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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

PETITIONER'S REQUEST FOR REHEARING PURSUANT TO 37 C.F.R. § 42.71

I. Introduction

Breckenridge Pharmaceutical, Inc. ("Petitioner" or "Breckenridge") hereby respectfully requests rehearing of the October 27, 2016 Decision ("Decision") Granting, Granting-In-Part, and Denying Motions for Joinder *35 U.S.C. § 315(c); 37 C.F.R. § 42.122(b)*. In particular, Petitioner requests rehearing of the Board's decision not to grant joinder with regard to claim 7 in U.S. Patent No. 5,665,772 to IPR2016-00084.

Breckenridge is aware that Par Pharmaceutical, Inc. ("Par") is concurrently filing its "Petitioner's Request for Rehearing of The Board's Decision Denying Joinder" in IPR2016-01059 on November 10, 2016. The subject of Par's Request for Rehearing is the same as that of the present Request for Rehearing. Breckenridge requests that to the extent Par's Request for Rehearing is granted, so too should the present Request for Rehearing be granted.

Breckenridge's Request for Rehearing should also be granted on two separate, additional grounds. These include: (1) the Board misapprehending the different nature of Breckenridge's procedural posture when compared to that of Par; and (2) the Board overlooking the fact that it specifically stated that it would issue a decision on the schedules for the five cases involving joinder within a week of June 17, 2016.

II. Applicable Rules

37 C.F.R. § 42.71(d) states:

> (d) Rehearing. A party dissatisfied with a decision may file a single request for rehearing without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply. A request for rehearing does not toll times for taking action. Any request must be filed:
>
> (1) Within 14 days of the entry of a non-final decision or a decision to institute a trial as to at least one ground of unpatentability asserted in the petition; or
>
> (2) Within 30 days of the entry of a final decision or a decision not to institute a trial.

In accordance with 37 C.F.R. § 42.71(d)(1), this Request is being filed within 14 days of the entry of the October 27, 2016 Decision Denying Breckenridge's Motions for Joinder.

III. Requested Relief

Breckenridge respectfully requests reconsideration of the Board's decision not to grant joinder with regard to claim 7 in U.S. Patent No. 5,665,772 to IPR2016-00084. Petitioner submits that the Board recognized that "[i]nstitution of trial as to claim 7 on the Par II, Breckenridge II, and Roxane Petitions is warranted." (IPR2016-01103, October 27, 2016 Decision (Paper 18) at 12.) However, the Board denied joinder on bases germane to Par and not Breckenridge and despite telling Breckenridge that it would issue a schedule within one week of the June 17, 2016 teleconference with the Board that would have reduced any potential complication with the existing proceeding.

IV. Argument

In its Decision, the Board stated that "[t]hough we recognize the arguments in favor of joining the claim 7 ground to the pending *inter partes* review, two factors weigh strongly against such joinder." *Id.* at 15. The first factor the Board identified was "that no explanation has been given for why claim 7 – the validity of which, according to the Petitioners, is so closely related to claim 1, 8, and 9 – was not raised in the *Par I Petition*." *Id.* (emphasis added) The second factor identified was that the Board "consider[ed] the effect joinder would have on the already-instituted trial." *Id.* at 17. Stating that "[t]hough the statute provides that the one-year deadline for rendering a final decision may be adjusted in the case of

joinder…, we are hesitant to do so in cases where joinder will unduly complicate the existing proceeding…" *Id.*

For the Board to base its decision to deny joinder to Breckenridge on these two factors demonstrates that it misapprehended and overlooked two critical issues. These errors unfairly prejudice Breckenridge.

Regarding the first factor, Breckenridge should not be prejudiced for Par failing to provide an explanation why claim 7 was not raised in the "Par I Petition." Breckenridge is neither related to nor a real party-in-interest of Par so there is no need for Breckenridge to provide any explanation regarding the Par I Petition. In fact, Breckenridge could never resolve the issue as to claim 7 because at no time did it have the opportunity to include it in an original petition addressing the patentability of the claims in the '772 patent. As a result, this issue is strictly unique to Par. Breckenridge's motion for joinder should be considered separately. Indeed, the Board recognized that institution of trial as to claim 7 was warranted based on Breckenridge' Petition. *Id*. at 12; IPR2016-01103, Petition, Paper 1. Because of this and in keeping with the Office's anticipation that "joinder will be allowed as of right," the second step in the analysis would include joining Breckenridge's claim 7 petition to that of IPR2016-00084. 157 Cong. Rec. S1376 (Sen. Kyl). The Board, however, erred by applying its basis for denying Par's

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