Practice Group Overview

Arnold & Porter

UPDATE

Washington DC-based **Arnold & Porter** has long been considered a major player in the realms of regulatory law, government investigations, product liability and healthcare pricing and reimbursement. These areas of expertise, combined with a large contingent of IP and transactional attorneys, allows the firm to service industry clients looking for top-tier life cycle representation. One peer, in the course of describing Arnold & Porter, says, "There are very few practices within the firm that don't deal with life sciences, quite frankly." Another peer, speaking specifically to the regulatory strengths, says, "Regulatory laws are so interconnected it's important to know them all, and Arnold & Porter provides the necessary breadth of knowledge." Another peer, offering a different take, raised the issue of recent departures at the firm, particularly the loss of Ellen Reisman and a number of other partners who left Arnold & Porter to form the DC tort firm, Reisman Karron Greene. Still, despite these departures, the peer went on to say, "I have enormous respect for them, being another DC firm full of incredibly smart people."

Daniel Kracov, one of the firm's top regulatory lawyers, serves as co-chair of the Life Sciences and Healthcare Regulation Practice. He is nationally recognized as an expert in food and drug law, and has established a successful track record representing pharmaceutical, biotechnology, medical device and diagnostic companies, among other industry clients. Kracov, representing Celgene, recently led the firm's work preparing and submitting a complex citizen petition to the FDA seeking to ensure that the agency considers a broad range of scientific issues relating to generic and 505(b) (2) NDA applications for drugs incorporating nanotechnologies that reference Celgene's Abraxane product, or similar products, prior to drug approval. In another matter that falls more in the corporate realm, Kracov helped lead the firm's representation of Aduro Biotech in the negation of a major collaboration with Novartis for the worldwide research, development and commercialization of novel immuno-oncology products.

Three of the firm's leading attorneys in the non-IP space are **Baruch Weiss**, **Anand Agneshwar** and **Lisa Blatt**. Weiss is praised by peers and clients for his work defending companies facing government investigations, while Agneshwar is a product liability expert known for representing leading pharmaceutical companies. Agneshwar currently leads the firm's work serving as national counsel to Bristol Myers Squibb and US affiliates of Sanofi in product liability cases involving the drug Plavix. Blatt is an appellate specialist who one peer describes as having a "really 'hot hand' in appellate work for life sciences companies."

Covington & Burling

UPDATE

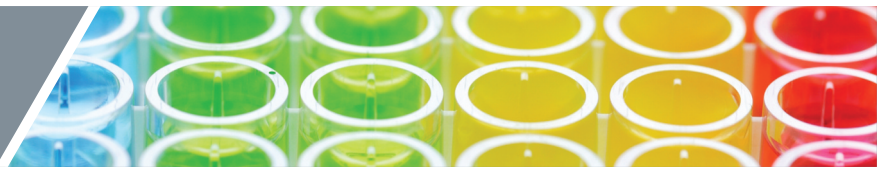
With five domestic offices, and additional locations in China, Korea and Europe, **Covington & Burling** has developed a truly global reach, offering clients expertise across a full range of contentious and noncontentious practice areas. Yet it is Covington's deep roots in Washington, D.C. that give the firm a distinctive advantage when it comes to pitching clients searching for high-level understanding of government and legislation. Covington's regulatory attorneys, for instance, are regarded as second to none for their ability to delve into the inter-workings of food and drug policies both domestically, and around the world. Within the life sciences realm, the firm's regulatory and transactional specialists are particularly esteemed for work in the pharmaceutical industry, representing heavyweight clients such as AbbVie, AstraZeneca, Merck, Genentech, Allergan, Shire and Regeneron. Partners **Richard Kingham** and **Peter Safir** are two of the leading regulatory names. Kingham recently counseled client PhRMA in a range of regulatory matters, including potential reforms of drug approval laws in China and India, and the ramifications of the U.S. Drug Quality and Security Act of 2013. Safir, who one client describes as "the best regulatory lawyer around," recently provided FDA advice to Sanofi, AstraZeneca, Shire, Lilly, Salix and Astellas, regarding the approval of drugs, non-patent exclusivity and manufacturing and quality issues.

The highly regarded transactional attorneys are another fundamental arm of the firm's traditional life sciences services. **Amy Toro** and **John Hurvitz** are two key partners who lead the firm's representation in matters involving mergers and acquisitions, licensing and collaboration and other finance-driven areas. Toro recently counseled client Sanofi in a number of significant licensing and collaboration deals, one of which secured an agreement with Google Life Sciences regarding diabetes disease management. Hurvitz, in a pro bono capacity, counseled The Leukemia & Lymphoma Society in a deal to enhance development of Kite Pharma's lead product candidate for the treatment of refractory aggressive non-Hodgkin lymphoma.

Although the regulatory and transactional services have long been the bread and butter of the firm's work in the life sciences realm, Covington now has both intellectual property and white-collar practices specifically dedicated to pharmaceutical clients. One peer, speaking to this expansion, says, "They didn't have either of those practices before but in classic Covington style they quickly discovered that you need these if you're going to make yourself available to solve any problem for the pharmaceutical industry. Covington is now officially at that 'one-stop shop' level." Recent successes for branded clients in Hatch Waxman litigation typify Covington's evolving capabilities, as does the firm's work across non-IP realms, including product liability, antitrust and government investigations.

Christopher Sipes, whose practice also encompasses regulatory and public policy, is a top litigator for the firm who recently led the representation of client Amarin in

Practice Group Overview



Hatch-Waxman litigation against a number of drug companies. The matter involved Vascepa, a prescription medicine used to lower high levels of triglycerides in adults. **Mark Lynch** is a lauded product liability expert, who one peer describes as a "seasoned statesman of the pharmaceutical bar." The peer goes on to say of Lynch, "He has done a great deal of product liability trial work and has managed difficult cases like a true gentleman." **Ethan Posner** is a seasoned expert in government investigations. He recently managed the defense of client Gilead against a Department of Justice investigation, and represented a major healthcare company over the course of investigations stemming from the recall of OTC products.

Goodwin Procter UPDATE

Goodwin Procter's mission is to provide full service, high-level representation of emerging life sciences clients: in patent prosecution, strategy, and litigation; collaboration and licensing; and regulatory. The firm represents over 50 public life science companies and operates on the East and West coasts of the US and in Europe.

Goodwin's transactional practice consists of about 70% company-side representation and 30% venture capital, banking, and miscellaneous. The focus of the practice is on emerging biotech companies. **Mitchell Bloom**, national chair of Goodwin's life sciences practice, specializes in financings and public offerings for later-stage private companies and public biotech companies. **Kingsley Taft** is a senior partner and co-chair of Goodwin's Life Sciences practice who leads a licensing and strategic alliance practice that does complex deals for the likes of JP Morgan.

The firm's IP practice has continued to grow over the few years since bringing in a lateral pharmaceuticals group from Kenyon & Kenyon headed by **Elizabeth Holland.** Goodwin represents a broad swathe of generic companies and is growing in Hatch Waxman, biosimilars, and IPRs. **Duncan Greenhalgh** works primarily on the IP side, after joining Goodwin in 2005 from Testa Hurwitz & Thibeault along with a lot of other emerging company lawyers. **David Hashmall** is a renowned IP attorney known by one client as the "master of the client relationship" who "really understands the business and works to provide service and advice that matches the business goals." **Daryl Wiesen's** practice focuses on Hatch Waxman litigation on both the brand and generic side. Last year, he tried a case for Cephalon on the brand side against the FDA in relation to Treanda, which treats chronic lymphocytic leukemia and non-Hodgkin's lymphoma and has annual sales between $750-800 million. In a case representing MIT enforcing patents against Shire, he got a judgement of infringement and validity, which Shire has appealed to the Federal Circuit. **Douglas Kline**, chair of the IP litigation group, is a new LMG Life Sciences star who is particularly active in *inter partes* and *ex-parte* and reexamination proceedings.

The firm has regulatory capabilities, after bringing in a regulatory team from Wilmer-Hale several years ago led by **Mark Heller**. One client praises him for being "one of the most knowledgeable US FDA regulatory attorneys in the country because of his former affiliation with FDA and his formulation of the medical device regulations gives him an understanding of the regulations that can lead to successfully dealing with the FDA."

Hogan Lovells UPDATE

Hogan Lovells has a global footprint with a roughly 50-50 split between the Americas and countries outside; its largest offices are in London and Washington D.C. The life sciences practice is very substantial, providing a large portion of the firm's revenue, and Hogan Lovells represents many of the leading innovator companies. Within that global practice, the firm operates in corporate litigation, IP and operates a hefty government regulatory practice.

The firm has strong links with the Chief Counsel's Office at the FDA and aligns itself with major therapeutic and practice areas within the FDA. In the US, the firm has more than 50 attorneys doing pharma, biotech, foods, dietary supplements, cosmetics, and agricultural products. This is in addition to a small contingent of 12 attorneys in Europe.

David Fox is active in combination products, crossovers, drugs, biologics, devices, and human tissues, but his main area of expertise is in defending pioneer companies against generic exclusionary issues. He works in collaboration with **Jonathan Kahan** and new LMG Life Sciences star **Michael Heyl** who are both active in medical devices. **Yarmela Pavlovic**, based ouf the San Francisco office, is known by peers as a digital health regulatory specialist who represents big-name Silicon Valley companies. **Janice Hogan** is co-director of the FDA medical device practice and focuses on orthopedics, women's health, personalized medicine, and cancer medications. One colleague praises Hogan for her attention to detail as witnessed by her thorough memos and for her overall skill in running a multi-million dollar medical devices practice in Philadelphia. Fellow stars include **Joy Sturm**, **Meredith Manning**, and **Marcy Wilder**.

Fox co-chairs the lifecycle management subgroup with **Phil Katz** who heads the firm's pharmaceutical/biotech practice. The practice deals in GMP manufacturing compliance, advertising and promotion and exclusivities. Katz' own practice is primarily in regulatory exclusivity and patent protection with clients spanning from large international players to companies without a product on the market to their name.

The standout corporate attorney at the firm is **Asher Rubin**, who co-chairs the life sciences practice and keeps an impressive client list. Silicon Valley-based practitioner **Laura Berezin** is a securities expert specializing in IPOs and private placement transactions, and regularly works with venture

Practice Group Overview

capital, investment banks and both emerging and established corporations. **Adam Golden** is an M&A and licensing expert who regularly represents Novartis in both acquisitions and divestments of multi-billion dollar business units as they seek new and more lucrative portfolio assets.

Latham & Watkins UPDATE

Latham & Watkins is a full-service, international firm, whose record representing life sciences-industry clients has traditionally been built around success in the financial and transactional realms. Lately, however, one of the key storylines at Latham has centered around a concerted effort to grow IP litigation capabilities. For instance, the 2014 hire of ex-Kirkland & Ellis partner, **David Callahan**, marked a significant boon for the firm. Callahan currently serves as chair of the litigation and trial department and maintains a broad practice – a substantial portion of which is devoted to representing medical device and pharmaceutical industry clients in high stakes contentious matters. Since Callahan's hire, the firm has also picked up a number of top names from Finnegan & Henderson. These include **Mike Morin**, a noted trial and appellate lawyer, and **David Frazier**, whose practice combines biosimilars expertise with significant experience in PTAB proceedings. These acquisitions, coupled with other hires in the San Francisco and New York offices, have not gone unnoticed by industry peers, one of whom characterizes the firm as "top of the heap" within the context of overall life sciences expertise. One client, speaking to the firm's ability to represent industry clients across a product's life cycle, says "They deliver results, are cost-effective, possess expertise, have good communication and understand our needs and the industry."

Kenneth Shuler, out of the Chicago office, is another key litigator whose work on behalf of generic clients recently earned the attorney a place on *LMG Life Sciences* 2016 shortlist for Hatch Waxman (Generic) Litigator of the Year. In one recent matter of note, Schuler represented Roxane Laboratories in ANDA litigation brought by Janssen Pharmaceuticals involving the pain medications, Nucynta ER and Nucynta IR. **Daniel Brown** is a leading partner in the New York office who recently represented Par Pharmaceuticals in litigation brought by Novartis involving a rivastigmine patch product.

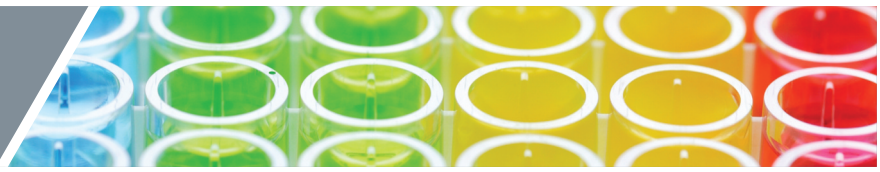
Judith Hasko, global Chair of the Life Sciences Licensing Group, is a leading transactional partner who was named by *LMG Life Sciences* as the 2015 Finance and Transactional Attorney of the Year. One competitor says of Hasko, "She plays a big role in some of the firm's largest cases and deserves credit for that." In just one representative matter of note, Hasko represented the biotechnology company X-Rx in reaching a collaboration agreement with Gilead to develop proprietary small molecule autotoxin inhibitors. **Charles Ruck** is a highly regarded name at the firm who a competitor calls, "the guru in the corporate transactional space." One client says of Ruck: "He and his team have been meaningful thought partners with an eye towards finding optimal solutions for our business and our stakeholders." **Mark Roeder**, based in the Silicon Valley office, is global Co-chair of the Life Sciences Industry Group. A substantial portion of Roeder's practice is focused on venture capital financing and counseling clients in mergers and acquisitions. In one notable matter of late, Roeder led the cross-office corporate team advising client Relypsa in the company' acquisition by Galenica – a deal valued at $1.53 billion.

Morgan Lewis & Bockius UPDATE

Morgan Lewis & Bockius is a global full-service law firm with the size and scope to service every need of life sciences companies. Next to financial services, life sciences is the firm's largest practice area. The firm has offices across the world and is particularly well known for its regulatory capabilities based out of Washington D.C **Stephen Paul Mahinka** leads the firm's life sciences practice; he also founded the FDA regulatory practice and has led the antitrust practice for awhile. Through his interest in product lifecycle development, he was integral to changing the firm's management structure to an industry-based approach around the year 2000. This has shaped the firm's hiring moves and geographic expansions within the last 15 years. The firm is now active in about 40 percent more areas, having expanded its West Coast capabilities through its acquisition of the Brobeck, Phleger & Harrison in 2003 and boosted East Coast capabilities with acquisition of Bingham McCutcheon. Morgan has extended its IP capabilities, and Chicago and California are home to many of the firm's patents litigators, who deal regularly with Hatch Waxman and biosimilars issues. Integral to this was this year's addition of four K&L Gates partners including new LMG Life Sciences Star **Michael Abernathy** who have expertise in drug patent litigation in federal district courts and before the U.S. International Trade Commission Today, Morgan services both startups and established companies in corporate structuring, formation, and funding, while also protecting technology on the patent, trademark, and FDA exclusivity ends. Additionally, Morgan Lewis has the R&D capabilities to assist with agreements, clinical trials, regulatory approvals, and clinical trials. Morgan Lewis prides itself on its team-oriented work culture.

The regulatory practice comprises FDA, healthcare, and regulatory capabilities. **Kathleen Sanzo**, a 2016 addition to the LMG Life Sciences Hall of Fame is an FDA practice leader active in foods, drugs, combination products, and diagnostics. She is one of a handful of leading drug lawyers in the nation and, with Mahinka, she has co-written the chapter on pharmaceutical marketing and promotion for a Food and Drug Law Institute treatise.

Practice Group Overview



Donna Yesner is a valuable asset to the firm's general health-care reimbursement capabilities, specializing in government purchasing and contracting. The rising importance of e-health, telemedicine, and medical devices has raised FDA regulatory and corporate issues, as well as FCC-FTC regulation questions in the last couple of years. The Bingham merger allowed Morgan to expand into telecommunication, since Bingham has one of the leading telecommunications practice in the US. **Michele Buenafe** is a leading attorney in digital health issues who focuses her practice on counseling, pre-market issues, and postmarket compliance.

Morgan has extended its IP capabilities, and Chicago and California are home to many of the firm's patents litigators, who deal regularly with Hatch Waxman and biosimilars issues. This practice feeds into the firm's regulatory practice bringing up issues around market exclusivity, counterclaims for improper orange book listing, and patent extension issues. Based on the West Coast, **Rich De Bodo** is a lead trial counsel in patent and trade secrets cases and tries Hatch-Waxman cases and cases. **Jeffry Mann** is primarily a prosecutor in a diverse grouping of areas through the life sciences and is active in transactional and premarketing diligence.

Morgan is very active with emerging businesses in the big centers of finance and developments for life sciences companies including Boston and Silicon Valley. From the Princeton office, **Randall Sunberg**, **Emilio Ragosa**, **Alan Leeds**, and **David Glazer** are active in M&A, collaboration and licensing which is split between pharma, biotech, and medical devices. Morgan represents banks in transactions, but more often than not, life sciences companies. The firm's FDA group is tightly knit to the corporate business and finance group, being active in pharmaceutical due diligence. Morgan Lewis has a handful attorneys in the US that focus on life sciences licensing transactions dealing with product approval processes and split territories.

Ropes & Gray

UPDATE

Ropes & Gray is a global, full-service firm with the capacity to provide industry clients a complete range of services across the life cycle of any given product. Although Ropes and Gray has reportedly lost a number of key IP litigators of late – a fact repeatedly pointed out by industry peers – the firm maintains a stellar reputation for expertise across regulatory and transactional law, as well as areas of non-IP litigation. Speaking to the broad corporate abilities of the firm, one highly respected peer says, "They are very good. They do mergers and acquisitions transactions for Johnson & Johnson for example, and they do a very good job." Another peer states, "Ropes is a big player in this industry. They do a ton of work for Pfizer and Johnson & Johnson. I have lots and lots of respect for Ropes." Some of the leading corporate and transactional partners responsible for the above-mentioned sentiments are **Marc Rubenstein**, **Marko Zatylny**, **Steven Wilcox** and new star **Christopher Comeau** – the latter of whom was shortlisted by *LMG Life Sciences* for the 2016 Finance and Transactional Attorney of Year award. In one high-profile matter of late, Comeau led the firm's representation of Shire in that company's $32 billion acquisition of Illinois-based Baxalta, a leading biopharmaceutical company that produces products used in oncology, hematology and immunology treatment. Rubenstein, representing Vertex Pharmaceuticals, recently led the company through its $2.6 billion strategic research and collaboration agreement with CRISPR Therapeutics. The deal centered around the use of CRISPR's gene editing technology, which is being used to discover and develop possible treatments for underlying causes of genetic diseases. Zatylny serves as co-chair of the firm's energy and infrastructure group, and focuses his practice on advising clients in mergers and acquisitions, capital markets and corporate governance issues. Wilcox, the former chair of the firm's life sciences practice group, has a demonstrated record of success counseling top-name pharmaceutical clients such as Johnson & Johnson, Pfizer and AstraZeneca. On behalf of leading medical research institutions, Wilcox also provides counsel related to the licensing and commercialization of technologies. One satisfied client says of Wilcox, "I wouldn't trade his experience and judgment for anything. When I have a big problem, Steve is right there to help me sort it out."

A distinguishing characteristic of Ropes & Gray is the degree to which the firm's corporate capabilities combine with deep experience in regulatory matters and government investigations. Referring to the firm's ability to navigate companies through complex investigations, one satisfied client says, "Ropes & Gray is one of the leading firms in combining life sciences industry expertise with excellent service in defending companies against government investigations. Their team is broad and deep, and they have shown a terrific willingness to deliver cost-effective service in unique ways." The regulatory practice group is led by Washington D.C.-based **Greg Levine**, who also serves as co-chair of the life sciences practice group. Levine focuses his practice on life cycle compliance for leading pharmaceutical, medical device and biotechnology clients. Another key regulatory partner is **Paul Rubin**, who one client says is "exceptionally bright," and "has a grasp of legal rules, regulations, and the legal landscape, and can apply them practically to the current business environment and corporate needs." Speaking to the firm's overall regulatory strength, another client says, "We've been really pleased with Ropes & Gray. They have been instrumental in helping us navigate regulatory compliance situations and assisted us in investigations of significant importance to the company."

As mentioned above, the firm's IP litigation capabilities have reportedly taken a hit. Former partner Bradford Badke, in one notable example, recently departed the firm for Sidley Austin. One leading industry peer says the IP litigation group has "been deci-

Practice Group Overview

mated," and goes on to question the commitment to investing in new litigation hires. Another peer says, "Lots of people are departing Ropes." Regardless of these developments, however, Ropes & Gray's work across non-contentious patent prosecution and strategy and management remains strong. **Anita Varma** is co-head of the IP rights and management group, and possesses more than 25 years of experience across a wide cross-section of IP law. Varma has for years led the firm's representation of Bayer Healthcare in a variety of matters involving IP transactions, portfolio development and strategy, litigation and due diligence.

Sidley Austin

UPDATE

There are few, if any firms that can match the breadth of life sciences services offered by Chicago-based **Sidley Austin**. Sidley's dominance across the industry is reflected in the perennial top-tier rankings found throughout *LMG Life Sciences*. Likewise, the firm recently swept the publication's 2016 awards, winning the coveted Life Cycle Firm of the Year, as well as IP General Patent Litigation Firm of the Year, Regulatory Firm of the Year, and Product Liability Firm of the Year, among other honors. One peer, referencing the firm's overall strength across contentious and non-contentious practice areas, says, "Sidley is the definitive 'life cycle' firm. They seem to tick all the boxes." Another industry competitor – this one speaking to general patent litigation work – says, "They are good. They've only gotten stronger." A satisfied client rattles off terms such as "outstanding," and timely," in the course of describing the firm. Yet another client, referring to the IP litigation group, says, "We had a short deadline to find new counsel for a difficult IPR proceeding. The team at Sidley Austin understood our needs immediately. In a very short time and with considerable efficiency, the team got up to speed on the technology and the procedural and substantive issues we faced. They provided excellent representation."

Three of Sidley's leading IP litigators are **Patricia Thayer, Jeffrey Kushan** and **David Pritikin** – the latter of whom heads up the national IP practice group. Pritikin currently represents Johnson and Johnson in Hatch-Waxman litigation against a dozen generic drug manufacturers. The matter, which involves Zytiga, a blockbuster drug used to treat metastatic prostate cancer, is playing out in proceedings in the U.S., Europe and Australia. Simultaneously, Pritikin is representing Johnson & Johnson against seven generic companies in the District of Delaware in litigation involving Xarelto, an anticoagulant that prevents blood clots. One client, in the course of speaking to the firm's litigation strength, says, "I hold David Pritikin's group at Sidley in a very high regard." The client goes on to describe Pritikin himself as "a talented lawyer who represents his clients zealously in court." Kushan, the head of the firm's Washington, D.C.-based patent group, is an experienced ANDA litigator, who worked as a patent examiner and attorney advisor at the Patent and Trademark Office before entering private practice. Kushan's resultant expertise in *inter partes* reviews is highlighted by one client, who adds, "He managed the team at Sidley to deliver the desired result on time and well within budget." Thayer is a highly regarded litigator out of the San Francisco office who currently represents Gilead, Hoffmann-La Roche, and Genentech in Hatch Waxman litigation against Natco involving the Tamiflu product for treatment of influenza.

Beyond the consistent accolades for contentious IP work, Sidley's record of success in the regulatory realm is second to none. One competitor says the firm has "the most complete regulatory practice in the industry." A satisfied client says Sidley's partners were "very responsive" in the course of providing "excellent health care regulatory expertise." Yet another client praised the firm's "sophisticated and thoughtful advice," and "deep understanding of our industry and of FDA regulatory trends." The roster of star regulatory attorneys at Sidley includes names such as **Coleen Klasmeier, Jeffrey Senger** and **Torrey Cope**.

Star attorneys in the non-IP litigation and enforcement spheres include **Rebecca Wood, Sara Gourley, John Treece**, and **Maja Eaton.** The latter partner is a renowned product liability expert described by one client as "very responsive," "solution oriented," and "always able to substantiate guidance with relevant case law or advisor opinions." Treece, in a recent antitrust matter of note, served as lead counsel to Astellas Pharma in consolidated class actions brought by purchasers of Prograf, an immunosuppressant drug utilized by organ transplant recipients. Wood is an experienced commercial and appellate lawyer whose practice also involves product liability and mass tort work for industry clients.

Key partners specializing in financial and transactional work include, **Sam Zucker, Deborah Marshall** and **Pran Jha**. Jha brings more than 20 years of experience working with industry clients in M&A transactions, capital markets, joint ventures, and other transactional and corporate governance matters. In a recent high profile matter of note, he represented GlaxoSmithKline on a long-term joint venture and research collaboration with the University of North Carolina involving efforts to conduct research aimed at a possible cure for HIV.