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Paper 21
Date: November 10, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2021-00881
Patent 9,254,338 B2

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, Viatris 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-FcΔC1(a)' or 'aflibercept.'" *Id.* at 2:30–37. "VEGFR1R2-FcΔC1(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 232–457of 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-FcΔC1(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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