From: Robert Counihan

To: <u>Trials</u>

Cc: UCB-Xyzal; Malik, Jitty; Soderstrom, Lance A.; Janusz, Joe; Pacchioli, Alissa M.; Jim Trainor; Erica Sutter

 Subject:
 UCB v. Apotex - IPR2019-00400

 Date:
 Wednesday, July 24, 2019 4:36:53 PM

## Confidential

Your Honors:

I am counsel for Patent Owner UCB Biopharma Sprl in IPR2019-00400 involving U.S. Patent No. 8,633,194.

In its July 15, 2019 Decision on Institution of *Inter Partes* Review of U.S. Patent No. 8,633,194 B2 (IPR2019-00400, Paper 17), the Board requested clarification as to why only UCB entities were named as the real parties-in-interest when Petitioner's tentative FDA approval letter and the current Orange Book listing for various Xyzal® formulations lists Sanofi Aventis US LLC as the NDA holder. (Paper 17 at 2, fn. 1).

Patent Owner respectfully clarifies that the named party, UCB Biopharma Sprl, is the assignee of the '194 patent and party to the district court litigation involving the '194 patent (*UCB, Inc. v. Apotex Inc.*, No. 0-18-cv-60846 (S.D. Fla.)). The other UCB entities are identified as real parties-in-interest because UCB S.A. is the ultimate parent company of UCB Biopharma Sprl, UCB Pharma S.A. and UCB Manufacturing Inc. both own shares of UCB Biopharma Sprl, and UCB, Inc. is the second plaintiff in the '194 district court litigation.

With respect to Sanofi Aventis, while Sanofi is listed as the NDA holde	er for various Xyzal <sup>®</sup>
formulations, Sanofi is	. Accordingly, Patent Owner
understands that Sanofi is not a real party-in-interest to this matter.	

Patent Owner is available to provide further clarification to the Board if necessary.

Counsel for Petitioner Apotex has been copied on this email.

Regards, Robert Counihan

## **ROBERT COUNIHAN**

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Admitted to practice only in New York.

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