UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APOTEX CORP.,
Petitioner

v.

ALCON RESEARCH, LTD.,
Patent Owner.

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

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**PATENT OWNER ALCON RESEARCH, LTD.'S PRELIMINARY RESPONSE TO PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,268,299 UNDER 35 U.S.C. §§ 311–319 AND 37 C.F.R. §§ 42.1–.80, 42.100–.123**

## TABLE OF CONTENTS

U.S. Patent No. 8,268,299 ("the '299 patent") is directed to "multi-dose, self-preserved ophthalmic compositions." When ophthalmic compositions—such as eye drops—are administered to a patient, it is critical that the compositions not contain harmful microorganisms that can cause sight-threatening eye infections. Eye drops that are packaged in multi-dose containers must therefore be able to resist the growth of microbes from the time the container is opened until the last dose is used. Traditionally, that resistance to microbial growth has been provided by preservative chemicals that are included in the compositions. Conventional ophthalmic preservatives, however, have disadvantages; in particular, they can be toxic to parts of the eye and thus cause side effects. Every claim of the '299 patent is directed to ophthalmic compositions that are "self-preserved"—that is, they "do not contain a conventional antimicrobial preservative." APO 1001, col. 3, ll. 27–29.

Apotex Corp.'s ("Apotex's") Petition for *inter partes* review of the claims of the '299 patent attempts to write the "self-preserved" limitation out of the claims altogether. Despite the fact that the specification expressly defines "self-preserved" to mean that the compositions "do not contain a conventional antimicrobial preservative," APO 1001, col. 3, ll. 27–29, Apotex premises its Petition on the proposition that "[t]he specification of the '299 patent does not define the term 'self-preserved.'" Pet. at 5. Having ignored the specification's

definition for this claim term, Apotex then proceeds to define "self-preserved" to mean that a composition "can be administered to patients in a multi-dose container and need not be maintained aseptically because of [the composition's] antimicrobial properties"—*without regard to whether the composition achieves those properties by using conventional antimicrobial preservatives*. Pet. at 5. Apotex's definition, however, is fundamentally inconsistent with the definition of this term set forth in the specification, and as a result, is incorrect and unreasonable. Therefore, it cannot be the "broadest reasonable interpretation consistent with the specification" that is to be used in IPR proceedings. *In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 1148 (Fed. Cir. 2012); *see* 37 C.F.R. § 42.100(b).

Because Apotex has based its Petition on an erroneous construction of "self-preserved," it has failed to demonstrate, as it must, that it has a reasonable likelihood of success in showing that the challenged claims are obvious over the prior art. "Self-preserved" is a limitation of every claim and is emphasized throughout the specification as an important aspect of the invention, and yet not one of Apotex's proposed Grounds for unpatentability describes where this limitation is present in the cited art. The result of Apotex's failure to apply the proper construction of this claim term is that each of its proposed Grounds for unpatentability effectively fails to account for an express claim limitation and fails

to show that the claims as a whole containing this express limitation would have been obvious over the prior art. Accordingly, Apotex's Petition fails to show that the person of ordinary skill in the art would have used the particular ingredients and quantities in the challenged claims to make a self-preserved composition—as that term is properly construed—or that the person of ordinary skill would have had a reasonable expectation of success in making such a self-preserved composition. The Petition should therefore be denied.

## BACKGROUND

The '299 patent is directed to "multi-dose, self-preserved ophthalmic compositions." APO 1001, Abstract. An example of such a composition is a pharmaceutical eye drop sold in a bottle containing more than one dose. *See* APO 1001, col. 1, ll. 33–46. A patient may administer medication from one such bottle every day for weeks at a time. Each time the patient opens the bottle and applies an eye drop to their eye, the potential for microbial contamination of the drug product exists. This can occur in a variety of ways; for example, a user may inadvertently touch the tip of the bottle with a finger or eyelash, providing a potential source of microbial contamination. Thus, even if an eye drop is manufactured under sterile conditions, it must be able to resist the growth of both bacteria and fungi that, if allowed to multiply, could cause an eye infection. That

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