UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.
Petitioner

v.

ICOS CORP.
Patent Owner

Case: IPR2018-01183

Patent 6,943,166

EXPERT DECLARATION OF ROGER WILLIAMS, M.D. REGARDING U.S. PATENT NO. 6,943,166

Table of Contents

I, Roger Williams, M.D., hereby declare and state as follows:

I. INTRODUCTION AND SCOPE OF WORK

1. My name is Roger Williams, M.D. I have been asked to provide my opinions by Petitioner Aquestive Therapeutics, Inc., in this *Inter Partes* Review ("IPR") as an expert in the relevant art.

2. I have been asked to provide my opinions and views on the materials I have reviewed in this IPR related to U.S. Patent No. 6,943,166 (the "'166 patent") (EX1001), and the scientific and technical knowledge regarding the same subject matter. I have been asked to consider what one of ordinary skill in the art would have understood from the '166 patent. I have also considered whether certain references disclose or suggest the features recited in the claims of the '166 patent. My opinions are set forth below.

3. My opinions are guided by my appreciation of how a person of ordinary skill in the art would have understood the claims of the '166 patent at the time of the alleged invention, which I have been asked to initially assume is April 30, 1999, the earliest filing date potentially attributable to the '166 patent.

4. Based on my experience and expertise it is my opinion that certain references as discussed in detail below alone or in combination disclose or suggest all the features recited in the claims of the '166 patent, that any differences from these prior references are obvious, and that these claims combine well known features to

provide predictable results. Attached as Appendix A to this report is a detailed chart showing where each claim limitation is disclosed in the prior art.

II. PROFESSIONAL BACKGROUND

5. I earned a B.A. in Chemistry and Zoology from Oberlin College, and an M.D. from the University of Chicago School of Medicine 1967. I was Board Certified in Internal Medicine in 1972 and Board Certified in Clinical Pharmacology in 1991. From 2000 to 2014, I was the CEO and Chair, Council of Experts of the United States Pharmacopeial Convention (USP). From 1995 to 2000, I was the Deputy Center Director for the Office of Pharmaceutical Science (CDER) at the United States Food and Drug Administration (FDA). I am currently an expert consultant and partner at NDA Partners, LLC.

6. I have taught courses in Introductory Pharmacokinetics, Pharmacokinetics for Pharmaceutical Students, Pharmacology, Clinical Pharmacology and Therapeutics, and Clinical Drug Investigations. I have authored and reviewed articles and literature on response relationships for both efficacy and toxicity, the drug development and regulatory processes and reviewing doses, including maximum tolerated doses, based on in vitro potency.

7. I am or have been a member of the American Medical Association, the American Society of Clinical Pharmacology and Therapeutics, American Association of Pharmaceutical Scientists, the American Association for the Advancement of Science, and the International Pharmaceutical Federation.

8. With respect to the subject matter at issue in this IPR, I have extensive experience. I have coordinated more than 100 clinical and related investigations during my time as a clinical investigator at the University of California, San Francisco. While at FDA, I worked with many internal and external topic experts to advance regulatory policy represented in guidances that covered clinical, clinical pharmacology, biopharmaceutics, microbiology, and chemistry, manufacturing and controls. During my time at USP, I engaged in a similar broad variety of topics, adding also experience in adverse event and other reporting programs, dietary supplements, dietary supplement verification programs, compounded medicines, and general standards setting for chemical and biological medicines. My special expertise is in understanding equivalence questions for drugs and biologics, which include a broad and detailed understanding of new drug development in Phases 1, 2, 3 and 4, with specific understanding of how to generate dose/response information for a new drug or biologic medicine. I have worked extensively in the International Council for Harmonization and the World Health Organization.

9. The opinions set forth in this declaration are my own, and I have no financial ties to the litigation.

10. I am informed by counsel that the '166 patent has been challenged in a related IPR proceeding brought by IntelGenx Corp. against ICOS Corp., Case IPR2016-00678, and that the Patent Trial and Appeal Board (PTAB) denied institution of the IPR. I am also informed that Eli Lilly has filed suit based on the

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.