Trials@uspto.gov
571.272.7822

Paper 13
Entered: November 17, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2023-00884
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
Granting 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 April 27, 2023, Samsung Bioepis Co., Ltd. ("Petitioner") filed a Petition for *inter partes* review challenging the patentability of claims 1–30 (all claims) of the '572 patent. Paper 2, 1 ("Pet."). On August 25, 2023, Patent Owner filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp."). With our authorization (*see* Ex. 3001), Petitioner filed a Reply to the Preliminary Response to address the issue of the priority date to be accorded the '572 patent as it relates to asserted references, and Patent Owner filed a respective Sur-Reply.

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 in view of the preliminary record, we conclude Petitioner demonstrates a reasonable likelihood it would prevail in showing that at least one challenged claim of the '572 patent is unpatentable under the presented grounds. Therefore, we grant institution of *inter partes* review. We note that there are disputed issues in this proceeding under 35 U.S.C. § 325(d) and § 314(a) concerning discretionary denial; however, we determine institution should be not be denied. *See* Pet. 63–68; Prelim. Resp. 49–62. Our reasoning is discussed below.

A. REAL PARTIES-IN-INTEREST

Each party identifies only itself as a real party-in-interest. Pet. 6; Paper 3, 1.

B. RELATED MATTERS

Petitioner identifies the following regarding related matters: IPR2022-01524 concerning the '572 patent (institution denied); IPR2021-00881 concerning U.S. Patent 9,254,338; IPR2021-00880 concerning U.S. Patent 9,669,069; IPR2022-01225 concerning U.S. Patent 10,130,681; IPR2023-00442 also concerning U.S. Patent 10,130,681; IPR2022-01226 concerning U.S. Patent 10,888,601, to which IPR2023-00566 is joined; IPR2023-00739 also concerning U.S. Patent 10,888,601; *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, NDWV-1-22-cv-00061 (NDWV); and *United States v. Regeneron Pharms., Inc.*, No. 1:20-cv-11217-FDS (D. Mass.).

Patent Owner identifies the same matters and adds: IPR2023-00532 also concerning U.S. Patent 10,130,681; IPR2022-00257 and IPR2022-00301 joined with IPR2021-00880; IPR2022-00258 and IPR2022-00298 joined with IPR2021-00881; PGR2021-00035 concerning U.S. Patent 10,828,345; and appeals to the U.S. Court of Appeals for the Federal Circuit ("Fed. Cir." or "Federal Circuit") from the Board's final decisions in IPR2021-00880 and IPR2021-00881 in *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 2023-1395, and *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 2023-1396. Paper 3, 1–2.

Regarding the above-noted district court litigation, *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, NDWV-1-22-cv-

00061, the evidence of record indicates, *inter alia*: (1) Petitioner is not a party to this litigation; (2) on April 19, 2023, the District Court entered an Order on Claim Construction (discussed *infra* Section II.B); (3) on April 27, 2023, Patent Owner expressly stipulated to, *inter alia*, the invalidity of the '572 patent's claims 1–5, 8–11, 14, and 26–28, reserving rights to appeal; and (4) a bench trial was held and all briefing, closing arguments, and post-trial briefing is concluded. Ex. 1063 (Order on Claim Construction); Ex. 2003 (Bench Trial Transcript); Ex. 2031 (Stipulation); Ex. 2032 (post-trial brief); Prelim. Resp. 10–12. Patent Owner states that the parties now "await the [D]istrict [C]ourt's judgment," and "[a]n expedited appeal is likely to follow." Prelim. Resp. 11–12 (citing Ex. 2031; Ex. 2033; Ex. 2034, 20:11–19).

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. However, priority is an issue raised by the parties in this proceeding and we discuss the matter below at Section II.C.

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. The '572 patent defines certain terms relevant to the above passage. The Specification states, for example, that "the VEGF antagonist comprises one or more VEGF receptor-based chimeric molecule(s), (also

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