

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 Peter Kador, Ph.D.

TABLE OF CONTENTS

| | | |
|-------|--|----|
| I. | INTRODUCTION..... | 1 |
| II. | QUALIFICATIONS..... | 1 |
| III. | SCOPE OF ENGAGEMENT..... | 5 |
| IV. | SUMMARY OF OPINIONS..... | 7 |
| V. | THE '162 PATENT OVERVIEW. | 17 |
| A. | The '162 Patent Specification. | 17 |
| B. | The '162 Patent Claims. | 19 |
| 1. | Independent Claims..... | 19 |
| 2. | Composition Dependent Claims. | 20 |
| 3. | “Efficacy” and Comparative Efficacy Dependent Claims. | 22 |
| 4. | “Substantially No Detectable Concentration of CsA” Dependent Claims. 23 | |
| C. | '162 Patent File History. | 23 |
| VI. | THE PERSON OF ORDINARY SKILL IN THE ART. | 27 |
| VII. | CLAIM CONSTRUCTION. | 28 |
| A. | “Buffer” | 29 |
| B. | “Substantially No Detectable Concentration Of The Cyclosporin A” | 30 |
| C. | “Effective Amount,” “Substantially Therapeutically Effective As,” and “As Much Therapeutic Effectiveness As” | 31 |
| D. | “Adverse Events” and “Side Effects” | 33 |
| E. | “Breaks Down” | 34 |
| VIII. | LEGAL STANDARDS. | 35 |
| A. | Anticipation – 35 U.S.C. § 102. | 35 |
| B. | Obviousness – 35 U.S.C. § 103..... | 35 |
| IX. | DISCLOSURES, KNOWLEDGE & INFORMATION AVAILABLE IN THE ART AS OF SEPTEMBER 15, 2003..... | 39 |
| A. | State of the Art Generally..... | 39 |
| 1. | CsA Was a Known Treatment for Dry Eye Disease..... | 39 |
| 2. | CsA-in-Castor Oil Emulsions Were Known In the Art..... | 43 |
| B. | Ding '979..... | 49 |
| C. | Sall..... | 55 |

| | | |
|------|---|-----|
| D. | Acheampong..... | 63 |
| E. | Glonek. | 65 |
| X. | DETAILED ANALYSIS OF THE '162 PATENT CLAIMS..... | 67 |
| A. | Ground 1: '162 patent Claims 1-24 Are Obvious In View Of Ding '979 and Sall..... | 68 |
| 1. | Claims 1-24. | 68 |
| 2. | Reasonable Expectation of Success. | 109 |
| B. | Ground 2: '162 Patent Claims 11 And 21 Are Obvious In View Of Ding '979, Sall, and Acheampong. | 111 |
| C. | Ground 3: '162 Patent Claim 15 Is Obvious In View Of Ding '979, Sall and Glonek. | 113 |
| XI. | SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS. | 116 |
| XII. | CONCLUDING STATEMENTS..... | 120 |

TABLE OF EXHIBITS

| Exhibit | Description |
|---------|---|
| 1001 | U.S. Patent No. 8,633,162 B2 (“the ’162 patent) |
| 1002 | Intentionally Blank |
| 1003 | Declaration of Dr. Michael A. Lemp |
| 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., <i>Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease</i> , 107 OPTHALMOLOGY 631 (2000) (“Sall”) |
| 1008 | A. Acheampong et al., <i>Cyclosporine Distribution into the Conjunctiva, Cornea, Lacrimal Gland, and Systemic Blood Following Topical Dosing of Cyclosporine to Rabbit, Dog, and Human Eyes</i> , 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, <i>Intraocular Penetration of Topically Applied Cyclosporine</i> , 20 TRANSPL. PROC. 650 (1988) (“Kaswan”) |
| 1012 | K. Kunert et al., <i>Analysis of Topical Cyclosporine Treatment of Patients with Dry Eye Syndrome</i> , 118 ARCH OPHTHALMOL 1489 (2000) (“Kunert”) |

| | |
|------|--|
| 1013 | PHYSICIANS' DESK REFERENCE FOR OPHTHALMOLOGY 13-18 (Medical Economics Co., 27th ed. 1999) ("Ophthalmic PDR") |
| 1014 | K. Turner et al., <i>Interleukin-6 Levels in the Conjunctival Epithelium of Patients with Dry Eye Disease Treated with Cyclosporine Ophthalmic Emulsion</i> , 19 CORNEA 492 (2000) ("Turner") |
| 1015 | D. Stevenson et al., <i>Efficacy and Safety of Cyclosporin A Ophthalmic Emulsion in the Treatment of Moderate-to-Severe Dry Eye Disease</i> , 107 OPHTHALMOLOGY 967 (2000) ("Stevenson") |
| 1016 | REMINGTON'S 20 TH EDITION: THE SCIENCE AND PRACTICE OF PHARMACY (A. Gennaro ed. 2003) ("Remington") |
| 1017 | E. Goto et al., <i>Low-Concentration Homogenized Castor Oil Eye Drops for Noninflamed Obstructive Meibomian Gland Dysfunction</i> , 109 OPHTHALMOLOGY 2030 (2002) ("Goto") |
| 1018 | A. Kanpolat et al., <i>Penetration of Cyclosporin A into the Rabbit Cornea and Aqueous Humor after Topical Drop and Collagen Shield Administration</i> , 20 CLAO J. 119 (1994) ("Kanpolat") |
| 1019 | C. Vieira et al., <i>Effect of Ricinoleic Acid in Acute and Subchronic Experimental Models of Inflammation</i> , 9 MEDIATORS INFLAMMATION 223 (2000) ("Vieira") |
| 1020 | R. Murphy, <i>The Once and Future Treatment of Dry Eye</i> , REVIEW OF OPTOMETRY ONLINE (Feb. 15, 2000) ("Murphy") |
| 1021 | D. Small et al., <i>Blood Concentrations of Cyclosporin A During Long-Term Treatment with Cyclosporin A Ophthalmic Emulsions in Patients with Moderate to Severe Dry Eye Disease</i> , 18 J. OCULAR PHARMACOLOGY & THERAPEUTICS 411 (2002) ("Small") |
| 1022 | STEDMAN'S MEDICAL DICTIONARY 944, 1300, 1548, 1634, 1821 (27th ed. 2000) ("Stedman's") |
| 1023 | Allergan, Inc.'s Complaint for Patent Infringement, <i>Allergan, Inc. v. Famy Care Ltd.</i> , No. 2:16-cv-401 (E.D. Tex. Apr. 12, 2016) |

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.