

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

Patent No. 8,410,131

EXPERT DECLARATION OF DR. HOWARD A. BURRIS, III

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I. Introduction

1. Challenged claims 1-3 and 5-9 of U.S. Patent No. 8,410,131 (“the ’131 Patent”) relate to “[a] method for inhibiting growth of solid excretory system tumors in a subject, said method consisting of administering to said subject a therapeutically effective amount of [everolimus].”

2. At this preliminary stage of the proceedings, I have been asked by counsel for Novartis Pharmaceuticals Corporation (“Novartis”) to provide my opinion on six issues: (1) the construction of certain claim terms in the ’131 Patent; (2) whether application GB 0104072.4 (“the GB ’072 application”) reasonably conveys to a person of ordinary skill in the art (“POSA”) that the inventors had possession of the claimed methods directed to “solid excretory system tumors, and “advanced solid excretory system tumor[s],” and “kidney tumor[s]” as of February 19, 2001 as those terms would be understood in the context of the ’131 Patent; (3) whether Wasik disclosed, taught or suggested the claim elements “solid excretory system tumors,” “advanced solid excretory system tumor[s],” “kidney tumor[s],” and inhibiting growth of “advanced solid excretory system tumor[s]”; (4) whether a POSA would have been motivated to select everolimus to treat advanced renal cell carcinoma (“RCC”) in February 2001; (5) whether a POSA would have been motivated to combine the everolimus and rapamycin references in Ground 3; and

(6) whether a POSA would have been motivated to combine the temsirolimus and everolimus references in Ground 4 or Ground 5.

3. As to the first issue, in the context of the '131 Patent, a POSA would have understood the meaning of the claim terms below as follows:

- “solid excretory system tumors” meant “tumors and/or metastases other than tumors and/or metastases of the blood or lymphatic system, which arise from the cells of the urinary excretory system”;
- “advanced solid excretory system tumors” meant “locally advanced or metastatic tumors, other than tumors and/or metastases of the blood or lymphatic system, which arise from the cells of the urinary excretory system”; and
- “kidney tumor” meant “a tumor and/or metastasis, other than a tumor and/or metastasis of the blood or lymphatic system, which arises from the cells of the kidney.”

4. As to the second issue, the GB '072 application contains a written description that reasonably conveys to a POSA that the inventors had possession of the claimed methods directed to “solid excretory system tumors,” “advanced solid excretory system tumor[s],” and “kidney tumor[s]” as of February 19, 2001 as those terms would be understood in the context of the '131 Patent.

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