

On behalf of: Par Pharmaceutical, Inc. *et al.*

Entered: December 5, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC., BRECKENRIDGE PHARMACEUTICAL,
INC., AND ROXANE LABORATORIES, INC.

Petitioners

v.

NOVARTIS AG

Patent Owner

Case IPR2016-00084¹
U.S. Patent No. 5,665,772

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLEY, and
ROBERT A. POLLOCK, *Administrative Patent Judges.*

**DECLARATION OF MARK J. RATAIN, M.D. IN SUPPORT OF
PETITIONERS' REPLY IN THE *INTER PARTES* REVIEW OF U.S.
PATENT NO. 5,665,772**

¹ Breckenridge Pharmaceutical, Inc. was joined as a party to this proceeding via a Motion for Joinder in IPR2016-01023; Roxane Laboratories, Inc. was joined as a party via a Motion for Joinder in IPR2016-01102.

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I, Mark J. Ratain, M.D., resident of Chicago, Illinois, hereby declare as follows:

I. INTRODUCTION AND QUALIFICATIONS

1. I have been retained by Par Pharmaceutical, Inc. (“Par”) to provide my opinion concerning the validity of U.S. Patent No. 5,665,772 (Exhibit 1001; “the ’772 patent”) in support of Petitioners’ Petition for *Inter Partes* Review of the ’772 patent (“the ’772 Petition”).

2. I graduated from Harvard University *magna cum laude* in 1976 with an A.B. in Biochemical Sciences. I obtained my M.D. from Yale University School of Medicine in 1980. I completed my internship and residency at the Johns Hopkins Hospital in Baltimore, MD from 1980-1983. I completed a fellowship in Hematology/Oncology at the Department of Medicine at the University of Chicago from 1986-1988.

3. In 1986, I joined the Department of Medicine, Section of Hematology/Oncology at the University of Chicago as an Instructor and was promoted to Professor in that department in 1995. In 2002, I was appointed as the first Leon O. Jacobson Professor, an endowed chair, at the University of Chicago.

4. I have had a secondary appointment on the Committee on Clinical Pharmacology and Pharmacogenomics (previously Committee on Clinical Pharmacology) since joining the University of Chicago faculty. I also chaired this

interdepartmental unit from 1992-2010. In 2010, I founded the University's Center for Personalized Therapeutics, and still serve as its Director, as well as serving as the Chief Hospital Pharmacologist at University of Chicago Medicine.

5. I have also had a number of leadership roles in the University's Comprehensive Cancer Center. I served from 1995-1999 as Co-Director of the Clinical and Experimental Therapeutics Program and in 1999 was appointed as the Associate Director for Clinical Sciences at the Comprehensive Cancer Center at the University of Chicago.

6. I have received numerous honors and awards over my career. These include election to the Association of American Physicians in 2007, and awards from multiple institutions (MD Anderson Cancer Center, University of North Carolina, University of Nebraska, University of Utah), foundations (Pharmaceutical Research and Manufacturer's Association of America Foundation) and professional societies (American Association of Pharmaceutical Scientists, American Society for Clinical Pharmacology and Therapeutics, American Society of Clinical Oncology, American College of Clinical Pharmacology).

7. I have also had extensive involvement with the American Society of Clinical Oncology (ASCO), dating back to 1990 when I was appointed Chair of ASCO's Audit and Finance Committee. I was subsequently elected to the position of Secretary-Treasurer of ASCO, and served in that capacity as an Officer and

Director from 1994 to 1997. I also served as the Chair of ASCO's Continuing Medical Education Committee from 1997 to 1999. In my capacities as Committee Chair, Officer, and Director, I participated actively in ASCO Board meetings and am familiar with ASCO's policy and lobbying efforts to modify Medicare reimbursement policies for oral oncology drugs during the period from 1990 to 1999.

8. I have also had extensive involvement in clinical pharmacology organizations, including the American Society for Clinical Pharmacology and Therapeutics (ASCPT) and the American Board for Clinical Pharmacology (ABCP). ASCPT is the premier international society for clinical pharmacology and therapeutics, and includes a diverse membership from academia, industry, and government (especially FDA). I have chaired multiple committees for ASCPT over the past 25 years, and served as a Director from 1997-2001. ABCP is the entity that accredits training programs and certifies trainees in clinical pharmacology. I served ABCP as a member of its Governing Board from 2002-2007 and Chair of its Credentials Committee from 2004-2007, and continue to direct the University's ABCP-accredited training program, which is funded in part by a Federal training grant from the National Institute of General Medical Sciences (part of the National Institutes of Health).

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