

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

UNITED THERAPEUTICS CORPORATION,
Petitioner,

v.

ACTELION PHARMACEUTICALS, LTD.,
Patent Owner.

Case IPR2025-01139
U.S. Patent No. 8,268,847

**DECLARATION OF RAVI PATEL IN SUPPORT OF
PETITIONER'S RESPONSE TO PATENT OWNER'S
REQUEST FOR DISCRETIONARY DENIAL**

DECLARATION OF RAVI PATEL

I, Ravi Patel, declare as follows:

1. I have been employed by UTC since 2016. Currently, I am Senior VP, Global Patient Safety and GxP Audits & Compliance at United Therapeutics Corporation (“UTC”), a position I have held since March 2021. In that capacity, I am responsible for strategic and leadership responsibility over all aspects of pharmacovigilance (including adverse events and product complaints) across development and commercial assets and auditing and compliance oversight across all areas of GxP.

2. I submit this declaration in support of UTC’s Response to the request for discretionary denial by Patent Owner Actelion Pharmaceuticals Ltd (“Patent Owner” or “Actelion”). This declaration is made on my personal knowledge and belief, and I could and would testify competently as to the contents if called as a witness.

3. Based on my time and roles at UTC, I am familiar with UTC’s currently marketed pulmonary hypertension products and the products in its pipeline.

4. To date, UTC has not marketed or filed an application with FDA seeking approval to market any product containing macitentan. UTC does not have any macitentan monotherapy products.

5. UTC is currently developing ralinepag, a next-generation, once-daily,

oral, selective, and potent prostacyclin receptor agonist for the treatment of PAH. Enrollment in a phase 3 study, ADVANCE OUTCOMES, is complete and data is expected in 2026.

6. Assuming the ADVANCE OUTCOMES study is successful, UTC plans to develop an oral triple-combination therapy consisting of ralinepag, an endothelin receptor antagonist, and a PDE-5 inhibitor. In approximately April 2024, UTC commenced development activities on a triple combination product, which included API procurement to begin research and development and manufacturing development related activities. I am not aware of any products containing macitentan in research or development at UTC before April 2024.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct and that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.



Ravi Patel

01-Oct-2025
Date