STINSON

Life Sciences

Our life science team navigates the complexities of the highly regulated and rapidly evolving life sciences industry across the full spectrum of biologic, pharmaceutical, medical device and related industries and their investors. The attorneys in this group blend health law, corporate, intellectual property and product liability experience to help life sciences companies, from start-ups to international organizations, achieve their product development and business goals.

Members of our life sciences team include former in-house counsel, scientists and engineers. We bring insights into industry dynamics and implementation challenges, and offer practical solutions. We protect and defend intellectual property and technology rights, advise on regulatory compliance, and structure transactions to support our clients' long-term business strategies.

We represent a diverse spectrum of health care and life sciences companies involved in research, development, technology transfer, commercialization, and delivery of innovative products and services. For example, our team is currently helping device and pharmaceutical companies develop national strategies for innovative product offerings in telehealth, remote monitoring, genome sequencing and drug delivery. Industry-wide, our depth of experience offers life sciences clients a distinct advantage in today's competitive marketplace.

Many of our life sciences attorneys have worked in-house at major health care and life sciences companies, including device manufacturers, hospitals, and health plans, and several attorneys have advanced degrees in biology, microbiology, biotechnology, chemistry, pharmaceutical sciences, agricultural biochemistry and engineering.

CAPABILITIES

Our Life Sciences practice focuses on the laws, regulations, and transactional issues relevant to life sciences and health care companies and provides guidance in bringing innovative health care products and services to market, including:

INTELLECTUAL PROPERTY & TECHNOLOGY

- Collaborations, licensing, tech transfer and strategic alliances

Life Sciences

- Counseling on corporate IP strategy and infringement avoidance
- Patent and trademark preparation, prosecution and maintenance
- IP enforcement and defense litigation
- Patent post grant review proceedings
- Due diligence and IP support for mergers and acquisitions as well as extensive infringement and validity opinion work, including ANDA Paragraph IV opinions
- Draft patents and applications involving pharmaceutical formulations and novel chemical compounds and biologics in areas including contraception and treatment of HIV and cancer

REGULATORY & COMPLIANCE

- Antitrust and trade regulation
- Fraud and abuse laws (e.g., anti-kickback, civil monetary penalty, Stark law, state law)
- HIPAA, GDPR, FTC, state privacy and confidentiality
- Internal investigations
- Civil and criminal compliance and enforcement matters
- Coding, coverage and reimbursement, including defending against exclusion, recoupment and offsets
- Compliance audits, investigations, training and programs
- Contract research organizations (CROs) and clinical trials
- Crisis-management strategies
- FDA compliance (e.g., off-label promotion issues, product labeling, recalls, ANDA)
- Marketing and promotion of products
- Manufacturer, distributor, sales force and vendor relationships
- Medicare, Medicaid, TriCare and VA regulation
- Preparing responses to FDA warning and inquiry letters
- Product life cycle management
- Product packaging and labeling
- Product recalls
- Responding to competitor inquiries
- Sunshine Act and state aggregate spend compliance
- Telemedicine and remote health monitoring

Life Sciences

LICENSING

- Extensive experience drafting licenses and other agreements related to all aspects of the pharmaceutical product life cycle — from MTAs and drug discovery, to formulation research and development, to clinical trials and ultimate commercialization
- Drafting and negotiating agreements with a wide variety of key players including:
  - University technology transfer offices
  - Drug discovery and research and development companies
  - Contract research organizations
  - Large and small pharmaceutical manufacturers

CORPORATE FINANCE

- Loans
- Private equity financing
- Public and private equity, including tax-exempt financing
- Strategic corporate investments
- Venture capital and emerging companies
- Transactions, Governance and Business Counseling
- Strategic mergers and acquisitions
- Business entity organization, formation, and governance
- Vertical integrations including health plan-provider combinations and hospital-clinic combinations
- Review, analysis and drafting of contracts, including physician and non-physician provider contracting, management and administrative services agreements
- Joint ventures, including physician-hospital joint ventures, accountable care organizations (ACOs)

LITIGATION

- Administrative and regulatory hearings
- Antitrust and trade regulation
- Business torts
- Class action
- Intellectual property enforcement and infringement defense
- Product liability

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- White collar defense, including qui tams

OTHER RELEVANT SERVICES

- Employment and labor law
- Government relations
- Tax and exempt organization law
- Health Law
- Insurance Law
- Representing PBMs and GPOs
- Leasing of hospital and other clinical facilities and equipment

EXPERIENCE

Our significant experience representing life sciences and related industries includes:

- Represent a life sciences company in the conduct of an internal investigation relating to whistleblower allegations of off-label promotion.
- Represent a device importer/distributor in the conduct of a recall.
- Develop national strategies for innovative product offerings by device and pharmaceutical companies in telehealth, remote monitoring, genome sequencing and drug delivery.
- Represent life sciences companies before federal (DOJ, FDA, CMS) and state (Department of Health, Department of Insurance, professional licensing boards), in connection with investigations, inquiries, disputes and requests.
- Represent a private pharmaceutical company in raising more than $30 million in start-up and mezzanine financing through a series of U.S. and overseas debt and equity offerings.
- Represent drug manufacturers in a diverse range of competition cases including cases brought under federal and state antitrust and competition laws in more than 35 states. Representative cases include *In re Ciproflaxin Hydrochloride Antitrust Litigation*, *In re Cardizem Hydrochloride Antitrust Litigation*, *In re Brand name Pharmaceutical Drugs Antitrust Litigation* and *Clayworth v. Aventis Pharmaceuticals Inc.*
- Represent a Fortune 500 company, as lead investor, in a $20 million convertible preferred stock investment in a molecular technology company.
- Represent several large colleges and universities in their efforts to patent and commercialize bioscience and other technologies.
- Represent a variety of life sciences companies in their patent and trademark filings throughout the world.

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- Serve as IP counsel for an early stage life sciences company's spin-out of its technology for a field of use to a non-U.S. company
- Represent Sanofi-Aventis U.S. LLC in anti-trust litigation involving patent settlements.
- Serve as national counsel for an international pharmaceutical company responsible for coordinating more than 100 product liability cases filed in various state court and federal districts, including two multidistrict litigations.
- Represent both brand name and generic drug manufacturers in product liability litigation throughout the U.S.
- Represent drug manufacturers in mass tort suits alleging heart disease, heart failure, stroke and wrongful death from hormone replacement therapy prescription medication.
- Represent a drug manufacturer in a suit brought in Florida involving allegations that our client monopolized the anticoagulant market.
- Serve as co-lead and liaison defense counsel for medical device manufacturer in multidistrict litigation involving dual modular hip replacement prostheses.
- Represent pharmaceutical and device manufacturers in product liability suits involving pain pumps.
- Represent drug manufacturers in pharmaceutical product liability cases.
- Represent a drug manufacturer in mass tort suits alleging heart disease, heart failure, stroke, and wrongful death from hormone replacement therapy prescription medication.
- Serving as counsel for ERISA and non-ERISA disputes for group health plans and their third-party administrators.

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TEAM

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RELATED CAPABILITIES

Animal Health & Nutrition

Chemical & Pharmaceutical

Cybersecurity & Data Privacy

Health Care Litigation

Health Care Providers

Intellectual Property & Technology

Pharmaceutical & Medical Device Litigation

CLIENTS

We work with the following types of life sciences companies:

- Academic Medical Centers
- Animal Health Companies
- Biologics
- Clinical research organizations (CRO)
- Clinical/surgical supplies
- Diagnostic research
- Dietary supplement & General nutrition
- Genomic testing and personalized medicine
- Group purchasing organizations
- Inventors
- Investigators
- Medical device
- Patient assistance programs

Life Sciences

- Pharmaceuticals & Vaccines
- Pharmacies, including retail, mail-order, specialty and compounding pharmacies
- PBM
- Plant science
- Resellers and distributors

NEWS

Kracl Featured in *Minnesota Lawyer*'s Breaking the Ice Series
12.28.2023

Health Care Attorney Kracl Returns to Stinson in Minneapolis
11.29.2022

PUBLICATIONS

Health App Vendors Be Warned: You Could Be Subject to FTC's Health Breach Notification Rule
10.05.2021