

ALEXANDRA HANER, PhD

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SUMMARY

Experienced Patent Attorney (law firm & in-house) in the pharmaceutical, chemical & medical device industries with expertise in patent preparation and prosecution, counseling (including regulatory, product launch, portfolio product selection, freedom-to-operate & validity opinions), licensing and management of patent litigations.

LEGAL WORK EXPERIENCE

ADRIANO & ASSOCIATES, New York NY 1/2022 – present
Of Counsel

Patent practice, including preparing and prosecuting U.S. and international patent applications (chemical, pharmaceutical and consumer products). Patent opinions (freedom-to-operate, validity), patent landscapes, patent due diligence and patent competitive monitoring.

VORYS, SATER, SEYMOUR & PEASE LLP, Pittsburgh PA 4/2018 – 12/2021
Of Counsel

Patent preparation and prosecution, patent opinions (FTO, validity and due diligence). Provided global patent strategy to clients. Filed IPR petition (IPR2019-01446) including Expert Report. Presentations: Effects of PTAB/EP Oppositions on US Application Drafting; Lessons Learned from Studying Prosecution Histories for FTO Opinions; Email Do's and Don'ts.

BECK & THOMAS, P.C., New York NY (merged into Vorys) 9/2016 – 4/2018
Of Counsel

Counseling, regulatory work and patent opinion (FTO, validity and due diligence) work for the pharmaceutical industry. Prepared Expert Declarations. Submitted Citizen Petition to the FDA (FDA-2017-P-1039). Presentation: The Patent Application and Prosecution Process.

HANER & KUO PLLC, New York NY (merged into Beck & Thomas) 6/2014 – 12/2016
Senior Patent Attorney and Founding Member

Counseling, opinion (FTO and validity), regulatory work and patent prosecution. Provided counseling to investment community on biosimilars. Developed Document Retention Policy for client. Submitted correspondence to the FDA (FDA-2016-P-1249). Presentations: Update on the Legal Environment for Biosimilars, Hatch-Waxman Basics, and ANDA Litigation Discovery Best Practices. Representative case: *L.A. Gem v. Robin Milliman, et al.* (copyright litigation).

LAW OFFICE OF ALEXANDRA HANER, New York NY (merged into H&K) 6/2012 - 5/2014
Senior Patent Attorney and Founding Member

Consulting, counseling, opinion, and litigation for the pharmaceutical and chemical industries including start-up companies. Representative cases included: *Forest Labs v. First Time US Generics* (ANDA litigation); *Sanofi v. First Time US Generics* (ANDA litigation).

SANDOZ, Princeton NJ 9/2007 – 4/2012
Senior Patent Attorney; Head U.S. Patent Litigation (2011 – 2012)

Provided strategic and legal counsel to regulatory, BD&L, portfolio, launch and R&D teams.

- Drafted settlement, licensing, and supply agreements. Monitored and provided counsel on competitive landscape (including global and US patent filings, oppositions and litigations).

- Managed outside counsel on patent litigations. Provided counsel and developed litigation strategy from pre-litigation to appeal. Deposition preparation of corporate witnesses.
- Presented “U.S. Litigation Perspective on Label Inventions” at Novartis Labeling Workshop (2011). Co-chaired 3rd Annual Pharmaceutical Congress on Paragraph IV Disputes (2010). Round-table member at ACI “Paragraph IV on Trial” (2009).
- Developed and prepared P4 certifications, Notice Letters, and section viii labels.
- Patent due diligence of M&A candidates. Global prosecution and strategy of Sandoz patents.

GOODWIN PROCTER LLP, New York NY

6/2003 – 8/2007

Senior Associate

Practice focused on litigation and opinion work involving all aspects (opinion, pre-litigation, trial, appeal) of Hatch Waxman patent cases. Representative cases included: *Forest Labs. v. Ivax* (appeal to Federal Circuit); *Eisai v. Teva* (ANDA litigation); *Teva v. PAR Pharm.* (patent infringement litigation). Opinion work included validity and freedom-to-operate opinions.

PENNIE & EDMONDS LLP, New York NY

10/1997 – 5/2003

Associate

Practice focused on litigation, opinion work, and patent prosecution and preparation.

- Litigations concerned: AAA stent medical devices (*Scimed v. Medtronic*, patent litigation), fragrance samplers (*AKI v. Delta Graphics*, patent litigation), vitamin supplements (*Virgin Enterprises v. American Longevity*, trademark litigation), and inkjet printer cartridges and inks (*HP v. Nu-kote*, patent, trademark and antitrust litigation).
- Preparation and prosecution of U.S. and foreign patent applications (chemical, pharmaceutical, consumer products). Interference practice (*Fogarty v. Cragg*, AAA stent medical devices; *Stepniewski v. Arnaud*, cosmetic silicone compositions).
- Validity, clearance (freedom-to-operate) and due diligence opinions.
- Managed US & global patent portfolios. Mentored junior associates in patent prosecution.

EDUCATION

FORDHAM LAW, New York NY

J.D., 1997; Fordham Int’l. Law Journal, Associate Editor.

PRINCETON UNIVERSITY, Princeton NJ

Ph.D., Chemistry, 1987; Graduate Teaching Award, 1985; *M.A.*, Chemistry, 1984.

WELLESLEY COLLEGE, Wellesley MA

B.A., Chemistry and English, 1982; Honors in Chemistry, Sigma Xi.

PROFESSIONAL AFFILIATIONS AND ADMISSIONS

- Admitted to New York Bar (1997), SDNY (1999) and EDNY (1999). NY Bar Reg. No. 2850642. Admitted to PA Bar (2017). PA Bar Reg. No. 324978.
- USPTO Registered Patent Attorney (2000). PTO Registration No. 45641
- Member, *National Asian Pacific American Bar Association*. Member, *National Filipino American Lawyers Association*. Member, *American Intellectual Property Law Association*.

NON-LEGAL WORK EXPERIENCE

Environmental Defense Fund , New York NY, Research Associate	1994 - 1996
Army Research Lab. , Fort Monmouth NJ, NRC Research Associate	1991 - 1993
Princeton University , Dept. of Chemistry, Princeton NJ, Visiting Lecturer	1991 - 1992
Univ. of California , Lawrence Berkeley Lab., Berkeley CA, Post-doc	1987 – 1990

CURRENT VOLUNTEER EXPERIENCE

New Jersey Wellesley Club, Treasurer.