

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner,

v.

CELGENE CORPORATION,
Patent Owner

Case IPR2023-00512
Patent 8,846,628

EXPERT DECLARATION OF GEORGE M. GRASS IV, PH.D.

CELGENE 2052

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I, George M. Grass IV, Ph.D., declare as follows:

I. INTRODUCTION AND BACKGROUND

1. I have been retained by counsel for Celgene Corporation (“Patent Owner”) as an expert in *Apotex Inc. v. Celgene Corporation*, No. IPR2023-00512, challenging claims 1, 2, 6-9, 11-28, 32-36, and 38-43 of U.S. Patent No. 8,846,628 (“the ’628 patent”).

2. I understand that Apotex Inc. (“Apotex”) have filed an Inter Partes Review (IPR) at the USPTO challenging claims 1, 2, 6-9, 11-28, 32-36, and 38-43 of the ’628 patent.

A. Qualifications and Experience

3. I am President of G2 Research, Inc., a company I founded in August 2001 to provide consulting services to pharmaceutical and biotechnology companies in a variety of areas. Among other things, I have performed pharmacokinetic modeling to evaluate clinical regimens for antibodies and small molecules. I have also developed computer simulation software and models to predict drug pharmacokinetics.

4. I obtained a Ph.D. in Pharmaceutics at the University of Wisconsin, Madison in 1985. My Ph.D. thesis was entitled “Mechanisms of Corneal Drug Penetration.” As a result of this research, I was the co-recipient of the 1989 Ebert Prize, awarded by the American Pharmacists Association Academy of

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