

By: B. Jefferson Boggs, Esq.  
Matthew L. Fedowitz, Esq.  
Daniel R. Evans, Esq.  
MERCHANT & GOULD P.C.  
1900 Duke Street, Suite 600  
Alexandria, VA 22314  
Main Telephone: (703) 684-2500  
Main Facsimile: (703) 684-2501

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

BRECKENRIDGE PHARMACEUTICAL, INC.  
Petitioner

v.

NOVARTIS AG  
Patent Owner

---

Case No. IPR2016-01103  
Patent No. 5,665,772

---

**REPLY TO PATENT OWNER NOVARTIS'S OPPOSITION TO  
PETITIONER BRECKENRIDGE'S MOTION FOR JOINDER OF ITS  
PETITION ON CLAIM 7**

## TABLE OF CONTENTS

I.	Breckenridge’s Petition Is Not Time-Barred.....	1
II.	Breckenridge Is Not Seeking or Obtaining a Strategic Advantage .....	2
III.	Claim 7 Is Patentably Indistinct .....	4
IV.	Joinder Will Not Unreasonably Expand the Instituted Proceedings .....	5

## **TABLE OF AUTHORITIES**

### **STATUTES**

35 U.S.C. § 315(b) .....1

35 U.S.C. § 315(c) .....1

### **OTHER AUTHORITIES**

37 C.F.R. § 42.122(b) .....1, 3

Petitioner Breckenridge Pharmaceutical, Inc. has agreed (and will agree) to any reasonable request to accommodate joinder of its challenge to claim 7. Novartis steadfastly opposes joining claim 7, going so far as to accuse Breckenridge of making a strategic decision to delay requesting *inter partes* review of claim 7—which is asserted in the district court litigation—in order to somehow improperly manipulate the IPR procedure and gain an unfair advantage. Instead, it is Novartis that seeks to leverage the situation to its strategic advantage and avoid consideration of its patentably-indistinct composition claim in the same proceeding as its compound and method of treatment claims.

#### **I. Breckenridge’s Petition Is Not Time-Barred**

Despite Novartis’s allegation that Breckenridge’s petition is “time-barred”, Breckenridge’s petition accompanying its motion for joinder was timely filed. 35 U.S.C. § 315(b) states the one year deadline for filing a petition does not apply to a request for joinder under § 315(c). Section 315(c) contemplates filing a motion for joinder in an already instituted IPR. *Inter partes* review in IPR2016-00084 was not instituted until April 29, 2016 and Breckenridge filed its petition regarding claim 7 and motion to join on May 26, 2016, which is within one month of the institution date and in compliance with 37 C.F.R. § 42.122(b). IPR2016-00084, Paper 8; IPR2016-01103, Papers 1, 4, and 5.

Breckenridge separately filed its petition and motion for joinder of claim 7 from its petition and joinder motion in IPR2016-01023 (claims 1-3 and 8-10) in order to mirror those petitions currently before the Board that it wished to join.

## **II. Breckenridge Is Not Seeking or Obtaining a Strategic Advantage**

Novartis attempts to misdirect the Board and argue that Breckenridge not challenging claim 7 prior to institution of the Par IPR somehow provided it with a strategic advantage. Paper 10 at 7-9. Novartis’s *post hoc* reasoning—that the obviousness grounds for claim 7 are somehow in tension with those for the compound claims (1-3 and 10) and the treatment claims (8-9)—is merely an attempt to prop up claim 7 in view of prior art that would render it unpatentable. What is more, Novartis’s arguments are simply incorrect and inaccurately characterize both the claims and Breckenridge’s and Par’s petitions.

There is no conflict between Breckenridge’s ground of unpatentability on claim 7 and the instituted grounds in IPR2016-00084. For claims 1-3 and 8-10, Par argued it would be obvious to modify rapamycin at the C40 position to make everolimus. For claim 7, Breckenridge still maintains it would be obvious to modify rapamycin at the C40 position to make everolimus and also asserts it would be obvious to formulate everolimus with a pharmaceutically acceptable carrier in view of the prior art. Novartis mischaracterizes Breckenridge’s position by repeating one of its old arguments suggesting “a POSA did not have to modify

# 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.