



LORI A. HARDAWAY • DIRECTOR

Lori's principle legal work is food, drug, and medical device matters, including regulatory compliance, hazard analysis, patent prosecution, and infringement opinions. She has represented OTC and prescription pharmaceutical manufacturers, as well as medical device and component manufacturers in the US and in Europe.

During her time at an intellectual property boutique firm and an international general practice firm, Lori's work primarily focused on patent prosecution for pharmaceutical and biotechnology entities in the technical areas of proteins and molecular biology.

Before her legal work began, Lori researched the structure-function relationships of small pharmaceutical proteins using Nuclear Magnetic Resonance (NMR) Spectroscopy. Her pharmacy work has focused on inpatient and outpatient care at hospital, retail, hospice, and home infusion services, including psychiatric pharmacotherapy, pain management, formulary management, and clinical health care consultation.

EDUCATION

- University of Arizona College of Pharmacy, Pharm.D. 1991;
- University of Arizona College of Pharmacy, Ph.D. 1995;
- Sandra Day O'Connor School of Law, Arizona State University, J.D. 2001

ADMITTED TO PRACTICE

- California, 2002
- District of Columbia, 2003
- USDC, Northern District of California, 2002
- U.S. Patent Trademark Office, 2005
- Pharmacy, Arizona, 1991

CONTACT

PHOENIX

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LEGAL EXPERIENCE

RELEVANT REPRESENTATION

- Developed regulatory compliance program for medical device manufacturer, including best manufacturing practices to meet industry standards.
- Conducted hazard analysis for medical devices.
- Advised on regulatory issued for veterinary supply manufacturer.
- Worked as in-house counsel on patent strategy and patent prosecution matters.
- Prepared Clinical Trial agreements and Clinical Data Sharing Agreements with special attention to HIPAA compliance.
- Issue consultant on food, drug, dietary supplement, and medical device issues, including clinical trials, HIPAA, and Hatch-Waxman.
- US and foreign patent prosecution for pharmaceutical and biotech companies in technical areas of proteins, molecular biology, and small molecules.
- Interviewed engineers and scientists for inventorship determinations.
- Conducted due diligence and freedom-to-operate analyses.
- Prepared patent claims and responses to U.S. and foreign patent actions.
- Determined patent validity and prepared infringement opinions.

OF NOTE

In the early 1990s, Lori researched and published in scientific literature on several pharmaceutical topics, including small pharmaceutical proteins using Nuclear Magnetic Resonance Spectroscopy. This was the subject of her graduate research, which was performed in cooperation with the Eli Lilly Company. Specifically, this work focused on the effects of the antibacterial agent, phenol, on the hexameric association tendencies of insulin and possible implications for delayed bioavailability.





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PRODUCT EXPERIENCE

*Over-The-Counter
Drugs*

Pharmaceuticals

*Dietary
Supplements*

Medical Devices

Foods

Veterinary Products

ARTICLES/PAPERS

- Bioindustry in Arizona: Recommendations for Economic Development, April 2001.
- "Amide Hydrogen Exchange of the Central B-Chain Helix within the T-and R- States of Insulin Hexamers," *Biochimica Biophysica Acta* (1994) 1208: 101-103.
- "Solving Solution Structure of Physiologically Relevant Proteins" *Annual Reviews of Physiology* (1992) 54: 749-73.
- "Cosolvent Effect on Diuron Solubility" *Journal of Pharmaceutical Sciences* (1990) 80: 197-98.

PROFESSIONAL AFFILIATIONS AND LEADERSHIP

- *Former Vice Chair*, Health & Human Services, ABA Section on Administrative Law and Regulatory Practice.
- Food and Drug Law Institute, Annual Meeting, Hatch-Waxman Updates, and Summer Internship Program 2000-2003.

LECTURES/SPEECHES

- "Money and Medicine: The Impact on FDA Regulation of Pharmaceuticals," November 2003, ABA Section on Administrative and Regulatory Practice.