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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,

Petitioner,

v.

ALCON RESEARCH, LTD.,

Patent Owner.

Case IPR2017-01053
Patent 8,268,299 B2

Before RICHARD E. SCHAFER, GRACE KARAFFA OBERMANN, and SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

OBERMANN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner requests institution of an *inter partes* review of claims 1–28 of U.S. Patent No. 8,268,299 B2 (Ex. 1001, "the '299 patent"). Paper 2 ("Petition" or "Pet."). Patent Owner did not file a preliminary response.

Applying the standard set forth in 35 U.S.C. § 314(a), which requires a demonstration of a reasonable likelihood that Petitioner would prevail at trial with respect to at least one challenged patent claim, we institute an *inter partes* review of claims 1–28 of the '299 patent. The following findings of fact and conclusions of law are not final, but are made for the sole purpose of determining whether Petitioner meets the threshold for initiating review. Any final decision shall be based on the full trial record, including any response timely filed by Patent Owner. In that regard, any arguments not raised by Patent Owner in a timely-filed response shall be deemed waived.

Taking account of the information provided at this stage of the proceeding, we determine that Petitioner shows sufficiently the following facts for the purposes of trial institution.

A. Related Matters

The '299 patent previously has been the subject of seven district court actions and one *inter partes* review. "Petitioner was not a party to any of these cases." Pet. 1. We instituted trial in the prior *inter partes* review, which was terminated after the parties entered a settlement agreement. *Apotex Corp. v. Alcon Research, Ltd.*, IPR2013-00428 ("Apotex IPR"), Papers 9, 58, 60.

B. The '299 Patent

The '299 patent describes "multi-dose, self-preserved ophthalmic compositions." Ex. 1001, Abstract. The specification states that pharmaceutical compositions, such as irrigating solutions for the eye, "are typically utilized multiple times by the patient, and are therefore frequently referred to as being of a 'multi-dose' nature." *Id.* at 1:44–46. The specification also explains that, although such compositions can be prepared under sterile conditions, *see id.* at 1:26–39, "[d]ue to the frequent, repeated exposure of multi-dose products to the risk of microbial contamination, it is necessary to employ a means for preventing such contamination from occurring." *Id.* at 1:47–50.

The '299 patent discloses "multi-dose products that do not require a conventional antimicrobial preservative (e.g. benzalkonium chloride)" (hereinafter "BAC"), "and yet are preserved from microbial contamination." *Id.* at 3:10–13. Such compositions are known in the art as "preservative free" or "self-preserved." *Id.* at 3:14, 19. According to the '299 patent, aqueous ophthalmic compositions may be preserved from microbial contamination, despite the absence of conventional preservatives such as BAC, by including low concentrations of zinc ions and a borate polyol complex in the compositions, and by limiting the concentration of buffering anions and metal cations other than zinc in the compositions. *See id.* at 3:33–62. The specification further discloses that the claimed composition is "able to satisfy the USP preservative efficacy requirements . . . without employing any conventional antimicrobial preservatives" (*id.* at 4:10–17), in a field where the goal is "to use such preservatives at the lowest possible concentrations." *Id.* at 1:64–65.

C. Illustrative Claim

Claim 1, reproduced below, illustrates the claimed subject matter:

1. A multi-dose, self-preserved ophthalmic composition, comprising:

zinc ions at a concentration of 0.04 to 0.4 mM; and

borate and polyol, the borate being present in the composition at a concentration of 0.1 to 2.0% w/v and the polyol being present in the composition at a concentration of 0.25 to 2.5% w/v, the polyol comprising propylene glycol in the composition at a concentration of 0.25 to 1.25% w/v and sorbitol in the composition at a concentration of 0.05 to 0.5% w/v

wherein: (i) the composition has a concentration of anionic species less than 15 mM; and (ii) the composition exhibits sufficient antimicrobial activity to allow the composition to satisfy USP 27 preservative efficacy requirements.

Ex. 1001, 25:31–47.

D. Asserted Prior Art and Other Evidence

The Petition asserts the following references as prior art:

1. Xia *et al.*, WO 2005/097067, "Zinc Preservative Composition and Method of Use" (filed March 24, 2005; published October 20, 2005) ("Xia") (Ex. 1003);

2. Chowhan *et al.*, U.S. Patent No. 6,143,799, "Use of Borate-Polyol Complexes in Ophthalmic Compositions" (filed July 2, 1998; issued November 7, 2000) ("Chowhan") (Ex. 1004);

3. Gadd *et al.*, "Microorganisms and Heavy Metal Toxicity," *Microbial Ecology*, 4:303-317 (1978) ("Gadd") (Ex. 1005);

4. FDA Approved Drug Label "TRAVATAN® (travoprost ophthalmic solution) 0.004% Sterile" (2001) ("TRAVATAN® Label") (Ex. 1006); and

5. Schneider *et al.*, U.S. Patent No. 6,011, 062, "Storage-Stable Prostaglandin Compositions" (Filed February 9, 1999; issued January 4, 2000) ("Schneider") (Ex. 1007).

The Petition is supported by the Declaration of Dr. Erning Xia (Ex. 1002). Based on the information provided at this preliminary stage of the proceeding, we are persuaded that Dr. Xia is qualified to opine from the perspective of a person of ordinary skill in the art at the time of the invention. Ex. 1002 ¶¶ 6–14 (discussion of technical qualifications and bases for opinions); Ex. 1015 (curriculum vitae).

The Petition also is accompanied by the Declaration of Dr. Richard P. Parrish (Ex. 1022), which previously was submitted by Patent Owner as Exhibit 2020 in the Apotox IPR. The Parrish Declaration states that TRAVATAN Z®, a commercial product alleged to embody the claimed invention, satisfied a "long-felt, unmet need for a highly-effective, [BAC]-free antiglaucoma drug." Ex. 1022 ¶ 26. Petitioner also submits the Declaration of Dr. Henry Grabowski (Ex. 1037), which, like the Parrish Declaration, was submitted by Patent Owner in the Apotox IPR. The Grabowski Declaration relies on information in the Parrish Declaration, and is directed to a contention that TRAVATAN Z® has enjoyed commercial success in the marketplace. *See, e.g.*, Ex. 1037 ¶¶ 18–21, 38.

The Petition further is supported by the Declaration of Dr. Yvonne Buys (Ex. 1021), which identifies alleged "deficiencies" and "points of disagreement with" the Parrish Declaration. Ex. 1021 ¶ 11. Specifically, Petitioner submits the Buys Declaration to rebut evidence of secondary considerations of nonobviousness advanced by Patent Owner in the Apotex IPR. Pet. 60–63. Based on the information provided at this preliminary stage of the proceeding, we are persuaded that Dr. Buys is qualified to opine on the question whether TRAVATAN Z® satisfied a long-felt need in the

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