

Biotechnology & Life Sciences

Biotechnology—Navigating New Twists and Turns

Uncertain science and long product-development life cycles are just some of the challenges facing biotech innovators. Evolving judicial limits on patentability, interpretation of the Biologics Price Control and Innovation Act (BPCIA) rules for biosimilars, the introduction of post-grant proceedings, and other emerging issues have made it more difficult than ever to know if a new product or process will help a company meet its business goals.

Strategies for every stage of biotech development

Marshall, Gerstein & Borun LLP offers continuity and predictability along the challenging path to biotech success. We have advised startups on the road to initial public offerings (IPOs) and acquisitions, helped middle-market businesses crack the Fortune 500, and counseled multinational companies on how to protect key assets around the world.

We have vast experience helping biotech clients devise successful IP strategies that build U.S. and foreign patent portfolios, protect commercial products and processes, maximize returns, and extend patent life cycles. We focus on client goals first and foremost, while maintaining a laser focus on legal, scientific, and industry developments that could require strategic adjustments.

Exceptional experience

Marshall Gerstein lawyers have procured, enforced, and/or defended key patents for more than a dozen commercially marketed drugs, along with dozens of clinical trial candidates. We have successfully defended well-known commercial pharmaceuticals, including Cialis® and Epogen®, in court. And we have assisted clients in billion-dollar portfolio acquisitions and company sales, as well as in high-profile IPOs and licensing agreements.

Excellent client service, drawing on in-house experience

We have been repeatedly ranked as a top biotech and life sciences firm by *Managing Intellectual Property*—the only Midwest IP boutique to be so honored—and were recently named *Lawyer Monthly's* “Biotechnology Law Firm of the Year.” More than 75 percent of our biotech group members have advanced degrees in biotech disciplines and half have in-house experience as general and patent counsel, technology transfer managers, scientists, and engineers. We know firsthand our clients' needs and leverage this experience to help companies achieve their business goals. As a result, numerous Fortune 500 companies have chosen Marshall Gerstein as a preferred provider.

Flexible partnerships for the long run

Marshall Gerstein serves all four major biotech market segments: Fortune 500 companies, middle-market businesses, startups, and universities and medical research institutions. We are known for long-term client relationships, many of which have endured for decades. Each client benefits from our commitment to providing flexible service options at every stage of the business cycle, from launch, through growth and market leadership, to spin off or sale. In fact, *Chambers USA* has described Marshall Gerstein as “Excel[ling] in understanding [each client's] unique business and tailoring ... legal work to the specific needs of the client's business.”

Our biotech practice offers a one-stop shop for sophisticated prosecution, litigation, and licensing services, delivered with the focus, depth, and personal service of a boutique law firm. We regularly counsel clients on:

- Patent prosecution strategies
- Global portfolio management and strategies

- Early-stage product development initiatives
- Patent-term extension counseling
- Competitor IP landscape analyses
- Freedom-to-operate analyses
- Due diligence investigations
- Post-grant proceeding challenges
- IP aspects of finance transactions

Focused on key areas

We develop and deploy creative, forward-looking IP strategies that align with rapidly changing technology in a variety of industries:

- Biopharmaceuticals and immunotherapy
- Diagnostics and personalized medicine
- Biosimilars
- White biotech
- Agricultural biotech
- Bioinformatics
- Vaccines
- Microfluidics
- CRISPR gene-editing technologies
- Enzyme replacement therapeutics

Representative clients

- Amgen Inc.
- Baxter Healthcare Corp.
- BioMarin Pharmaceutical, Inc.
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CRISPR Therapeutics AG

- deCODE Genetics, Inc.
- Electrochaea GmbH
- InterMune, Inc.
- Ludwig Institute for Cancer Research
- Merck Serono
- NEUVOGEN
- Onyx Pharmaceuticals
- University of Michigan
- University of Miami
- XOMA Corp.
- Numerous emerging companies, universities, and hospitals

Representative matters

- **Transformative Immunoncology Approach Achieved: Marshall Gerstein Advances Patent Strategy for NEUVOGEN**
NEUVOGEN has turned to Marshall Gerstein for patent strategy as they advance a broad pipeline of therapeutic whole cell cancer vaccine candidates designed to activate the patient's immune system to target and eliminate existing tumors and prevent future metastases.
- **From Patent Protection to IPO Due Diligence: Marshall Gerstein Delivers IP Strategy for Immune Design**
On behalf of Immune Design Corporation, whose technologies help the body's immune system create antigen-specific T-cells that fight cancer and other chronic diseases, we obtained patents covering two key discovery platforms and played a primary role conducting due diligence for the company's \$60 million IPO.
- **No Pain, No Gain: Marshall Gerstein Secures Key Arthritis Drug Patent for Longtime Client Amgen**
We served as part of the team that argued for and won a key patent related to Amgen's FDA-approved drug ENBREL, used to treat moderate to severe rheumatoid arthritis in adults and children.
- **Persistence Pays Off: Marshall Gerstein Fends Off 20 Years of Patent Claims for FDA-Approved Drug**
We helped our client succeed in the highly contentious prosecution of patent claims for Actimmune™, an FDA-approved drug used to treat serious infections related to chronic granulomatous disease and to delay the progression of severe, malignant osteopetrosis. The two-decades-long prosecution included appeals and interferences before the U.S. Patent and Trademark Office, and an appeal to the U.S. Court of Appeals for the Federal Circuit.

Client Successes

Fierce Advocates

In presenting this gift of Samurai armor to Marshall, Gerstein & Borun LLP, a grateful client explained that he chose the gift because Marshall Gerstein's team of trial lawyers had "represented him as loyally and fiercely as any Samurai warrior." Also, he added, he feared he could not have carried an actual Samurai sword through the building security.

Our client, a pioneer in reconstructive surgery, invented a revolutionary device known as a differential tissue expander. This balloon-like device, when implanted beneath the skin and inflated in stages over time, permitted a surgeon to expand a patient's skin—in fact prompting the body to grow new tissue—for use in reconstructing adjacent wounds or defects. The invention, for the first time, permitted surgeons to tailor this skin expansion to more easily perform truly anatomic surgical reconstructions.

A professor of surgery who had devoted his career to academic medicine, the client faced the deliberate infringement of his patent by one of the largest manufacturers of these silicone devices. Despite relentless assaults by the defendant and its expansive team of attorneys, we did not waver, shrink or give ground. Through such tenacity, we successfully achieved a highly favorable result for the client.

Whether our client is an individual or corporation, patentee or defendant, we approach each engagement with the same commitment, the same fierce dedication, the same tenacity and the same focus and resolve which prompted this particular grateful client to liken us to Samurai warriors.

It's in our Blood

Today, cancer patients around the world will get more out of life, thanks to a remarkable therapeutic drug used during chemotherapy to stimulate the production of red blood cells and combat the debilitating effects of anemia. In 1983, the

startup company that cloned the gene for this medication turned to the Marshall Gerstein Biotechnology & Life Sciences team to help protect its discovery. Nearly thirty years later, the patent applications written by our attorneys have withstood not only the breath taking changes in the field of biotechnology, but challenges in courts and patent offices throughout the U.S., Europe and the Pacific Rim. The result? Our client enjoys the rewards of its creativity, while millions of individuals experience the benefits of better health.

Successful IP-Intensive Acquisition

Monopar Therapeutics, a biopharmaceutical company focused on developing innovative drug combinations to improve clinical outcomes in cancer patients, turned to Marshall Gerstein to assist with the acquisition of GPX-150, a broad spectrum Phase II Cancer drug candidate from Gem Pharmaceuticals. Marshall Gerstein's attorneys, who also serve as Monopar's IP prosecution counsel, structured the intellectual property contribution and assignment components for the IP-intensive acquisition. Our attorneys' experience in both biopharmaceutical transactions and this specific technology, enabled us to efficiently and effectively identify and integrate key terms to address the full range of intellectual property critical to the deal, which ultimately led to a timely and successful acquisition.