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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

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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 parties* 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

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