

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

ALLERGAN, INC.
Patent Owner

Case IPR2016-01131
Patent 8,648,048

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

TABLE OF CONTENTS

I. INTRODUCTION 1

II. BACKGROUND OF THE ‘048 PATENT 7

 A. Dry Eye Disease is a Serious Disease 7

 B. Palliative Treatments Only Alleviate the Symptoms of Dry Eye Disease..... 8

 C. Allergan’s Development of RESTASIS® 9

III. THE ‘048 PATENT 10

 A. It was counterintuitive to combine 0.05% cyclosporin with a vehicle containing 1.25% castor oil 11

 1. Castor oil is cytotoxic and an irritant..... 11

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

 3. PK data predicted 0.05% cyclosporin/1.25% castor oil would be less effective than 0.05% cyclosporin/0.625% castor oil and 0.10% cyclosporin/1.25% castor oil..... 13

 B. During prosecution the Examiner agreed that the performance of the claimed emulsion relative to the Ding ‘979 patent emulsions was unexpected 17

IV. ARGUMENT..... 19

 A. An emulsion that is “therapeutically effective” must treat the underlying disease 21

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

 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..... 24

 2. Sall would not have motivated a person of ordinary skill to prepare an emulsion containing 0.05% cyclosporin and 1.25% castor oil 27

 3. There was no reasonable expectation that increasing castor oil concentration would increase therapeutic efficacy 29

4. The differences between the claimed emulsion and the Ding ‘979 emulsions are differences in kind, not degree 31

5. Allergan did not admit that the claims were unpatentable 32

C. Claims 11 and 21 would not have been obvious over Ding ‘979 plus Sall plus Acheampong..... 34

D. Claim 15 would not have been obvious over Ding ‘979 plus Sall plus Glonek. 34

V. CONCLUSION..... 34

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	RESTASIS® label
EX. 2009	Murphy, R., "The Once and Future Treatment of Dry Eye," Review of Optometry, pp. 73-75 (Feb. 15, 2000)

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)	38
<i>Atofina v. Great Lakes Chem. Corp.</i> , 441 F.3d 991 (Fed. Cir. 2006)	24
<i>Cuozzo Speed Techs., LLC v. Lee</i> , 136 S. Ct. 2131 (2016).....	22
<i>In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.</i> , 676 F.3d 1063 (Fed. Cir. 2012)	35
<i>Galderma Laboratories L.P. v. Tolmar, Inc.</i> , 737 F.3d 731 (Fed. Cir. 2013), explained.....	31, 39
<i>Sanofi-Synthelabo v. Apotex, Inc.</i> , 550 F.3d 1075 (Fed. Cir. 2008)	24
<i>In re Translogic Tech., Inc.</i> , 504 F.3d 1249 (Fed. Cir. 2007)	22
<i>Verdegaal Bros. v. Union Oil Co. of California</i> , 814, F.2d 628, 631 (Fed. Cir. 1987)	24
Other Authorities	
37 C.F.R.	22
37 CFR §§ 42.6(e)(4) and 42.205(b)	43

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.