Paper No. __

Filed: July 1, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.

&

FRESENIUS KABI USA, LLC

PETITIONERS

V.

ELI LILLY & COMPANY

PATENT OWNER

CASE NO.: UNASSIGNED
PATENT NO. 7,772,209
FILED: JULY 11, 2007
ISSUED: AUGUST 10, 2010
INVENTOR: CLET NIYIKIZA

TITLE: ANTIFOLATE COMBINATION THERAPIES

Teva-Fresenius

DECLARATION OF MARK J. RATAIN, MD

I, Mark J. Ratain, MD, hereby declare as follows:

I. INTRODUCTION AND SCOPE OF WORK

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of Teva Pharmaceuticals USA, Inc. ("Teva") and Fresenius Kabi USA, LLC ("Fresenius") for the above-captioned *inter partes* review ("IPR"). I understand that the petition for *inter partes* review involves U.S. Patent No. 7,772,209 ("the '209 patent"), Exhibit 1001, which issued from U.S. Patent Application No. 11/776,329 (the "'329 Application"), filed July 11, 2007. (Ex. 1001 at Front Cover.) The '209 Patent claims priority to U.S. Patent App. No. 60/215,310 (filed June 30, 2000). The '209 Patent names Clet Niyikiza as an inventor. The '209 Patent issued on August 10, 2010. (*Id.*)

3. I served as a testifying expert for Teva and Fresenius in a federal court action against Eli Lilly and Company involving the '209 patent, captioned *Eli Lilly and Co. v. Teva Parenteral Medicines, Inc. et al*, Case No. 10-cv-1376-TWP-DKL. The opinions I offered in that litigation have not changed, and they are consistent with the opinions I set forth and agree to in this declaration.

4. To prepare this Declaration, I have reviewed the '209 Patent in light of general knowledge in the art as of June 30, 1999. In formulating my opinions, I have relied upon my experience, education and knowledge in the relevant art as would be relevant to the viewpoint of a person of ordinary skill in the art prior to June 30, 1999.

5. I am being compensated for my time in connection with this IPR at my standard consulting rate, which is $800 per hour for general consulting and $8000 per day for testimony and preparation for testimony. My compensation is not contingent on the conclusions I reach herein or on the specifics of my testimony. I have no financial stake in the outcome of this proceeding.

6. I understand that the '209 patent is currently subject to three previous IPRs, including *Neptune Generics, LLC v. Eli Lilly & Co.* IPR2016-00237 ("Neptune IPR 1"), *Neptune Generics, LLC v. Eli Lilly & Co.* IPR2016-00240 ("Neptune IPR 2"), and *Sandoz Inc. v. Eli Lilly & Co.* IPR2016-00318 ("Sandoz IPR"). I understand that Petitioners Teva and Fresenius seek to become a party to each of the foregoing IPRs, and that this declaration is being submitted in furtherance of specifically Neptune IPR 2.

7. I have reviewed the materials submitted with the petition filed in the Neptune IPR 2, including the petition (Paper No. 1), the Declaration of W. Archie

Bleyer, MD, FRCP [GLASG] (filed as Exhibit 1024 in Neptune IPR 2) and materials cited therein, and the Board's Decision Instituting *Inter Partes* Review (Paper No. 14.) I have also reviewed and considered other documents (such as the relevant prior art) in arriving at my opinions.

8. I agree in all material respects with the analysis and opinions set forth by Dr. Bleyer in his declaration and submitted as Exhibit 1024 in Neptune IPR 2. Because my independent analysis of the claims and prior art led to the same substantive conclusions as Dr. Bleyer, coupled with the fact that the Petitioners Teva and Fresenius are seeking to become a party to the Neptune IPR 2, I adopt Dr. Bleyer's substantive opinions as my own. I have appended those opinions after my signature of this declaration for convenience, and understand that a copy of Dr. Bleyer's declaration is being submitted in this IPR as Exhibit 1024.

9. I understand that in its Decision Instituting *Inter Partes* Review in connection with Neptune IPR 2, the Board concluded that Petitioner Neptune demonstrated a reasonable likelihood of prevailing on its assertion that claims 1-22 of the '209 patent are unpatentable. Specifically, the Board instituted review on the following basis: Rusthoven et al., Multitargeted Antifolate LY231514 as First-Line Chemotherapy for Patients with Advanced Non-Small-Cell Lung Cancer: A Phase II Study, Journal of Clinical Oncology, Vol. 17, No. 4, (April 1999), pp.

1194-1199 (“Rusthoven”) (Ex. 1011) in view of European Patent Application No. 0,595,005 A1 (“EP 005”). Because Petitioners Teva and Fresenius are seeking to join Neptune IPR 2, I have limited my opinions in this IPR to the references discussed in the petition (Paper No. 1) and supporting materials filed in that proceeding.

II. BACKGROUND AND QUALIFICATIONS

10. I have been a practicing oncologist since 1986.

11. I received an M.D. from the Yale University School of Medicine in 1980.

12. I am a Diplomate of the National Board of Medical Examiners (1981), and have been a Licensed Physician and Surgeon in the State of Illinois since 1983. I am Board Certified by the American Board of Internal Medicine in Internal Medicine (1983), Medical Oncology (1985) and Hematology (1986). I am also Board Certified by the American Board of Clinical Pharmacology (1993).

13. I am the Leon O. Jacobson Professor of Medicine and Associate Director for Clinical Sciences at the University of Chicago Comprehensive Cancer Center, and I have held that title since 2002. I specialize in the use of investigational agents to treat advanced solid tumors. I also specialize in pharmacogenetics — the study of how genetic variation affects the body’s

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.