POLSINELLI

Hatch-Waxman & Biologics

Polsinelli's multidisciplinary pharmaceuticals team includes trial attorneys, FDA and antitrust counsel, patent attorneys and agents. We are skilled courtroom advocates, and we bring to bear our team members' backgrounds in chemistry, organic chemistry, biochemistry, biology, pharmacy, medicine, molecular biology, microbiology, neuroscience, pharmacology, genetics, immunology and molecular biophysics, among others. We have knowledge and experience in cases related to compositions and APIs, formulations (e.g., oral dosage forms, controlled release, ODTs, transdermal, topical, ophthalmic, transmucosal, parenteral, etc.), methods of use, polymorphs, enantiomers, drug delivery devices (including combination products), and methods of manufacture, including cell lines and expression systems. Our attorneys have first-chair experience litigating cases on behalf of pharmaceutical companies in key venues, including the federal courts in Delaware, New Jersey, the Eastern District of Texas, the Southern District of New York, the Northern District of Illinois and the District of Massachusetts.

Hatch-Waxman

Polsinelli's attorneys have significant experience representing both brand and generic drug companies in Hatch-Waxman drug patent cases. We assist clients every step of the way—from pre-litigation planning and strategy, assistance with the regulatory review process, and advocating for our clients through trial, appeal and/or settlement.

Our attorneys have litigated everything from blockbuster products to smaller market and specialty pharmaceuticals. We understand that each case, and each client, requires its own approach, and we partner with our clients to develop a strategy to achieve their specific business goals in a cost-efficient manner.

Biologics Price Competition and Innovation Act (BPCIA)

Polsinelli also has a robust Biologics Price Competition and Innovation Act (BPCIA) practice. The framework of the BPCIA process is unique and requires attorneys with experience in the specialized considerations that drive strategic decisions, including the "Patent Dance" and notice provisions of the BPCIA. Our attorneys have counseled some of the world's largest, best-known, and most influential pharmaceutical companies regarding the regulatory and legal issues associated with this process and have repeatedly presented at conferences and seminars on these topics. We provide patent landscape opinions, due diligence reviews, and pre-litigation strategy in advance of the filing of BLA and aBLA applications and stand prepared to guide clients through successful resolution of litigation. Our deep bench of attorneys with specialized technical degrees and industry experience are instrumental to both understanding the intricate science involved and to being able to explain it in a compelling manner to judges and juries.

Food and Drug Administration (FDA)

Polsinelli is one of the few firms in the country that have attorneys that assist clients in navigating not only the thicket of patent issues involved in getting products to market but also the complex FDA regulatory issues

involved in clearing approval hurdles and bringing product to market in the most profitable manner. Our attorneys regularly use their regulatory and scientific experience to provide counseling, advocacy and litigation services on behalf of clients before the FDA. Our attorneys have in-depth knowledge and first-hand experience with the complex and shifting regulatory landscape, enabling them to provide a holistic approach to supporting our pharmaceutical and biologic clients.

Matters

- ACETADOTE®(acetylcysteine)
- ACTOPLUS MET XR®(pioglitazone HCl+metformin HCl)
- ADENOSCAN®(adenosine)
- ALOXI®(palonosetron HCl)
- ANGIOMAX®(bivalirudin)
- APTENSIO XR®(methylphenidate hydrochloride)
- ASTEPRO®(azelastine)
- AVODART®(dutasteride)
- BEPREVE®(bepotastine besilate) ophthalmic solution
- CENESTIN® (synthetic conjugated estrogens, A)
- COMBIGAN®(brimonidine tartrate+timolol maleate)
- DUREZOL (Difluprednate)
- ENABLEX®(darifenacin hydrobromide)
- FAZACLO ODT®(clozapine ODT)
- FORTAMET®(metformin HCl)
- HYSINGLA®(hydrocodone bitartrate)
- IMBRUVICA®(ibrutinib)
- ISTALOL®(timolol maleate) ophthalmic solution
- JALYN®(dutasteride+tamsulosin HCl)
- JUBLIA®(efinaconazole)
- LATISSE®(bimatoprost) ophthalmic solution
- MIRALAX®(polyethylene glycol 3350)
- MUCINEX®(guaifenesin)
- MYDAYIS®(mixed amphetamine salts)
- NEXAVAR®(sorafenib)
- OTEZLA (apremilast)
- OXECTA®(oxycodone HCl)
- PEPCID COMPLETE®(famotidine + calcium carbonate + magnesium hydroxide)
- PICATO®(ingenol mebutate)
- PRECEDEX®(dexmedetomidine HCl)
- PREPOPIK®(sodium picosulfate + magnesium oxide + anhydrous citric acid)
- PREVACID® (lansoprazole)
- PRILOSEC®(omeprazole)
- PROLENSA®(bromfenac sodium) ophthalmic solution
- RAPAFLO®(silodosin)
- REMERON® (mirtazapine)
- RESTASIS (cyclosporine ophthalmic emulsion)
- SANCUSO®(granisetron)
- SOOLANTRA®(invermectin)
- TRAVATAN Z®(travoprost ophthalmic solution)
- VANOS (fluocinonide)
- VELCADE®(bortezomib)

- VIAGRA®(sildenafil citrate)
- XYREM®(sodium oxybate)
- ZOFRAN® (ondansetron)
- ZOMETA®(zoledronic acid)

News

April 9, 2026
Polsinelli Attorneys Named to Law360's 2026 Editorial Advisory Boards

February 3, 2026
28 Polsinelli Attorneys Recognized as Thomson Reuters Stand-out Lawyers

November 6, 2025
Polsinelli Promotes 35 Attorneys to Shareholder Nationwide

October 17, 2025
Two Polsinelli Attorneys Recognized in 2025 LMG Life Sciences Rankings

October 10, 2025
Polsinelli Secures Appellate Victory for MSN Pharmaceuticals in Challenge to FDA Approval of Entresto Generic

May 7, 2025
Polsinelli Recognized by BTI Consulting Group Among Most Recommended Law Firms for the Pharma Industry

March 24, 2025
Eight Polsinelli Attorneys Selected to Serve on Law360's 2025 Editorial Boards

October 22, 2024
Polsinelli Continues Life Sciences Growth With Experienced Hatch-Waxman and Biologics Attorney Stacie Ropka

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Polsinelli Recruits High-Profile FDA/Hatch-Waxman Attorney Chad Landmon as Practice Chair

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