Schiff Hardin

# Pharmaceuticals

## Overview

Pharmaceutical clients require a broad spectrum of legal services, ranging from patent litigation and licensing to technology transfers and corporate transactions. For pharma companies, Schiff Hardin offers **thoughtful, effective, and diligent** representation throughout the full spectrum of service.

We are **thoughtful** because we understand the industry and have a deep technical bench. Many of our attorneys hold degrees in disciplines such as biology, biochemistry, biomedical engineering, cell biology, chemical engineering, chemistry and microbiology. We are industry thought leaders, regularly publishing articles in academic and industry journals and speaking at conferences on industry issues. In addition, many of us are registered to practice before the United States Patent and Trademark Office.

We are **effective** because we have been doing this a long time, and did not just start a pharma practice when it became popular. Our group represents worldwide generic pharma clients and has done so for over fifteen years. Our experience puts us in a position to team with our clients to meet budgets for smaller, second-filer matters and larger first-filer challenges alike.

We are **diligent** because we have the resources of a full-service firm. Our clients appreciate our size, a sweet spot that sets us apart, as we are neither too big nor too small. Our clients appreciate service that precisely fits their individual needs. While we offer all the resources and the depth and breadth of experience associated with a large law firm, we are committed to providing personalized client service. We are responsive: when clients call on us, they hear directly and promptly from the partner in charge, and can access any of our team members.

### A Select Hatch-Waxman Litigation Practice

The pharmaceutical landscape has shifted dramatically since 1984, when the Hatch-Waxman Act took effect. At that time, only 14% of the drugs prescribed in the United States were generic. Now, about 80% of all prescriptions written in the United States are for generics. The result: billions of dollars of savings for American consumers.

Schiff Hardin has one of the inaugural Hatch-Waxman Litigation practices in the nation. We were one of the first law firms to represent generic pharmaceutical companies seeking to make medicine affordable to consumers. We continue to represent the world's leading generic companies in ongoing litigation, including *inter partes* review, trials and appeals – and for precedent-setting cases for some of the largest first-to-file matters.

Our experience spans the full range of Hatch-Waxman issues, from product screening and selection through trial and appeal. Over the years, we have worked with more than a dozen generic pharmaceutical companies on more than 100 pharmaceutical products in abbreviated new drug application (ANDA) patent litigations, as well as 505(b)(2) applications. Working closely with each client, we craft customized strategic solutions to meet their individual objectives.

### Intellectual Property Creation, Management and Protection

Innovative trademarked and patented products are among our pharmaceutical clients' most valuable assets. We regularly help clients create, protect and defend their IP properties. Clients turn to us for assistance with everything from technology transfers, patent licensing and software licensing to trademark searches, counseling on the selection of trademarks and filing of U.S. and foreign trademark applications. We are experienced in both patent prosecution and litigation support for our pharmaceutical and biotechnology clients.

### A Leader in Biologics and Biosimilars Patent Litigation

As patents for small molecule drugs expire, the pharmaceutical industry has increasingly looked to biologics and biosimilars. Applications for approval of biosimilar products – some of which will be subject to challenge under dozens of patents – are certain to provoke litigation under the Biologics Price Competition and Innovation Act of 2009.

With experience litigating patents related to biotechnology spanning more than 20 years, the Schiff Hardin team is fully equipped to handle biosimilars patent litigation successfully. Our clients benefit from our extensive experience with the complex patent, regulatory, scientific and business issues that must be addressed well in advance of the filing of an application for approval of a biologic product.

Because both Biologics Act and Hatch-Waxman litigation is inherently uncertain, our primary goal is to identify, and then manage uncertainties for our clients, while helping them achieve their business objectives. When settlement is appropriate, we can also call on our antitrust and corporate colleagues for input as needed. Underscoring these options, though, our group has successfully litigated cases in key national jurisdictions as well as argued appellate cases before the Federal Circuit.

### A Broad Range of Services

Pharmaceuticals industry clients call on us to counsel them on a wide range of issues, including:

- Labor and employment compliance and litigation
- Regulatory compliance and Citizen Petitions
- Mergers and acquisitions
- Venture capital financing
- Startups
- General corporate transactions
- Environmental compliance, permitting and litigation
- Internal investigations, corporate compliance and white collar criminal defense

## Experience

- Our pharma group has nationally recognized first-chair trial attorneys, and broader support throughout the firm as needed.
- Our cases have set legal precedents in Paragraph IV litigation.
- Over the years, we have successfully represented clients in litigation involving over twenty-five products. A representative list includes: azithromycin, bupropion (Wellbutrin®), cardizem beta blockers, cefaclor, docetaxel (Taxotere®), escitalopram (Lexapro®), epinephrine, eszopiclone (Lunesta®), esomeprazole (Nexium®), lanthanum carbonate (Fosrenol®), fenofibrate, gabapentin (Neurontin®), levonorgestrel and ethinyl estradiol (Seasonale®, Seasonique® and Loseasonique®), lopinavir/ritonavir (Kaletra®), loratadine (Claritin®), malathion, memantine (Namenda®), metaxalone (Skelaxin®), metformin HCl (Fortamet®), mirtazapine (Remeron®), norethindrone acetate and ethinyl estradiol (Femcon Fe® and Loestrin®24 Fe), omeprazole (Prilosec®), oxaliplatin (Eloxatin®), quetiapine (Seroquel®), quinapril (Accupril®), ramipril (Altace®), and others, including many ongoing litigations.
- We also have significant experience litigating cases related to medical devices, including, for example, heart stents and computer-based systems for detecting cancerous and precancerous conditions, and medical implants and related technology.

## AWARDS & HONORS

- BTI “Innovation Builder”

  We were singled out by corporate counsel as one of only 28 percent of law firms clients view as a BTI “Innovation Builder,” which recognizes firms that bring change to the legal market through new technology, services, strategies, or structures.

- Top “Clientopia” Law Firm (2017)

  *BTI Industry Power Rankings*

- IP Practice Group Leader Recognized Among World’s Leading Patent Professionals (2017)

  *IAM Patent 1000*

- Schiff Hardin IP Litigation Group Achieves Clientopia® for Pharma (2016)

  BTI Power Ranking



Schiff Hardin LLP schiffhardin.com