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Life Sciences & Biotech

Our deep bench of life science attorneys offers our pharmaceutical and biotech clients the full range of IP services, including patent litigation and post-grant proceedings, global patent prosecution and portfolio management, freedom-to-operate and validity opinions, due diligence counseling and license negotiation.

With strong technical backgrounds and decades of legal experience, our attorneys effectively counsel our clients in navigating complex IP issues, involving small molecule therapeutics, biologics, diagnostics, vaccines and biomedical devices. We are proud to provide service to pharmaceutical and biotech companies of all sizes from Fortune 500 companies to startups and research universities.

Partnering With You to Solve IP Issues

We are keenly aware of the challenges and opportunities inherent in the life sciences and biotech spaces. We partner with our innovator and generic clients to develop and execute successful IP strategies, from building strong patent portfolios through patent prosecution and strategic acquisitions to litigating and resolving high-stakes patent disputes in federal district court and before the Patent Trial and Appeal Board (PTAB).

Patent Counseling, Licensing & Transactions

IP is the cornerstone of a life science company's business. The strength of patents covering an asset often determines whether the asset is developed or a transaction proceeds. We regularly provide counseling and due diligence for transactions involving small molecules, biologics and cellular therapies, evaluating risks and helping structure and close mid-to-high value deals in upfront, milestone, and royalty payments. We draft license agreements that enable our clients and their partners to unlock value in IP through joint efforts. In addition, we provide

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RELATED CLIENT SERVICES

Intellectual Property Litigation & Enforcement
Patents
Trademarks, Copyrights & Trade Secrets
Commercial & Technology Transactions
Cybersecurity & Data Privacy
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Life Sciences & Biotech

actionable advice by performing white-space analysis; investigating and issuing opinions relating to patentability and freedom-to-operate; and investigating and issuing opinions relating to non-infringement, invalidity and/or enforceability. We also counsel U.S. and foreign clients on patent eligibility questions unique to the United States that often arise for diagnostics, bioinformatics, laboratory management and other life science innovations.

Patent Litigation

Our team has decades of experience litigating life science disputes, including Hatch-Waxman litigation in federal district court, post-grant proceedings before PTAB, and appeals in the U.S. Court of Appeals for the Federal Circuit, as well as in other federal circuit courts. Harnessing our diverse technical backgrounds and extensive trial and appellate experience, we provide effective litigation strategies focused on achieving our clients' business goals. To ensure the best outcomes, whether it be by engaging in litigation or avoiding it, we counsel our clients on legal strategy at every stage of a product's life cycle, from acquisition or concept through product development, FDA approval and launch. We pride ourselves on communicating efficiently and effectively with our clients to ensure that they have a clear understanding of each action we advise taking, and to reduce uncertainty both prior to and during litigation.

Patent Prosecution

We have decades of experience working with clients to develop carefully tailored patent prosecution strategies that meet our clients' particular needs, goals and constraints. We counsel start-up companies that need to protect their early discoveries while attracting funding or collaborating with others, all the while making the company more attractive for investment or acquisition. We also manage critical global patent portfolios for Fortune 500 companies as they strive to bring life-saving technologies to the world. We have an excellent network of foreign associates who partner with us to secure patent protection for clients around the world. We have successfully obtained patents, including Orange Book listed patents, covering our client's FDA-approved treatments. We have garnered patent protection in a wide variety of life science technologies, including small molecules, biologics, vaccines, peptides, CRISPR-based genome editing, viral vectors for gene therapy, CAR-T and other cellular therapies, medical devices, diagnostic tools, nutritional supplements, biocides, nanotechnologies, drug delivery technologies and others.

Experience

Patent Counseling, Licensing & Transactions

- Advising clients on licensing or acquiring patent portfolios relating to therapeutic small molecules, antibodies and antibody-drug conjugates, allogeneic CAR-T cells, CRISPR-enabled gene editing, and viral vectors for gene therapy

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- Providing strategic analysis of IP landscapes for various disease states, including cancer & immuno-oncology, inflammatory disorders, neurodegenerative disorders, cardiovascular disorders, neuropathic and visceral pain, viral infection and metabolic diseases
- Providing IP due diligence for partnerships with and acquisitions of early- and mid-stage companies for therapeutics and diagnostics, including for transactions valued from several hundred million to more than one billion dollars
- Strategic patent counseling in support of acquisitions of medical device technology

Patent Prosecution

- Patenting novel compounds, polymorphs, methods of treatment, dosing regimens, clinical indications, and pharmaceutical formulations
- Patenting biologics, such as therapeutic antibodies, mRNA-based vaccines, peptides, cellular therapies, and adult stem cells
- Advising clients on patent prosecution for prognostic and diagnostic markers, including as companion diagnostics
- Strategic patent prosecution and advice on drug discovery programs for infectious diseases such as Hepatitis C, and neuroscience, such as Alzheimer's Disease and Multiple Sclerosis

Trade Secret Counseling & Litigation

- Lead counsel for a 503(B) sterile compounding company in trade secret litigation relating to vasopressin for injection in U.S. District Court of the District of New Jersey. The litigation was successfully settled.

Patent Litigation

- *InfoRLife SA and WG Critical Care, LLC v. Hikma Pharmaceuticals USA, Inc.* – Counsel for Hikma in Hatch-Waxman litigation concerning Hikma's Abbreviated New Drug Application for midazolam 0.9% sodium chloride (50 mg/50 ml and 100mg/100 ml) solution, for intravenous use.
- Successfully defended private pharmaceutical company at trial against alleged infringement of Orange Book-listed patents for lansoprazole delayed-released orally disintegrating tablets (ODT). As a result of this ruling, the first lansoprazole ODT product was sold Over-The-Counter ("OTC") in the U.S. market.
- Counsel for innovator company in multiple Hatch-Waxman litigations filed against generic drug companies concerning RAVICTI® for the treatment of UCD in patients two months of age and older. Those litigations were successfully settled.
- Counsel for innovator company in Hatch-Waxman litigation filed against generic drug companies concerning Rayos®. That litigation was successfully settled.

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- Counsel for a pharmaceutical company in two Hatch-Waxman litigations relating to linagliptin tablets. Prevailed after trial in the action brought in U.S. District Court for the District of New Jersey. Both litigations were later successfully settled.
- Represented NDA holder and patent owner in Hatch-Waxman litigation concerning Cambia® (diclofenac potassium powder for oral solution). Obtained favorable settlement.
- Co-lead counsel for a pharmaceutical company that was sued for patent infringement relating to an oral testosterone product in U.S. District Court for the District of Delaware. Led summary judgment briefing and argument regarding a summary judgment motion of invalidity for lack of written description, which was granted by the court. After the client prevailed on summary judgment, the litigation was successfully settled.
- Represented multinational pharmaceutical company in litigation arising from its Abbreviated New Drug Application seeking approval to market a generic desvenlafaxine product. That litigation was successfully settled.
- Represented pharmaceutical company in litigation arising from its Abbreviated New Drug Application seeking approval to market generic oxycodone extended release products.
- Represented pharmaceutical company in litigation arising from its Abbreviated New Drug Application seeking approval to market a generic posaconazole product.
- Representedmultinational pharmaceutical company in litigation arising from its Abbreviated New Drug Application seeking approval to market a generic choline fenofibrate product. That litigation was successfully settled.
- Represented pharmaceutical company at trial in litigation arising from its Abbreviated New Drug Application seeking approval to market a generic pemetrexed product.