

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner.

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IPR2021-00881  
Patent 9,254,338 B2

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Before ERICA A. FRANKLIN, JOHN G. NEW, and  
SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION  
Granting Institution of *Inter Partes* Review  
35 U.S.C. § 314

## I. INTRODUCTION

Mylan Pharmaceuticals, Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1, 3–11, 13, 14, 16–24, and 26 of U.S. Patent No. 9,254,338 B2 (Ex. 1001, “the ’338 patent”). Paper 1 (“Petition” or “Pet.”). Regeneron Pharmaceuticals, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 10 (“Prelim. Resp.”). With our authorization, Paper 13, Petitioner filed a Reply to the Preliminary Response, and Patent Owner filed a Sur-reply to address further issues involving 35 U.S.C. § 325(d). Paper 16 (“Reply”); Paper 19 (“Sur-reply”).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314 (2018). Upon considering the parties’ arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of claims 1, 3–11, 13, 14, 16–24, and 26 of the ’338 patent.

### A. *Real Parties in Interest*

Petitioner identifies itself, Viatrix Inc., Mylan Inc., Momenta Pharmaceuticals, Inc., Janssen Research & Development LLC, and Johnson & Johnson as the real parties-in-interest. Pet. 3, Paper 18 (Petitioner’s Amended Mandatory Notices). Patent Owner identifies itself as the real party-in-interest. Paper 5, 2.

### B. *Related Proceedings*

Petitioner and Patent Owner identify *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00880 (PTAB May 5, 2021) (“the -880 petition”) as a related matter. Pet. 3; Paper 5, 2. The -880 petition challenges claims of U.S. Patent No. 9,669,069 B2 (“the ’069 patent”). The parties further identify *Chengdu Kanghong Biotechnol. Co. v. Regeneron*

*Pharms., Inc.*, PGR2021-00035 (petition dismissed and proceeding terminated, Paper 8 (PTAB June 25, 2021)) challenging the claims of U.S. Patent No. 10,828,345 B2 (“the ’345 patent”), which is related to the ’338 patent and the ’069 patent. Pet. 4; Paper 5, 2.

Petitioner identifies additional patents and patent applications that claim priority to the ’338 patent, namely: U.S. Patent Nos. 10,130,681 B2, 10,857,205 B2, 10,828,345 B2, and 10,888,601 B2; and U.S. Application Serial Nos. 17/072,417, 17/112,063, and 17/112,404. Pet. 4.

### C. *The ’338 Patent*

The ’338 patent relates to methods for treating angiogenic eye disorders. Ex. 1001, 1:63–64. Angiogenic eye disorders include age-related macular degeneration (“AMD”) and diabetic macular edema (“DME”). *Id.* at 1:24–34. According to the Specification, “[r]elease of vascular endothelial growth factor (VEGF) contributes to increased vascular permeability in the eye and inappropriate new vessel growth. Thus, inhibiting the angiogenic-promoting properties of VEGF appears to be an effective strategy for treating angiogenic eye disorders.” *Id.* at 1:44–48.

The Specification describes inhibiting the angiogenic-promoting properties of VEGF by administering a VEGF antagonist. *Id.* at 4:37–42. VEGF antagonists may include “VEGF receptor-based chimeric molecule(s), (also referred to herein as a ‘VEGF-Trap’ or ‘VEGFT’). An exemplary VEGF antagonist . . . is a multimeric VEGF-binding protein comprising two or more VEGF receptor-based chimeric molecules referred to herein as ‘VEGFR1R2-Fc $\Delta$ C1(a)’ or ‘aflibercept.’” *Id.* at 2:30–37. “VEGFR1R2-Fc $\Delta$ C1(a) comprises three components: (1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2; (2) a VEGFR2 component comprising amino acids 130 to 231 of SEQ ID NO:2;

and (3) a multimerization component [] comprising amino acids 232 to 457 of SEQ ID NO:2.” *Id.* at 4:58–5:3 (citing U.S. Patent No. 7,396,664 B2).

The Specification discloses that, despite the known methods for treating eye disorders using VEGF antagonists, “there remains a need in the art for new administration regimens for angiogenic eye disorders, especially those which allow for less frequent dosing while maintaining a high level of efficacy.” *Id.* at 1:53–61. The Specification discloses that

[t]he present inventors have surprisingly discovered that beneficial therapeutic effects can be achieved in patients suffering from angiogenic eye disorders by administering a VEGF antagonist to a patient at a frequency of once every 8 or more weeks, especially when such doses are preceded by about three doses administered to the patient at a frequency of about 2 to 4 weeks.

*Id.* at 2:3–10. The Specification describes this dosing regimen as sequentially administering initial, secondary, and tertiary doses. *See id.* at 1:62–2:3. The Specification refers to “sequentially administering” as “each dose of VEGF antagonist is administered to the patient at a different point in time, e.g., on different days separated by a predetermined interval (e.g., hours, days, weeks or months).” *Id.* at 3:22–26. The Specification refers to the “initial dose” as “the dose which is administered at the beginning of the treatment regimen;” the “secondary doses” as “the doses which are administered after the initial dose;” and the “tertiary doses” as “the doses which are administered after the secondary doses.” *Id.* at 3:31–38.

#### *D. Illustrative Claims*

Petitioner challenges claims 1, 3–11, 13, 14, 16–24, and 26 of the ’338 patent. Claims 1 and 14, the only independent claims, are set forth below and are illustrative of the claimed subject matter.

1. A method for treating an angiogenic eye disorder in a patient, said method comprising sequentially administering to the patient a single initial dose of a VEGF antagonist, followed by one or more secondary doses of the VEGF antagonist, followed by one or more tertiary doses of the VEGF antagonist;

wherein each secondary dose is administered 2 to 4 weeks after the immediately preceding dose; and

wherein each tertiary dose is administered at least 8 weeks after the immediately preceding dose;

wherein the VEGF antagonist is a VEGF receptor-based chimeric molecule comprising (1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2; (2) a VEGFR2 component comprising amino acids 130–231 of SEQ ID NO:2; and (3) a multimerization component comprising amino acids 232–457 of SEQ ID NO:2.

Ex. 1001, 23:2–18.

14. A method for treating an angiogenic eye disorder in a patient, said method comprising sequentially administering to the patient a single initial dose of a VEGF antagonist, followed by one or more secondary doses of the VEGF antagonist, followed by one or more tertiary doses of the VEGF antagonist;

wherein each secondary dose is administered 2 to 4 weeks after the immediately preceding dose; and

wherein each tertiary dose is administered at least 8 weeks after the immediately preceding dose;

wherein the VEGF antagonist is a VEGF receptor-based chimeric molecule comprising VEGFR1R2-Fc $\Delta$ C1(a) encoded by the nucleic acid sequence of SEQ ID NO:1.

*Id.* at 24:2–15.

*E. Asserted Grounds of Unpatentability*

Petitioner asserts that claims 1, 3–11, 13, 14, 16–24, and 26 are unpatentable on the following grounds:

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