

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI LLC

PETITIONER

V.

CELGENE

PATENT OWNER

CASE NO.: UNASSIGNED

PATENT NO. 6,315,720

FILED: OCTOBER 23, 2000

ISSUED: NOVEMBER 13, 2001

INVENTORS: BRUCE A. WILLIAMS AND JOSEPH K. KAMINSKI

TITLE: METHODS FOR DELIVERING A DRUG TO A PATIENT WHILE
AVOIDING THE OCCURRENCE OF AN ADVERSE SIDE EFFECT KNOWN
OR SUSPECTED OF BEING CAUSED BY THE DRUG

**DECLARATION OF
JEFFREY FUDIN, R.PH., PHARM.D., DAAPM, FCCP, FASHP**

I, Jeffrey Fudin, R.Ph., Pharm.D., DAAPM, FCCP, FASHP, hereby declare as follows:

I. Introduction

1. I am over the age of eighteen and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of the COALITION FOR AFFORDABLE DRUGS VI LLC for the above-captioned *inter partes* review (“IPR”). I am being compensated for my time in connection with this IPR at my standard legal consulting rate, which is \$450 per hour. I understand that the petition for *inter partes* review involves U.S. Patent No. 6,315,720 (“the ’720 Patent”) which resulted from U.S. Application No. 09/694,217 (“the ’217 application”), which was filed October 23, 2000, its earliest priority date. The ’720 Patent names Bruce A. Williams and Joseph K. Kaminski as inventors and lists Celgene Corporation as the original assignee. The ’720 Patent was issued on November 13, 2001.

3. In preparing this declaration and formulating my opinions, I have reviewed the ’720 Patent and considered each of the documents cited herein, in light of the knowledge of a person of ordinary skill in the art (“POSA”) (i.e., a person of ordinary skill in the field of prescribing and dispensing pharmaceutical ingredients) as of October 23, 2000.

II. My Background and Qualifications

4. I am presently the Director of the PGY2 Pain and Palliative Care Pharmacy Residency at the Samuel Stratton Department of Veterans Affairs Medical Center located at 113 Holland Avenue, Albany, New York (“Samuel Stratton”). I have held this position since April of 2012. I am also currently the Clinical Pharmacy Specialist at the Pain Management Department at Samuel Stratton and have held that position since June of 1994. I worked as a Clinical Pharmacy Specialist in Oncology/Hematology and as Staff Pharmacist at Samuel Stratton from July of 1982 until June 1994.

5. As a Clinical Pharmacy Specialist, I work in close collaboration with medical staff members in the management of various acute and chronic pain disease states. I order and interpret clinical laboratory tests necessary to monitor and support drug therapy based on consult requests made by physicians to (a) monitor disease states, (b) assess medication regimens, and (c) adjust, initiate, or discontinue therapy for individual patients.

6. I received my B.S. in Pharmacy from Albany College of Pharmacy (Union University) in May of 1981, received my Pharm.D. from the same school, but name was changed to Albany College of Pharmacy and Health Sciences, in May of 1998, and completed an Oncology/Hematology Fellowship in October 1981 at the Upstate Medical Center in Syracuse, New York.

7. Since October 1998, I have held the title of Adjunct Associate Professor of Pharmacy Practice at Albany College of Pharmacy & Health Sciences/Union University in Albany, New York. I teach a course entitled “Pain Management Pharmacotherapy,” PHM 551. I am also an Adjunct Assistant Professor of Pharmacy Practice at University of Connecticut School of Pharmacy located in Storrs, Connecticut, and Adjunct Associate Professor of Pharmacy at Western New England University College of Pharmacy located in Springfield, Massachusetts.

8. From February 1989 to October 1989, as the Director of Clinical Pharmacy Affairs of O.P.T.I.O.N. (Outpatient Parenteral Therapy and Intravenous Ongoing Nutrition) Care, I had direct experience planning, setting up, and registering two pharmacies. One was located at 57 Phila Street, Saratoga, New York, and the other, an O.P.T.I.O.N. Care facility, was located at 58 Hackett Boulevard, Albany, New York. At this time, I had direct experience with the types of computerized billing and patient record systems that were required for pharmacies by Medicare, Medicaid, and various third party insurance payers.

9. I am currently a registered pharmacist in New York and am assigned the license number 34085. I am also board certified as a Diplomat to the American Academy of Pain Management. I am a Fellow to the American College of Clinical Pharmacy and a Fellow to the American Society of Health-system

Pharmacists. In addition, I am currently certified in American Heart Association Basic Life Support for Healthcare Providers (CPR and AED) until September of 2015.

10. I have co-authored at least 65 articles in peer-reviewed scientific and medical journals. I am the author of seven chapters, including several chapters related to pharmaceuticals, including opioids and analgesics. Much of my publications involve research in the field of analgesic therapy and the effects of such therapies on patients and the therapies' legal distribution including chain of custody from manufacturer to wholesaler, to pharmacy, and eventually to the patients.

11. In certain circumstances, drug ordering, distribution to pharmacies, and dispensing to patients are overseen by the Federal Risk Evaluation Mitigation Strategies (REMS) program which requires additional training and certification because of certain dangers inherent to the drug.

12. In some cases, certain pharmaceutical manufacturers have taken steps to require such training even without FDA requirement.

13. I am an expert in the field of prescribing pharmaceutical drugs, including the use of computer systems for regulating access to prescription drugs and the potential influence of these distribution systems on medication access to patients and caregivers.

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