

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

J KYLE BASS and ERICH SPANGENBERG,
Petitioner

v.

FRESENIUS KABI USA, LLC
Patent Owner

Case No. **IPR2016-00254**
U.S. Patent No. 8,476,010

EXHIBIT 2036 - DECLARATION OF STANLEY S. DAVIS Ph.D.

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

I, STANLEY DAVIS, Ph.D., hereby declare and state as follows:

1. I submit this expert declaration at the request of counsel for patentee Fresenius Kabi USA, LLC (“Fresenius”) in the above-captioned matter. My compensation pertaining to this matter is not dependent on the outcome of this matter.

I. QUALIFICATIONS AND EXPERIENCE

2. I am an Emeritus Professor of Pharmacy at the University of Nottingham, United Kingdom. For over forty years, I have been active in the field of pharmaceutical science. I have taught courses, conducted research, written papers, edited books, and consulted for industry on a wide-range of topics, to include emulsion formulations and their use in drug delivery.

3. I am the co-founder of three pharmaceutical companies and the recipient of awards relating to my research. I have authored or co-authored over 750 scientific papers and have co-edited seven books relating to the pharmaceutical sciences. I am also a named inventor on several patents in the pharmaceutical area.

4. I continue to provide consulting services relating to the development of pharmaceutical formulations and stay abreast of relevant scientific publications.

5. I have consulted for various pharmaceutical companies all over the world on matters relating to pharmaceutical formulation, pharmaceutical analysis, processing, scale-up, material science, drug stability, controlled release, and other

formulation issues. These companies have included: Abbott, Pharmaceutical Profiles, Hoechst, Alza, Synthelabo Pharma, Pierre Fabre, Jouveinal, Eli Lilly, Glycoform, Aradigm, Gene Medicine, Leopold, ICI Pharmaceuticals (Zeneca), Marion Merrell Dow, Fresenius, Baxter and Arakis. I was also a visiting scientist at Allergan, Syntex and Alza in the United States.

6. I graduated from the School of Pharmacy at the University of London in 1964 with a Bachelor's degree in Pharmacy. I continued my studies at the University of London and received a Ph.D. in 1967 for studies on emulsion systems. I was awarded a Doctor of Science degree (higher doctorate) in 1982 for my subsequent research work.

7. In 1967, I was appointed to the faculty of the University of London and in 1968 I was awarded a one year Fulbright Scholarship to undertake postdoctoral studies with Professor Takeru Higuchi at the University of Kansas in the field of solution thermodynamics.

8. In 1970, I moved to the University of Aston in Birmingham, UK, as Senior Lecturer and Head of the Pharmaceutics section where I developed an active research group in the field of drug delivery systems that included work on emulsions and other colloidal systems.

9. In 1975, I became Lord Trent Professor of Pharmacy at the University of Nottingham. In this role, I ran a large research group specializing in

the study of novel drug delivery systems including disperse systems such as emulsions, liposomes and microparticles for human and animal use.

10. I have supervised over 100 Ph.D. candidates and 20 post-doctoral fellows in different areas of pharmacy.

11. In 2003, I became an Emeritus Professor of Pharmacy at the University of Nottingham.

12. I have served on numerous committees and panels including the British and European Pharmacopoeias, the Medicines Commission (United Kingdom), and the Science & Engineering Research Council (United Kingdom).

13. I am or have been a member of many learned pharmaceutical societies, including the Royal Pharmaceutical Society, Royal Institute of Chemistry, Society of Rheology, Society of Chemical Industry, American Association of Pharmaceutical Scientists, Controlled Release Society and the Society for Drug Research.

14. I have served as an Editorial Board member for many journals dealing with the pharmaceutical sciences as well as the materials sciences.

15. I have received awards from various organizations to include the Swedish Pharmaceutical Society, the Royal Pharmaceutical Society of Great Britain, and in 2005 I received the Høest-Madsen Medal for lifetime achievement in the pharmaceutical sciences from the International Pharmaceutical Federation

(FIP).

16. In 2008, I was awarded an honorary Doctor of Science degree from London University and in 2012 I was made a Fellow of University College London.

17. I have more than 40 years of experience in development of commercial drug products in the pharmaceutical industry and academic research, with specific focus on drug product formulation development. Specifically, I have extensive personal research experience in the area of colloids and colloidal drug product formulations, including emulsions and suspensions, and in particular, oil-in-water emulsions containing propofol, including Diprivan®, and have authored or co-authored many reviewed publications and made numerous presentations in this area at scientific meetings. I have also authored or co-authored several scientific publications and book chapters on physicochemical properties of emulsions and emulsion stability, including propofol oil-in-water emulsions, large particle contaminants in intravenous emulsions (e.g. Davis *et al.*, *Encyclopedia of Emulsion Technology, Chapter 3, Applications*). I am an author of the Han, Washington and Davis reference describing the physical stability of commercially marketed Diprivan® that is cited in Petitioner's Expert Declaration (*see* Exh. 1002, Feinberg Declaration at ¶16).

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.