

Paper No. \_\_\_\_\_  
Filed: January 6, 2017

Filed on behalf of Teva Pharmaceuticals USA, Inc.  
By: Mark D. Schuman  
Gary J. Speier  
CARLSON, CASPERS, VANDENBURGH,  
LINDQUIST & SCHUMAN, P.A.  
225 South Sixth Street, Suite 4200  
Minneapolis, MN 55402

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

TEVA PHARMACEUTICALS USA, INC.  
Petitioner,

v.

ALLERGAN, INC.,  
Patent Owner.

---

Patent No. 8,685,930

---

**DECLARATION OF WALTER G. CHAMBLISS, PH.D.**

TABLE OF CONTENTS

I. QUALIFICATIONS ..... 1

II. SCOPE OF WORK ..... 3

III. OVERVIEW OF THE '930 PATENT ..... 4

IV. FILE HISTORY OF THE '930 PATENT ..... 7

V. LEGAL STANDARDS ..... 10

VI. LEVEL OF ORDINARY SKILL AND RELEVANT TIME ..... 14

VII. CLAIM CONSTRUCTION ..... 15

VIII. THE STATE OF THE ART ..... 19

IX. ASSERTED REFERENCES DISCLOSE OR SUGGEST EACH OF THE CLAIMED FEATURES OF THE '930 PATENT ..... 28

    A. Brief Overview of the Asserted References ..... 28

    B. Detailed Analysis of the Claims ..... 43

        GROUND 1. EACH OF CLAIMS 1-36 IS ANTICIPATED BY DING '979 ..... 43

        GROUND 2. THE TEACHINGS OF DING '979 AND SALL MAKE CLAIMS 1-10, 12-22, 24-34, AND 36 OBVIOUS. .... 51

        GROUND 3. THE TEACHINGS OF DING '979, SALL, AND ACHEAMPONG MAKE CLAIMS 11, 23, AND 35 OBVIOUS. .... 60

X. NO UNEXPECTED RESULTS ..... 63

XI. CONCLUDING STATEMENTS ..... 78

XII. APPENDIX – LIST OF EXHIBITS ..... 80

;

I, Walter G. Chambliss, declare as follows:

**I. QUALIFICATIONS**

1. My name is Walter Chambliss. I received a B.S. in Pharmacy in 1977, an M.S. in Pharmaceutics in 1980, and a Ph.D. in Pharmaceutics in 1982 from the University of Mississippi.

2. I worked for seventeen years in research and development in the pharmaceutical industry at G.D. Searle, Bristol-Myers and Schering-Plough, where I was involved in formulation development and/or process development of over 300 products. I was Vice President of Research and Development for the HealthCare Products Division of Schering-Plough for five years.

3. For the past seventeen years, I have been a Professor of Pharmaceutics at the University of Mississippi, where I teach graduate courses in pharmaceutics. I am also a Research Professor in the Research Institute of Pharmaceutical Sciences where I am responsible for managing pharmaceutical development projects. In addition, I am the Director of Technology Management and oversee the technology transfer activities for the University.

4. I provide broad research and development consulting to the pharmaceutical industry, and have been an invited speaker in the areas of formulation and product development.

5. I have authored or co-authored over twenty publications in the field of pharmaceutical development, including a book chapter concerning delivery of pharmaceutical products to the eye, and I am a co-inventor of a U.S. patent.

6. I am a member of numerous technical societies, including the Academy of Pharmaceutical Research and Sciences of the American Pharmacists Association, and the American Association of Pharmaceutical Scientists. I am also a member of Rho Chi, a national professional honor society. I am a Past President of the Academy of Pharmaceutical Research and Sciences, and previously served as a member of the Board of Trustees of the American Pharmacists Association. I received the Distinguished Alumni Award from the University of Mississippi School of Pharmacy, and have served on several external scientific advisory boards of profit and non-profit organizations. I am also a Fellow of the Academy of Pharmaceutical Research and Science of the American Pharmacists Association and the American Association of Indian Pharmaceutical Scientists. I served on the International Steering Committee for the 2nd, 3rd and 4th Editions of the Handbook of Pharmaceutical Excipients and wrote monographs for excipients included in several editions.

7. I was responsible for the formulation development of numerous oil-based and water-based formulations at Bristol-Myers and Schering-Plough including formulations designed to be administered to the eye. A majority of these

formulations were oil-in-water emulsions for topical administration consisting of the active pharmaceutical ingredient(s) dispersed or dissolved in oil. I have significant experience in the use of polymers, including acrylate/C10-30 alkyl acrylate cross-polymer, and surfactants, including polysorbate 80, as inactive ingredients in oil-in-water emulsion formulations. In addition, I have significant experience in the selection of other inactive ingredients commonly used in oil-in-water emulsion formulations including tonicity agents, demulcents, pH adjusting agents, and buffers.

8. A summary of my education, experience, publications, awards and honors, patents, publications, and presentations is provided in my CV, a copy of which is submitted separately. Ex. 1027.

## **II. SCOPE OF WORK**

9. I understand that a petition is being filed with the United States Patent and Trademark Office for *Inter Partes* Review of U.S. Patent No. 8,685,930 (“the ’930 patent,” Ex. 1001). I have been retained by the Petitioner as a technical expert to provide analysis and opinions regarding the ’930 patent. I have reviewed the ’930 patent and relevant sections of its prosecution history in the United States Patent and Trademark Office. Ex. 1004. I understand that the ’930 patent is currently subject to another IPR, Mylan Pharmaceuticals Inc., v. Allergan, Inc., Case IPR2016-01127 (the “Mylan IPR”). I understand that Petitioner Teva seeks

# 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.