IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FAMY CARE LIMITED
Petitioner

v.

ALLERGAN, INC. Patent Owner

Patent No. 8,633,162 B2

Declaration of Michael A. Lemp, M.D.

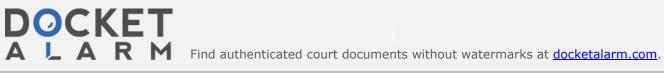


TABLE OF CONTENTS

| I. | INTR | RODUCTION1 | | | | | |
|-------|---|---|---|----|--|--|--|
| II. | QUA | LIFICATIONS1 | | | | | |
| III. | SCOI | PE OF ENGAGEMENT. | | | | | |
| IV. | SUM | IMARY OF OPINIONS4 | | | | | |
| V. | THE | '162 PA | ATENT OVERVIEW | 7 | | | |
| | A. | The '162 Patent Specification. | | | | | |
| | B. | The '1 | 62 Patent Claims. | 8 | | | |
| | | 1. | Independent Claims. | 8 | | | |
| | | 2. | Formulation Dependent Claims | 10 | | | |
| | | 3. | "Efficacy" and Comparative Efficacy Dependent Claims | 11 | | | |
| | | | "Substantially No Detectable Concentration of CsA" Dependent Claims. | 11 | | | |
| | C. | '162 P | atent File History | 12 | | | |
| VI. | LEGAL STANDARDS | | | | | | |
| | A. | Obvio | usness – 35 U.S.C. § 103 | 15 | | | |
| VII. | STATE OF THE ART AS OF SEPTEMBER 15, 200320 | | | | | | |
| | A. | CsA Was A Known Treatment For Dry Eye Disease20 | | | | | |
| | B. | CsA-ii | n-Castor Oil Emulsions Were Known In The Art | 26 | | | |
| VIII. | DETAILED BASES FOR OPINIONS. | | | | | | |
| | A. | Person Of Ordinary Skill In The Art3 | | | | | |
| | B. Claim Construction | | | | | | |
| | | | "Substantially No Detectable Concentration Of [The] | 31 | | | |



| 2. | | | ""As Substantially Therapeutically Effective As Much Therapeutic Effectiveness As." | 32 |
|----|------|---------|--|----|
| 3. | "Adv | verse E | Events" and "Side Effects." | 34 |
| 4. | "Bre | aks Do | own." | 35 |
| | _ | | The Claims Of The '162 Patent To The Prior | 36 |
| 1. | Grou | ınd 1: | Obviousness In View Of Sall And Ding '979 | 37 |
| | a. | | and Ding '979 Teach an Emulsion with 0.05% and 1.25% Castor Oil. | 38 |
| | | i. | 0.05% CsA | 44 |
| | | ii. | 1.25% Castor Oil | 47 |
| | b. | CsA | ce Daily Administration of the 0.05% /1.25% Castor Oil Emulsion Taught by Sall Ding '979 Renders Claims 1-24 Obvious | 51 |
| | | i. | Preamble Elements | 58 |
| | | ii. | Frequency Elements | 60 |
| | | iii. | Formulation Elements | 61 |
| | | iv. | Efficacy Elements | 63 |
| | | v. | Comparative Efficacy Elements | 64 |
| | | vi. | CsA Blood Level Elements | 69 |
| | | vii. | All Performance-Related Elements: Inherency | 73 |
| 2. | | | Obviousness Of Claims 11 And 21 In View Of '979, And Acheampong | 73 |
| 3. | | | Obviousness Of Claim 15 In View Of Sall, And Glonek | 76 |
| | _ | | | |



| D. | Secondary Considerations Of Nonobviousness | | | | |
|----|--|----|------|--|-----|
| | | 1. | No | Unexpected Results | 84 |
| | | | a. | Schiffman Exhibit B. | 86 |
| | | | b. | Schiffman Exhibit C/Attar Exhibit B | 91 |
| | | | c. | Schiffman Exhibit D | 93 |
| | | | d. | Schiffman Exhibits E and F/Attar Exhibits D and E. | 98 |
| IV | CON | | DINC | CT A TEMENITO | 102 |



TABLE OF EXHIBITS

| Exhibit | Description |
|---------|---|
| 1001 | U.S. Patent No. 8,633,162 B2 to Acheampong et al. ("the '162 patent") |
| 1002 | Declaration of Peter Kador, Ph.D. |
| 1003 | Intentionally Blank |
| 1004 | File history of U.S. Patent No. 8,633,162 to Acheampong et al. ("'162 patent FH") |
| 1005 | File history of U.S. Patent Application No. 10/927,857 to Acheampong et al., filed August 27, 2004 ("'857 application FH'') |
| 1006 | U.S. Patent No. 5,474,979 to Ding et al., filed May 17, 1994 ("Ding '979") |
| 1007 | K. Sall et al., Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease, 107 Ophthalmology 631 (2000) ("Sall") |
| 1008 | A. Acheampong et al., Cyclosporine Distribution into the Conjunctiva, Cornea, Lacrimal Gland, and Systemic Blood Following Topical Dosing of Cyclosporine to Rabbit, Dog, and Human Eyes, in 2 LACRIMAL GLAND, TEAR FILM, & DRY EYE SYNDROMES 1001 (David A. Sullivan et al. eds., 1998) ("Acheampong") |
| 1009 | U.S. Patent No. 5,578,586 to Glonek et al., filed February 4, 1994 ("Glonek") |
| 1010 | U.S. Patent No. 5,981,607 to Ding et al., filed January 20, 1998 ("Ding '607") |
| 1011 | R. Kaswan, Intraocular Penetration of Topically Applied Cyclosporine, 20 Transpl. Proc. 650 (1988) ("Kaswan") |



DOCKET A L A R M

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.

