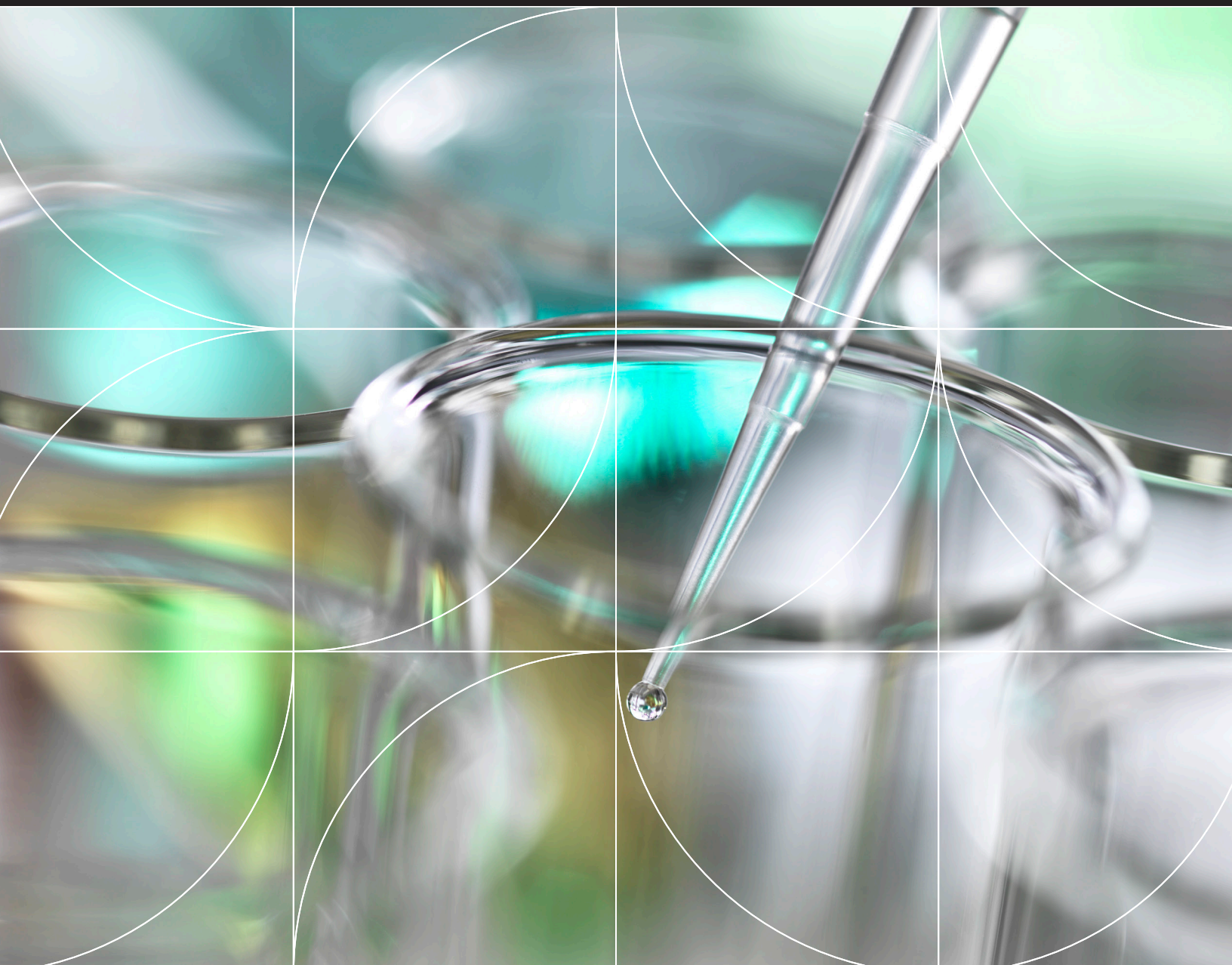
Seyfarth

Life Sciences and Pharmaceutical Industry

PRACTICE OVERVIEW



Competitive Advantage: An Integrated Approach

The legal and business issues arising in the pharmaceutical, biotechnology, bioinformatics, digital health, veterinary, and medical devices industries are unique. Faced with an ever-changing array of regulations, litigation strategies, and market pressures, we know that our life sciences clients—including branded pharmaceutical, generic pharmaceutical, biotechnology, bioinformatics, digital health, veterinary products, and medical device companies—must balance legal compliance, and litigation needs with their promising business opportunities. Seyfarth's dedicated life sciences attorneys have the skills and experience necessary to help our clients meet these challenges.

At Seyfarth, our litigation, intellectual property, eDiscovery, corporate, finance, tax, labor and employment, and employee benefits attorneys all stay abreast of the ever-changing regulations and legal developments in their fields so that we may assist our clients with day-to-day compliance, provide top-notch litigation coverage and also devise long-term strategies. We provide legal solutions and results that support our clients' overall business objectives.

About Our Life Sciences and Pharmaceutical Industry Team

Seyfarth has long represented clients in the life sciences and pharmaceutical industry in commercial litigation, restrictive covenants and trade secrets management and litigation, patent litigation, trademark litigation, false advertising litigation, copyright litigation, eDiscovery, corporate, tax, employee benefits, and labor and employment matters throughout the United States.

Seyfarth attorneys help our clients drive innovation and excellence across a national platform. With offices strategically located across the country, we form integrated teams to work with our clients from coast-to-coast.

Cost-Effective Matter Management for Pharmaceutical and Life Science Companies

We understand the increased economic pressures on the legal departments in life sciences and pharmaceutical companies, and we have been working with clients to address these challenges and deliver real value.

Seyfarth's Life Sciences and Pharmaceutical attorneys understand the need to achieve results in the most cost-effective manner possible. Through our award-winning client service model, SeyfarthLean, our firm has made a significant investment in technology and innovation so that we can provide you state-of-the-art solutions and efficiency. We have broad experience working with litigation support personnel, both inside and outside of the firm, and we can streamline the litigation process to make the most effective use of resources.

Finally, to meet our client's needs, we have devised numerous alternative fee arrangements. These include fixed and flat rate approaches based on the types of work, volume of work, and matter management processes we can employ to add value.

Our Services

Labor & Employment

Seyfarth's Labor & Employment attorneys' vast experience in this industry comes from years of representing life sciences and pharmaceutical clients. Our attorneys are well versed in the various employment issues impacting the industry, and are equipped to handle any employment concerns or litigation encountered. We have a team of attorneys who specialize in international labor law and can support global expansion objectives. Additionally, we recognize how important recruiting and retaining qualified scientific and medical professionals is to life sciences and pharmaceutical companies, and we appreciate that many of your quality employees are foreign nationals in need of immigration legal support. We have developed a proprietary automated program that provides effective compliance support cost-effectively.

Our employment attorneys counsel our clients about their welfare and retirement plans, profit-sharing, deferred compensation and other executive compensation plans, employment policies and procedures, and labor negotiations. Our team of wage and hour attorneys has significant experience handling misclassification litigation in the pharmaceutical industry.

Single-Plaintiff Litigation

We are frequently called upon when a pharmaceutical company receives a charge alleging age, race, national origin, disability or sex discrimination. Seyfarth's single plaintiff attorneys manage and litigate employment-related lawsuits, arbitrations, and administrative agency complaints for pharmaceutical clients each year.

Our attorneys have represented clients before judges and juries in virtually every federal and state court in the country. In addition, we frequently litigate precedent-setting cases before federal and state appellate courts nationwide, including the US Supreme Court. We take pride in handling each of these cases efficiently while delivering excellent results.

Complex Discrimination and Product Liability Litigation

Life Sciences and Pharmaceutical companies turn to Seyfarth to defend class cases in jurisdictions across the country under Title VII, the ADEA, the ADA, the FMLA and ERISA, Equal Employment Opportunity Commission (EEOC) pattern or practice suits as well as product liability suits. Our attorneys have developed strategies to navigate through the often-thorny procedural and substantive issues that can arise in any multiple-party action. Our experience has demonstrated that class action cases are defensible, and that companies need not succumb to the pressure of adverse publicity and huge settlement demands.

Wage Hour

Wage and hour litigation has become one of the hallmarks of the firm's nationally recognized Labor & Employment Department. Our Wage & Hour Litigation practice group consists of more than 100 attorneys in our 11 offices across the US, who collectively have represented employers by defending of more than 500 class and collective actions during the past two years alone, including non-union and unionized employers in the pharmaceutical and medical device industry. We constantly review recent legal developments, investigate how to counter new tactics forged by plaintiffs' counsel, and develop appropriate defense strategies.

We have defended our clients against all forms of multi-plaintiff wage and hour lawsuits, ranging from small regional classes and opt-in groups of less than 100, to large nationwide classes numbering in the tens of thousands and more, and in nearly every federal jurisdiction and state court system, as well as before the US Department of Labor and comparable agencies. These cases include claims alleging:

- Misclassification of employees as exempt
- Misclassification of workers as independent contractors
- Failure to pay otherwise exempt employees on a salary basis

- Regular rate and minimum wage issues
- Failure to pay for pre- and post-shift activities, including donning and doffing and other "off-the-clock" activities
- Miscalculation of commissions and bonuses
- Failure to pay overtime to drivers based on the SAFETEA-LU amendments to The Motor Carrier Act exemption and the Department of Transportation Act
- Unpaid on-duty meal periods
- Improperly denied reimbursements
- Other state law pay practices claims

Training

Through Seyfarth at Work, a subsidiary of our firm created to formalize our training capabilities, we are able to provide engaging employment law-related training over a wide variety of topics and platforms.

We are committed to partnering with clients to deliver legally accurate, highly effective training programs to all levels of their organization. We offer training programs to pharmaceutical and life sciences companies on sexual harassment, general employment litigation avoidance, and management or other employment-related training. We can also help clients devise training or other remedial measures as part of a court decree or agency settlement.

Due to the geographically diverse nature of sales forces in the pharmaceutical industry, our e-learning courses provide a cost-effective training solution.

Intellectual Property

Seyfarth's Intellectual Property practice offers answers to our clients' challenges and opportunities in the pharmaceutical, chemical, bioinformatics, digital health, biotech, veterinary, and genetic engineering industries. We provide legal counsel on patent strategy, prosecution, opinions, and litigation; ANDA (Paragraph IV) opinions, certification, and litigation; intellectual property transactional work, including due diligence for mergers, licensing, acquisitions, financing, and contracts relating to executives and key employees; copyright, trademark, and design patent strategy, prosecution opinions, and litigation; branding; and general IP portfolio management and growth counseling.

Our attorneys have served as former in-house patent counsel, law clerks in district and appellate courts, including the Court of Appeals for the Federal Circuit, general counsel, and private equity investors.

Operating under a single national practice infrastructure, we are able to provide clients with the best industry and practice experience in response to specific engagement requirements.

- We have experience in all aspects of pharmaceutical regulation and litigation, from inception to end-of-product life cycle management, product selection, including intellectual property review, freedom to operate, non-infringement and invalidity opinions, regulatory affairs counseling, size/shape/color opinions, and litigation management.
- We counsel and provide strategy relating to NDA, 505(b)(2) "Paper NDA," ANDA applications, and assistance in moving applications through the system from active FDA meetings to drafting suitability petitions, and Rx to OTC switching. This includes a robust Hatch-Waxman litigation practice, with attorneys experienced in both brand and generic representation including experience in multi-district litigation and proceedings before the USPTO relating to such litigation.
- We provide biologics and biosimilar counseling, with experience in portfolio management and expansion, "defensive" patenting, as well as brand-on-brand and biosimilar BPCIA litigation management.
- We assist in legal issues related to new indications, new exclusivities, development of intellectual property estates to protect the repositioned drug, development of strategies to minimize competition, and maximize returns.
- We counsel and litigate in branding matters, including copyright, trademark, false advertising, and allegations of violations of the Federal Food, Drug, and Cosmetic Act.

Intellectual Property Litigation

Our national practice is comprised of more than 40 attorneys who have litigated hundreds of patent cases nationally and internationally.

We recognize the intersection that patent litigation has with other legal issues such as trademarks, copyrights, antitrust, licensing, and unfair competition. We navigate these minefields with our client's business goals in mind.

We also serve as appellate counsel to clients when other law firms have obtained a particularly good or bad result at trial. We work to ensure that a client's victory is preserved on appeal or a negative verdict is overturned. Furthermore, we can assist clients in appeals to the US Supreme Court either as counsel of record or as amicus counsel.

In the event remedies are appropriate at the International Trade Commission, our firm also has significant experience in handling ITC actions.

Intellectual Property - Post-Grant Practice

We also represent clients in patent reexaminations, patent reissues and AIA post-grant patent review proceedings, before the U.S. Patent and Trademark Office (USPTO). Our team includes skilled intellectual property attorneys that have extensive experience in understanding complex, multi-disciplinary technologies to successfully undertake the administrative trial proceedings to review the patentability of previously issued patents: inter partes review, post-grant review, and covered business method patent review proceedings. Our expertise in these areas allows us to offer clients effective alternatives that can be utilized in addition to or instead of patent litigation. As with our patent prosecution practice and patent litigation practice, our post-grant review practice covers all aspects of science, technology and engineering. Seyfarth's post grant patent law practice leverages strategic insight of thorough understanding of technical issues and in-depth knowledge of USPTO proceedings to effectively navigate the complex procedural, substantive, and strategic issues posed by post-grant proceedings, providing the best results for our clients.

Intellectual Property - Prosecution

Our attorneys also regularly prepare, file and prosecute patent applications for chemical compounds, pharmaceuticals, biologics, therapeutics and diagnostics, biotechnology, medical devices, health related systems and software, digital health solutions, bioinformatics, and virtually every area of technology. In particular, we have prosecuted patents in the areas of both large and small molecules and have done extensive work in the areas of design-around and formulation. We help develop and manage patent prosecution portfolios throughout the world, counseling where and when to file if desired. Our attorneys also have extensive experience in preparing, filing, and prosecuting trademark matters for life science companies. We recognize the importance of branding to the industry and help counsel on such matters regularly.

Hatch-Waxman Experience

Seyfarth attorneys have represented some of the top innovators and generic drug companies in Hatch-Waxman litigation, including AIA proceedings, district court trials, and Federal Circuit appeals. Our legal team includes Ph.D.s that have expertise in organic chemistry, pharmacology, molecular biology; as well as drug synthesis, formulation, and polymorphs. Our Life Sciences and Pharmaceutical Industry team services key needs of the worldwide pharmaceutical industry, including:

- Intellectual property counseling and litigation, including ANDA Paragraph IV suits
- Regulatory filings and citizen petitions
- Regulatory and government pricing issues impacting generic drug companies
- Administrative actions, compliance issues and audits

FDA Counseling, Litigation and Enforcement

Our practice also includes experience in food and drug law involving pharmaceuticals and medical devices as well as veterinary medical technologies. Seyfarth represents clients whose businesses are regulated by the Food and Drug Administration (FDA) and the Federal Trade

Commission (FTC). Our clients include companies that manufacture and distribute pharmaceuticals, bulk chemicals, vaccines, biologics, medical devices, and cosmetics, as well as food and dietary supplements. Our attorneys provide strategic guidance from the initial product idea through product design and selection, R&D, and clinical trials to FDA approval and product launch.

We provide valuable counsel to FDA-regulated companies and we understand the regulatory and policy components of FDA as well as the relationship between FDA, Congress, and FTC.

We further advise companies conducting clinical studies on a national and international basis, on regulatory submissions and manufacturing as well as on FDA enforcement matters. Our practice further includes assisting clients with FDA enforcement defense and counseling, including:

- Good Manufacturing Practices (GMP) violations
- 180-Day marketing exclusivity and forfeiture
- Label/Label carve-outs and advertising review
- Guidance and compendial review for impact on drug marketing
- Citizen Petition drafting or responses

Global Health Regulatory Approval Coordination

Our experience ranges from drug design, development, clinical trial compliance, advertising and marketing review, cGMP compliance, inspections, litigation, and enforcement.

We handle "Park" doctrine white-collar criminal defense of corporate executives and other corporate responsible parties.

We have deep knowledge in cGMP compliance and resolution, including Form 483 and Warning Letter resolution, assisting in inspection violation resolutions, crafting new SOPs, aligning with external cGMP consultants on remediation plans, Part 210 & 211 compliance, and third-party surveillance review/PQA review.

We can assist clients in navigating the global regulatory environment and harmonizing legal strategies because the FDA Office of Global

Regulatory Operations and Policy and the Office of Regulatory Affair shares compliance information internationally.

Trade Secrets

While much of a company's intellectual capital may be protected by patents, trademarks or copyrights, many other intangible assets such as customer lists and information, pricing margins, product design specifications, formulas, business practices, and strategic plans may be considered trade secrets and must be safeguarded through other means. Trade secrets are what give pharmaceutical and life sciences companies a competitive advantage in the marketplace, which is why a company's survival can hinge on just one case.

Seyfarth has one of the country's pre-eminent groups dedicated to trade secrets, restrictive covenant, computer fraud, and unfair competition matters. Our attorneys have significant experience advising pharmaceutical industry clients on trade secret issues, litigating trade secret cases, drafting protection agreements and conducting trade secret audits.

Unlike our peer firms, we work exclusively to help clients prevent trade secret theft or misappropriation, violations of non-competes and computer fraud and, if necessary, pursue aggressive litigation tactics to stop the further spread or use of information and other improper activities.

Trade Secrets and Restrictive Covenants

Seyfarth has long represented pharmaceutical and life sciences companies seeking the very best for high-exposure trial work and counseling in the areas of trade secrets, restrictive covenants, corporate espionage and unfair competition in both federal and state courts. Given the depth and breadth of our experience in this area, we have likely seen every possible variation and nuance in restrictive covenant and trade secrets law. Our attorneys have prosecuted all forms of restrictive covenants or defended against accusations that our clients imposed an unfair restrictive covenant agreement on an employee. We also work diligently on behalf of employees and companies that are accused of violating an agreement.

Over the years, our team has also developed an interesting niche practice of representing or defending claims involving departing or entering top-level executives. We are experienced in investigating situations in which a departing employee is suspected of taking information, as well as situations when a company is suspected of hiring someone who possesses confidential information. Seyfarth has led many high-profile, "bet the company" trade secrets and restrictive covenants cases over the years, and our success in cases like these have earned our clients' trust for handling such issues.

eDiscovery and Information Governance

Although on some level eDiscovery must be understood by all litigators, as early as 2004, Seyfarth saw the need for a dedicated group of attorneys and IT professionals who must understand the eDiscovery case law, but more importantly, also have a deep knowledge and understanding of the underlying technology.

Our dedicated eDiscovery attorneys differentiate themselves from other firms because of their education, training, technical knowledge, and experience in a wide range of IT-related areas, including software engineering, network administration, messaging, mainframe applications, web-based applications, computer forensics, and data storage to name a few. Seyfarth's National eDiscovery and Information Governance Practice Group is the largest dedicated eDiscovery group in the country and is able to effectively bridge the gap between Legal and IT. We consistently see IT groups relieved to finally meet lawyers that they can talk to on a technical level and who understand their issues. Conversely, we consistently see Law Departments pleased to finally be able to effectively communicate their legal needs to the IT groups.

As National eDiscovery and Information Governance Counsel, we offer broad knowledge and skills to help pharmaceutical companies maintain an overall program that effectively deals not only with managing eDiscovery in individual cases, but also seeks to maintain continuity across the related areas of records information management, data privacy and information security. We have aided many companies, and particularly pharmaceutical and life sciences companies, in developing cost-effective programs that manage risk in a manner acceptable to the company. We have helped clients develop internal eDiscovery teams or, as desired, develop an effective vendor management program. In individual cases, we can assist in all phases of the EDRM, ensuring an appropriate preservation plan is developed and executed with a strong emphasis on cost-controls throughout the process.

Corporate

Our Corporate attorneys represent pharmaceutical, biotechnology and medical device clients in mergers, acquisitions, and divestitures, as well as in drafting and reviewing licensing and distribution agreements, product sales, manufacturing agreements, wholesaler agreements, group purchasing agreements, supply agreements,

and distribution agreements for both generic and branded manufacturers, distributors, and wholesalers. We also assist with start-up financing, private placements, and public offerings.

Our life sciences clients look to us for help in evaluating, developing, and implementing comprehensive, effective fraud and abuse compliance programs in order to minimize the risks of financial loss and criminal prosecution resulting from regulatory and qui tam enforcement actions. Additionally, certain attorneys within our Corporate Practice are focused on the life sciences and high-tech industries, providing legal services support to start-ups, emerging companies, and technology transfer offices at universities, in order to enable the development of biotechnology and pharmaceuticals.

We regularly:

- Advise branded and generic pharmaceutical companies in areas involving rebates, discounts and pricing matters.
- Develop fraud and abuse and sales and marketing compliance training programs and compliance plans.
- Provide analysis of regulatory concerns involved with product and company acquisitions.
- Advise pharmaceutical and medical device companies regarding pricing, sales and marketing initiatives.

Regulatory Compliance

In this highly regulated industry, compliance and licensing issues are extremely important and must be addressed in a consistent, timely manner. We work with biotechnology, medical device and pharmaceutical clients with respect to applicable state licensing laws, change of ownership requirements, certificates of need and certificates of authority.

- We have reviewed and drafted corporate codes of compliance.
- We have advised pharmaceutical and medical device clients with respect to licensing agreements, manufacturing and supply contracts, fraud and abuse compliance, group purchasing agreements, medical director agreements, and compliance with marketing standards.
- We work with clients with respect to regulatory strategies in medical device approvals, from counseling on strategies of 510(k) and PMA submissions, to humanitarian use exceptions, product recalls, product liability lawsuit defense, and corporate transactions.

Recognition

Our work has been recognized for innovation and client value by the following organizations:

National Recognition in Labor & Employment — *Chambers USA* and *Legal 500*

National recognition in health & life sciences and middle market M&A — *Legal 500*

About Seyfarth Shaw LLP

With more than 900 lawyers across 16 offices, Seyfarth Shaw LLP provides advisory, litigation, and transactional legal services to clients worldwide.

Our unique combination of high-caliber legal representation and advanced service delivery allows us to take on our clients' unique challenges and opportunities—no matter the scale or complexity. Whether navigating complex litigation, negotiating transformational deals, or advising on cross-border projects, our attorneys achieve exceptional legal outcomes. Our drive for excellence leads us to seek out better ways to work with our clients and each other. We have been first-to-market on many legal service delivery innovations—and we continue to break new ground with our clients every day. This long history of excellence and innovation has created a culture with a sense of purpose and belonging for all. In turn, our culture drives our commitment to the growth of our clients, the diversity of our people, and the resilience of our workforce.

SEYFARTH IS:

BOLD We are strong in the face of uncertainty, leading our clients through a rapidly changing landscape.	**INVESTED** We are committed to partnership for the benefit of our clients, our people, and our community.
INVENTIVE Our work makes a big impact through skill, creativity, and collaboration.	**CONFIDENT** We are excellent at what we do, delivering exceptional results with purpose and determination.

Our innovation, culture, and legal work have been recognized by top-tier organizations around the world:

- Association for Corporate Counsel
- Chambers Asia-Pacific
- Chambers USA
- Financial Times Innovative Lawyers
- Human Rights Campaign Corporate Equality Index
- The Legal 500
- The Legal 500 Asia-Pacific
- Working Mother

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