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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.

IPR2021-00880
Patent 9,669,069 B2

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

NEW, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner Mylan Pharmaceuticals Inc. ("Petitioner") has filed a Petition (Paper 1, "Pet.") seeking *inter partes* review of claim 1 and 8–12 of US Patent 9,669,069 B2 (Ex. 1001, the "'069 patent"). Patent Owner Regeneron Pharmaceuticals, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 10 ("Prelim. Resp."). With our authorization (*see* Paper 13), Petitioner filed a Reply to the Preliminary Response (Paper 16 ("Reply")), and Patent Owner filed a Sur-Reply. Paper 19 ("Sur-Reply").

Under 35 U.S.C. § 314, the Board "may not authorize an *inter partes* review to be instituted unless … the information presented in the petition … and any response … shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the Petition, Preliminary Response, Reply, Sur-Reply, and the evidence of record, we determine that the evidence presented demonstrates a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of at least one challenged claim of the '069 patent.

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies Viatris Inc., Mylan Inc., Mylan Pharmaceuticals Inc., Momenta Pharmaceuticals, Inc., Janssen Research & Development LLC, and Johnson & Johnson as the real parties-in-interest. Paper 18. Patent Owner identifies Regeneron Pharmaceuticals, Inc. as the real party-in-interest. Paper 5, 2.

B. Related Matters

Petitioner and Patent Owner identify *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00881 (PTAB May 5, 2021) (the "-881 petition") as a related matter. Pet. 4; Paper 5, 2. The -881 petition challenges claims of U.S. Patent No. 9,254,338 B2 ("the '338 patent"). The parties further identify *Chengdu Kanghong Biotechnol. Co. v. Regeneron Pharms., Inc.*, PGR2021-00035 (PTAB Jan. 7, 2021) challenging the claims of U.S. Patent No. 10,828,345 B2 ("the '345 patent"), which is related to the '069 patent and the '338 patent. Pet. 5. This latter proceeding has been terminated. *See Chengdu*, PGR2021-00035, Paper 8.

Petitioner also identifies additional patents and patent applications that claim priority to the '069 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. 5.

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1 and 8–12 of the '069 patent are unpatentable, based upon the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
I	1, 9–12	102	Dixon[1]

[1] J.A. Dixon et al., *VEGF Trap-Eye for the Treatment of Neovascular Age-Related Macular Degeneration*, 18(10) EXPERT OPIN. INVESTIG. DRUGS 1573–80(2009) ("Dixon") Ex. 1006.

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
II	1, 9–12	102	Heier 2009[2]
III	1, 9–12	102	Regeneron I[3]
IV	1, 8–12	102 and/or 103	Dixon
V	1, 8–12	103	Heier-2009 and Mitchell[4] or Dixon, and optionally, Papadopolous[5] or Dix[6]

Petitioner also relies upon the Declarations of Dr. Thomas A. Albini (the "Albini Declaration," Ex. 1002) and Dr. Mary Gerritsen (the "Gerritsen Declaration," Ex. 1003).

[2] J.S. Heier, *Intravitreal VEGF Trap for AMD: An Update*, October 2009 RETINA TODAY 44–45 (2009) ("Heier 2009") Ex. 1020.

[3] Press Release, *Bayer and Regeneron Extend Development Program for VEGF Trap-Eye to Include Central Retinal Vein Occlusion*, April 30, 2009 ("Regeneron I") Ex. 1028.

[4] P. Mitchell et al., *Ranibizumab (Lucentis) in Neovascular Age-Related Macular Degeneration: Evidence from Clinical Trials*, 94(2) Br. J. Ophthalmol. 2–13 (2010) Ex. 1030.

[5] Papadopoulos et al. (US 7,374,758 B2, May 20, 2008) ("Papadopolous") Ex. 1010.

[6] Dix et al., (US 2006/0217311 A1, May 20, 2008) ("Dix") Ex. 1033.

D. The '069 Patent

The '069 patent is directed to methods for treating angiogenic eye disorders by sequentially administering multiple doses of a vascular epithelial growth factor ("VEGF") antagonist to a patient. Ex. 1001, Abstr. These methods include the administration of multiple doses of a VEGF antagonist to a patient at a frequency of once every 8 or more weeks, and are useful for the treatment of angiogenic eye disorders such as, *inter alia*, age related macular degeneration. *Id.*

In an exemplary embodiment, a single "initial dose" of VEGF antagonist ("VEGFT") is administered at the beginning of the treatment regimen (i.e., at "week 0"), two "secondary doses" are administered at weeks 4 and 8, respectively, and at least six "tertiary doses" are administered once every 8 weeks thereafter, i.e., at weeks 16, 24, 32, 40, 48, 56, etc.). Ex. 1001 col. 2, ll. 56–62.

E. Representative Claim

Claim 1 is the sole independent claim of the '069 patent, and recites:

> 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 on an as needed/ pro re nata (PRN) basis, based on visual and/or anatomical outcomes as assessed by a physician or other qualified medical professional;

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