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Filed: July 29, 2015

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 IPR2015-01102
Patent 6,315,720

PATENT OWNER PRELIMINARY RESPONSE PURSUANT TO 35 U.S.C. § 313 AND 37 C.F.R. § 42.107

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I. INTRODUCTION

Pursuant to 35 U.S.C. § 313 and 37 C.F.R. § 42.107(a), Patent Owner Celgene Corporation ("Celgene") submits this Preliminary Response to Coalition For Affordable Drugs VI LLC's ("CFAD") Petition for *Inter Partes* Review (the "Petition") of U.S. Patent No. 6,315,720 (the "'720 patent").

The '720 patent describes and claims improved methods for delivering a potentially dangerous drug to a patient (including teratogenic drugs such as thalidomide) while avoiding the occurrence of adverse side effects (such as birth defects of the type associated with thalidomide). The inventions were conceived as part of Celgene's efforts to significantly improve its existing program for controlling patient access to thalidomide, which was known as the System for Thalidomide Education and Prescribing Safety, or S.T.E.P.S.® The improved program, which Celgene called Enhanced S.T.E.P.S.®, is an embodiment of the '720 patent and has been used in connection with thalidomide and other potentially teratogenic pharmaceutical products since 2001. During that time it has successfully prevented 100% of drug-related birth defects. In fact, the inventions of the '720 patent were so successful and innovative that the FDA required other drug manufacturers to copy Celgene's patented methods if they wanted to keep their products on the market, resulting in licenses to several of Celgene's patents, including the '720 patent.

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