

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BRECKENRIDGE PHARMACEUTICAL, INC.

Petitioner

v.

NOVARTIS PHARMACEUTICALS CORPORATION

Patent Owner

Case IPR2017-01592

U.S. Patent No. 8,410,131

DECLARATION OF DANIEL R. EVANS

I, Daniel R. Evans, declare as follows:

1. I am a partner at Merchant & Gould, P.C. I am lead counsel for Breckenridge Pharmaceutical, Inc. in the above-styled *Inter Partes* Review (IPR2017-01592).

2. As part of the preparation of the petition for *inter partes* review, I researched and located certain prior art references identified in the petition, including an abstract entitled "Sirolimus Prevents Tumor Progression: mTOR Targeting For The Inhibition Of Neoplastic Progression," which was authored by Fulung Luan and other authors (the "Luan Abstract").

3. I identified the Luan Abstract and its date of publication from a review of other prior art references. One of those references was an article entitled "Inhibitors of mTOR and FTY 720" by D. Morel (hereinafter referred to as "Morel"). Morel, which was originally published in French in the September 1, 2001 issue of *La Press Médicale*. I commissioned an English translation of Morel as part of my prior art search in preparation of Breckenridge's IPR petition. A copy of both the French version and English translation of Morel is attached hereto as Exhibit 1113. Therein, Morel includes reports of a meeting referred as "Transplant 2001" that took place in Chicago, Illinois on May 11-16, 2001. It can be seen that Morel was publicly available at least as early as October 29, 2001. (*See Ex. 1113, p. 9.*)

4. I noticed that Morel summarizes several sessions of the Transplant 2001 meeting with citations to the Supplement 1 issue of the 2001 American Journal

of Transplantation ("AJT") publication. (See Ex. 1113, p. 2.) As explained below, the AJT publication is the official journal of the American Society of Transplantation ("AST") and the American Society of Transplant Surgeons ("ASTS"). I also noticed that Morel summarizes an "exciting abstract" that relates to "the ability of sirolimus to inhibit tumor proliferation and metastatic diffusion of a renal adenocarcinoma in the mouse, as compared to a control, unlike the highly stimulative effect of cyclosporine on tumor diffusion." (See Ex. 1113, p. 2.) I considered the "exciting abstract" relevant to Breckenridge's petition.

5. I decided to research the materials that were presented at Transplant 2001. From online research, I located a "Program Book" for the Transplant 2001 conference. My experience attending conferences such as these is that these Program Books are compilations of information to be presented at conferences such as Transplant 2001. The Program Books are provided to conference attendees at the conference. A copy of the "Transplant 2001 Program Book" available online is attached as Exhibit 1114 to this declaration.

6. The Transplant 2001 Program Book states that the Transplant 2001 conference was organized by the AST and the ASTS, and was held in Chicago, Illinois on May 11-16, 2001. (See Ex. 1114, pp. 6, 15.) The Transplant 2001 Program Book included, among other things, copies of abstracts presented in "plenary, concurrent and poster sessions" that took place at Transplant 2001. (See Ex. 1114,

p. 7.) As pages 6-7 of the Transplant 2001 Program Book state under the heading
Abstracts:

All oral abstract presentations listed in the program section have been assigned a chronological program number. This number corresponds with the number of the abstract printed in this supplement. Poster presentations will be held in the River Exhibition Hall. All poster presentations have been assigned a chronological program number for reference when locating your printed abstract. Board numbers for poster presentations are identified with a P before the number. Please refer to the program for the appropriate board number when locating a poster for viewing.

* * *

All accepted abstracts are published in this official TRANSPLANT 2001 program book, a supplement to the new joint AST/ASTS journal, American Journal of Transplantation (AJT). All abstracts selected for presentation and the final program are available on-line through the TRANSPLANT 2001 website, www.transplant2001.org.

(See Ex. 1114, pp. 6, 7.)

7. I reviewed the Transplant 2001 Program Book after I located it. As part of that review, I discovered the Luan Abstract (Abstract# 428) on page 243 of the Transplant 2001 Program Book. (See Ex. 1114, p. 243.) It is this copy of the Luan Abstract from the Transplant 2001 Program Book that was submitted as page 001 in Ex. 1005 to Breckenridge's IPR petition. I also discovered that pages 75-77 of the Transplant 2001 Program Book show the schedule for the presentations at a plenary session of Transplant 2001 on Monday, May 14, 2001. (See Ex. 1114, pp. 75-77.) Page 77 of the Transplant 2001 Program Book states that the Luan Abstract was presented at a Joint Plenary Session in the Sheraton Chicago Ballroom at 10:30am on May 14, 2001. (See Ex. 1114, p. 071; see also Ex. 1010, p. 96 (¶190).) Copies of pages 75-77 of the Transplant 2001 Program Book were submitted as pages 007-009 in Ex. 1005 to Breckenridge's IPR petition.

8. After it was determined that Luan would be submitted as part of the grounds in Breckenridge's IPR petition, I contacted Mr. Terrence L. Stokke of E.L.F. Research Services LLC ("ELF") in St. Paul, Minnesota. ELF provides document research services. I asked Mr. Stokke to help confirm that the Transplant 2001 Program Book was a publication that was publicly available in May 2001.

9. Mr. Stokke originally provided me with a copy of the Luan Abstract with a date stamp of November 7, 2001. (See Ex. 1115.) Therein, it can be seen that the AJT publication is the official journal of the AST and ASTS. (See Ex. 1115, p. 1.) Subsequently, I conducted an online search to determine if the Luan Abstract had

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