

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

Inter Partes Review No.: IPR2021-00880

U.S. Patent No. 9,669,069 B2

Filed: December 17, 2015

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Inventor: George D. Yancopoulos

Title: USE OF A VEGF ANTAGONIST TO TREAT
ANGIOGENIC EYE DISORDERS

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 9,669,069 B2**

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Cases

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