

PHARMACEUTICAL MANUFACTURERS



Husch Blackwell attorneys advise manufacturers of prescription and over-the-counter products, as well as other stakeholders in the drug supply chain, on matters ranging from regulatory compliance to litigation. Drawing on our technical know-how and industry insights, we help clients position themselves to best advantage under existing laws and policies, while working to shape new policies that reflect today's complex economic realities.

Our team counsels clients on Food and Drug Administration (FDA) regulatory issues such as post-market reporting obligations, product recalls, product labeling, establishment registration, compliance plans, and product sales and distribution requirements. Additionally, we advocate for pharmaceutical clients in class action and multidistrict litigation, claims for disgorgement of profits, government investigations, whistleblower claims, and actions by health insurers.

Representative Experience

Represented FlatWing Pharmaceuticals, LLC, in an Inter Partes Review regarding Anacor Pharmaceuticals, Inc.'s, (acquired by Pfizer Inc.) patents listed in the Orange Book for its Kerydin product. FlatWing demonstrated that 39 claims in four patents listed by Anacor were unpatentable, leading to the cancellation of all claims of all listed patents

“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 —

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by the Patent Trial and Appeal Board at the USPTO. The PTAB decision is currently on appeal to the Court of Appeals for the Federal Circuit—for which appeal Marc is also counsel of record. IPR2018-00168, IPR2018-00169, IPR2018-170, IPR2018-171.

Represented Amerigen Pharmaceuticals, Ltd., in a patent infringement case alleging its generic version of Shire LLC's Adderall XR infringed several patents. The case was favorably settled after three days of trial. *Shire v. Amerigen* (D.N.J.)

Advised client in developing Shared Risk Evaluation and Mitigation Strategies ("REMS") for its ANDA product, successfully navigating oppressive and unreasonable demands by the REMS originator for generic participation and facilitating commercial launch of client's product.

Represented FlatWing Pharmaceuticals, LLC, in a multidistrict patent infringement litigation alleging its generic version of Anacor Pharmaceuticals, Inc.'s, (acquired by Pfizer Inc.) Kerydin infringed several patents. In a separate proceeding, FlatWing demonstrated that all claims in all asserted patents were unpatentable. The case is currently stayed pending appeal of the PTAB proceeding at the Court of Appeals for the Federal Circuit—for which appeal Marc is also counsel of record. *In re: Kerydin (Tavaborole) Topical Solution 5% Patent Litigation*.

Represented TWi Pharmaceuticals, Inc. in a patent infringement case alleging its generic version of Par Pharmaceutical's Megace ES infringed Alkermes' (formerly

Élan) patent for nanocrystal megestrol acetate. After a seven-day bench trial, the court entered judgment for TWi in February 2014 finding Alkermes' patent invalid as obvious. *Par, Alkermes v. TWi*, 2014 WL 694976 (D. Md.)

Represented Amerigen Pharmaceuticals, Ltd. in a patent infringement case alleging its generic version of Shire LLC's Adderall XR infringed several patents. The case was favorably settled after three days of trial. *Shire v. Amerigen* (D.N.J.)

Represented TWi Pharmaceuticals Inc. in a patent infringement case alleging its generic version of Cephalon's Amrix infringed several patents. After conducting a seven-day bench trial, the court issued an opinion in May 2011 finding that TWi's product did not infringe any claims of the '793 and '372 patents and entered judgment in its favor. Following the decision, TWi filed a motion to deem the case exceptional and for fees. The court granted TWi's motion and awarded TWi attorneys' fees. *In re Cyclobenzaprine Hydrochloride Extended Release Patent Litigation* (D.Del. 2012)

Represented Virtus Pharmaceuticals, Inc. in litigation at the International Trade Commission (ITC) alleging Virtus' potassium chloride products unfairly competed against similar products marketed by Par Pharmaceuticals. The case settled favorably after Virtus filed suit against FDA challenging the agency's enforcement policies applicable to potassium chloride products. *In Matter of: Certain Potassium Chloride Products* (ITC); *Virtus v. FDA* (M.D.

Fla)

Represented Teh Seng Pharmaceutical Mfg. Co. Ltd. and TWi Pharmaceuticals Inc. in a patent infringement case alleging their generic version of Endo's Lidoderm transdermal patch infringed several patents. The case was favorably settled on the eve of trial. *Endo, Teikoku v. TWi, Teh Seng* (D. Del. 2014)

Represented TWi Pharmaceuticals, Inc. in a patent infringement case alleging its generic version of Purdue's Intermezzo infringed several patents. After trial appeal, the patents were found invalid as obvious. *Purdue Pharmaceuticals v. TWi* (D. N.J. 2015)

Represented TWi Pharmaceuticals Inc. (and its predecessor Anchen Pharmaceuticals Inc.) in a patent infringement case alleging its generic version of Shire's Intuniv infringed several patents. The case was favorably settled after the filing of a motion for summary judgment. *Shire v. Anchen, TWi* (D.Del. 2012)

Represented MedPharmex in a patent infringement case regarding its generic version of Merck's animal drug Mometamax. After initial proceedings, the Court entered a judgment of noninfringement in favor of our client.

Successfully defended pharmaceutical manufacturer in U.S. International Trade Commission (ITC) against competitor's claim that generic drug was marketed unfairly.

Aided Sigmapharm Laboratories in arguing for claim construction. Court adopted proposed construction

verbatim.

Secured victory for TruPharma, LLC in federal court litigation brought by a competitor alleging false advertising and unjust enrichment, among other counts, in connection with the manufacture and sale of a medical cream. Complaint dismissed with prejudice.

Counseled large Canadian pharmaceutical corporation on Abbreviated New Drug Application (ANDA) litigation and Hatch-Waxman patent litigation matters.