

Hatch-Waxman Litigation

The Hatch-Waxman Amendments to the Food, Drug & Cosmetic Act, which were passed in 1984, essentially created the current generic drug industry by allowing sponsors to demonstrate bioequivalence without having to conduct costly and time-consuming clinical trials. With that market-entry barrier removed, real competition developed in what was previously a monopolistic marketplace. Generic drugs now account for about 90 percent of the total prescriptions dispensed in the United States but only about 23 percent of all dollars spent on prescription medications, saving American consumers almost two trillion dollars over the last decade.

Hatch-Waxman meaningfully incentivized generic drug companies' ability to provide life-saving, cost-effective medications by granting 180-days of market exclusivity to the first applicant with a so-called Paragraph IV certification in an Abbreviated New Drug Application (ANDA). Innovator companies were equally incentivized to participate by being granted an automatic 30-month stay of approval of the ANDA upon filing a patent infringement suit against the ANDA applicant within statutory time limits. The United States is one of the only countries in the world to link regulatory approval of generic pharmaceutical products to its patent system.

The Hatch-Waxman patent certification and regulatory approval process is rife with complexity and nuance. Cozen O'Connor's experienced attorneys have been lead litigation counsel for generic clients in scores of Paragraph IV litigations, and we have counseled clients on scores more. The vast majority of our cases have been litigated to a successful conclusion or settled favorably for our clients. After one negotiation, our adversary, the chief patent counsel for a well-known innovator company, said that our settlement agreement was so thorough, it addressed generic opportunities that the innovator had not even considered.

We closely track the fast-moving pharmaceutical marketplace to help industry participants identify and pursue market opportunities without delay. Two examples of changes that have significantly altered the competitive landscape for our clients are the Inter Partes Review procedure established by the America Invents Act of 2012 and the Food and Drug Administration's Safety and Innovation Act of 2012. Cozen O'Connor advises clients on how these and other regulatory shifts alter decisions of how and when to pursue market entry.

In addition to regulatory change, pharmaceutical companies are also coming under increasing scrutiny by federal and state regulators charged with enforcing fraud, abuse and anti-corruption laws. The Cozen O'Connor Hatch-Waxman team works in close coordination with the firm's recognized Internal Investigations & Criminal Defense group to respond to inquiries, investigations, and civil or criminal charges. We have experience handling enforcement actions by the Food & Drug Administration, Federal Trade Commission, Office of the Inspector General, Centers for Medicare & Medicaid Services, Department of Justice, Department of Health and Human Services, individual U.S. attorney's offices, and state attorneys general.

The members of Cozen O'Connor's Hatch-Waxman team are leaders in the intellectual property litigation bar. Our attorneys hold advanced degrees in the natural sciences and nearly all members have experience as research scientists in industry or academia, and we understand the intersection of law and science with respect to small molecules, biosimilars and hybrids. Our team includes former senior government attorneys, registered patent attorneys, and patent examiners for the U.S. Patent and Trademark Office.

Experience

Currently representing Amneal Pharmaceuticals, Inc. in a patent infringement action concerning



W. Blake Coblentz

Chair, Hatch-Waxman & Biologics Litigation

wcoblentz@cozen.com
Phone (202) 912-4837
Fax (202) 861-1905



Barry P. Golob

Co-Chair, Intellectual Property Litigation

bgolob@cozen.com
Phone (202) 912-4815
Fax (202) 861-1905

Related Practice Areas

- Biologics/Biosimilars
- Domains
- e-commerce
- Franchising
- Intellectual Property
- Intellectual Property Litigation
- Licensing & Transfer
- Patents
- Trade Secrets, Restrictive Covenants, and Computer Abuse
- Trademark & Copyright

Industry Sectors

- Health Care & Life Sciences

Amneal's ANDA to make a generic version of Pfizer's KERYDIN® (Tavaborole) topical solution product. Case is currently stayed in Delaware district court pending resolution of inter partes review petitions at the Patent Trial and Appellate Board.

Currently representing 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® (Tasimeleuton) oral capsule product. Case is pending in Delaware district court.

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.

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.

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.

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.

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

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

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;

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

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

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.

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

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.

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.

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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).

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).

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.

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.

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).

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).

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