IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX CORP.
APOTEX, INC.
Petitioner
v.
ALLERGAN, INC.
Patent Owner

U.S. Patent No. 8,642,556 to Acheampong *et al*.
Issue Date: February 14, 2014
Title: Methods of Providing Therapeutic Effects Using Cyclosporin Components

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Inter Partes Review No. Unassigned

Petition for *Inter Partes* Review of U.S. Patent No. 8,642,556 Under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.123

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I. INTRODUCTION

APOTEX CORP. AND APOTEX, INC. petition for *Inter Partes* Review, seeking cancellation of claims 1-20 of U.S. Patent No 8,642,556 to Acheampong *et al.* ("the '556 patent") (APO1001), which is purportedly owned by ALLERGAN, INC.

II. OVERVIEW

The claims of the '556 patent should be cancelled. They recite formulations of well-known topical ophthalmic emulsions for treating dry eye disease (also referred to as keratocunjunctivitis sicca or KCS). APO1003, 1:14-15; APO1005, ¶¶4 and 15. The claimed emulsions contain cyclosporin A (CsA) at 0.05% and castor oil at 1.25%, along with excipients at identical concentrations to those taught in the art. (Percent values refer to percent weight throughout this petition.) APO1005, ¶66. As described in detail below, the prior art '979 patent (APO1003) provides working examples that recite formulations for CsA in castor oil emulsions: one emulsion contains 0.05% CsA with 0.625% castor oil; and another emulsion contains 0.10% CsA with 1.25% castor oil. APO1003, 3, 4:33-43; APO1005, ¶65. And as Allergan conceded during prosecution, the other ingredients of the examples in the '979 patent "are otherwise the same" as the challenged claims. APO1019, 949; APO1005, ¶¶16 and 116.

As explained by Apotex's formulation expert Dr. Xia, a person of ordinary skill in the art (POSA) would have understood that the '979 patent discloses a small

genus of four CsA concentrations and four castor oil concentrations. APO1005, ¶17. Dr. Xia testifies that "a POSA would have readily envisioned a 0.05% CsA emulsion with 1.25% castor oil" because it is one of only seven exemplified CsA and castor oil concentrations within the '979 patent's especially preferred CsA to castor oil ratio. APO1003, 3, 3:17-20; APO1005, ¶100. Moreover, during prosecution of a parent application Allergan stated that, based on the '979 patent, "one of ordinary skill in the art 'would readily envisage' such a composition [having 0.05% CsA and 1.25% castor oil], especially in view of Example 1B: having selected 0.05% as the concentration of cyclosporin, Example 1B (wherein the ratio of cyclosporin to castor oil is 0.04) teaches that the concentration of castor oil should be 1.25% (0.05%/1.250% = 0.04)." APO1019, 951; APO1005, ¶106.

Oddly, Allergan did not face an anticipation rejection during prosecution of the '556 patent. But because the prior art '979 patent teaches a genus sufficiently small so that a POSA would have readily envisaged the claimed emulsions, the challenged claims are anticipated by the '979 patent. APO1005, ¶107. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

The challenged claims also would have been obvious. Both CsA and castor oil were known in the prior art as useful agents to treat dry eye. APO1002, 3:41-60; APO1003, 4, 5:9-12; APO1004, 1; APO1005, ¶¶63 and 68. A prior art publication of clinical trials testing 0.05% CsA in a castor oil emulsion reported

that such emulsions were safe and efficacious for dry eye/KCS therapy. APO1004, 1; APO1005, ¶20. So before the September 2003 alleged priority date of the '556 patent, POSAs were aware of ophthalmically-acceptable castor oil emulsion formulations containing 0.05% CsA for the treatment of dry eye. APO1003, 3, 4:33-43; APO1004, 1; APO1005, ¶65.

Furthermore, during the prosecution of a parent application, Allergan admitted that its emulsions containing 0.05% CsA and 1.25% castor oil "would have been obvious" and that the differences between the claimed formulation and the prior art "are insignificant." APO1019, 951; APO1005, ¶187. Allergan also admitted that there would have been a reasonable expectation of success in arriving at the formulations because the differences between the claimed formulations and the prior art "are too small to believe otherwise." APO1019, 951; APO1005, ¶187.

During prosecution, Allergan asserted that it was unexpected that the combination of 1.25% castor oil and 0.05% CsA would be "*equally* or more therapeutically effective for the treatment of dry eye/keratoconjunctivitis sicca than the [prior art] formulation containing 0.10% by weight cyclosporin A and 1.25% by weight castor oil. . . ." APO1019, 2578, ¶14 (emphasis added). But equivalent performance does not meet the standard for unexpectedly superior results, and moreover, does not control the conclusion of obviousness over a strong case based

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