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Sent: Friday, October 27, 2017 4:29 PM
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Cc: Kallas,Nicholas <NKallas@fchs.com>; Fishwick, Laura <LFishwick@FCHS.COM>; #ZortressAfinitorIPR <ZortressAfinitorIPR@fchs.com>; Jeffrey Blake <JBlake@MerchantGould.com>; Melissa M. Hayworth <MHayworth@merchantgould.com>
Subject: RE: IPR2017-01592 -- Request for permission to file reply to POPR pursuant to 37 C.F.R. § 42.108(c).

Dear PTAB,

Thank you for your email dated October 24, 2017, inviting Petitioner to renew its request for leave to file a reply to Patent Owner's Preliminary Response ("POPR"). In response to that email, Breckenridge conferred with Patent Owner Novartis, who confirmed its opposition to Breckenridge's request to file a reply. Should the Board wish to have a call to discuss Breckenridge's request, the parties are available on November 8, 2017 (1:00 PM to 5:00 PM ET) and November 9, 2017 (2:00 PM to 5:00 PM ET).

As stated previously, I am counsel for Petitioner Breckenridge Pharmaceutical, Inc. ("Breckenridge") in IPR2017-01592. Breckenridge submits this email to seek leave to file a reply to the POPR pursuant to 37 C.F.R. § 42.108(c). Breckenridge submits that good cause exists for a focused reply because the POPR raises a number of issues that could not have been reasonably anticipated when the Petition was submitted. Further, the POPR states factual and legal inaccuracies, and in certain places omits evidence that directly contradicts Patent Owner's arguments. Principles of due process and fairness require that Breckenridge be allowed to respond to the new issues raised in the POPR, correct the factual and legal inaccuracies, and present the Board with the evidence relevant to Patent Owner's positions that Patent Owner chose to omit.

The proposed subject matter for Breckenridge's reply includes the following:

1. Priority Date for the '131 Patent - Breckenridge established in its Petition that U.S. Patent No. 8,410,131 ("the '131 Patent") is not entitled to a priority date before February 18, 2002, because the priority documents were lacking in their written description. (Pet. at 11-14.) Patent Owner, which has the burden to establish the priority date, challenges the priority date issues by arguing what the '131 Patent and prosecution history teach. (POPR at 10-21.) Patent Owner, however, omits evidence that an Examiner of an application for a European counterpart to the '131 Patent directly contradicted these new positions from Patent Owner. Due process and

fairness dictate that Breckenridge be allowed to submit the contradictory evidence that Patent Owner omitted from its argument. Moreover, Breckenridge should be allowed to demonstrate Patent Owner's misleading citations to the disclosure of the priority documents.

2. The Wasik Prior Art Reference – Patent Owner argues in the POPR that the Wasik prior art reference in Grounds 1-2 should not be relied upon because it discloses information only about treatment of lymphatic tumors, not solid excretory system tumors. (POPR at 21-33.) Patent Owner again omits relevant evidence that directly undermines its position. For example, Patent Owner chose not to disclose that multiple Examiners of the application for a European counterpart to the '131 Patent concluded that the disclosure of Wasik applied to solid excretory system tumors, not just lymphatic tumors. Further, Patent Owner fails to mention that statements Patent Owner relies upon from the prosecution of Wasik were made in 2007 – five years after the February 18, 2002 filing date for the '131 patent. (See POPR at 25.) In addition, Patent Owner incorrectly characterizes its own admission from the prosecution of the '131 Patent that the Cottens WO '010 patent is not "limited to solid tumors." (POPR at 28-29.) As Breckenridge could not anticipate that Patent Owner would fail to disclose evidence directly contrary to its arguments in the POPR (or would misrepresent the evidence), Breckenridge now seeks an opportunity to present such evidence in a reply to the POPR.

3. The Anti-Tumor Activity of Everolimus – The POPR raises a number of arguments that there was no motivation to select or combine the prior art references relied upon in the Petition because there were other prior art therapies available for excretory cancers and some of the prior art references discuss immunosuppression. (POPR at 33-35.) First, Patent Owner is legally incorrect in claiming that a patent challenger must establish that the claimed compound was “preferred” over other potential therapeutic agents in order to establish the obviousness of claims to a method of using a known compound. Second, Patent Owner’s immunosuppressant argument directly ignores the fact that the prior art disclosed that the immunosuppressant drugs (rapamycin and everolimus) exhibited anti-tumor activity and disclosed inhibiting the growth of advanced solid excretory system tumors. Patent Owner ignores these points, and Breckenridge should be allowed to clarify any inaccuracies about the purpose of the prior art references.

4. The Luan Prior Art Reference – The POPR raises two arguments relative to the prior art Luan reference cited in Grounds 3 and 5 that Petitioner could not have reasonably anticipated. First, Patent Owner takes issue with documents submitted in Ex. 1028 to authenticate the Luan reference as prior art. (POPR at 46-49.) Patent Owner characterizes these authentication documents as hearsay, but that is incorrect. The

documents are submitted merely for authentication support of information on the face of the Luan reference showing it to be prior art. Second, Patent Owner alleges without proof that Breckenridge "made alterations" to an email submitted as authentication support that Luan is prior art. (POPR at 48.) While Breckenridge had no way to know Patent Owner would make this "alteration" allegation, Breckenridge should be allowed to show that the Patent Owner's allegation is plainly wrong.

In view of the foregoing, therefore, Breckenridge respectfully requests leave to file a reply to the POPR pursuant to 37 C.F.R. § 42.108(c).

Respectfully submitted,

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