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Paper 9
Entered: March 10, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2022-01524
Patent 11,253,572 B2

Before SUSAN L. C. MITCHELL, ROBERT A. POLLOCK, and RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

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

I. INTRODUCTION

Regeneron Pharmaceuticals, Inc. ("Patent Owner") is the owner of U.S. patent 11,253,572 B2 ("the '572 patent"). Paper 5, 1. On September 9, 2022, Apotex Inc. ("Petitioner") filed a Petition for *inter partes* review challenging the patentability of claims 1–14 and 26–30 of the '572 patent (claims 15–25 are not challenged). Paper 1, 1 ("Pet."). On December 23, 2022, Patent Owner filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp."). No further briefing was requested or authorized.

Under 37 C.F.R. § 42.4(a), we have authority to determine whether to institute trial in an *inter partes* review. We may institute an *inter partes* review if the information presented in the petition filed under 35 U.S.C. § 311, and any preliminary response filed under § 313, shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314.

After reviewing the parties' submissions, we conclude Petitioner does not demonstrate a reasonable likelihood it would prevail in showing that any challenged claim of the '572 patent is unpatentable under the presented grounds. Therefore, we deny institution of *inter partes* review.[1] Our reasoning is discussed below.

A. REAL PARTIES-IN-INTEREST

Petitioner lists Apotex Inc., Apotex Corp, Apotex Pharmaceutical Holdings Inc, and Aposherm Delaware Holdings Corp. as real parties-in-

[1] We note that there are disputed issues in this proceeding under 35 U.S.C. § 325(d) and § 314(a). *See* Pet. 6–11; Prelim. Resp. 47–57. However, because we determine institution should be denied on the merits, we do not address these matters.

interest. Pet. 2. Patent Owner identifies itself as the only real party-in-interest. Paper 5, 1.

B. RELATED MATTERS

Petitioner identifies the following as related matters: IPR2021-00881 (concerning U.S. Patent 9,254,338 ("the '338 patent"); IPR2022-00258 (also concerning the '338 patent); IPR2022-00298 (also concerning the '338 patent); IPR2021-00880 (concerning U.S. Patent 9,669,069 ("the '069 patent)); IPR2022-0257 (also concerning the '069 patent); IPR2022-00301 (also concerning the '069 patent); IPR2022-01225 (concerning U.S. Patent 10,130,681 ("the '681 patent"); and IPR2022-01226 (concerning U.S. Patent 10,888,601 ("the '601 patent"). Pet. 3–4. Petitioner also identifies as related *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.,* No. 1:22-cv-00061-TSK (N.D. W.Va), and PGR2021-00035 (concerning U.S. Patent 10,828,345). *Id.* at 5. In addition to the above-listed patents, Petitioner identifies U.S. Patent Application Nos. 17/072,417; 17/112,404; 17/112,063; and 17/350,958 as related. *Id.* Patent Owner identifies the same matters, patents, and applications as related. Paper 5, 2–3.

C. THE '572 PATENT

The '572 patent issued on February 22, 2022, from U.S. Application 17/352,892, which was filed on June 21, 2021. Ex. 1001, codes (45), (21), (22). The '572 patent ultimately indicates priority to U.S. Provisional Application 61/432,245, filed on January 13, 2011. *Id.* at code (60), 1:7–29. Petitioner declines to challenge whether the '572 patent is entitled such priority. *See, e.g.*, Pet. 1 ("Long before the patent's alleged 2011 priority date . . . .").

The '572 patent's abstract states:

> The present invention provides methods for treating angiogenic eye disorders by sequentially administering multiple doses of a VEGF antagonist to a patient. The methods of the present invention include the administration of multiple doses of a VEGF antagonist to a patient at a frequency of once every 8 or more weeks. The methods of the present invention are useful for the treatment of angiogenic eye disorders such as age related macular degeneration, diabetic retinopathy, diabetic macular edema, central retinal vein occlusion, branch retinal vein occlusion, and corneal neovascularization.

Id. at Abstract.

As background, the '572 patent states that "[r]elease of vascular endothelial growth factor (VEGF) contributes to increased vascular permeability in the eye and inappropriate new vessel growth," and "inhibiting the angiogenic-promoting properties of VEGF appears to be an effective strategy for treating angiogenic eye disorders." *Id.* at 1:60–65. As further background, the '572 patent identifies that "FDA-approved treatments of angiogenic eye disorders such as AMD and CRVO include the administration of an anti-VEGF antibody called ranibizumab (Lucentis®, Genentech, Inc.) on a monthly basis by intravitreal injection." *Id.* at 1:66–2:2. The '572 patent indicates that its invention is a response to the need for "new administration regimes" of "less frequent dosing while maintaining a high level of efficacy." *Id.* at 2:6–9.

In summarizing its invention, the '572 patent states:

> The 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. Thus, according to the methods of the present invention, each secondary dose of VEGF antagonist is administered 2 to 4 weeks after the immediately preceding dose, and each tertiary dose is administered at least 8 weeks after the immediately preceding dose.

Id. at 2:22–33. Relating to this, the '572 patent defines certain terms. For example, "the VEGF antagonist comprises one or more VEGF receptor-based chimeric molecule(s), (also referred to herein as a 'VEGF-Trap' or 'VEGFT')," and an example of this includes a product called "aflibercept," marketed as "EYLEA" by Regeneron Pharmaceuticals, Inc. and approved by the FDA in November 2011 at a dose of 2 mg via intravitreal injection every 4 weeks for three months and then every 8 weeks. *Id.* at 2:47–67.

On the aforementioned FDA-approved dosing regimen, the '572 patent further defines the terms (ultimately used in the claims) "initial dose, "secondary doses," and "tertiary doses" as follows:

> the "initial dose" is the dose which is administered at the beginning of the treatment regimen (also referred to as the "baseline dose"); the "secondary doses" are the doses which are administered after the initial dose; and the "tertiary doses" are the doses which are administered after the secondary doses.

Id. at 3:51–58.

The '572 patent describes a series of Examples detailing clinical trials conducted to validate the VEGFT drug and the dosing regimen. *Id.* at 8:12–18:3. Example 4 details two "Phase III Clinical Trials of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGFT in Subjects with Neovascular Age-Related Macular Degeneration" (AMD) (Study 1 and Study 2), which followed dosing regimens using 2 mg doses of aflibercept at the aforementioned initial dose, then two 4-week doses, and then doses every 8-weeks through the end of the 52-week study (the "2Q8"

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