

Resume of Srikumaran Melethil, Ph.D., J.D.

CONTACT INFORMATION

1341 White Oak Drive, Springfield, OH 45504

Phone: 419-581-1114 Email: melethils@umkc.edu Web site: www.lawandscience.com

EDUCATION

JD University of Missouri-Kansas City School of Law
Bar Admissions: Missouri Bar (# 48508) and USPTO (Reg. No. 57622)

PhD Department of Pharmaceutics, State Univ. of NY, Buffalo, NY

BS & MS Department of Pharmacy, Andhra University, Waltair, India
B. Pharmacy (First Class, First Rank, Gold Medalist)
M. Pharmacy, Manufacturing Pharmacy (First Class)

HS All Saints' High School, Hyderabad, India (First Class)

EMPLOYMENT EXPERIENCES

2017-DATE Of Counsel, Shumaker, Loop & Kendrick, LLP, Toledo, OH 43604

2011-2017 Of Counsel, Fraser Clemens Martin & Miller, LLC, Perrysburg, OH 43551

2003-DATE President/Founder, Law and Science Consulting

2002-DATE Professor Emeritus, University of Missouri-Kansas City

2006-2010 Founding Chair, Dept. of Pharmaceutical Sciences, Univ. of Findlay, OH 45840

1979-2002 Professor, Pharmaceutics and Medicine, 1988-2002; Assoc. Prof. 1979-1988
(tenured 1983); Schools of Pharmacy & Medicine, Univ. Missouri-KC 64110

PROFESSIONAL HONORS

- Elected Fellow, American Association of Pharmaceutical Scientists, 2010
- Distinguished Scientist, American Association of Indian Pharmaceutical Scientists, 2007
- Rho Chi (National Pharmacy Honor Society, UM-Chapter) Teacher of The Year, 1990
- Elected Fellow, American College of Clinical Pharmacology, 1988
- Nageswara Rao Pantulu Gold Medal, First Rank, B. Pharmacy, 1967

MAJOR PROFESSIONAL EXPERIENCES

Pharmaceutical Sciences (additional details upon request)

- **Expertise:** Designing, conducting, and analyzing data from in-vivo (whole body) and in-vitro (cell culture) pharmacokinetic (ADME) studies, including modeling; drug transport/delivery studies; clinical pharmacology; bioequivalence testing; analytical methodology development (HPLC/MS, atomic absorption)
- **Research Publications/Areas/Funding:** Publications: About 50 publications and 140 abstracts. Areas: Pharmacokinetics, pharmacodynamics, drug analysis, drug interactions, drug formulations and bioequivalence, clinical pharmacology, gastrointestinal and blood-brain barrier transport of drugs and metals, nanopharmaceuticals, biosimilars. Funding: Federal, state and industrial sectors
- **Teaching:** Courses in pharmacokinetics to: (1) graduate (MS, PhD) and professional (BS and PharmD) pharmacy students, and (2) chemical engineering (BS and MS students)
- **Student Mentoring:** search advisor to graduate (PhD. and MS) and post-doctoral (PhD, MD and PharmD) students

Resume of Srikumaran Melethil, Ph.D., J.D.

- **Scientific Reviewer:** Grants: National Institutes of Health; University of Missouri Research Board; Science Education Partnership, Marion Merrell Dow; Journals: (partial list): Pharmaceutical Research, J. Pharmaceutical Sciences, J. Pharmacology Experimental Therapeutics
- **Consultant:** FDA/Center for Veterinary Medicine; pharmaceutical industry; Midwest Research Institute, Kansas City, MO; startup biotech company (development of a new diabetes test)
- **Expert Testimony/Affidavits:** lethal injection protocol (therapeutic incompatibilities), marijuana pharmacokinetics (duration of exposure), breathalyzer tests (partition ratio), chemical and drug toxicity
- **Editorial Board:** Clinical Research and Regulatory Affairs

Patent and Drug Law (additional details upon request)

- **Practice areas:** Patent prosecution and infringement opinions; medical devices
- **Recent Publications/Presentations:** Areas: Biosimilars litigation, e.g., What's going on in US Biosimilars Litigation? Centre for Information & Innovation Law (CIIR), University of Copenhagen, June 1, 2017); Hatch-Waxman litigation, e.g., Case Law Report: *Eurand, Inc. v. Mylan Pharms Inc.* - Case No. 2011-1399, -1409 (Fed. Cir. Apr. 16, 2012); nanopharmaceuticals, e.g., Nanopharmaceuticals: Regulatory and Patent Challenges (Invited Keynote Speaker), 2nd Symposium on Nanomedicine and Nano safety, Colorado Center for Nanomedicine and Nanosafety (CCNN), University of Colorado, Denver, CO, March 24, 2017); FDA Dietary Supplement Regulations , e.g., Proposed Rule for Current Good Manufacturing Practice for Dietary Supplements: A Critical Review *Life Sciences*, 78, 2049-2053, 2006; patents and drug development, e.g., Patent Issues in Drug Development: Perspectives of a Pharmaceutical Scientist *Attorney AAPS J.*, 7 (No. 3), E723-727, 2005]; patent law for pharmaceutical scientists (<https://youtu.be/LbmqjjVU0>); drug doping in sports, e.g., Making the World Anti-Doping Agency Prohibited List: Show Me the Data, *St. Louis Law Journal*, 50(No. 1), 75-89, 2006 (invited) and state-federal conflict in marijuana laws and regulation (e.g., What is the Path Forward for Federal Regulation of Cannabis?, Georgetown University Law Center, Washington DC, November 2, 2018) (invited).
- **Editorial Board:** Pharmaceutical Patent Analyst
- **Technology Transfer:** University of Colorado (2012)

Communications Skills

- **Effective Written and Oral Styles:** Class room experiences have honed my skills to effectively explain complex scientific and legal concepts to professional and general audiences (e.g., jury members, judges).

MEMBERSHIPS

- American Association of Pharmaceutical Scientists
- American Association for the Advancement of Science
- American Intellectual Property Law Association

Melethil_ResumeJun2019.docx