

# Hatch-Waxman & Biologics

Cozen O'Connor's nationally recognized Hatch-Waxman and Biologics/Biosimilars practice provides strategic counsel to companies seeking to enter the U.S. small molecule and biologics/biosimilars markets.

Our dedicated team includes licensed patent attorneys with advanced degrees in organic chemistry, molecular cell biology, immunology, and biophysics; former research scientists in industry and academia; and intellectual property litigators with decades of first-chair trial experience.

The **Hatch-Waxman Amendments** to the Food, Drug & Cosmetic Act in 1984 created a new marketplace for generic pharmaceuticals by lowering barriers to FDA approval and establishing a period of exclusivity through the Abbreviated New Drug Application (ANDA) process. Cozen O'Connor has high-level experience representing both branded and generic drug companies from the earliest stages of drug development through regulatory review, and, in some cases, litigation. Our team has successfully partnered with clients on more than 60 drug products, including for Apotex Inc.; ApoPharma, Inc.; Amneal Pharmaceuticals, Inc.; Sandoz Inc.; Mylan; Kyowa Kirin, Inc.; and Endo Pharmaceuticals Inc.

The firm also has a cutting-edge **Biologics Price Competition and Innovation Act (BPCIA)** practice. In September 2016, Cozen O'Connor attorneys won the first-ever patent trial under the BPCIA, which set the precedent that informs the "patent dance" and notice requirements under the BPCIA. As the market for biologic/biosimilar products continues to grow, so will the need for legal counsel with a sophisticated understanding of the unique legal questions arising from the development, approval, sales, and marketing of biologic/biosimilar drugs.

Cozen O'Connor's Hatch-Waxman and Biologics attorneys continue to distinguish themselves by providing comprehensive legal services. Our attorneys work closely with clients to monitor competitors, clear obstacles to the development and launch of new products, advise on the regulatory review process, and negotiate and draft settlement agreements between market competitors. When settlement is not possible or not advisable, Cozen O'Connor is fully prepared to go to trial — and win.

## Services

- Competitive intelligence concerning patent strategy, patentability, and freedom-to-operate
- Assist with regulatory submissions, responses, and approvals
- Advise on regulatory requirements concerning patent listing, exclusivity, and forfeiture
- Guide strategic decisions around validity and/or infringement challenges to competitors' IP
- Counsel on market entry and expansion
- Respond to government investigations
- Lead counsel for litigation and settlement negotiations under Hatch-Waxman and the BPCIA

## Experience

Represented Amneal Pharmaceuticals, Inc. in a patent infringement action concerning Amneal's ANDA to make a generic version of Pfizer's KERYDIN® (Tavaborole) topical solution product. After a favorable result on inter partes review petitions at the Patent Trial and Appellate Board, the district court case was dismissed.

Secured a bench trial victory for Apotex Inc. and Apotex Corp. in a patent infringement action concerning Apotex's ANDA to make a generic version of Vanda Pharmaceuticals, Inc.'s HETLIOZ® (Tasimelteon) oral capsule product, with the district court invalidating Vanda's disputed patents. This result was affirmed by the U.S. Court of Appeals for the Federal Circuit, and the Supreme Court denied



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## Related Practice Areas

- Copyright & Content
- Franchising
- Health Care & Life Sciences
- Intellectual Property
- Intellectual Property Litigation
- IP Transactions & Licensing
- Patents
- Trade Secrets, Restrictive Covenants, and Computer Abuse
- Trademark & Brand

Vanda's petition for certiorari.

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Represented Kyowa Kirin, Inc. and Strakan International S.A. against Actavis Labs' attempt to make a generic version of Kyowa Kirin's SANCUSO® (granisetron) transdermal patch product. Following a bench trial, the judge ruled in our clients' favor on all contested issues and rejected the defendant's claims of non-infringement, invalidity, and unenforceability. Successfully argued on appeal with the Federal Circuit affirming the trial court decision without opinion.

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Represented Apotex Inc. and Apotex Corp. in a patent infringement action concerning Apotex's ANDA to make a generic version of AstraZeneca's ONGLYZA® (Saxagliptin) oral tablet product. Case settled prior to trial.

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Represented Apotex Inc. and Apotex Corp. in a patent infringement action concerning Apotex's ANDA to make a generic version of SPRIX® (Ketorolac Tromethamine) nasal solution. Case settled prior to trial.

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Represented Endo Pharmaceuticals Inc. and Strakan International S.à r.l. against Watson Labs' attempt to make a generic version of Endo's FORTESTA® product. Following a bench trial, the judge ruled in our clients' favor on all contested issues and rejected the defendant's claims of non-infringement, invalidity, and unenforceability. Successfully argued on appeal with the Federal Circuit affirming the trial court decision.

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Secured affirmance of patent invalidity and unenforceability, allowing launch of generic Taxotere® (docetaxel).

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Favorably settled challenges to client launches of generic versions of Diprivan® (propofol), Biaxin XL® (clarithromycin), Eloxatin® (oxaliplatin), Omnicef® (cefdinir), and Solodyn® (minocycline);

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Defended our generic client against a challenge to its launch of Vasotec® (enalapril), with the innovator dropping its case before trial and covenanting not to sue our client;

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Defended our generic client at trial against two patents asserted against its at-risk launch of a generic version of Allegra® (fexofenadine).

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Successfully litigated through appeal challenges to client launches of generic drugs, including generic versions of Taxol® (paclitaxel), Zantac® (ranitidine), and Megace® (megestrol acetate).

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Resolved favorably at trial the at-risk launch of generic Neurtonin® (gabapentin) in a case where the innovator was claiming several billion dollars in damages.

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Obtained appellate affirmance of judgment on the pleadings for the at-risk launch of generic Yasmin® (drospirenone + ethinyl estradiol).

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Defended the at-risk launch of generic Skelaxin® (metaxalone). A jury found the patent invalid and not infringed, and the innovator withdrew its appeal after our appellate brief was filed.

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Represented Apotex Inc. and Apotex Corp. in a patent infringement action regarding Apotex's biosimilar applications to make biosimilar versions of Amgen's NEULASTA® and NEUPOGEN® products. We navigated Apotex through the Biologics Price Competition and Innovation Act's "patent dance," and in the first BPCIA case to go to trial, we obtained a verdict of noninfringement. This result was affirmed on appeal to the U.S. Court of Appeals for the Federal Circuit.

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Lead counsel in damage phase of a patent infringement action regarding Sandoz's ANDA to make a generic version of Pfizer's seizure and neuropathic pain product, Neurontin®, the active ingredient of

which is gabapentin. The case settled during the pre-trial phase and after successful Motions in Limine by Sandoz.

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Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic version of AVODART® (dutasteride). Settled prior to trial.

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Handled a patent infringement action regarding Sandoz's ANDA to make a generic version of Alcon's eye allergy product Pataday®, the active ingredient of which is olopatadine hydrochloride.

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Handled a patent infringement action regarding Sandoz's ANDA to make a generic version of Pfizer's antimuscarinic tablet Detrol and Detrol LA®, the active ingredient of which is tolterodine tartrate.

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Handled a patent infringement action regarding Sandoz's ANDA to make a generic version of Pfizer's antifungal medication VFEND®, the active ingredient of which is voriconazole.

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Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Alcon's eye allergy product PATANOL® (olopatadine hydrochloride). Case settled.

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Represented Sandoz Inc. in a patent infringement action concerning Sandoz's ANDA to make a generic version of Abbott's NIASPAN® (Niacin) controlled-release tablets. Case settled prior to trial.

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Represented Sandoz Inc. in a patent infringement action concerning Sandoz's ANDA to make a generic version of Abbott's TRILIPIX® (Fenofibric Acid) capsules. Case settled prior to trial.

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Represented Innopharma, Inc. and Amneal Pharmaceuticals, Inc. in patent infringement actions concerning our clients' ANDAs to make generic versions of Spectrum's FUSILEV® (Levoleucovorin) Injection product.

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Represented Sandoz Inc. in patent infringement action concerning Sandoz's ANDA to make a generic version of Helsinn's anti-nausea product Helsinn's ALOXI® (Palonosetron Hydrochloride) injection product. Case settled prior to trial.

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Represented Sandoz Inc. in a patent infringement action concerning Sandoz's ANDA to make a generic version of Roche's VALCYTE® (Valganciclovir Hydrochloride) capsule product. Case settled prior to trial.

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Represented Sandoz Inc. in a patent infringement action concerning Sandoz's ANDA to make a generic version of Shire's ADHD product INTUNIV® (Guanfacine Hydrochloride). Case settled prior to trial.

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Represented Apotex Inc. and Apotex Corp. in a patent infringement action concerning Apotex's ANDA to make a generic version of Pfizer's PRISTIQ® (Desvenlafaxine) extended-release oral tablet products. Case settled prior to trial.

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Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic version of ACULAR LS® (0.4% ketorolac tromethamine). Led the negotiations that resulted in a successful settlement of the matter after the close of expert discovery.

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Trial counsel for Apotex Inc. and Apotex Corp. in a patent infringement action regarding Apotex's ANDA to make a generic version of LYSTEDA® (tranexamic acid). After a two week trial, received a favorable decision of non-infringement on all three patents in-suit. Successfully argued on appeal with the Federal Circuit affirming the trial court decision.

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Represented Sandoz Inc. in a patent infringement action concerning Sandoz's ANDA to make a

generic version of Abbott's ZEMPLAR® (Paricalcitol) oral capsule product. Case settled prior to trial.

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Represented Mylan Pharmaceuticals, Inc. in a patent infringement action concerning Mylan's ANDA to make a generic version of Pfizer's CADUET® (Atorvastatin Calcium and Amlodipine Besylate) oral tablet products. Case settled prior to trial.

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Represented Actavis in a patent infringement action concerning Actavis's ANDA to make a generic version of King's pain product AVINZA® (Morphine Sulfate) oral capsule products. Case settled prior to trial.

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Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Merck's anti-nausea product EMEND® (aprepitant).

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Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Allergan's glaucoma drops COMBIGAN® (brimonidine tartrate/timolol maleate).

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Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic version of Sanofi-Aventis' anticancer product TAXOTERE®, the active ingredient of which is docetaxel. Following a two-week trial, obtained an order for Apotex striking down the patents-in-issue as invalid as obvious and unenforceable due to Sanofi-Aventis' inequitable conduct in procuring the patents. Successfully argued on appeal with the Federal Circuit affirming trial court decision (April 2012). Of import is that inequitable conduct defense remains viable in ANDA litigations because of this ruling.

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Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic version of Wyeth's anti-depressant product EFFEXOR XR® (venlafaxine hydrochloride). Settled on favorable terms during trial.

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Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Endo's pain product OPANA® ER (oxymorphone hydrochloride).

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Lead counsel for Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Medicis' acne product SOLODYN® (minocycline hydrochloride).

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Lead counsel for Barr Labs in a patent infringement case involving Barr's drug, TAMBACOR®.

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