



Aziz Burgy

Partner

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SPOTLIGHT

"[Aziz Burgy] is a highly experienced patent litigator with an in-depth knowledge of the generic pharmaceutical industry. He is very knowledgeable, responsive, and excellent to work with."

- *IAM Patent 1000*

PRACTICE AREAS

Biotechnology

FDA

Intellectual Property

ITC Section 337

Patents

Pharmaceuticals

Trade Secret, Trademark & Copyright

EDUCATION

JD, magna cum laude – University of New Hampshire School of Law (2003);
Editor, *IDEA: The Journal of Law and Technology*

MS, Biotechnology – Johns Hopkins University (2000)

BS, Biology – University of North Carolina at Chapel Hill (1996)

PROFILE

EXPERIENCED HATCH-WAXMAN PATENT LITIGATOR

As a first-chair trial attorney for major brand and generic drug companies in over 80 Hatch-Waxman Act cases, Aziz Burgy brings a wealth of experience to pharmaceutical patent litigation. Aziz has been honored among the top 3% of ANDA litigators in Patexia intelligence reports and is consistently recognized by various publications, including *IAM Patent 1000*, *LMG Life Sciences*, and *Benchmark Litigation*. Aziz also advises clients on FDA matters and with product selection using a proprietary in-house database to help clients target products for acquisition or development.

Aziz has influenced patent-related legislation by advising Congress on the America Invents Act's (AIA) impact on industries in which his clients operate, including the:

- pharmaceutical;
- medical device;
- biotechnology;
- banking;
- Internet security;
- robotics;
- software; and
- GPS technology sectors.

ADMISSIONS

District of Columbia

Maryland

U.S. Court of Appeals for the Federal Circuit

U.S. Court of Federal Claims

U.S. District Court District of Columbia

U.S. District Court District of Maryland

U.S. District Court Northern District of Ohio

U.S. Patent and Trademark Office

LEADING LITIGATOR FOR COMPLEX CASES

Drawing on his in-house experience, Aziz leverages his dual legal and technical perspective to lead scientifically complex litigation in U.S. district courts, the Federal Circuit, the U.S. Court of Federal Claims, the Patent Trial and Appeal Board (PTAB), and the U.S. International Trade Commission (ITC).

COMMUNITY INVOLVEMENT

Aziz frequently lectures on patent, copyright, trademark, and Hatch-Waxman Act issues and has taught courses at George Mason University. He was a board member for the University of North Carolina (UNC) Department of Biology, where he served as a liaison to faculty, students and alumni. He proudly supports nonprofit organizations serving indigent persons and children with intellectual disabilities in Northern Virginia and has successfully represented Afghans seeking asylum on a pro bono basis.

CLERKSHIPS

- Hon. Arthur J. Gajarsa, U.S. Court of Appeals for the Federal Circuit, Judicial Intern (2003)

PROFESSIONAL ACTIVITIES

- UNC Department of Biology, Advisory Board Member (2018– 2023)
- American Bar Association, Section of Intellectual Property Law
- American Intellectual Property Law Association
- District of Columbia Bar Association
- Federal Circuit Bar Association
- ITC Trial Lawyers Association
- Maryland State Bar Association
- PTAB Bar Association

EXPERIENCE

- ***Novo Nordisk Inc. v. Alvogen Inc. (22-cv-00299, D. Del.)***
Representing Alvogen in a patent infringement action filed by Novo Nordisk Inc. and Novo Nordisk A/S. The suit initially involved four patents and 26 claims.

- ***Salix Pharmaceuticals Ltd. et al v. Norwich Pharmaceuticals Inc. (20-cv-00430, D. Del.)***

Represented Norwich Pharmaceuticals Inc. in a patent infringement action filed by Salix Pharmaceuticals Ltd., Salix Pharmaceuticals Inc., Bausch Health Ireland Ltd., and Alfasigma S.P.A. The suit sought to estoppel Norwich from gaining approval to market a rifaximin 550 mg tablet, a generic of Salix's Xifaxan®. Obtained judgment of invalidity on asserted claims, which halted the trading of the plaintiff's parent company stock after it dropped more than 50% following the decision.

- ***Alcon Inc. v. Alembic Pharmaceuticals Ltd. et al. (22-cv-00299, D. Del.)***

Represented Alembic Pharmaceuticals Ltd. and Alembic Pharmaceuticals Inc. in a case in which Alcon Inc. and Alcon Laboratories Inc. asserted two patents relating to Alembic's ANDA product, an ophthalmic solution containing olopatadine hydrochloride used to treat symptoms of ocular allergies.

- ***Cosette Pharmaceuticals Inc. v. Azurity Pharmaceuticals Inc. (23-cv-0018, D. Del.)***

Lead counsel to Cosette in a Hatch-Waxman suit against Azurity Pharmaceuticals Inc. involving Cosette's vancomycin hydrochloride product. Secured total victory and consent judgment on all six asserted patents.

- ***iCeutica Pty Ltd. et al. v. Novitium Pharma LLC (No. 18-cv-599-CFC, D. Del.)***

Represented generic drug manufacturer Novitium in Hatch-Waxman litigation involving multiple patents for meloxicam, Vivlodex®. Secured dismissal based on noninfringement, resulting in favorable settlement for Novitium. Defended depositions of two 30(b)(6) corporate witnesses.

- ***AstraZeneca AB et al v. Alembic Pharmaceuticals Ltd. et al. (1:20-cv-00202-RGA, D. Del.)***

Represented Alembic in a lawsuit filed by AstraZeneca involving the generic version of the drug, Tagrisso®.

- ***Merck Sharp & Dohme Corp. v. Anchen Pharmaceuticals Inc. and Par Pharmaceutical Inc (C.A. No. 1:19-cv-00311-RGA, D. Del.)***

Secured favorable settlement for Anchen and Par Pharmaceutical in one of the largest Hatch-Waxman cases in the District of Delaware. The case, filed by Merck Sharp & Dohme Corp., involved

the generic version of Janumet XR®.

- ***Merck Sharp & Dohme Corp. v. Wockhardt Bio AG and Wockhardt USA LLC (C.A. No. 1:19-cv-00321-RGA, D. Del.)***
Secured favorable settlement for Wockhardt in a lawsuit filed by Merck Sharp & Dohme Corp. relating to the generic version of Janumet IR® and Januvia®.
- ***Taro Pharmaceutical Industries Ltd., Taro Pharmaceuticals North America Inc., and Taro Pharmaceuticals U.S.A. Inc. v. Novitium Pharma LLC (3:19-cv-01028-FLW-LHG, D.N.J.)***
Secured favorable settlement for Novitium in a lawsuit filed by Taro Pharmaceutical Industries Ltd., Taro Pharmaceuticals North America Inc., and Taro Pharmaceuticals U.S.A. Inc. relating to the generic version of Ovide®.

More

- ***Hospira Inc. v. Par Sterile Products LLC (No. 1:16-cv-00879-RGA, D. Del.)***

Represented Par Sterile Products LLC in litigation relating to five patents covering Precedex® Premix Injectables.

- ***Fresenius Kabi USA LLC and Fresenius Kabi Deutschland GmbH v. Wockhardt USA LLC, Wockhardt Bio AG, and Wockhardt Ltd (No. 2:19-cv-20383-CCC-MF, D.N.J.)***
Secured early favorable settlement for Wockhardt in litigation relating to the drug Naropin®.
- ***American Bankers Association v. SS&C Technologies Inc. (19-cv-11592, S.D.N.Y)***
Secured early favorable settlement for American Bankers Association in copyright litigation relating to several copyrighted courses.
- ***Keryx Biopharmaceuticals Inc. and Panion & BF Biotech Inc. v. Par Pharmaceutical Inc. (No.19-cv-4876., S.D.N.Y.)***
Secured early favorable settlement for Par Pharmaceutical in a lawsuit filed by Keryx Biopharmaceuticals and Panion & BF Biotech relating to the generic version of Auryxia®.
- ***Novartis Pharmaceuticals v. Accord Healthcare Inc. (1:18-cv-01043, D. Del.)***
Secured favorable settlement for Par in a lawsuit filed by Novartis

Pharmaceuticals involving a generic version of the multiple sclerosis drug, Gilenya®.

- ***Valeant Pharm. N. America LLC v. Par Pharm. Inc. (1:18-cv-08221, D.N.Y.)***

Defended Par in a lawsuit filed by Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals Ireland Ltd., Dow Pharmaceutical Sciences Inc., and Kaken Pharmaceutical Co. Ltd. involving eight patents relating to the generic version of Jublia®. Obtained a favorable settlement for Par and dismissal prior to filing an answer.

- ***Par Pharmaceutical Inc. v. Pfizer Inc., Pfizer Products Inc., and C.P. Pharmaceuticals International C.V. (1:19-cv-00615, D.N.Y.)***

Represented Par in filing a lawsuit against Pfizer Inc., Pfizer Products Inc., and C.P. Pharmaceuticals International C.V. relating to the generic version of Chantix®.

- ***Noven Pharmaceuticals Inc. v. Alvogen Pine Brooke LLC, Alvogen Inc., and 3M Company (1:17-cv-1429, Del.)***

Represented Alvogen and 3M in a patent infringement action filed by Noven Pharmaceuticals involving four patents and 48 asserted claims. Developed significant noninfringement and invalidity theories on behalf of Alvogen, which were featured prominently in the Court's denial of a motion for a preliminary injunction against a co-defendant's "at-risk" launch. Alvogen settled the case prior to expert discovery.

- ***Par Pharmaceutical / Relistor® v. Valeant Pharmaceuticals Inc. (2:17-cv-06449-SRC-CLW, D.N.J.)***

Represented Par in a case filed by Valeant Pharmaceuticals claiming Par's generic version of Relistor® infringed six patents. Obtained favorable settlement and dismissal.

- ***Insys Therapeutics Inc. v. Par Pharmaceutical Inc. (17-cv-01078-LPS, D. Del.)***

Represented Par in Hatch-Waxman litigation involving multiple patents directed to FDA-approved cannabinoid, Syndros®, used to treat anorexia in people with AIDS. Secured dismissal based on noninfringement position, which enabled Par to launch upon approval of its ANDA product.

- ***Noden Pharma DAC v. Anchen Pharm. Inc. (17-cv-00728-MPT, D. Del.)***

Represented Anchen in securing favorable license to manufacture and commercialize generic version of Tektura®.

- ***Par Pharmaceutical Inc. v. Horizon Therapeutics LLC* (IPR2015-01127, PTAB)**

Represented petitioner in review of US Patent No. 8,404,215 directed to nitrogen scavenging drug Ravicti®, resulting in invalidity of all challenged claims.

- ***AstraZeneca Pharmaceuticals LP v. Sylvia Burwell* (16-cv-01336-RDM, D.D.C.)**
Represented intervenors Apotex and Par in opposing AstraZeneca's motion for temporary restraining order, allowing generic versions of blockbuster Crestor® to immediately enter the market.
- ***Purdue Pharmaceuticals Products L.P. v. Actavis Elizabeth LLC et al.* (12-cv-05311-JLL, D.N.J.) (Intermezzo)**
Represented generic drug manufacturer Par in Hatch-Waxman litigation involving two patents for an insomnia drug. Obtained invalidation of two patents-in-suit at trial. Affirmed by Federal Circuit.
- ***Jazz Pharmaceuticals Inc. v. Par Pharmaceutical Inc.* (IPR2015-00548-00551 and 00554, PTAB)**
Served as lead *inter partes* review (IPR) petition counsel orchestrating the drafting of multiple petitions for three risk evaluation and mitigation strategies (REMS) patents for Jazz's narcolepsy drug, Xyrem®. Obtained invalidity of all claims on obvious grounds. Affirmed by Federal Circuit.
- ***Certain Bulk Welding Wire Containers and Components Thereof and Welding Wire* (337 TA 686, USITC)**
Represented respondent accused of infringing six patents related to bulk weld wire containers. After trial, the case resulted in complainant dropping five patents, invalidation of one claim, and a noninfringement ruling against all accused products. Affirmed by Federal Circuit.
- ***Cross Medical Prods. Inc. v. Medtronic Sofamor Danek Inc.* (No. 05-1415, Fed. Cir.)**
Represented Medtronic in a patent infringement case involving six patents covering spinal implant technology. Federal Circuit reversed district court's finding that Medtronic's modified surgical

screw infringed the claimed limitation under the Doctrine of Equivalents and affirmed district court's summary judgment of noninfringement on a claimed anchor seat.

- ***Tulip Computers International v. Dell Computer Corp.* (00-cv-00981-KAJ, D. Del.)**

Represented patentee against Dell Computer in a lawsuit involving patented computer motherboard technology. Case settled for \$49.5 million after a one-week jury trial.

HONORS

- *Benchmark Litigation*, C. Litigation Star: Intellectual Property (2020 – 2023)
- *IAM Patent 1000*, World's Leading Patent Professionals (2020 – 2023)
- *LMG Life Sciences*, Life Sciences Star (2020 – 2023)
- *ANDA Litigation Intelligence Report*, Best Performing ANDA Attorneys Representing Defendants (2021)
- *ANDA Litigation Intelligence Report*, Top 100 Most Active ANDA Attorneys (2021)
- *ANDA Litigation Intelligence Report*, Top ANDA Litigator (2020)
- *Super Lawyers*, Intellectual Property (2020 – 2024)