioners object to Exhibit 2059 under F.R.E. 802 (hearsay), F.R.E. 901 (lacking authentication), and under F.R.E. 1001 and 1002 (best evidence). Petitioners also object to Exhibit 2059 under F.R.E. 106 (completeness), as the document is incomplete and includes only a select portion of a larger document. Petitioners object to Exhibit 2059 under F.R.E. 402 (relevance) and F.R.E. 403 (confusing, waste of time) because it is not relevant to any issue in this IPR proceeding at least because Patent Owners failed to have an expert explain the significance of the document or how it relates to any issue, opinion or position by any party in this proceeding. To the extent Patent Owners attempt to rely on Exhibit 2059 to show the results of stress testing/degradation pathways, Petitioners

object under 37 C.F.R. § 42.65 and F.R.E. 1006 at least because Patent Owners failed to provide supporting facts and data and did not provide an affidavit providing necessary information. To the extent that Patent Owners attempt to rely on Exhibit 2059 or on any testimony from the April 18, 2015 deposition of Dr. Schöneich relating to Exhibit 2059, Petitioners object under F.R.E. 611 and 37 C.F.R. § 42.53(d)(5)(ii) as being outside the scope of the direct testimony set forth in Dr. Schöneich's Reply Declaration (Ex. 1032). To the extent that Patent Owners attempt to rely on Exhibit 2059 to rebut any opinions provided by Dr. Schöneich, Petitioners object to the use of the document as violating the scheduling order (Paper 11), which set forth the timing of Patent Owners' Response and did not provide for a Sur-reply.

### **Exhibit 2060**

Petitioners object to Exhibit 2060 under F.R.E. 402 (relevance), F.R.E. 403 (unduly prejudicial, confusing, misleading or cumulative), and under F.R.E. 106 (completeness).

To the extent that Patent Owners attempt to rely on Exhibit 2060 or on any testimony from the April 18, 2015 deposition of Dr. Schöneich relating to Exhibit 2060, Petitioners object under F.R.E. 611 and 37 C.F.R. § 42.53(d)(5)(ii) as being outside the scope of the direct testimony set forth in Dr. Schöneich's Reply

Declaration (Ex. 1032).

### **Exhibit 2061**

Petitioners object to Exhibit 2061 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), as it purports to be testimony but is not in affidavit form and is self-serving hearsay by Patent Owners' employee. Petitioners also object to Exhibit 2061 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. Petitioners also object to Exhibit 2061 under 37 C.F.R. § 42.53(a) as an incomplete transcript from a proceeding that did not include Noven or Mylan.

To the extent that Patent Owners attempt to rely on Exhibit 2061 or on any testimony from the April 20, 2015 deposition of Dr. Kydonieus relating to Exhibit 2061, Petitioners object under F.R.E. 611 and 37 C.F.R. § 42.53(d)(5)(ii) as being outside the scope of the direct testimony set forth in Dr. Kydonieus' Reply Declaration (Ex. 1031). To the extent that Patent Owners attempt to rely on Exhibit 2061 to rebut any opinions provided by Dr. Kydonieus, Petitioners object to the use of the document as violating the scheduling order (Paper 11), which set forth the timing of Patent Owners' Response and did not provide for a Sur-reply.

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