

Filed On Behalf Of:

Novartis AG and LTS Lohmann Therapie-Systeme AG

By:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVEN PHARMACEUTICALS INC.,
Petitioner

v.

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

Inter Partes Review No. 2014-00549

U.S. Patent 6,316,023

UNOPPOSED MOTION TO FILE CORRECTED PATENT OWNERS'
RESPONSE, CORRECTED AND SUPPLEMENTAL EXHIBITS, AND
CORRECTED EXHIBIT LIST

Patent Owners Novartis AG and LTS Lohmann Therapie-Systeme AG respectfully move the Board for leave to submit a corrected Patent Owners' Response (Paper 25), corrected Exhibits 2012, 2023, 2035, 2044, 2050, 2051 and supplemental Exhibit 2054, and for leave to submit an amended Patent Owners' Exhibit List 3 as set forth below.

On January 27, 2015, Noven Pharmaceuticals ("Petitioner") served objections pursuant to 37 C.F.R § 42.64(b)(1) to all of Patent Owners' filed exhibits. Petitioner's objections included (i) general evidentiary objections and (ii) specific objections due to clerical and typographical errors addressed herein. On February 10, 2015, pursuant to 37 C.F.R § 42.64(b)(2), Patent Owners provided a list of corrections and supplemental evidence to address certain errors raised in Petitioner's objections. In a communication dated February 18, 2015, Petitioner agreed that the proposed corrections and supplemental evidence cured the defects to which they were addressed but maintained all remaining objections. Patent Owners have provided the corrected and supplemental exhibits and amended Exhibit List 3 to the Petitioner, and Petitioner has stated that it does not oppose this motion.

In addition, after submitting their Patent Owners' Response (Paper 25) on January 20, 2015, Patent Owners noticed that the response inadvertently referenced the prosecution history of related patent 6,335,031 (Exhibit 2029) on pages 21 and

24 rather than the prosecution history of patent 6,316,023 (Exhibit 2028.) In a communication on February 10, 2015 Patent Owners advised Petitioner of this discrepancy and on February 18, 2015 Petitioner confirmed that it would not oppose a motion to correct.

Patent Owners sought permission to file this motion, which was granted in an email from the Board on March 10, 2015.

I. Motion To File Corrected Patent Owners' Response

To facilitate the Board's review of this matter and to cure a clerical error, Patent Owners seek permission to file a corrected Patent Owners' Response (Paper 25) with the following changes:

- Page 21: Change "Ex. 2029 at N0001063" to "Ex. 2028 at N0000914"
- Page 24: Change "Ex. 2029 at N0001083" to "Ex. 2028 at N0000914"

II. Motion To File Corrected And Supplemental Exhibits And Corrected Exhibit List 3

To facilitate the Board's review of this matter, Patent Owners further seek permission to file the following exhibits and amended exhibit list to correct clerical and typographical errors:

Exhibit 2012

To correct the following clerical and typographical errors in paragraph 85 and Appendix A paragraph 1 of Exhibit 2012, Patent Owners provide the Supplemental Declaration of Alexander M. Klibanov, Ph.D., dated February 10,

2015, making the following corrections to Dr. Klibanov's January 20, 2015

Declaration:

- Paragraph 85: Change “(Ex. 2040, USP XX (1979) at 1079; Ex. 2041, USP XXII (1989) at 624.)” to “(Ex. 2040, United States Pharmacopeia and National Formulary (USP 20-NF 15), Rockville, MD: United States Pharmacopeial Convention, 1980 at 624; Ex. 2041, United States Pharmacopeia and National Formulary (USP 22-NF 17), Rockville, MD: United States Pharmacopeial Convention, 1990 at 1079.)”
- Appendix A, Paragraph 1: Change “(Ex. 40, Rosin, col. 4, ll. 21-53.)” to “(Ex. 1008, Rosin, col. 4, ll. 21-53.)”

Exhibits 2023, 2035, 2044 and 2050

To address, in part, Petitioner's objections, Patent Owners provide replacement exhibits 2023, 2035, 2044, and 2050 with associated cover pages.

Patent Owners request permission to file an amended Exhibit List 3 to clarify the entry for Exhibit 2023:

- Change “U.S. Pharmacopeial Convention, Revision Bulletin, Clonidine Transdermal System (Jan. 1, 2011)” to “U.S. Pharmacopeial Convention, Revision Bulletin, Clonidine Transdermal System (Jan. 1, 2011) *incorporated into* United States Pharmacopeia and National Formulary (USP

34-NF 29) Supplement 2, 5407-5410, Rockville, MD: United States Pharmacopeial Convention, 2011”

Exhibits 2040 and 2041

To address, in part, Petitioner’s objections to Exhibits 2040 and 2041, Patent Owners request permission to file an amended Exhibit List 3 with the following corrections:

- The entry for Exhibit 2040 change “The United States Pharmacopeia, 624-625 (20th ed., 1979) (Entry for Physostigmine Salicylate Injection)” to “United States Pharmacopeia and National Formulary (USP 20-NF 15), 624-625, Rockville, MD: United States Pharmacopeial Convention, 1980”
- The entry for Exhibit 2041 change “The United States Pharmacopeia, 1078-1079 (22nd ed., 1989) (Entry for Physostigmine Salicylate Injection)” to “United States Pharmacopeia and National Formulary (USP 22-NF 17), 1078-1079, Rockville, MD: United States Pharmacopeial Convention, 1990”

Exhibit 2047

To address, in part, Petitioner’s objections to Exhibit 2047, Patent Owners provide the Declaration of Lisa Butler (supplemental Exhibit 2054), dated February 10, 2015.

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