

GENERIC DRUG / ANDA LITIGATION



Our law firm helps manufacturers of generic pharmaceuticals navigate the regulatory thicket of the Food and Drug Administration (FDA) and bring products to market quickly. To advance clients' business goals, our team develops innovative strategies that include District Court litigation, *inter partes* reviews (IPR), and work-arounds. Our record of success with Abbreviated New Drug Application (ANDA) and generic drug cases includes advising clients on bringing to market generic competitors for brand-name drugs such as Ambien CR®, Clarinex®, Cymbalta®, Lidoderm®, Trintellix®, and Wellbutrin XL®.

Husch Blackwell has one of the premier ANDA and generic drug patent litigation practices in the country. Our ANDA litigation and pharmaceutical patent attorneys have extensive experience at the trial and appellate levels litigating Hatch-Waxman statutory patent infringement and other actions involving prescription drugs. We are recognized leaders in using IPR to challenge the validity of existing patents more quickly and economically. In addition, Husch Blackwell is the only law firm that is a member of the Association for Accessible Medicines (AAM), the leading trade association for the generic drug industry.

"The Husch Blackwell attorneys were fierce and tireless advocates for Virtus. In the face of aggressive actions by our competitors and FDA regulators, they developed and executed a legal plan that protected an important market for us. They have my gratitude and highest recommendation."

— Tina Guilder,
CEO, Virtus
Pharmaceuticals —

Contact Information

Don J. Mizerk
312.526.1546
don.mizerk@
huschblackwell.com

Representative Experience

Represented TWi Pharmaceuticals Inc. and Teh Seng Pharmaceutical Mfg. Co. Ltd. in a patent infringement case

alleging their generic version of Endo's Lidoderm infringed several patents. The case was favorably settled on the eve of trial.

Represented a generic drug manufacturer in a patent infringement lawsuit involving an osteoporosis drug. We obtained summary judgment that two patents were invalid for obviousness. Our team also defeated motion for preliminary injunction to prevent client from launching a generic version of the drug. This preliminary injunction decision was upheld on appeal to a federal court.

Defended Virtus Pharmaceuticals against a competitor's claim that Virtus unfairly marketed one of its generic drugs. After opening statements at the U.S. International Trade Commission (ITC), the judge told the competitor that Virtus' prehearing submissions were so persuasive that he was unlikely to rule in the competitor's favor, and the competitor withdrew its complaint.

Represented generic pharmaceutical manufacturer in Hatch-Waxman patent litigation in a first-to-file (FTF) opportunity relating to a methylphenidate transdermal patch. Obtained partial summary judgment rulings of noninfringement and invalidity due to inadequate written description.

Defended an API supplier to a generic pharmaceutical company and forced the brand drug company to withdraw all patent infringement claims against our client, resulting in a final termination of the ITC investigation. Later, challenged the validity of four of those same patents in

review proceedings The USPTO held all of the challenged claims were invalid or canceled.

Represented Apotex Inc. and Apotex Corp. on their generic risedronate product against brand-name Actonel, invalidating the patent with summary judgment of obviousness and taking the lead among co-defendants in defending the appeal.

Advised Watson Pharmaceuticals Inc. and Watson Laboratories Inc. on a case relating to a methylphenidate transdermal patch sold by Noven as Daytrana. Obtained partial summary judgment rulings of noninfringement and invalidity due to inadequate written description, leading to settlement allowing launch before patent expiration.

Represented Lupin Limited and Lupin Pharmaceuticals Inc. in obtaining a judgment invalidating the patent on brand-name Generess Fe following a bench trial.

Defended TWi Pharmaceuticals Inc. (and its predecessor, Anchen Pharmaceuticals Inc.) in a patent infringement case alleging its generic version of Amrix infringed Cephalon's patents. After the court entered judgment in TWi's favor, TWi also was awarded attorneys' fees.

Represented Apotex Inc. and Apotex Corp. on their generic hypertension drug amlodipine besylate against brand-name Norvasc, clearing the way for Apotex's launch by invalidating for obviousness the brand's patent claiming a particular salt form.

Defended TWi Pharmaceuticals Inc. in a patent

infringement case alleging its generic version of Purdue's Intermezzo infringed several patents. After trial and appeal, the patents were found invalid as obvious.

Represented Apotex Inc. and Apotex Corp. on their generic antibiotic eardrop ofloxacin product against brand-name Floxin Otic, clearing the way for Apotex's launch by invalidating the patent for obviousness by showing that the relevant level of skill in the art was a pharmaceutical researcher and not a treating physician.

Represented Anchen Pharmaceuticals Inc. (now Par Pharmaceutical) in a patent infringement case involving its generic version of Jazz's Luvox CR. The case was favorably settled after filing a motion for summary judgment.