UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI LLC
Petitioner,

v.

CELGENE CORPORATION
Patent Owner

Case IPR2015-01103
Patent 6,315,720

DECLARATION OF
DR. LOURDES M. FRAU, M.D., FAAP, FISPE

I, Dr. Lourdes M. Frau, M.D., FAAP, FISPE do hereby declare as follows:

I. INTRODUCTION

1. I am over eighteen and otherwise competent to make this declaration. I have been retained in this case by Patent Owner Celgene Corporation ("Celgene" or "Patent Owner").

2. In this report, I have been asked to respond to the opinions in the Declaration of Jeffrey Fudin ("Fudin Declaration") regarding the alleged invalidity of U.S. Patent No. 6,315,720 (the "'720 patent") that was submitted on behalf of Petitioner Coalition for Affordable Drugs VI LLC ("CFAD" or "Petitioner"), as well as to provide my own understanding of the state of the relevant art at the time of the invention claimed in the '720 patent.

3. I am being compensated for my time at my usual rate of $520 per hour. My compensation does not depend in any way on the substance of my testimony or on the outcome of this or any other case.

4. I expressly reserve the right to supplement the opinions expressed herein, as well as the bases for the opinions, in response to additional expert declarations submitted by CFAD, or any additional discovery or other information provided in this matter.

5. An identification of materials I have relied on is set forth in Appendix B hereto.

II. BACKGROUND, EXPERIENCE AND QUALIFICATIONS

6. I am a physician and pharmacoepidemiologist. Since 2004, I have been a consultant on matters pertaining to pharmaceutical safety and epidemiology.

7. I am a Fellow of the International Society of Pharmacoepidemiology and the American Academy of Pediatrics. I was a member of the Pharmaceutical Research Manufacturers Association, Clinical Safety Surveillance Committee from 1994-1999. A complete list of my professional affiliations is provided in my *curriculum vitae*, a copy of which is attached hereto as Appendix A.

8. I received a Bachelor's degree in chemistry from the University of Connecticut in 1972, and an M.D. and M.M.S. from Robert Wood Johnson Medical School at Rutgers University in 1976. I received postgraduate training at Boston City Hospital, Tufts-New England Medical Center. A full description of my formal education is provided in my *curriculum vitae*.

9. I practiced general family medicine and pediatrics with the National Health Service Corps in upstate New York and in Boston, MA, before training in epidemiology at the Centers for Disease Control in Atlanta, Georgia as an Epidemic Intelligence Service officer in the Division of Sexually Transmitted Diseases, Epidemiology Research Branch. At the CDC, I was in charge of the national surveillance of congenital syphilis and Chlamydia trachomatis, from 1983-1985.

10. I am currently a Distinguished Lecturer at New York Medical College, School of Health Sciences and Practice. I was an Instructor at Mercer County Community College for continuing education courses on "Regulatory and Legal Issues in Clinical Development" and "Introduction to Pharmacovigilance" from 2005-2009.

11. After serving as a Senior Public Health Physician in the Division of Maternal and Child Health, New Jersey Department of Health and Human Services, I have worked in the pharmaceutical industry since 1988. Prior to my current position, I served as the head of several pharmaceutical departments of drug safety, pharmacovigilance, and epidemiology, for all drugs and devices, both marketed and in clinical development. That includes domestic responsibilities at Hoechst-Roussel Pharmaceuticals and Knoll Pharmaceuticals. It also includes worldwide responsibilities at Bristol-Myers Squibb, Johnson & Johnson Pharmaceutical Research Institute, Aventis Pharmaceuticals, and Cephalon. A full description of my work history is provided in my *curriculum vitae*.

12. In my professional career I have developed numerous risk management plans (including RiskMAPs and REMS). I have overseen three risk management programs within the U.S. and Europe, assuming responsibility for their success. I served as a member of PhRMA's Clinical Safety Surveillance Committee in the 1990s. I have served as Chair of a corporate Risk Management

Strategy Team, which was a multi-disciplinary group supervising and coordinating five Risk Minimization Plans for opioids and CNS products in the U.S. and Europe. I developed and established a U.S. corporate drug safety department to handle investigational and marketed products, and medical information services for patient and health professional queries. A complete list of my past professional responsibilities is provided in my *curriculum vitae*.

13. I am an expert in the field of pharmaceutical risk management—in particular safety surveillance, pharmacovigilance, and pharmacoepidemiology—including the development and administration of restricted-distribution programs.

III. SUMMARY OF OPINIONS

14. Based on my knowledge, experience, and training and my review of the '720 patent, the alleged prior art relied on by Fudin, the IPR Petition, the Fudin Declaration, the Fudin deposition, and other materials cited herein, it is my opinion that Petitioner has failed to establish that the claims of the '720 patent would have been obvious over the cited references and/or general knowledge in the field, at the time of the '720 patent's invention, which I understand to be October 23, 2000.

15. Specifically, it is my opinion that as of October 2000, a person of ordinary skill in the art ("POSA") would have had no motivation to combine the cited references in order to come up with the inventions claimed by the '720 patent,

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