

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner,

v.

AGIOS PHARMACEUTICALS, INC.,
Patent Owner.

IPR2026-00351
Patent No. 11,878,049

DECLARATION OF THEODORE JAMES WASHBURN JR.

I, Theodore James Washburn Jr., hereby declare as follows.

1. I am the Vice President, Controller at Agios Pharmaceuticals, Inc. (“Agios”), and I have personal knowledge of the facts set forth in this declaration. If called as a witness, I could and would testify competently thereto.

2. Agios is sponsor of New Drug Application No. 216196 for PYRUKYND[®] and AQVESME[™]. The active ingredient in both PYRUKYND[®] and AQVESME[™] is mitapivat, a molecule that activates the pyruvate kinase enzyme, which plays a critical role in red blood cell energy production and overall health.

3. Agios is a Delaware corporation with its principal place of business in Cambridge, Massachusetts.

4. On July 24, 2026, I was informed by a representative from Agios’s Human Resources department that Agios’s current active employee headcount was 509 employees as of that date, all but three of whom are located in the United States.

5. From 2013 to 2025, Agios spent at least approximately six hundred eighty-eight million dollars (\$688,000,000) to support the research and development of mitapivat, including planning and implementing multiple clinical trials that led to the Food & Drug Administration’s approval of PYRUKYND[®] and AQVESME[™]. Agios continues to invest in the post-approval development of mitapivat.

6. In addition to the clinical trials that were instituted and completed to support the development and approval of mitapivat, Agios also conducted a clinical trial to develop a safe and effective dosing regimen for PYRUKYND[®] and AQVESME[™] patients who are concomitantly taking a moderate inducer of cytochrome P450 enzyme 3A4/5. In doing so, Agios spent approximately [REDACTED] [REDACTED] conducting the Phase I trial NCT03991312. This trial included 28 patients, for an approximate per patient investment of [REDACTED].

7. From 2021 to 2025, Agios spent approximately [REDACTED] [REDACTED] to support the marketing and sale of PYRUKYND[®] and AQVESME[™].

Declaration of Theodore J. Washburn Jr.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on July 24, 2026, at Easton, MA.



Theodore James Washburn Jr.