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 WILLIAM G. BLUM, MD

CELGENE 2053

TABLE OF CONTENTS

I, William G. Blum, M.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 a board-certified hematologist-oncologist specializing in treatment of acute myeloid leukemia (AML), myelodysplastic syndromes (MDS), acute lymphoblastic leukemia and other myeloid malignancies. I have over 20 years of experience treating patients in this field including 19 years treating patients with injectable 5-azacytidine (Vidaza®) and 3 years treating patients with oral 5-azacytidine (Onureg®).

4. I am currently a professor in the Department of Hematology and Medical Oncology at Emory University School of Medicine. I serve as Director of the Acute Leukemia Program at Winship Cancer Institute and also serve on the clinical team in the Bone Marrow and Stem Cell Transplant Center at Winship. I

have worked at Emory since 2017. Prior to working at Emory, I was a Professor in the Division of Hematology in the Department of Internal Medicine at The Ohio State University - James Cancer Hospital and Solove Research Institute from 2003-2017.

5. I am a member of several professional organizations including American Society of Hematology, American Association of Cancer Research, American Society of Clinical Oncology, American Society of Bone Marrow Transplantation and Alliance Cooperative Group for Clinical Trials in Oncology. Additionally, I am a cadre member of the Alliance Leukemia Committee and principal investigator/study chair for The Leukemia & Lymphoma Society's Beat AML Master Trial. I have been an invited speaker at international meetings of the American Society of Hematology, American Society of Clinical Oncology, European Hematology Association, and the Tandem Transplant meetings of the Center for International Blood and Marrow Transplant Research/American Society of Blood and Marrow Transplantation, among others.

6. I received my Medical Degree from the Medical School of Georgia in Augusta, Georgia, completed my residency at the University of Virginia in Charlottesville, Virginia, and completed my fellowship in medical oncology at Washington University in St. Louis, Missouri.

7. My curriculum vitae, which lists my professional experience and qualifications in greater detail, is attached hereto as **Appendix A**.

B. Compensation

8. I am being compensated for my time in connection with this matter at my standard consulting rate, which is $1,000.00 per hour. My compensation is not dependent in any way upon the substance of my opinions or the outcome of this matter.

II. PERSON OF ORDINARY SKILL IN THE ART

9. I understand that a POSA relating to the subject matter of the '628 patent would have had (1) a Pharm.D., and/or a Ph.D. in pharmaceutical sciences, biomolecular engineering, chemical engineering, chemistry, or related discipline or an M.D.; and (2) at least two years of experience with oncology, medicine, pharmaceutical design, or formulation of oral dosage forms. As of December 2008 I would have been a POSA.[1]

[1] I understand Petitioner's experts, Drs. Buckton and Batchelor, each put forth identical definitions of a POSA, and that they both opine that a POSA as of December 5, 2008 would have had (1) a Pharm.D., or a Ph.D. in pharmaceutical sciences, chemical engineering, chemistry, or related discipline; and (2) at least two to four years of experience with pharmaceutical design, formulation,

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.