UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX CORP. APOTEX, INC. Petitioner

v.

ALLERGAN, INC. Patent Owner

Case IPR2015-01278 Patent 8,633,162

PATENT OWNER ALLERGAN, INC.'S PRELIMINARY RESPONSE

DOCKET

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I.	INTR	ODUCTION 1
II.	BAC	KGROUND OF THE '162 PATENT
	A.	Dry Eye Disease is a Serious Disease7
	B.	Palliative Treatments Only Alleviate the Symptoms of Dry Eye Disease
	C.	Allergan's Development of RESTASIS®
III.	THE	°162 PATENT
	A.	It was counterintuitive to combine 0.05% cyclosporin with a vehicle containing 1.25% castor oil
	1.	Castor oil is cytotoxic and an irritant
	2.	Increasing the amount of castor oil in the emulsion would be expected to reduce the thermodynamic activity of the emulsion
	3.	PK data predicted 0.05% cyclosporin/1.25% castor oil would be less effective than 0.05% cyclosporin/0.625% castor oil and 0.1% cyclosporin/1.25% castor oil
	B.	During prosecution the Examiner agreed that the performance of the claimed emulsion relative to the Ding '979 patent was unexpected
IV.	ARG	UMENT
	A.	An emulsion that is "effective in treating dry eye disease" or therapeutically effective" must treat the underlying disease 21
	B.	Claims 1-10, 12-14, 16-20. and 22-24 would not have been obvious over Ding '607/Ding '979 plus Sall
	1.	The inventors proceeded contrary to the teachings of the prior art and developed an emulsion that has surprising therapeutic efficacy against dry eye disease

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2.	There was no reasonable expectation that increasing castor oil concentration would increase therapeutic efficacy	9
3.	The differences between the claimed emulsion and the Ding '979 emulsions are differences in kind, not degree	3
4.	Allergan did not admit that the claims were unpatentable 3	4
C.	Claims 11 and 21 would not have been obvious over Ding '607/Ding '979 plus Sall plus Acheampong	6
D.	Claim 15 would not have been obvious over Ding '607/Ding '979 plus Sall plus Glonek	6
CON	CLUSION	6

V.

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 Opthamology & 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. 13/967,979

TABLE OF AUTHORITIES

Page(s)

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<i>Allergan, Inc. v. Sandoz Inc.</i> , No. 2014-1275, slip op. (Fed. Cir. Aug. 4, 2015)	passim
Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953 (Fed. Cir. 1997)	
<i>In re Cuozzo Speed Techs., LLC,</i> No. 2014-1301, slip op. (Fed. Cir. 2015)	
In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063 (Fed. Cir. 2012)	
Galderma Laboratories L.P. v. Tolmar, Inc., 737 F.3d 731 (Fed. Cir. 2013)	25, 33
<i>In re Translogic Tech., Inc.,</i> 504 F.3d 1249 (Fed. Cir. 2007)	
Other Authorities	
37 CFR § 42.100(b).	
37 CFR §§ 42.6(e)(4) and 42.205(b)	

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