UNITED STATES P	ATENT AND TRA	DEMARK OFFICE
-		
BEFORE THE PAT	ENT TRIAL AND	APPEAL BOARD
-		
	APOTEX CORP. APOTEX, INC. Petitioner	
	V.	
4	ALLERGAN, INC. Patent Owner	
C	Case IPR2015-01283 Patent 8,685,930	3

PATENT OWNER ALLERGAN, INC.'S PRELIMINARY RESPONSE



Case IPR2015-01283 Attorney Docket No: 13351-0063IP1

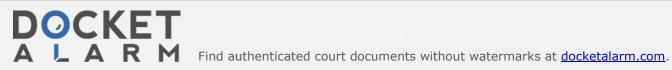
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II.	BACKO	GROUND OF THE '930 PATENT	7
	A.	Dry Eye Disease is a Serious Disease	7
	В.	Palliative Treatments Only Alleviate the Symptoms of Dry E Disease	•
	C.	Allergan's Development of RESTASIS®	8
III.	THE '9	30 PATENT	9
	A.	It was counterintuitive to combine 0.05% cyclosporin with a vehicle containing 1.25% castor oil	
	1.	Castor oil is cytotoxic and an irritant	. 10
	2.	Increasing the amount of castor oil in the emulsion would be expected to reduce the thermodynamic activity of the emuls	ion
	3.	PK data predicted 0.05% cyclosporin/1.25% castor oil woul be less effective than 0.05% cyclosporin/0.625% castor oil a 0.1% cyclosporin/1.25% castor oil	and
	В.	During prosecution the Examiner agreed that the performance of the claimed emulsion relative to the Ding '979 patent emulsions was unexpected	
IV.	ARGU	MENT	. 20
	A.	An emulsion that is "therapeutically effective" must treat the underlying disease	
	B.	The Ding '979 patent does not anticipate claims 1-36	. 23
	C.	Claims 1-10, 12-22, 24-34, and 36 would not have been obvious over Ding '607/Ding '979 plus Sall	. 29



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	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	
	2.	There was no reasonable expectation that increasing castor oil concentration would increase therapeutic efficacy	
	3.	The differences between the claimed emulsion and the Ding '979 emulsions are differences in kind, not degree	38
	D.	Claims 11, 23, and 35 would not have been obvious over Ding '607/Ding '979 plus Sall plus Acheampong	10
V	CONCL	USION	10



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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 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 prosecution history of USSN 13/961,828



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<i>In re Translogic Tech., Inc.,</i> 504 F.3d 1249 (Fed. Cir. 2007)	23
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