



ANDA 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 international group to ward off challenges from generic competitors in 130 ANDA litigations since 2015, 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.
- 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 85% of our 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. This has been critical in the wake of the Supreme Court's decision in *TC Heartland*.
- We build our ANDA 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.

520+

IPRs handled by WilmerHale attorneys

130+

ANDA litigations handled by WilmerHale since 2015

100+

IP lawyers with technical and scientific degrees

25

different drug products among our ANDA matters

EXPERIENCE

When we counsel clients facing litigation, we have a keen sense of when a trial will prove to be most advantageous, and when to negotiate a settlement that provides a measure of stability as they manage their products and their business.

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

- Astellas
- Bristol-Myers Squibb
- Gilead
- GlaxoSmithKline
- Takeda Pharmaceuticals
- Novartis
- Pfizer
- Shionogi

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

- *Bristol-Myers Squibb Company et al. v. Aurobindo Pharma, USA Inc. et al.*: WilmerHale obtained a decisive trial victory for BMS and Pfizer in what began as one of the largest Hatch-Waxman cases ever filed, with 25 different generic companies as defendants. The matters concerned mega-blockbuster drug Eliquis®. Favorable settlements were reached with most defendants, and following the trial against the remaining defendants in the District of Delaware, Judge Stark ruled that the proposed generic products infringed patents held by plaintiffs.
- *OSI Pharm., LLC v. Apotex Inc.*: WilmerHale 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.
- *Millennium Pharms., Inc. v. Sandoz Inc.*: WilmerHale 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 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*: WilmerHale represented 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.

RECOGNITION

- **Chambers USA** has ranked WilmerHale Band 1 since 2011, with every US office ranked. Clients note that we are "one of the top IP litigation practices in the country" and that we "are outstanding at all levels, combining first-rate technical and legal acumen and great trial skills."
- **Chambers Global** recognized WilmerHale as a leader in life sciences since 2013 and quoted sources as saying that the firm has an "outstanding US practice coupled with international reach" and "a team of lawyers with a valuable scientific background."
- **U.S. News - Best Lawyers** named WilmerHale the 2020 Patent Law Firm of the Year and the 2019 Biotechnology Law Firm of the Year in addition to consistently ranking us Tier 1 in these categories.
- **Managing IP** consistently recognizes WilmerHale as one of the best firms for life sciences and has named us the US Patent Contentious Firm of the Year seven times since 2011.
- **LMG Life Sciences** named WilmerHale the General Patent Litigation Firm of the Year and IP Firm of the Year in 2019, as well as consistently recognizing us for Hatch-Waxman patent litigation since 2012.

For more information, please contact:

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