

---

## *Hatch-Waxman and Biologics Litigation*

Intellectual Property Litigation

[!\[\]\(666e09182d4cd268646ea700ea60dcdf\_img.jpg\) DOWNLOAD ANDA LITIGATION FACT SHEET](#)

Innovation is the key to success for any pharmaceutical or biotechnology company. Equally important is procuring intellectual property to safeguard those innovations and developing strategies to protect those valuable assets from unauthorized use by competitors. Our team has the litigation experience, patent proficiency and regulatory knowledge to do just that.

Industry leaders have relied on us to ward off challenges from generic competitors in more than 170 ANDA litigations in the past five years alone, making us one of the most seasoned teams in the field with expertise in various types of Orange Book listed patents. In 2022, *LMG Life Sciences* named WilmerHale the Hatch-Waxman Litigation Firm of the Year. We are also at the forefront of Biologics Price Competition and Innovation Act (BPCIA) litigation, having represented clients in the first BPCIA-related case ever decided by the US Supreme Court and some of the first BPCIA cases in the District of Delaware.

Life science companies trust us because our lawyers have extensive experience working with companies both large and small to protect their assets around the globe. Our team includes attorneys with deep scientific knowledge in a variety of arts. Because we have more than 100 lawyers with scientific and technical backgrounds, our clients trust us to truly understand their innovations and the business concerns related to their intellectual property. We understand the intricacies of compound, formulation and method-of-treatment patents, as well as best strategies for defending the patent estates of biologics products. We also build teams to include experienced antitrust and transactional lawyers who can offer advice with respect to agreements. Our attorneys take a unique multidisciplinary approach to staffing cases: each is handled by both skilled litigators and lawyers with deep technical knowledge, who also work efficiently with colleagues across practices to achieve results for clients ranging from Fortune 500 companies to startups.

---

## Key Contacts

---



**David B. Bassett**

PARTNER

✉ [david.bassett@wilmerhale.com](mailto:david.bassett@wilmerhale.com)

📍 NEW YORK ☎ + 1 212 230 8858

📍 BOSTON



**Christopher R. Noyes**

PARTNER

✉ [christopher.noyes@wilmerhale.com](mailto:christopher.noyes@wilmerhale.com)

📍 NEW YORK

☎ + 1 212 295 6823



**Lisa J. Pirozzolo**

PARTNER

✉ [lisa.pirozzolo@wilmerhale.com](mailto:lisa.pirozzolo@wilmerhale.com)

📍 BOSTON

☎ + 1 617 526 6388



**Amy Kreiger Wigmore**

PARTNER

✉ [amy.wigmore@wilmerhale.com](mailto:amy.wigmore@wilmerhale.com)

📍 WASHINGTON DC

☎ + 1 202 663 6096



**Robert J. Gunther Jr.**

PARTNER

✉ [robert.gunther@wilmerhale.com](mailto:robert.gunther@wilmerhale.com)

📍 NEW YORK

☎ + 1 212 230 8830



**Vinita Ferrera**

PARTNER

✉ [vinita.ferrera@wilmerhale.com](mailto:vinita.ferrera@wilmerhale.com)

📍 BOSTON

☎ + 1 617 526 6208



## Kevin S. Prussia

PARTNER

✉ [kevin.prussia@wilmerhale.com](mailto:kevin.prussia@wilmerhale.com)

📍 BOSTON

☎ + 1 617 526 6243



## Andrew J. Danford

PARTNER

✉ [andrew.danford@wilmerhale.com](mailto:andrew.danford@wilmerhale.com)

📍 BOSTON

☎ + 1 617 526 6806

---

## Experience

Won a major, complete victory for **Bristol-Myers Squibb** and **Pfizer** in one of the largest Hatch-Waxman cases ever filed. A district judge found the patents covering our clients' blockbuster drug Eliquis® were valid and infringed by all generics challenging them. This case covered 25 generic companies and likely protects Eliquis® until at least 2031.

Achieved a significant victory for **Shionogi** when its motion for preliminary injunction was granted, preventing defendant Lupin Limited from further importation and sale of its generic copy of Shionogi's diabetes drug, Fortamet®.

Obtained an important victory for **Braintree Laboratories**, when the Federal Circuit reversed a district court's grant of summary judgment of noninfringement for Breckenridge Pharmaceutical and remanded with instructions to enter judgment in Braintree's favor. This matter involved a patent owned by Braintree pertaining to its product Suprep®, a highly successful product designed to cleanse the colon safely before a colonoscopy.

Achieved a significant victory for **Takeda's** wholly owned subsidiary, **Millennium Pharmaceuticals**, at the Federal Circuit, when the appeals court reversed a district court finding of patent invalidity and remanded the case with instructions to enter judgment in favor of Takeda. This matter involved a patent owned by the US government and exclusively licensed to Takeda covering the latter's blockbuster oncology drug Velcade®.

Represented **Gilead** in defending the patentability of several patents related to its blockbuster Hepatitis C drugs Sovaldi® and Harvoni®. Together with co-counsel Fish & Richardson, we successfully defended all of Gilead's challenged patents, obtaining denials of each of I-MAK's 10 IPR petitions at the institution stage.

Achieved a significant victory for **GlaxoSmithKline** when the Federal Circuit affirmed a district judgment finding that the patent covering dutasteride, the active ingredient in

GSK's Avodart and Jalyn products, was not invalid. After a three-day bench trial, the district court had concluded that the defendants failed to prove the asserted claims invalid under any theory.