Curriculum Vitae

ALYSON L. WOOTEN, PHARM.D., MBA, JD
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SUMMARY

Dr. Alyson Wooten is an Associate Director in the BRG Health Analytics Practice. She has over 18 years of experience as a pharmacist, Medical Information Specialist and as a legal advisor, advising on a variety of pharmacy and pharmaceutical operations matters, as well as matters involving regulatory, intellectual property, compliance, litigation and transactional issues matters, with emphasis in pharmaceutical and medical device products.

Drawing upon her retail, hospital, and pharmaceutical industry experience, Dr. Wooten has assisted numerous retail, mail order, specialty and hospital pharmacies, and pharmaceutical and medical device companies on operational and regulatory matters including medical affairs support, clinical development programs, corporate integrity agreements, promotional and sales training materials, safe harbor issues, pharmacy services agreements, HIPAA, fraud waste and abuse, medical device tracking, and due diligence projects for patent and investment portfolios.

Dr. Wooten focuses on assisting pharmaceutical, biotech and medical device manufacturers, pharmacies and pharmacy benefit managers facing litigation, compliance issues, disputes, investigations, pharmaceutical pre-clinical and clinical development contracts, and regulatory matters. She has significant experience in the areas of regulatory compliance, contracting, coupon programs, Controlled Substance Act requirements, and pedigree. She is also intimately familiar with the acquisition, synthesis, analysis, and reporting of large data sets of clinical trial data, pharmaceutical sales data, rebate and discount data, survey data, market data, and regulatory compliance data.

EDUCATION

Juris Doctor – Temple University, Philadelphia, PA

Doctor of Pharmacy (*Magna Cum Laude*) – Campbell University, Buies Creek, NC

Master of Business Administration – Campbell University, Buies Creek, NC

AWARDS

Recipient of the 2019 Pro Bono Freedom Award

EXTERNAL BOARDS

Chairman, Metropolitan Counseling Services, Atlanta, GA

Member, Georgia Law Center for the Homeless

EMPLOYMENT HISTORY

Berkeley Research Group, Washington, DC
Associate Director, Health Analytics Practice (April 2019 – present)

Kilpatrick Townsend & Stockton LLP, Atlanta, GA
Intellectual Property Attorney (April 2007-April 2019)

Philadelphia College of Osteopathic Medicine, School of Pharmacy, Suwanee, GA
Adjunct Professor (March 2013-April 2016)

Responsible for federal law component of Pharmacy Law and Ethics course and preparing students for the Multistate Pharmacy Jurisprudence Examination®.

GlaxoSmithKline, King of Prussia, PA
Patent Agent and Legal Intern (May 2005-April 2007)

GlaxoSmithKline, Philadelphia, PA
Medical Information Specialist and Medical Communication Scientist (Feb. 2001-Jan. 2006)

Partnered with internal stakeholders to provide medical information to enhance the commercial success of products and critically evaluate the validity of scientific literature on GSK and competitor prescription products. Provide accurate, balanced, and timely verbal and written responses for medical information questions, provide medical review and approval for promotional materials, partner with regulatory and marketing representatives on developing promotional strategy, provide sales and medical training on clinical launches, develop AMCP Formulary Dossiers and provide input and support regarding pricing, formulary, PBM payer, and health plan participants. Responsible for clinical trial data for pharmaceuticals, including design of case report forms to support primary safety and efficacy endpoints, analysis of data, and reporting final data analysis in clinical trial reports to support regulatory filings.

CVS Pharmacy, Cary, NC
Pharmacist/Pharmacy Technician (1996-2002)

Responsible for implementation and monitoring compliance with all federal and state laws concerning the dispensing of all drugs, including requirements under the Controlled Substance Act. Supervised daily activities of pharmacy and counsel patients regarding proper use of medications. Handled third party billing and distributor interactions. Responsible for reporting and audits by DEA. Provided compounding services for specialty products.

Betsy Johnson Memorial Hospital, Dunn, NC
Pharmacy Technician (April 1998-October 1998)

Provided pharmacy services and therapeutic management of patients for hypertension, diabetes, asthma, general medicine, and anticoagulation. Responsible for reviewing medication orders and patient's medical record as well as interacting with other health professionals to help prevent inappropriate or misuse of medications; provision of clinical services (e.g., pharmacokinetic dosing, therapeutic interchange, IV/PO conversions,

TPN and aminoglycoside monitoring, pharmacist interventions) to neonatal, pediatric and adult patients according to departmental policy and procedures. Responsible for compounding intravenous admixtures according to USP.

PROFESSIONAL LICENSES

Registered Pharmacist, State of North Carolina

Registered Patent Attorney/Agent, United States Patent and Trademark Office

Bar Admissions: Georgia, Pennsylvania, New Jersey

OTHER PROFESSIONAL EXPERIENCE

Clinical Clerkships

Internal Medicine
Moses H. Cone Memorial Hospital
Greensboro, North Carolina

Community Pharmacy
Eckerd Pharmacy
Cary, North Carolina

Internal Medicine
Moses H. Cone Memorial Hospital
Greensboro, North Carolina

Geriatric Medicine
Britthaven Nursing Home
Chapel Hill, North Carolina

Regulatory Affairs
Glaxo Wellcome Inc.
Research Triangle Park, North Carolina

Drug Information/Industrial Pharmacy
Glaxo Wellcome Inc.
Research Triangle Park, North Carolina

Ambulatory Medicine
Carolina Premier Medical Group
Cary, North Carolina

PUBLICATIONS AND SPEAKING ENGAGEMENTS

Switching Studies Crucial to Demonstrate Biosimilar Interchangeability. 2018 AAPS PharmSci 360, Washington, DC, Nov. 2018.

Navigating the Safe Harbor Provisions of the Hatch-Waxman Act. 3rd China Pharma IP Summit 2018, Beijing, China, Oct. 2018.

Meeting our Clients in Immigration Detention Opened Our Eyes. Daily Report, April 5, 2018.

Patent Acquisition: Due Diligence Issues. 2nd China Pharma Intellectual Property Summit 2017, Dec. 2017, Shanghai, China.

Patent Litigation 2017 & Case Law Update Roundtable. 29th Annual North America Law Summit, Nov. 2017.

The Summit Newsroom: Entertainment, Sports & IP News, Commentary & Mayhem. 29th Annual North America Law Summit, Nov. 2017.

Federal Circuit Holds that the "Required and Established Place of Business" for Patent Infringement Venue Under § 1400(b) Requires Identification of a Physical Location of the Defendant's Business. Legal Alert for Kilpatrick Townsend & Stockton LLP, Sept. 2017.

Pharmaceutical Due Diligence Investigations and the Orange Book. 2017 Intellectual Property Forum, April 2017, Shanghai, China.

Interpretation of Patent Dance of BPCIA and Its Influence on Biosimilars and Innovative Drugs. China Pharma Intellectual Property Summit 2016, Nov. 2016, Shanghai, China.

The Use of *Inter Partes* Review Petitions in Pharma Patent Litigation. China Pharma Intellectual Property Summit 2016, Nov. 2016, Shanghai, China.

Patent Law: Patent Law Update. 28th Annual North American Law Summit, Nov. 2016.

New Requirements for FDA Nutrition and Supplement Labels: What You Need to Know. Kilpatrick Townsend CLE Presentation, July 2016, New York City, NY.

Asserting Your Rights/Defending Your Rights – Overview of Litigation and Life Cycle Planning for Drugs and Biologics. Bio & Pharmaceutical Patent Forum, March 2016, Shanghai, China.

Amgen v. Apotex – 180-day Advance Notice of Biosimilar Marketing is Mandatory. Kilpatrick Townsend Knowledge Center, Dec. 2015.

Amgen files First Marketing Authorization Application for Humira® in the EU. Kilpatrick Townsend Knowledge Center, Dec. 2015

Patent Law – IPR Strategy in ANDA Litigation. CLE Presentation at ABA Law Summit, Entertainment, Sports & Intellectual Property, Nov. 2015.

Abbreviated New Drug Application (ANDA) with Paragraph IV Certification: Critical Insights in 2015, IPR Strategy in ANDA Litigation. CLE Presentation for Knowledge Group, Aug. 2015.

Down to the Wire: FDA Extends Deadline for Dispenser's Product Tracing Requirements Less than 24 Hours Before July 1, 2015 Deadline. Kilpatrick Townsend Knowledge Center, July 2015.

Patent Law Basics: An Overview of Patent Law and Avoiding the Loss of Rights. Kilpatrick Townsend & Stockton LLP Intellectual Property Desk Reference – 7th Edition, May 2015.

Post-Grant and Covered Business Method Patent Review. CLE Presentation at ABA Law Summit, Entertainment, Sports & Intellectual Property, Nov. 2014.

Anti-Patent-Troll Law. Presentation for Kilpatrick Townsend & Stockton LLP, Oct. 2014.

Negotiating a New Legal Landscape: The Advent of Follow-On Biologics. University of San Francisco Law Review, Vol. 46, pp. 1029-1076, Sept. 2014.

Separate Written Description – *En Banc* Decision in *Ariad v. Lilly*. Legal Alert for Kilpatrick Townsend & Stockton LLP, March 2010.

Separate Written Description? – Oral Arguments in *En Banc* Rehearing of *Ariad v. Lilly*. Legal Alert for Kilpatrick Townsend & Stockton LLP, Dec. 2009.

Protecting the Validity of Your Pharmaceutical Patents after *KSR*. 2009 BIO International Convention, May 2009.

In re Kubin – Another Hurdle for DNA Sequence Patents. Legal Alert for Kilpatrick Townsend & Stockton LLP, April 2009.