



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 close to 140 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.

555+

IPRs handled by WilmerHale attorneys

100+

IP lawyers with technical and scientific degrees

25

different drug products among our ANDA matters



2020 Impact Case of the Year:

Enzo Life Sciences v. Roche Molecular Systems

2018 Hatch-Waxman Impact Case of the Year:

Millennium Pharmaceuticals v. Sandoz

— LMG Life Sciences

EXPERIENCE

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 significant and complete 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, after Judge Stark found the patents that cover our clients' blockbuster drug Eliquis® valid and infringed by all generics challenging them and the Federal Circuit later affirmed. The Court's judgment likely prevents the three generics that went to trial from entering the market for Eliquis® until at least 2031, protecting billions of dollars of our clients' revenue.
- *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 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*: 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.
- *Roche Diagnostics v. Enzo Biochem*: WilmerHale achieved significant victories for Roche and Becton Dickinson in their ongoing battle with Enzo Life Sciences, Inc., when the US Court of Appeals for the Federal Circuit sided with Roche and BD in two separate appeals.

RECOGNITION

- **Chambers USA**: Earned Band 1 Life Sciences (nationwide) rankings each year since 2011
- **Chambers Global**: Recognized as a leader in life sciences since 2013
- **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 Contentious Firm of the Year eight times in the past 10 years
- **LMG Life Sciences**: Named 2019 Firm of the Year for General Patent Litigation and for IP, also shortlisted for Hatch-Waxman Litigation (Branded), Inter Partes Review and US Life Cycle Firm of the Year

“One of the top IP litigation practices in the country... outstanding at all levels, combining first-rate technical and legal acumen and great trial skills.”

— Chambers USA

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

— Chambers Global

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