

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.

Patent No. 8,629,111

DECLARATION OF MANSOOR AMIJI, PH.D.

TABLE OF CONTENTS

I.	QUALIFICATIONS	1
II.	SCOPE OF WORK.....	3
III.	OVERVIEW OF THE '111 PATENT	3
IV.	FILE HISTORY OF THE '111 PATENT.....	6
V.	LEGAL STANDARDS	10
VI.	LEVEL OF ORDINARY SKILL AND RELEVANT TIME.....	13
VII.	CLAIM CONSTRUCTION	14
VIII.	THE STATE OF THE ART.....	18
IX.	ASSERTED REFERENCES DISCLOSE OR SUGGEST EACH OF THE CLAIMED FEATURES OF THE '111 PATENT	25
	GROUND 1. EACH OF CLAIMS 1-27 IS ANTICIPATED BY DING '979	40
	GROUND 2. THE TEACHINGS OF DING '979 AND SALL MAKE CLAIMS 1-10, 12-15, AND 17-27 OBVIOUS.....	48
	GROUND 3. THE TEACHINGS OF DING '979, SALL, AND ACHEAMPONG MAKE CLAIMS 11 AND 16 OBVIOUS.	56
X.	NO UNEXPECTED RESULTS.....	58
XI.	CONCLUDING STATEMENTS.....	72
XII.	APPENDIX – LIST OF EXHIBITS.....	74

I, Mansoor Amiji, declare as follows:

I. QUALIFICATIONS

1. My name is Mansoor Amiji. I am currently the Bouvé College Distinguished Professor in the Department of Pharmaceutical Sciences in the School of Pharmacy at Northeastern University. I have been a member of the faculty at Northeastern since 1993. I am also an affiliate faculty member in the Departments of Chemical Engineering and Biomedical Engineering within the College of Engineering at Northeastern, as well as a Distinguished Adjunct Professor within the Faculty of Pharmacy at King Abdulaziz University.

2. I received a B.S. in Pharmacy from Northeastern University in 1988, and a Ph.D. in Pharmaceutics/Biomaterials Science from Purdue University in 1992. I have also conducted research as a Senior Research Scientist at the Columbia Research Laboratories in Madison, Wisconsin, as well as served as a Visiting Research Scholar in the Department of Chemical Engineering at MIT.

3. My current research focuses on the development of biocompatible materials from natural and synthetic polymers, target-specific drug and gene delivery systems for cancer and infectious diseases, and nanotechnology applications for medical diagnosis, imaging and therapy. I have extensive experience with pharmaceutical formulations, including oil-in-water emulsions containing various types of oils, including castor oil, as well as with sterile formulations and dosage forms for use in the eye. I have also taught courses on the development and characterization of ophthalmic formulations to undergraduate pharmacy and graduate students.

4. I have had extensive experience in the development and characterization of lipid-based drug delivery systems, including oil-in-water emulsion formulations intended for parenteral and oral administration. I have also worked on emulsion formulations that are targeted to different parts of the body, including the brain.

5. My research has been funded by such organizations as the National Institute of Health (NIH) and the National Science Foundation (NSF), as well as other government agencies and foundations. I also serve, or have served, on the editorial board of thirteen peer-reviewed journals such as *Drug Design: Development and Therapy*, *Expert Opinion on Drug Delivery*, *Pharmaceutical Formulations and Quality*, and *Tissue Barriers*. I have also served as a reviewer for 39 peer-reviewed journals including *Science*, *Angewandte Chemie International Edition*, *European Journal of Pharmaceutical Sciences*, *Journal of Pharmaceutical Sciences*, and *Nature Communications*.

6. I have authored or co-authored more than 200 peer-reviewed journal articles. I have also authored 43 book chapters and been listed as an inventor on 16 patents and patent applications. I have given over 170 invited seminars at scientific symposia and educational institutions.

7. I have received numerous honors and awards, including my 2014 induction into the College of Fellows at the Controlled Release Society, appointment as an Honorary Member in the Phi Lambda Sigma Pharmacy Leadership Society, a fellowship as well as the Meritorious Manuscript Award

from the American Association of Pharmaceutical Sciences, and the Eurand Award for Outstanding Research in Oral Drug Delivery.

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. 1003.

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. 8,629,111 (“the ’111 patent,” Ex. 1001). I have been retained by the Petitioner as a technical expert to provide analysis and opinions regarding the ’111 patent. I have reviewed the ’111 patent and relevant sections of its prosecution history in the United States Patent and Trademark Office. Ex. 1004. I have also reviewed and considered various other documents in arriving at my opinions, and cite them in this declaration. For convenience, documents cited in this declaration are listed in the Appendix in Section XII.

10. I am compensated at the rate of \$870/hour for my work. I have no financial interest in the outcome of this matter.

III. OVERVIEW OF THE ’111 PATENT

11. The ’111 patent issued January 14, 2014. The ’111 patent is entitled “Methods of Providing Therapeutic Effects using Cyclosporin Components.” The first page of the patent states that an application for the ’111 patent (U.S. Application No. 13/967,163, “the ’163 application”) was filed on August 14, 2013 and claims priority through a series of continuations to U.S. Application No.

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.