



AMY H. FIX COUNSEL

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EDUCATION

J.D.,
Campbell University, Normal Adrian Wiggins School of Law, 1997
B.S., cum laude, Chemistry
North Carolina State University, 1994

BAR ADMISSIONS

North Carolina
U.S. Patent & Trademark Office

With a career that has included in-house patent counsel positions with GlaxoSmithKline and Targacept, Inc. (now Catalyst Biosciences), Amy Fix understands the core business issues her pharmaceutical industry clients face. She has spent more than 16 years protecting pharmaceutical, agricultural, and polymer technologies, and is also a specialist in the growing sector of small-molecule drug development. Her clients range from large international pharmaceutical corporations to smaller companies producing innovative drugs and drug products.

Amy provides a full range of services to clients, including the preparation and prosecution of domestic and international patent applications, and post-grant review. A significant amount of her work involves conducting due diligence reviews for licensing or acquisition of worldwide patent portfolios, as well as negotiating and drafting the resulting agreements. Amy provides strategic guidance, including freedom-to-operate analyses, invalidity, and non-infringement opinions, as well as life-cycle management analyses, product portfolio reviews, and Abbreviated New Drug Application (ANDA) litigation support. In addition, she counsels clients on regulatory issues associated with research and development of pharmaceuticals, biologics, and medical devices.

Clients value Amy's creative approach, which draws on her significant in-house experience and thinks forward into all the possible options available for protecting valuable drug developments. She provides a unique perspective, one focused on understanding the science behind an innovation and, more importantly, where the technology is headed in the future. Amy has the technical background to speak with scientists about their developments, but also considers input from other departments in the company to appreciate the commercial potential of the innovation and offer risk management strategies. Informed by time spent around the boardroom table with all stakeholders, Amy poses the questions other patent lawyers may not think to ask. This holistic approach means Amy finds patent solutions that are both grounded in science and serve a client's broader business objectives

EXPERIENCE | OVERVIEW

- Managed worldwide patent portfolios for multiple pharmaceutical and biotech clients across several therapeutic and diagnostic areas, including the original drafting of patent applications for new chemical entities, which have gone on to become marketed products.
- Opinion practice, including freedom to operate, invalidity, and non-infringement analyses, including U.S. post-grant practice
- Competitive coordination of regulatory and patent exclusivities, regularly support to in-house regulatory staff at client companies as products move through the FDA approval process, coordinating Hatch-Waxman patent term extension strategies and other important data and marketing exclusivities.

Biographies | Amy H. Fix

- Due diligence support and coordination of collaborative relationships, including assumed responsibility for existing portfolios and the prosecution for products of joint development arrangements and strategic management, for a given market, to use patents and other exclusivities to maximize commercial prospects for all parties involved.

EXPERIENCE | LEGAL EXPERIENCE

- **Targacept, Inc.**
Senior Director, Legal Affairs and Intellectual Property, 2011-2014
- **Womble Carlyle Sandridge & Rice, LLP**
Patent Attorney, 2014-2015
Patent Attorney, 2007-2011
- **GlaxoSmithKline**
Senior Patent Counsel, 2001-2007
- **Rhodes, Coats & Bennett, LLP**
Patent Attorney, 1997-2001

EXPERIENCE | NON-LEGAL EXPERIENCE

- **Burroughs Wellcome, Inc.**
Medical Chemistry Laboratory Assistant, 1991-1994

PRACTICE GROUPS

Licensing
Patent Prosecution
Post-Grant Patent
International Patent

AREA OF FOCUS

Biotechnology & Pharmaceutical

FORWARD THINKING

Alerts

- The Federal Circuit: Actual Sale is Not Required for Triggering the On-Sale Bar under 35 U.S.C. § 102(b), May 19, 2016
- It Pays to be Persistent if PTAB Rulings Violate Due Process Ultratec v. CaptionCall and Matal (Fed. Cir. 2017), September 06, 2017

Blog Posts

- It Pays to be Persistent if PTAB Rulings Violate Due Process Ultratec v. CaptionCall and Matal (Fed. Cir. 2017), September 06, 2017

Presentations

- 2016 IP Developments, Brinks Webinar, January 28, 2016

AFFILIATIONS

- Regulatory Affairs Professional Society
- Women in BIO - Chicago Chapter
- RTP Chapter