On behalf of: Par Pharmaceutical, Inc. *et al.*

Entered: December 5, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC., BRECKENRIDGE PHARMACEUTICAL, INC., AND ROXANE LABORATORIES, INC.
Petitioners

v.

NOVARTIS AG
Patent Owner

Case IPR2016-00084[1]
U.S. Patent No. 5,665,772

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLEY, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

SUPPLEMENTAL DECLARATION OF WILLIAM L. JORGENSEN, PH.D. IN SUPPORT OF PETITIONERS' REPLY IN THE *INTER PARTES* REVIEW OF U.S. PATENT NO. 5,665,772

---

[1] Breckenridge Pharmaceutical, Inc. was joined as a party to this proceeding via a Motion for Joinder in IPR2016-01023; Roxane Laboratories, Inc. was joined as a party via a Motion for Joinder in IPR2016-01102.

CONTENTS

I, William L. Jorgensen, Ph.D. resident of Deep River, Connecticut, hereby declare as follows:

I. INTRODUCTION AND QUALIFICATIONS

1. I am the same William L. Jorgensen, Ph.D. who submitted an opening declaration (Ex. 1003) in support of Par Pharmaceutical, Inc.'s ("Par") petition for the *Inter Partes* Review of U.S. Patent No. 5,665,772 (Ex. 1001, "the '772 Patent"). My qualifications and experience in medicinal and organic chemistry are fully laid out in my opening declaration. (Ex. 1003 ¶¶ 2-9.)

2. I submit this supplemental declaration to respond to certain opinions offered in two declarations submitted by Dr. William Roush (Ex. 2093) and Dr. Alexander Klibanov (Ex. 2092) in support of the Response of Patent Owner Novartis AG ("Novartis") in this proceeding.

3. My work in this matter is being billed at a rate of $600 per hour, with reimbursement for necessary and reasonable expenses. My compensation is not in any way contingent upon the outcome of any *inter partes* review. I have no financial or personal interest in the outcome of this proceeding or any related litigation.

4. In forming my opinions, I have relied on the '772 Patent's claims, disclosure, and file history, on the materials cited in my opening declaration (Ex. 1003), as well as on materials cited in this supplemental declaration, and my own

experience, expertise, and knowledge of the person of ordinary skill in the art in the relevant timeframe.

II. SUMMARY OF OPINIONS REGARDING THE DECLARATIONS OF DR. ROUSH AND DR. KLIBANOV

5. As I stated in my opening declaration, the prior art taught that rapamycin was a prominent compound that generated intense interest in the medicinal chemistry community and that rapamycin had low water solubility that would have motivated a POSA to make modifications to improve its properties. (Ex. 1003 ¶¶ 132-140.) A POSA would have initially modified rapamycin at its hydroxyl groups, because such groups are the easiest and most straightforward to modify, and in particular would have selected C40 as the primary candidate for modification because the prior art taught that of the three hydroxyl groups it was least involved in binding to FKBP-12 and was not implicated in binding to the then-unknown effector protein. (*Id.* ¶¶ 141-145.) A POSA would have sought to add flexible side chains containing polar groups with known water-solubilizing potential as reflected in the teachings of Yalkowsky and Lemke. (*Id.* ¶¶ 146-156.) A POSA, seeking to maximize the probability of achieving a derivative with immunosuppressant activity and increased water solubility, would have started with the smallest substitutions that included flexible side chains and the most water-solubilizing potential. (*Id.* ¶¶ 150-153.) Among the first modifications that a POSA would have been motivated to use would be the 2-hydroxylethoxy group

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.