Paper No. __
Filed: February 12, 2016

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

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

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I. INTRODUCTION

United States Patent No. 6,315,720 (the "'720 patent") describes and claims improved methods for delivering potentially dangerous drugs, such as teratogenic drugs (in particular, thalidomide), to a patient while avoiding the occurrence of side effects (such as thalidomide-related birth defects). Ex. 1001 at Claims. The inventions were conceived as part of Celgene Corporation's ("Celgene") efforts to improve its existing System for Thalidomide Education and Prescription Safety, or S.T.E.P.S.®, which had been used to control patient access to Celgene's Thalomid® (thalidomide) drug product since it was approved by the U.S. Food and Drug Administration ("FDA") in July 1998. The original 1998 S.T.E.P.S.® program is an embodiment of U.S. Patent No. 6,045,501 (the "'501 patent," at issue in IPR2015-01092). Celgene's improved program—Enhanced S.T.E.P.S.®—is an embodiment of the improved methods claimed in the '720 patent.

Coalition for Affordable Drugs VI ("CFAD") filed a petition for *inter partes* review ("Petition" or "Pet.") seeking cancelation of claims 1-32 of the '720 patent. The Board instituted trial on the only ground raised in the Petition—CFAD's assertion that claims 1-32 would have been obvious over Mitchell, Dishman, Cunningham, Mundt, Mann, Vanchieri, Shinn, Linnarsson, Grönroos, Soyka, Hamera, Kosten, and Menill. Paper 22 at 25. CFAD's Petition lacks merit for several reasons.

First, CFAD conducted its obviousness analysis through the eyes of the wrong person of ordinary skill in the art ("POSA"). Because obviousness must be judged from the POSA's viewpoint, and because CFAD's POSA is improper, CFAD's arguments are deficient and fail as a matter of law.

Second, CFAD has failed to identify any known need or problem in the art at the time that the '720 patent was filed in October 2000. Without such an identification, there is no reason to arrive at the claimed inventions and the claims cannot have been obvious.

Third, CFAD has failed to prove that the asserted references would have rendered the claimed inventions obvious because the references fail to disclose, teach, or suggest each and every element of the claimed inventions.

Fourth, CFAD has failed to prove that a POSA would have been motivated to combine the asserted references. As already noted, there was no problem to be solved at the time of the '720 patent's invention and, therefore, no motivation to combine the asserted references for that reason alone. Further, even if there had been a problem to be solved, CFAD's expert admitted that he chose to combine at least Cunningham with the other asserted references because the '720 patent claims recite a "prescription approval code." In other words, Dr. Fudin admitted that he used the '720 patent as a roadmap to arrive at the claimed methods. This hindsight-driven analysis is impermissible and requires denial of the Petition.

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