



Hatch-Waxman Litigation

Intellectual property raises not only profound opportunities, but also fundamental challenges for the pharmaceutical industry. Our team has the litigation experience, patent proficiency and regulatory knowledge to protect those assets. Industry leaders have relied on our group to ward off challenges from generic competitors in over 180 Hatch-Waxman litigations in district courts, making us one of the most seasoned teams in the field. With the scientific knowledge to tackle a range of pharmaceutical and biologics concerns, WilmerHale is regarded as a trusted advisor in this domain.

PRACTICE AT A GLANCE

- Through the lens of our deep patent and general IP experience, we are well-positioned to truly understand the intricacies of compound, formulation, method-of-treatment and dosing patents.
- In addition to guiding clients through litigation, we strengthen their portfolios and extend the lifecycles of their products by providing strategic patent counseling, including analysis, risk assessment and global portfolio strategy.
- Companies need trial-experienced lawyers who know local judges, counsel and operating procedures in Delaware and New Jersey, where most ANDA litigation occurs. We have litigated more than 215 cases in these districts and have argued before every judge on the Delaware bench.
- Our litigation experience also extends beyond these high-volume districts: when clients face litigation on multiple fronts, we are ready to fight on all of them.
- We build our Hatch-Waxman teams to include antitrust lawyers who have years of experience collaborating across disciplines. These interdisciplinary case teams function as cohesive units, helping us achieve extraordinary results for our clients.
- We have the post-grant proceeding prowess to help clients minimize the unpredictability of developing new drugs by identifying patents likely to face an early *inter partes* review (IPR) challenge.

590+

IPRs handled by WilmerHale attorneys

125+

IP lawyers with technical and scientific degrees

30+

different drug products among our ANDA matters



**2022 Hatch-Waxman
Litigation Firm of the Year:**
LMG Life Sciences

EXPERIENCE

Over the past five years, we have achieved favorable settlements in Hatch-Waxman litigations for the following companies, among others:

- AbbVie
- Takeda Pharmaceuticals
- Astellas
- Novartis
- Bristol-Myers Squibb
- Shionogi
- Gilead

When litigation is unavoidable, our deep bench of experienced trial lawyers can defend clients in cases of any scope. The following are recent examples of our trial and appeals experience:

- **Bristol-Myers Squibb Company et al. v. Aurobindo Pharma, USA Inc. et al.:** Obtained a significant and complete victory for Bristol-Myers Squibb and Pfizer in one of the largest Hatch-Waxman cases ever filed covering 25 generic companies. A district judge found the patents covering our clients' blockbuster drug Eliquis® were valid and infringed, likely protecting Eliquis® until at least 2031. This matter involves global litigation in over 25 jurisdictions outside of the US, including Canada, China, Europe, India and Korea.
- **OSI Pharm., LLC v. Apotex Inc.:** Obtained a significant victory for Astellas affiliate OSI Pharmaceuticals and Genentech when the Federal Circuit reversed a PTAB decision holding the relevant patent claims obvious. The decision caps our successful four-year defense of the clients' patent covering Tarceva®, a blockbuster treatment of non-small cell lung cancer, against multiple generic challengers in Hatch-Waxman litigation in the District of Delaware.
- **Millennium Pharma., Inc. v. Sandoz Inc.:** Achieved an important 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 Millennium. This Hatch-Waxman matter involved a patent owned by the United States government and exclusively licensed to Takeda covering the latter's blockbuster oncology drug Velcade®.
- **Initiative for Medicines, Access & Knowledge (I-MAK) v. Gilead Pharmasset:** Achieved a complete victory for Gilead in defending the patentability of several patents related to their blockbuster Hepatitis C drugs Sovaldi® and Harvoni®. Together with co-counsel Fish & Richardson, WilmerHale successfully defended all of Gilead's challenged patents, obtaining denials of each of I-MAK's 10 IPR petitions at the institution stage.
- **Exelixis Inc. v. MSN Laboratories Private Limited:** Successfully represented Exelixis in an Hatch-Waxman litigation against MSN Pharmaceuticals related to patents covering the cancer treatment Cabometyx®. This included a bench trial held in the District of Delaware, in which we successfully defended the validity of the compound patent covering Cabometyx®.

RECOGNITION

- **Chambers USA:** Ranked Band 1 for nationwide life sciences and intellectual property each year since 2011; named 2024 Intellectual Property Firm of the Year.
- **Chambers Global:** Recognized as a leader in life sciences and intellectual property each year since 2009.
- **U.S. News - Best Lawyers:** Named 2022 and 2021 Patent Law Firm of the Year, 2020 Biotechnology Law Firm of the Year, 2018 IP Litigation Firm of the Year in addition to consistent Tier 1 rankings.
- **Managing IP:** Consistently recognized among best firms for life sciences; named US Patent Disputes Firm of the Year eight times since 2013.
- **The American Lawyer:** Named the 2023 "IP Litigation Department of the Year." The firm has been named a winner or a finalist for this biennial award nine times since 2004.

"Powerhouse for complex contentious proceedings, handling ANDA, Hatch-Waxman, infringement, biosimilars disputes and post-grant proceedings."

— Chambers USA

"A team of lawyers with valuable scientific background... outstanding US practice coupled with international reach"

— Chambers Global

For more information, please contact:

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