

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BRECKENRIDGE PHARMACEUTICAL, INC.,

Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Patent Owner.

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Case IPR2017-01592

Patent No. 8,410,131

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**DECLARATION IN SUPPORT OF PATENT OWNER NOVARTIS'S  
MOTION FOR *PRO HAC VICE* ADMISSION OF CHRISTINA SCHWARZ  
UNDER 37 C.F.R. § 42.10**

NOVARTIS EXHIBIT 2020  
Breckenridge v Novartis, IPR 2017-01592

1. I, Christina Schwarz, am more than twenty-one years of age, am competent to present this declaration, and have personal knowledge of the facts set forth herein.

2. This declaration is given in support of Patent Owner Novartis's Motion for *Pro Hac Vice* Admission.

3. I am a partner at the law firm of Fitzpatrick, Cella, Harper & Scinto, in the firm's New York office.

4. I have been a patent litigation attorney for more than nine years. I have been litigating patent cases for this entire time period and have been involved in numerous cases involving patent validity and infringement, at both the District Court and the Federal Circuit. I have also been involved in *inter partes* review proceedings and patent interference proceedings before the Board. A significant portion of my work has involved biological and chemical arts, with particular emphasis on pharmaceuticals. I am, therefore, an experienced litigating attorney.

5. I am a member in good standing of the State Bar of New York and the Province of Ontario. I have never been suspended or disbarred from practice before any court or administrative body.

6. No court or administrative body has ever denied my application for admission to practice before it.

7. No court or administrative body has ever imposed sanctions or contempt citations on me.

8. I have read and will comply with the Office Patent Trial Practice Guide and the Board's Rules of Practice for Trials set forth in part 42 of 37 C.F.R.

9. I understand that I will be subject to the Office's Rules of Professional Conduct set forth in 37 C.F.R. §§ 11.101 *et seq.* and disciplinary jurisdiction under 37 C.F.R. § 11.19(a).

10. I have applied to appear *pro hac vice* in two other proceedings before the Office in the last three (3) years: IPR2016-00084 and IPR2016-01096.

11. I have an established familiarity with the subject matter at issue in this proceeding. I have been involved consistently and substantively in the instant matter since its inception in June 2017. I have read in detail and understand the Petition filed by Petitioner and the challenged patent, U.S. Patent 8,410,131 ("the '131 patent"). I have also reviewed in detail all the exhibits relied upon by Petitioner in this proceeding, including Ex. 1002 (Wasik *et al.*, PCT Published App. No. WO 01/51049 A1); Ex. 1003 (Navarro *et al.*, PCT Published App. No. WO 00/33878 A2); Ex. 1004 (Crowe *et al.*, "Absorption and Intestinal Metabolism of SDZ-RAD and Rapamycin in Rats," *Drug Metab. Disp*, 27(5): 627-632 (1999)); Ex. 1005 (Luan *et al.*, "Sirolimus Prevents Tumor Progression: mTOR Targeting

for the Inhibition of Neoplastic Progression,” *Am. J. Transplant.* 1 Suppl 1, 243 (Abstr. No. 428) (2001)); Ex. 1006 (Hidalgo *et al.*, “The Rapamycin-sensitive Signal Transduction Pathway as a Target for Cancer Therapy,” *Oncogene* 19(56): 6680-6686 (2000)); Ex. 1007 (Alexandre *et al.*, “CCI-779, A new Rapamycin Analog, Has Antitumor Activity at Doses Including Only Mild Cutaneous Effects and Mucositis: Early Results of an Ongoing Phase I Study,” *Clin. Cancer Res. Suppl.* 5: 3730s, Abstr. No. 7 (1999)); Ex. 1008 (Schuler *et al.*, “SDZ RAD, A New Rapamycin Derivative,” *Transplantation* 64(1): 36-42 (1997)); Ex. 1009 (Neumayer *et al.*, “Entry-into-human Study with the Novel Immunosuppressant SDZ RAD in Stable Renal Transplant Patients,” *Br. J. Clin. Pharmacol.* 48(5): 694-703 (1999)).

12. I have engaged in extensive strategic and substantive discussions regarding this proceeding with Nicholas N. Kallas, who is the lead counsel for Patent Owner in this proceeding and a registered practitioner (Reg. No. 31,530).

13. Therefore, I have an established familiarity with the subject matter at issue in this proceeding.

14. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge

that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the '131 patent.

Dated: October 30, 2017

  
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Christina Schwarz