

Paper No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AGILA SPECIALTIES INC. and MYLAN LABORATORIES LIMITED,
Petitioner

v.

CEPHALON, INC.,
Patent Owner

Patent No. 8,791,270

DECLARATION OF SAMUEL H. YALKOWSKY, PH.D.

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I, Samuel H. Yalkowsky, declare as follows:

I. QUALIFICATIONS

1. My name is Samuel H. Yalkowsky. I am currently a Professor in the Department of Pharmaceutical Sciences at The University of Arizona. I have been a member of the faculty of this department since 1982. Prior to this I was a research scientist at the Upjohn Company in their Pharmaceutical Research Unit.

2. I received a B.S. in Pharmacy from Columbia University in 1965, and a Ph.D. in Pharmaceutical Chemistry from the University of Michigan in 1969.

3. While at Upjohn, I developed the marketed formulations of Xanax[®] tablets and Halcion[®] tablets. I also worked on a Xanax[®] injectable formulation. I formulated the first prostaglandin to be used in humans and received a patent for my formulation.

4. My research expertise lies in the relationship between chemical structure and physiochemical properties, especially the solubility and stability of organic compounds, and solubilization in aqueous media. I have extensive experience with pharmaceutical formulations, including the use of organic co-solvents in drug formulations and the optimization of formulations for the freeze-drying (lyophilization) of pharmaceuticals.

5. I developed the General Solubility Equation, GSE, which is the state of the art technique for estimating the solubility of organic compounds in water. I also developed an *in vitro* technique for evaluating whether or not a formulation is likely to precipitate when it is injected into blood or intravenous solutions. This technique is used by many pharmaceutical companies. I also provide a formulation

evaluation service to the industry. In addition, I have developed novel dosage forms of highly insoluble drugs and formulations to improve dissolution of important solutes from soil.

6. My research has been funded by such organizations as the National Cancer Institute, the Environmental Protection Agency, the Department of Defense, and the pharmaceutical industry.

7. I have authored or co-authored more than 260 scientific publications, including peer-reviewed journal articles. Two of my publications have been awarded the Ebert Prize for the best scientific paper in the Journal of Pharmaceutical Sciences. I have authored, co-authored, or edited eight books dealing with solubility and solubilization of drugs. I am presently Editor-in-Chief of the AQUASOL database, a comprehensive collection of solubility data for organic compounds.

8. I have also contributed to more than 40 symposia, conferences, short courses, and lectureships, including invited presentations both in The United States and across the world, including: the APhA Academy of Pharmaceutical Sciences, the American Association of Pharmaceutical Scientists, the American Chemical Society, and the Pharmaceutical Society of Great Britain.

9. I have received numerous honors and awards, and am an inventor or co-inventor on five United States patents relating to drug formulations.

10. I have taught courses at the University of Arizona for over 30 years in which students studied physiochemical properties, and solubility.

11. For the last ten years I have taught a short course titled Solubility and Solubilization at the College of Pharmacy, attracting scientists from across the country.

12. A summary of my education, experience, publications, awards and honors, patents, publications, and presentations is provided in my CV, a copy of which is submitted separately. Ex. 1003.

II. SCOPE OF WORK

13. I understand that a petition is being filed with The United States Patent and Trademark Office for *Inter Partes* Review of U.S. Patent No. 8,791,270 (hereinafter, “the ’270 patent,” Ex. 1001). I have been retained by the Petitioner as a technical expert to provide analysis and opinions regarding the ’270 patent. I have reviewed the ’270 patent and relevant sections of its prosecution history in The United States Patent and Trademark Office. Ex. 1004. I have also reviewed and considered various other documents in arriving at my opinions, and cite them in this declaration. For convenience, documents cited in this declaration are listed in the Appendix in Section XII.

14. I am compensated at the rate of \$1000/hour for my work. I have no financial interest in the outcome of this matter.

III. OVERVIEW OF THE ’270 PATENT

15. The ’270 patent is entitled “Bendamustine Pharmaceutical Compositions.” I have been advised that the ’270 patent issued from U.S. Patent Application No. 13/969,724 (the ’724 application), filed on August 19, 2013,

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