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Paper 9
Entered: January 2, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX CORP.,
Petitioner

v.

ALCON RESEARCH, LTD.,
Patent Owner

Case IPR2013-00428
U.S. Patent No. 8,268,299 B2

Before LORA M. GREEN, FRANCISCO C. PRATS, and RAMA G. ELLURU, *Administrative Patent Judges.*

PRATS, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Statement of the Case

Petitioner, Apotex Corp. ("Apotex"), filed a petition ("Pet.") to institute an *inter partes* review of claims 1-28 of U.S. Patent No. 8,268,299 B2 (Ex. 1001, "the '299 patent"). Paper 2. Patent Owner, Alcon Research Ltd. ("Alcon"), filed a Preliminary Response ("Prelim. Resp."). Paper 8. We have jurisdiction under 35 U.S.C. §§ 6(b) and 314.

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which states:

> THRESHOLD. -- The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 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.

Apotex has persuaded us that there is a reasonable likelihood that it will prevail with respect to claims 1-28 of the '299 patent. Accordingly, for the reasons below, we grant an *inter partes* review of claims 1-28 of the'299 patent.

B. Related Proceedings

Concurrently with the petition under consideration herein, Apotex filed petitions seeking *inter partes* review of U.S. Patent No. 8,323,630 B2 and U.S. Patent No. 8,388,941 B2, over references considered here. Pet. 3.

C. Proposed Grounds of Unpatentability

Apotex contends that the challenged claims are unpatentable under 35 U.S.C. § 103 on the following specific grounds (Pet. 8-60):[1]

[1] Apotex supports its challenge with a declaration, executed July 5, 2013, by

Reference[s]	Basis	Claims challenged
Xia[2] and Chowhan[3]	§ 103	1, 2, 4, 8, 16, 17, and 20
Xia, Chowhan, and Gadd[4]	§ 103	1-4, 8, 9, and 13-21
Xia, the Travatan Label,[5] and Chowhan	§ 103	5-7 and 28
Xia, the Travatan Label, Chowhan, and Gadd	§ 103	10-12 and 22-28
Xia, Kiyobayashi,[6] Chowhan, and Gadd	§ 103	13 and 14
Xia, Kiyobayashi, the Travatan Label, Chowhan, and Gadd	§ 103	24 and 27
Xia, Kiyobayashi, the Travatan Label, and Chowhan	§ 103	28

D. The '299 patent

The '299 patent describes "multi-dose, self-preserved ophthalmic compositions." Ex. 1001, Abstract. The '299 patent explains 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 '299 patent also explains that, while such

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Michael J. Miller, Ph.D. ("Miller Declaration") (Ex. 1002).
[2] Xia, WO 2005/097067 A1 (published Oct. 20, 2005) (Ex. 1003).
[3] Chowhan, U.S. Patent No. 6,143,799 (issued Nov. 7, 2000) (Ex. 1004).
[4] Geoffrey M. Gadd and Alan J. Griffiths, *Microorganisms and Heavy Metal Toxicity*, 4 MICROBIAL ECOLOGY 303-317 (1978) (Ex. 1005).
[5] FDA Approved Drug Label "TRAVATAN ® (travoprost ophthalmic solution) 0.004% Sterile" (Ex. 1006).
[6] Kiyobayashi, JP Appl. No. 2003-104870 (published Apr. 9, 2003) (Ex. 1007).

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 that the compositions of the invention "are multi-dose products that do not require a conventional antimicrobial preservative (e.g. benzalkonium chloride), and yet are preserved from microbial contamination." *Id.* at 3:10-13. More specifically, the '299 patent explains that aqueous ophthalmic compositions can be preserved from microbial contamination, despite the absence of conventional preservatives, 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.

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

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.

E. Claim Interpretation

Consistent with the statute and legislative history of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (AIA), the Board interprets claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Under that standard, terms in a claim of an unexpired patent are given "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the . . . specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Apotex submits proposed constructions for several claim terms. Pet. 4-6; *see also* Ex. 1002 ¶¶ 20-33. With one notable exception, we agree that, on the current record, Apotex's proffered claim constructions are consistent with the broadest reasonable meaning an ordinary artisan would have given to the cited terms, when viewing the claims in light of the '299 patent Specification.

Alcon's preliminary response is limited to the single issue of the interpretation of "self-preserved." *See* Prelim. Resp. 7-8.

Specifically, the preambles of each of the independent claims of the '299 patent requires the claimed compositions to be "self-preserved." Ex. 1001, 25:31 (claim 1); 27:13 (claim 22); 27:49 (claim 26); 28:14 (claim 27); 28:36 (claim 28). As evidenced by the discussion below, when reasonably interpreted in light of the Specification of the '299 patent, the term "self-preserved" breathes life and meaning into the claims, and we, therefore, conclude that it is construed properly as being a limitation of the claims, despite appearing in the preamble. *See Pitney*

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