Hatch-Waxman Litigation:

The Fish Differential

Fish is one of the largest firms in the U.S. practicing exclusively in the areas of intellectual property, litigation, and regulatory law. For more than a century, Fish has helped life sciences companies through waves of change within their industries—providing comprehensive advice and guidance to proactively protect their intellectual property and other assets.

Fish has the premier patent litigation practice in the world, handling approximately 230% more patent cases than our nearest competitor, but with the same number of people. This includes some of the most significant patent cases over the past decade as well as appellate victories that have had a broad-ranging impact on the development of patent law. It also includes an unmatched record of successful Hatch-Waxman and other patent litigations for leading pharmaceutical companies.

At Fish, we consistently deploy legal strategies and tactics that leverage our intellectual property, litigation, and regulatory practices and our technical expertise to achieve results for our pharmaceutical and life sciences clients.
An Integrated Approach and Strategy

Throughout our history we have maintained a simple but deeply rooted objective: protecting our clients’ intellectual property so that they can maximize market share and obtain a fair return on their hard work, investment, and innovation.

We do this by taking an interdisciplinary approach. We ensure that all scientific issues are understood fully in the context of the product development and commercialization process—relying on our expert knowledge of the pharmaceutical industry and our counseling experience in Hatch-Waxman and related matters. In addition, our patent litigators work closely with our patent prosecutors and trademark and regulatory attorneys to develop comprehensive solutions that achieve our clients’ goals.

In all matters—everything from pre-suit investigations to PTO actions, FDA tactics, and Hatch-Waxman strategies (especially ANDA certification requirements pursuant to Paragraph IV)—we bring together the best team of attorneys within our ranks to strategize the best course of action to achieve our clients’ objectives. This fully integrated approach has proven invaluable to our clients.

The Fish differential becomes most evident in Hatch-Waxman and other patent litigation. Hatch-Waxman is the door into the courthouse, but once in front of a judge or jury, you must still litigate the underlying science; it is there that the differences—in patent litigation experience, in technical mastery—become evident.
Our clients know they can rely on Fish as the world’s most experienced group of patent litigators to handle their cases. Our significant record of success, as partially demonstrated below, fortifies our ability to win and provide solutions that maximize the return on our clients’ significant investments.

ALPHAGAN®
Allergan, Inc., v. Alcon Laboratories, Inc., et al.
Allergan, Inc., et al. v. Bausch & Lomb Labs
Allergan, Inc., v. Alcon, Inc., et al.
Allergan, Inc., et al. v. Apotex Corp.
In re Brimonidine

Over the course of nearly a decade, Fish represented Allergan in multiple Hatch-Waxman litigations related to Allergan’s ALPHAGAN, ALPHAGAN P 0.15%, and ALPHAGAN P 0.1% glaucoma medications in the Central District of California, the District of Delaware, the Eastern District of Virginia, and the Federal Circuit Court of Appeals. In the final one of these litigations, Fish obtained a judgment of infringement, validity, and enforceability against defendant Apotex on all five patents-in-suit in multidistrict litigation tried in the District of Delaware. On appeal, Fish obtained an affirmation of the injunction against Apotex, successfully maintaining ALPHAGAN P’s market share for Allergan, and the Supreme Court denied certiorari.

AMRIX®
Eurand Inc., et al. v. Mylan Pharmaceuticals Inc. and Barr Pharmaceuticals, Inc., et al.
Eurand Inc., et al. v. Impax Laboratories, Inc.
In re Cyclobenzaprine

Represented plaintiffs Eurand, Cephalon, and Anesta in Hatch-Waxman litigation related to the extended-release muscle relaxant AMRIX. At the district court in Delaware, despite an adverse ruling that the two patents-in-suit were obvious and a subsequent launch-at-risk, Fish secured an injunction requiring defendant Mylan to withdraw from the market pending appeal. The Federal Circuit then affirmed that injunction and reversed the district court’s obviousness finding, after which the Supreme Court denied certiorari. After a four-day jury trial, regarding damages owed by Mylan and led by Fish, the parties settled after final arguments to the jury.

COMBIGAN®
Allergan, Inc., v. Sandoz Inc.
Allergan, Inc., v. Alcon Laboratories, Inc., et al.
Allergan, Inc., v. Apotex Inc., et al.
Allergan, Inc., v. Hi-Tech Pharmacal Co., Inc.

Represented Allergan in Hatch-Waxman litigation in the Eastern District of Texas over Allergan’s glaucoma drug COMBIGAN. At the district court, Fish obtained a judgment of infringement and validity against the four defendants that went to trial: Sandoz, Alcon, Apotex, and Watson. That judgment resulted in an injunction against generic product entry, which was affirmed on appeal, with the Federal Circuit ruling in favor of Allergan on three of the patents-in-suit. Fish continues to represent Allergan in district court litigation over COMBIGAN against defendants Sandoz, Alcon, Apotex, and Watson in the Eastern District of Texas, relating to additional patents covering the drug.

FENTORA®
Cephalon Inc., et al. v. Sandoz Inc.
Cephalon Inc., et al. v. Impax Laboratories, Inc.

Represented plaintiffs Cephalon and CIMA Labs in litigations relating to FENTORA, a rapid-onset fentanyl tablet used in the treatment of opioid-tolerant patients suffering from breakthrough cancer pain. Fish identified and successfully asserted a non-Orange Book patent in response to first-filer Watson Laboratories’ and second-filer Barr Laboratories’ attempted design-around of the FENTORA Orange Book patents. Fish obtained a judgment of infringement and validity against Watson in the District of Delaware that was subsequently affirmed by the Federal Circuit and favorably settled the Barr matter. After Sandoz and Impax also settled, Fish successfully tried four Orange Book patents against Mylan Pharmaceuticals, winning a judgment of infringement and invalidity and an injunction against generic entry. That case is currently on appeal.

Maximizing Market Exclusivity

Early-stage Orange Book strategy comes into play in ANDA litigation

We helped a branded-drug company facing generic competition on a key product by using a combination of litigation acumen and regulatory strategies.

Relying on our multidisciplinary expertise and technical knowledge of the underlying patent rights, we counseled the company on an aggressive posture with respect to Orange Book patent listing and subsequently advanced an equally novel theory of infringement in district court. During the litigation, we counseled the company on its withdrawal of the listed drug in favor of a new formulation that was protected by three-year Hatch-Waxman exclusivity.

We then assisted the company in the subsequent citizen petition filed by the generic manufacturer on the withdrawal issues while the FDA awaited a ruling by the Federal Circuit on the novel issues raised in litigation before approving any ANDAs.

In this way, we enabled the company to lawfully deal with the challenge of generic competition and maximize its market opportunities through the assertion of its underlying patent rights.
Our interdisciplinary teams provide a potent combination of attorneys and technology specialists who provide intricate, thorough, and expert knowledge to proactively and skillfully deliver results for our Hatch-Waxman clients.

**LUMIGAN®**

*Allergan, Inc. v. Barr Laboratories, Inc.*
*Allergan, Inc. v. Sandoz Inc.*

Represented Allergan in Hatch-Waxman litigation relating to its glaucoma drug LUMIGAN. Fish obtained a judgment of infringement and validity against defendants Barr Laboratories and Sandoz in the District of Delaware. Fish handled and argued the appeal before the Federal Circuit, which affirmed the district court’s findings.

**LUMIGAN® .01**

*Allergan, Inc. v. Sandoz Inc.*
*Allergan, Inc. v. Lupin Pharmaceuticals, Inc. et al.*
*Allergan, Inc. v. Hi-Tech Pharmacal Co., Inc.*
*Allergan, Inc. v. Watson Laboratories, Inc., et al.*

Represented Allergan in consolidated Hatch-Waxman actions over LUMIGAN 0.01, a treatment for glaucoma. After a one-week bench trial in the Eastern District of Texas, the court ruled that the defendants could not sell their generic versions of Allergan’s LUMIGAN 0.01 until Allergan’s last patent expires in 2027.

**SULAR®**


Represented plaintiffs in Hatch-Waxman action relating to Sciele’s blood-pressure drug, SULAR, in the District of Delaware. The matter resolved on patent expiry, preserving Sciele’s exclusivity through that time.

**XELODA®**

*Hoffman-La Roche Inc. v. Roxane Laboratories, Inc., et al.*
*Hoffman-La Roche Inc. v. Mylan Inc., et al.*
*Hoffman-La Roche Inc. v. Teva Pharmaceuticals USA, Inc., et al.*
*Hoffman-La Roche Inc. v. Intas Pharmaceuticals and Accord Healthcare*

Represented Roche in Hatch-Waxman litigation in the District of New Jersey involving XELODA, the first oral chemotherapy drug approved in the U.S. for treatment of breast and colorectal cancer and Dukes’ C Stage III colon cancer. Successfully settled the matter in 2013.

**RANEXA®**


Represented Gilead and Roche in Hatch-Waxman suit over RANEXA, a treatment for chronic angina. Following a three-week bench trial in the District of New Jersey, the case settled on terms favorable to plaintiffs, with Lupin agreeing to postpone market entry until February 27, 2019, just three months before patent expiry.
Fish & Richardson is a global patent, intellectual property (IP) litigation, and commercial litigation law firm with more than 400 attorneys and technology specialists across the U.S. and Europe. Fish has been named the #1 patent litigation firm in the U.S. for 10 consecutive years. Fish has been winning cases worth billions in controversy – often by making new law – for the most innovative clients and influential industry leaders since 1878. For more information, visit www.fr.com.

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