

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX CORP.
APOTEX, INC.
Petitioner

v.

ALLERGAN, INC.
Patent Owner

Case IPR2015-01284
Patent 8,648,048

**PATENT OWNER ALLERGAN, INC.'S
PRELIMINARY RESPONSE**

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 A. It was counterintuitive to combine 0.05% cyclosporin with a vehicle containing 1.25% castor oil 10

 1. Castor oil is cytotoxic and an irritant 10

 2. Increasing the amount of castor oil in the emulsion would be expected to reduce the thermodynamic activity of the emulsion 12

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 B. During prosecution the Examiner agreed that the performance of the claimed emulsion relative to the Ding ‘979 patent emulsions was unexpected 18

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 B. Claims 1-10, 12-14, 16-20. and 22-23 would not have been obvious over Ding ‘607/Ding ‘979 plus Sall 24

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LIST OF EXHIBITS

Exhibit No.	Description
EX. 2001	NDA 21-023 Cyclosporine Ophthalmic Emulsion 0.05%, Original NDA Filing, Vol. 1 (Feb. 24, 1999)
EX. 2002	U.S. Pat. No. 4,839,342
EX. 2003	Said et al., Investigative Ophthalmology & Visual Science, vol. 48, No. 11 (Nov. 2007):5000-5006
EX. 2004	Alba et al., Folia Ophthalmol. Jpn. 40:902-908 (1989)
EX. 2005	Stedman's Medical Dictionary, definition of therapeutic
EX. 2006	Dorland's Illustrated Medical Dictionary, definition of therapeutic
EX. 2007	Stedman's Medical Dictionary, definition of palliative
EX. 2008	Excerpts from the prosecution history of U.S.S.N. 13/967,168

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Allergan, Inc. v. Sandoz Inc.</i> , No. 2014-1275, slip op. (Fed. Cir. Aug. 4, 2015).....	<i>passim</i>
<i>Arkie Lures, Inc. v. Gene Larew Tackle, Inc.</i> , 119 F.3d 953 (Fed. Cir. 1997)	32
<i>In re Cuozzo Speed Techs., LLC</i> , No. 2014-1301, slip op. (Fed. Cir. 2015).....	21
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<i>Galderma Laboratories L.P. v. Tolmar, Inc.</i> , 737 F.3d 731 (Fed. Cir. 2013)	25, 26, 33
<i>In re Translogic Tech., Inc.</i> , 504 F.3d 1249 (Fed. Cir. 2007)	21
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