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 IPR2015-01096
Patent 6,315,720

---

**DECLARATION OF JOHN FREEMAN**

I, John Freeman, hereby declare and state as follows:

1. I submit this declaration on behalf of Celgene Corporation ("Celgene"), Patent Owner of U.S. Patent No. 6,315,720 (the "'720 patent") in connection with this *inter partes* review, Case IPR2015-01096.

## I. BACKGROUND

2. I am currently the Corporate Vice President, Head of Global Drug Safety & Risk Management for Celgene Corporation. I have held this position since I became employed by Celgene in September 2005.

3. In my role as Head of Global Drug Safety & Risk Management, I lead the group responsible for monitoring various safety aspects of Celgene's products. Specifically, my team is responsible for the assessment of data concerning the safe use of Celgene's products, both in the marketplace and in clinical development. My team works to ensure compliance with regulatory requirements with regard to the safety profile of Celgene's products, and to make safety information available to various regulatory agencies. These responsibilities involve the development and implementation of procedures relating to the restricted distribution of Celgene's products pursuant to regulatory requirements.

4. Prior to joining Celgene, I served as Global Head of Drug Safety Operations at Amgen, where I oversaw safety issues relating to Amgen's products.

5. In 1986, I received a degree in pharmacology form the University of Leeds in Leeds, United Kingdom. Subsequently, I received a post graduate diploma (1989) in Clinical Science and a Master's Degree in Clinical Research (1998), both from the Welsh School of Pharmacy, University of Wales, Cardiff, United Kingdom. I also received a law degree from the College of Law in London in 2003.

6. I am familiar with the restricted-distribution system known as the System for Thalidomide Education and Prescribing Safety, or S.T.E.P.S.® S.T.E.P.S.® was introduced with Celgene's Thalomid® brand thalidomide capsules in July of 1998.

7. Since July of 1998, there has not been a single birth defect in connection with Thalomid®, in the United States or elsewhere. There have also been zero birth defects associated with two of Celgene's other products, Revlimid® and Pomalyst®, both of which are believed to be teratogenic by the U.S. Food and Drug Administration.

8. Several materials associated with the original, 1998 S.T.E.P.S.® program are described below.

## II. S.T.E.P.S.® MATERIALS

9. Exhibit 2062 is a true and correct copy of the Pharmacy Registration Card that was used and distributed by Celgene in connection with the original S.T.E.P.S.® program.

10. Exhibit 2063 is a true and correct copy of the Dear Pharmacist Letter that was used and distributed by Celgene in connection with the original S.T.E.P.S.® program.

11. Exhibit 2064 is a true and correct copy of the template for the "Dear Dr." letter that was used and distributed by Celgene in connection with the original S.T.E.P.S.® program. The name of each registered physician, along with the name and phone number of the Celgene Immunology Specialist, were added to each letter before the letter was sent to each registered physician.

12. Exhibit 2065 is a true and correct copy of the Patient Registration Form that was used and distributed by Celgene in connection with the original S.T.E.P.S.® program.

13. Exhibit 2066 is a true and correct copy of the Instructions for Physicians that were used and distributed by Celgene in connection with the original S.T.E.P.S.® program.

Executed this 12th day of February 2016. I declare under penalty of perjury that the foregoing is true and correct.

John Freeman