

Biotechnology & Life Sciences Patent Prosecution

Polsinelli's intellectual property professionals include patent attorneys, patent agents and patent scientists highly experienced in the full range of IP considerations in the biotechnology industry. We assist our clients in securing and defending their intellectual property, routinely managing patent estates numbering from a few strategic filings to those in the thousands. We understand that innovation is especially important to companies in the fast-moving biotechnology space, and assist our clients to timely capture, leverage, and monetize their technological advancements. Our clients also want to understand the patent landscape in which their business operates, and our team is highly experienced in providing patent landscaping, patent clearance and opinions in order to develop strategies for advancing the IP and/or navigating around competitor IP.

Our Biotechnology and Life Sciences Patent Prosecution practice is a highly credentialed team trained in a diverse range of life sciences fields, so they can quickly grasp complex discoveries and inventions and appreciate how to protect them. Our team consists almost entirely of individuals with post-graduate credentials in technologies, including cell and molecular biology, biochemistry, chemistry, physiology, immunology, neuroscience and molecular biophysics, with many team members also having postdoctoral and industry experience. Our team handles patent prosecution matters all over the world. We work with high profile, biotechnology and life sciences companies, and also many globally recognized research institutes and universities, providing the following services:

- Patent drafting and patent prosecution
- Patent portfolio development
 - Global patenting strategy
- Patentability analyses
- Patent landscaping and patent clearance (Patent freedom to operate)
 - Non-infringement, invalidity analyses
 - Formal opinions
- Biotechnology and life sciences patent licensing and other transactions
- Prepare presentations and portfolio overviews for presentations and investment opportunities
- IP due diligence
 - Patent portfolio analysis
- Patent Trial and Appeal Board (PTAB)

We also collaborate with our colleagues in other practice groups across the firm, including:

- Chemical Intellectual Property
- Mechanical Engineering & Medical Devices
- Electrical Engineering & Computer Science Patent Prosecution
- Post Grant Proceedings
- Patent Litigation
- Hatch-Waxman Litigation & Opinion

- Corporate & Transactional

Representative subject matter that we routinely handle includes:

General Biotechnology

- Genetic engineering methods/tools
- Chimeric and fusion proteins
- Genetically engineered cells and whole organisms
- Methods/tools for tracking and validating genomic edits
- Expression systems engineered for target protein expression
- Bioinformatics – drug design and screening methods
- Bioassays
- Formulations for stabilizing and manufacturing biologics

Human and Animal Medicine

- Medical diagnostics – diagnostic compositions, tests and devices
- Medical treatments
 - Pre- and early clinical small molecules
 - Biologics and cell therapies
- Personalized medicine
- Stem cell-related technologies and treatments
- Vaccines and adjuvants
 - Molecular constructs
 - Attenuated pathogens
 - Vaccine formulations

Agricultural Technology

- Genetically engineered plant cells and whole plants
- Crop plants engineered for improved characteristics
- Pesticidal compositions and methods

Nutrition / Nutraceuticals

- Precision Fermentation of target proteins
- Plant-based food ingredients / Food substitutes for animal-derived foods
- Nutritional supplements

Matters

- Expanded foundational patent portfolio for startup client with new platform for producing engineered Natural Killer (NK) cells, and defended patent due diligence leading to the client's successful acquisition by an established, pre-clinical cell therapy company and shortly later the purchasing company by Big Pharma.
- Provided patent preparation and prosecution, patent portfolio management and freedom to operate advice to a Fortune 500 company regarding foundational CRISPR-cas genome editing tools and techniques.
- Provide patent preparation and prosecution, patent portfolio management and freedom to operate advice to an international company developing new cell therapies based on CRISPR genome editing techniques.
- Provide comprehensive General IP counsel for a cutting-edge food ingredient innovation company in the highly dynamic plant-based foods industry. We provide regular counsel relating to IP transactions, the scope

and strength of in-licensed patents, development of a comprehensive patent portfolio, and patent freedom-to-operate questions, supporting the company's mission to make plant-based foods more flavorful and healthier. Our ongoing IP counsel recently supported a highly successful, industry record-setting Series B Financing round for the company.

- Assist physicians and academic researchers, as well as their renown university's Ventures group, in the development, protection management and commercialization of IP to advance the reach and impact of groundbreaking treatments. This work encompasses a patent portfolio covering cord blood derived stem cells that are used for the treatment of autism, cerebral palsy and traumatic brain injury in children, as well as a key biologic used to treat Pompe disease.
- Assisted in formulating and implementing strategy at publicly traded bio-tech company to deal with influx of licensing demands through aggressive use of post grant proceeding. Results have substantially reduced client's expected licensing costs resulting in increased profitability for multiple product lines.
- Successfully argued against the institution of an Inter Partes Review (IPR) Petition filed by a large international animal health company against a composition patent owned by an international OTC animal health pharmaceutical company client. Based on arguments made in defense of the client's patent, the Patent Trial and Appeal Board (PTAB) declined to institute IPR of any challenged claims.
- Helped a company bring new animal health products to market by issuing freedom to operate opinions, drafting patent applications and working with executives to ensure entry into the marketplace and protection of intellectual property.
- Conducted intellectual property due diligence for the acquisition of a biomarker testing product company by a leading molecular diagnostic company.
- Negotiated a distribution/supply agreement between United States distributor and Korean manufacturing company covering distribution of immunochromatographic test kits for the qualitative detection of viruses affecting dogs or cats, including parvovirus, heartworm, and feline infectious peritonitis virus.
- Represent patent holder and prevented Inter Partes Review of orthopedic implant assemblies for joining bone segments.
- Prosecute and manage portfolio related to vaccine compatibility platform and timed vaccine delivery formulations platform.
- Regularly assist institution in evaluating early discoveries for potential patent filings and in consideration of international coverage value.

Publications

January 20, 2026

Supreme Court Grants Cert. Petition in Hikma / Amarin Skinny Labeling Case

January 14, 2026

Federal Circuit Strikes Life Sciences Patent Over Insufficient Disclosure of Particular Species

January 8, 2026

Polsinelli Life Sciences Spotlight - Volume 3 - Turning Insight into Action: A Life Sciences Playbook for 2026

November 17, 2025

New USPTO IDS Fees Raise Strategic Stakes for Biotech Filings

November 10, 2025

New Continuation Fee Among 2025 USPTO Changes Impacting Biotech

November 5, 2025

USPTO Launches Streamlined Claim Set Pilot to Accelerate Patent Examination

October 9, 2025

Justices Urged To Clarify Patent Validity In Entresto Case

Quoted, Law360

October 7, 2025

Patent Drafters Beware: Omitted Provisional Language Can Alter Claim Scope

September 9, 2025

Freedom to Operate: What It Is and Why Your Startup Can't Afford to Ignore It

Author, Life Science Nation Newsletter: Next Phase

July 21, 2025

FTC's Latest Effort To Dispute Improper Patent Listings Barely Made A Dent

Quoted, Generics Bulletin

July 14, 2025

Device Patents in the Orange Book: May 21, 2025, FTC Warning Letters Appear to have Minimal Impact

June 18, 2025

Opinion: Recent Precedent Shows Overseas Biosimilars Companies Can Be Sued in US

Author, BioSpace

May 23, 2025

Orange Book Listings: Republican Led FTC Picks Up Where Democrat Led FTC Left Off

March 14, 2025

Judge Connolly (D. Del.) Overturns \$96 Million Molecular Diagnostics Jury Verdict, Finds Patents Invalid Under § 112

March 11, 2025

Federal Circuit Affirms District Court's Obviousness Judgment on ImmunoGen Patent Application

March 5, 2025

Federal Circuit Refuses to Rehear Case Involving Orange Book Listing of Device Patents

February 6, 2025

New PTAB Guidance on Enabling Requirement Under § 102 of the AIA and Construction of Chemical Compound

December 23, 2024

Federal Circuit Decides Case Involving Orange Book Listing of Device Patents

July 17, 2024

The FTC's Challenge to the Listing of Device Patents in the Orange Book: What Challenge?

July 2, 2024

Federal Circuit Clarifies Rules for Skinny Labeling for Generics and Biosimilar Companies

May 2024

Patent Basics for Biotech Counsel

Co-Contributor, Bloomberg Law

February 13, 2024

Revisiting Government March-In Rights Under Bayh-Dole: The FTC Weighs In

January 16, 2024

Rethinking Examiner Interviews – A Data-Driven Analysis

2024

Biotech Patent Eligibility: Why we Care about Conventionality

Author, 7 Bus. Entrepreneurship & Tax L. Rev. 112

December 29, 2023

MAP9/MAPH-9 supports axonemal microtubule doublets and modulates motor movement

Co-Author, Developmental Cell. 59(2):199-210.e11

November 1, 2022

Novel insights into the fundamentals of palatal shelf elevation dynamics in normal mouse embryos

Co-Author, bioRxiv