

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 CORY BERKLAND, PH.D.

CELGENE 2001

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I. INTRODUCTION AND BACKGROUND

1. I, Cory Berkland, Ph.D., have been retained by counsel for Celgene Corporation (“Patent Owner”) as an expert in *Apotex Inc. v. Celgene Corporation*, No. IPR2022-00512, challenging claims 1, 2, 6-9, 11-28, 32-36, and 38-43 of U.S. Patent No. 8,846,628 (“the ’628 patent”).

A. Qualifications and Experience

2. I am currently a Professor of Pharmaceutical Chemistry and a Professor of Chemical and Petroleum Engineering at The University of Kansas. I also have an appointment as a courtesy professor in the Chemistry Department at The University of Kansas. I also assisted in designing the BioEngineering graduate program at The University of Kansas, and I am the former director of the Biomolecular Engineering track within the BioEngineering program.

3. I teach courses to undergraduate and graduate students at The University of Kansas on, among other things, pharmaceutical formulation (including solid oral dosage forms), drug delivery, dissolution methods, and modeling dissolution profiles.

4. I received a Doctor of Philosophy degree from the University of Illinois in 2003 and a Master of Science degree from the University of Illinois in 2001, both from the Department of Chemical and Biomolecular Engineering. I

received a Bachelor of Science degree in Chemical Engineering from Iowa State University in 1998.

5. I have worked in the area of pharmaceutical formulation for over 20 years. A significant portion of my career has been dedicated to the study of formulating therapeutics for delivery to patients. I currently research the design of molecules and materials specialized for a particular disease and targeted drug delivery to maximize their therapeutic effect while limiting side-effects. I have extensive experience in the area of pharmaceutical delivery design including preformulation, formulation, analysis, and related theories.

6. I have published over 200 peer-reviewed papers, and I have presented my research at many national and international research conferences and to companies, including more than 75 invited talks. I have also given distinguished lectures such as the Nagai Foundation Distinguished Lectureship in Japan and a lectureship at the Center of Excellence in Nanotechnology at the Massachusetts Institute of Technology. I also serve or have served on the editorial advisory board for a number of peer-reviewed journals: Therapeutic Delivery, The Journal of Pharmaceutical Sciences, and The Journal of Pharmaceutical Innovation. I also serve or have served on advisory boards for the Center for Cancer Engineering at The Ohio State University, the Drug Discovery and Development of Experimental

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