WILSON SONSINI

Global Generics

HIGHLIGHTS

LMG Names Wilson Sonsini the 2022 "Hatch-Waxman Litigation Firm of the Year – Generic"
Wilson Sonsini was named "Hatch-Waxman Litigation Firm of the Year – Generic" at the 2022 LMG Life Sciences Awards, and was also recognized under "Hatch-Waxman Impact Cases of the Year" for its work on *Celgene v. Mylan* (Federal Circuit, 2021) and "Patent Impact Cases of the Year" for its work on *ModernaTx v. Arbutus* (Federal Circuit, 2021).

OVERVIEW

In today's fast-growing, highly regulated generic pharmaceutical market, companies increasingly require specialized legal guidance as their products are developed, launched, and litigated. Wilson Sonsini's attorneys address this need by providing expert counsel to companies in the global generics industry, offering sophisticated representation far beyond the scope of general corporate and securities counsel. We have assembled a highly experienced team of experts from a cross-section of the firm's key practice areas, including intellectual property, litigation, antitrust, FDA/regulatory, technology transactions, exports and FCPA, trade secret, and trademark and copyrights.

Led by the former chief legal officer of Mylan Pharmaceuticals, one of the world's leading generic and specialty pharmaceutical companies, our attorneys work closely with our generic pharmaceutical clients' legal and scientific personnel and senior management to understand and meet their specific needs both in the U.S. and abroad. The members of our team, many of whom previously served as in-house general counsel of life sciences companies, possess a deep understanding of the complex international regulatory landscape, particularly as it pertains to life sciences, medical device, and pharmaceutical companies in the rapidly growing Chinese, Indian, and European markets.

Please see below for further information on our full range of offerings for generic pharmaceutical companies.

Strategic Business and Funding Initiatives

With more than 500 innovative life sciences clients and an extensive network of relationships within the private and public equity financing communities, we are uniquely positioned to facilitate connections between generics companies and potential partners and investors. In addition, we have several attorneys with life sciences GC experience who offer a unique perspective on the overall management of in-house legal affairs and strategic business initiatives.

Our attorneys routinely engage in global business development by providing a critical analysis of potential products, including products designed to address needs in niche markets, and product strategies. We work with our clients to identify products with favorable intellectual property assets and regulatory paths to commercialization, as well as potential formulations and delivery-system alternatives for generic drug development.

International Business Opportunities

We have a long and successful history of advising both U.S.- and foreign-based clients—particularly clients in China, India, and Europe—in connection with a variety of international matters, including intellectual property counseling, mergers and acquisitions, joint

ventures, foreign investment, branch operations, information technology outsourcing, spin-offs, public and private equity transactions, and capital markets. Of particular relevance to generic pharmaceutical companies, our attorneys are well equipped to provide expert counsel regarding offshore structures, especially those involving the establishment of international R&D and manufacturing facilities.

FDA/Regulatory

The firm's FDA/regulatory attorneys help clients successfully navigate complex regulatory and reimbursement mazes, comply with strictly enforced regulatory and healthcare laws in both the U.S. and abroad, and secure timely approvals and clearances. Our services in this area include representation in negotiations and administrative proceedings, crisis and compliance management, compliance counseling on broadly enforced anti-kickback laws and new patient privacy protection laws, assessment of product development and regulatory approval options, and counseling on advertising and promotional strategies.

Trade Secret

We have one of the country's leading trade secret practices, having provided representation in dozens of cases nationwide in the past several years alone. Our attorneys handle complex trade secret and related disputes—whether between business partners or employees—regarding restrictive covenants, invention assignments, employee mobility, work for hire, UTSA preemption, inevitable disclosure, threatened misappropriation, bad faith, choice of law, and licensing transactions. We possess unique trade secret expertise in both defense- and plaintiff-side cases, and pride ourselves on having raised creative, cutting-edge legal theories that have been adopted in many published cases and subsequently followed by other law firms. We also assist both new and established businesses in developing in-depth protective and preventative strategies.

Employment Law

Working closely with the firm's trade secret practice, our employment law attorneys are known for their ability to obtain favorable outcomes in complex, high-exposure cases, as well as to successfully handle EEOC, OFCCP, and wage-and-hour investigations. We have experience with every critical aspect of the employer/employee relationship, including employee mobility and noncompete disputes; recruiting, hiring, and promotion practices; compensation, leave, and wage-and-hour issues; sexual harassment and other forms of discrimination; executive misconduct and performance management; layoffs, restructurings, and terminations; internal and governmental investigations; and union organizing and NLRB proceedings.

Export Controls and FCPA

The firm's export controls and Foreign Corrupt Practices Act (FCPA) practices advise organizations with respect to a broad array of regulatory and compliance issues, including determining how regulations apply to their products and services, preparing for and conducting civil and criminal government investigations and enforcement actions, and developing compliance policies and procedures. Our attorneys regularly work with companies to resolve complex jurisdiction and classification issues, devise licensing strategies, design compliance programs, provide employee compliance training, prepare voluntary disclosures, assist with transactional due diligence, and conduct internal audits and investigations.

We also advise clients on compliance with the Export Administration Regulations (EAR), International Traffic in Arms Regulations (ITAR), and trade and economic sanctions administered by the Office of Foreign Assets Control (OFAC). Further, we regularly provide representation in enforcement-related matters before the Justice Department, the Commerce Department's Bureau of Industry and Security, the State Department's Directorate of Defense Trade Controls, and the Treasury Department's OFAC.

Antitrust and Settlement Strategies

Our internationally recognized antitrust practice advises clients on the full spectrum of pharmaceutical antitrust issues, including patent settlement counseling and related FTC investigations, private antitrust litigation, Hart-Scott-Rodino merger filings and compliance, and matters involving the intersection of antitrust and intellectual property law. Our team includes attorneys with unparalleled experience within the FTC, including the former director of the FTC's Bureau of Competition, who supervised all FTC pharmaceutical merger and conduct investigations during her tenure, and the former antitrust advisor to FTC Jon Chairman Leibowitz, who was involved in litigating the landmark *FTC v. Schering-Plough* case and played a leading role in investigations concerning Orange Book listings and patent settlements.

In addition, we have years of experience representing generic pharmaceutical companies in litigation settlements with brand pharmaceutical companies. As a result, we are highly skilled at crafting and negotiating favorable settlements and related licensing arrangements.

Patent Litigation

The firm's robust generic pharmaceutical patent litigation practice specializes in abbreviated new drug application (ANDA) and Paragraph IV suits. Our patent litigators have participated in more than 25 Hatch-Waxman Act/ANDA litigations, including trials, preliminary injunction proceedings, Federal Circuit appeals, and multi-district litigation.

Our team has significant experience with all types of complex litigation matters—including simultaneous litigation and interference proceedings, and litigation involving simultaneous patent, antitrust, and FDA cases—and complex settlements, licenses, product acquisitions, joint ventures, stock purchase agreements, and a variety of operational agreements (e.g., manufacturing, supply, distribution, marketing, and promotion). We also engage in litigation against or in support of the FDA, manage product development pipelines, file citizen petitions and responses, and conduct strategic due diligence. In addition, our patent litigators provide counseling with respect to patent and FDA issues surrounding new product regulatory filings and product acquisitions.

Patents and Innovations

We have more than 60 professionals with practices dedicated solely to life sciences intellectual property counseling and patent prosecution, with a focus on biotechnology and medical device companies. More than half of these individuals have Ph.D. degrees in biotechnology-related fields, including pharmacology, molecular biology, and organic chemistry.

Our patents and innovations attorneys have an impressive track record of IP value creation, having assisted in developing the IP portfolios covering such inventions as the DNA chip, cancer therapies, nanotechnology, and stem cell technologies. Our experience includes obtaining U.S. and foreign patent clearance for APIs, formulations, and manufacturing processes; integrating IP, regulatory, and commercial strategy for ANDA and 505(b)(2) filings; completing non-infringement and invalidity opinions; integrating citizen-petition filings; preparing pre-litigation strategy and ANDA notice letters; and devising comprehensive, worldwide strategies on reexam, reissue, and oppositions.

Technology Transactions

The firm has more than 70 attorneys dedicated solely to technology transactions. With extensive experience negotiating hundreds of successful business and strategic collaborations, our attorneys have placed the firm's life sciences clients in optimal positions to succeed in today's complex global marketplace. These collaborations include license agreements, joint ventures, co-branding and promotional agreements, R&D agreements, strategic alliances, joint development agreements, co-investment agreements, joint marketing agreements, and manufacturing, supply, and distribution agreements.

Trademark and Copyright

Our trademark and copyright attorneys provide clients with sophisticated and aggressive strategic counseling, transactional, and litigation expertise on matters involving trademark, copyright, advertising, Internet, retail, media, and consumer law. We counsel clients on the selection, protection, and enforcement of company names, brand names, slogans, and trade dress for U.S. and worldwide markets, including registration and licensing, and have engaged in cutting-edge litigation in U.S. courts on trademark, trade name, trade dress, domain name, copyright, right of publicity/privacy, and unfair competition issues. We also represent clients in connection with trademark opposition and cancellation proceedings in both the U.S. and abroad.