



## James F. Haley, Jr.

PARTNER

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Jim has focused his practice on the worldwide procurement, defense, and enforcement of patents in the biotechnology, biopharmaceutical, pharmaceutical, and chemical industries. He has counseled biotechnology and biopharmaceutical clients since 1978 and drafted, prosecuted, and defended some of the basic patents in recombinant DNA technologies. He has extensive experience in U.S. and worldwide patent prosecution and patent enforcement and defense in all areas of biotechnology and biopharmaceuticals.

Before co-founding Haley Guiliano, Jim was a Senior Counsel and Partner of Ropes & Gray, where he was co-head of the Intellectual Property Rights Management practice group. Prior to that, he was a partner of Fish & Neave, where Jim established and led the firm's Life Sciences Technical Advisor program and successfully mentored over seventy Ph.Ds. in the life sciences and organic chemistry as they transitioned from the laboratory, through law school, to attorneys at law specializing in intellectual property procurement, counseling, defense, and enforcement.

## Representative Clients & Matters

Jim has prosecuted and led the prosecution to issue more than 750 United States patents and many thousands of related patents worldwide. Among the technologies represented in these patents are new chemical entities, synthetic methods; methods of treatment, formulations, microorganisms and their uses, recombinant proteins and antibodies and their uses, viruses, vaccines, antigens, expression systems, DNA sequences and vectors, diagnostic kits, crystals, polymorphs, eutectics, enzymes, prodrugs and methods of using them to treat disease, receptors and binding pockets, imaging modalities, transgenic plants and animals and their uses, polymers, and ion channels. See, in particular, U.S. Patent 4,563,423 (hepatitis B viral antigens and vaccines – recognized by IP Worldwide (2002) as among "10 Patents That Changed the World"), 4,530,901 (recombinant alpha interferon – first "hybridization" claim) and 5,756,466 (first pharmacophore claim).

Jim has led numerous U.S. and foreign patent litigations, European and other patent oppositions, and U.S. interferences and other PTAB contested AIA proceedings in biotechnology and biopharmaceuticals.

Some of his representative patent infringement cases include: Ajinomoto Co. V. Cheiljedang (S.D.N.Y) Cherokee Gray Eagle IP v. Sky Zone (M.D. Fla); Cherokee Gray Eagle IP v. CircusTrix (M.D. Fla); Cherokee Gray Eagle IP v. Rockin' Jump (S.D. Fla); Trustees for Dartmouth College/ ChromaDex, Inc. v. Elysium Health (D. Del.), In the Matter of Certain L-Tryptophan, L-Tryptophan Products, And Their Methods of Production (U.S. International Trade Commission) (representing Petitioner C.J. Cheiljedang) (lead trial counsel) Regeneron Pharmaceuticals, Inc. v. Ablexis LLC (S.D.N.Y), Medac Pharma, Inc. et al v. Antares Pharma, Inc. et al (D.N.J.), Antares Pharma, Inc. v. Medac GmbH and Medac Pharma (D. Del), Genzyme v Anika Therapeutics (D. Mass.), Shelbyzyme v Genzyme (D. Del.), Genzyme v Seikagaku and Zimmer (D. Mass.), Genzyme v Medicis (D. Mass.), MEEI v. QLT/Novartis Ophthalmics (D. Mass), MEEI v. QLT (D. Mass) Amgen v. Aventis/TKT (D. Mass.), Oregon Health & Sciences University v. Vertex (D. Oregon), Pieczenik v. Dyax (D. Mass and S.D.N.Y.), Schering-Plough v. Sterling Winthrop (D. N.J.), Sheller Globe v. Milsco (D. Wisc.), Square D v. 3M (N.D. Ill), PPG v. Celanese (E.D. P.A.), Chiron v.

Vertex/Lilly (N.D. Cal.), Biogen/Harvard v. Pharmacia (D. Mass), Biogen v. Amgen (D. Mass), Biogen v. Berlex (D. Mass), Biogen v. Genentech/Roche (D. Mass), Schering v. Genentech (D. NJ), PPG v. Celanese (E.D. Pa), Case v. BASF (D. Mass) BASF v. United Carbide (S.D.N.Y.), Schering v. ISI/Busch Biotech (D. Del). Case v. BASF (D. Mass.), Amgen v. TKT/Aventis (UK), Biogen v. Boehringer Ingelheim (Germany, Austria, Poland), Boehringer Ingelheim v. Bioferon (Germany), Biogen v. Medeva (UK), Epix v. Bracco (France, Germany, Netherlands), Biogen v. Amgen (Japan), Biogen v. BTG (Israel), Biogen v. Scitech (Singapore), Biogen/Harvard University v. Sumitomo (Japan), Biogen/Harvard v. Pharmacia (Sweden).

Jim's representative oppositions include EPO (PTSD treatments), EPO (cyclobenzaprine eutectics), EPO (treatments for depression), EPO (bonemorphogenetic protein), EPO (BAFF antibodies), EPO (IL-1 Inhibitor), EPO (phage display), EPO (expression vector), EPO (alpha interferon), EPO (hepatitis B viral antigens), EPO (gamma interferon), EPO (beta interferon), Germany (beta interferon), EPO (protein secretion), EPO (xenomice and antibodies), EPO (imaging agents), Australia (gamma interferon), Australia (antiviral compounds), Japan (beta interferon), Japan (protein secretion), Japan (alpha interferon), Japan (antiviral nucleosides).

Jim's representative interferences and contested proceedings before the PTAB (all as lead counsel) include BAFF antibodies, BCR-ABL mutations in cancer diagnosis, Tweak proteins, IL-13 receptor, M-CSF antibodies, alpha interferon, hepatitis B viral antigens, protein secretion, leukocyte adhesion molecules, beta interferon, interleukin 1 converting enzyme inhibitors, and bone morphogenic proteins, CD40 counterreceptor antibodies, transgenic fibrinogen, single-chain antibodies, methods of treating inflammatory disease with methotrexate, and feedback inhibition in tryptophan biosynthesis, YddG in tryptophan biosynthesis, HIV protease inhibitors, mounts for attaching a suspension assembly to an actuator arm in a hard disc drive, and trampoline arena architecture. See in particular, Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993); Velandar v. Garner, 348 F. 3d 1359 (Fed. CIR. 2003); Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004); Sanofi-Aventis v. Pfizer, Inc., 733 F.3d 1364 (Fed. Cir. 2013); Koios Pharmaceuticals v. Medac GmbH, IPR2016-01370 (Final Decision, February 2018), NHK Spring Co. v. Intri-Plex Technologies, IPR 2018-00752 (Non-Institution Decision, September 12, 2018) (one of most important PTAB decisions in 2018).

## Related Practice Areas

- [Patents](#)
- [Patent Preparation and Prosecution](#)
- [Due Diligence](#)
- [Opinions](#)
- [Freedom to Operate/ Third Party Risk Assessment](#)
- [Competitive Landscape Analysis](#)
- [Patent Utilization](#)
- [Transactions](#)
- [Contested Proceedings](#)
- [USPTO Post-Grant Proceedings](#)
- [European Oppositions](#)
- [Litigation and Litigation Support](#)
- [Alternative Dispute Resolution](#)

## Related Industries

- [Medical Devices](#)
- [Pharmaceuticals and Chemicals](#)

- [Biotechnology](#)

## Bar Admissions

- Massachusetts
- New York
- U.S. Patent and Trademark Office
- U.S. Court of Appeals for the Federal Circuit
- U.S. Court of Appeals for the First Circuit
- U.S. District Court for the Southern District of New York
- U.S. District Court for the Eastern District of New York
- U.S. District Court for the District of Colorado
- U.S. District Court for the Northern District of California

## Publications

- Co-author, United States, in International Patent Litigation, Global Law and Business, 1st edition (2011), [2nd edition \(2018\)](#).
- Presenter, Building Up the Biosimilar's Marketplace: Adjusting Current Life Sciences Patent Strategies to Keep Up with the Evolving Landscape, ACI Advanced Summit on Life Sciences Patents (February 2017)
- Co-author, "From Clones to Claims," An Encyclopedia of the European Patent Office's Case Law on the Patentability of Biotechnological Inventions with a Comparison to the United
- Co-author "Drug Repurposing and Skinny Labels", IAM Life Sciences (2021)
- States and Japanese Practice, Heymanns Intellectual Property, 6th edition (2016) (and the earlier 5th, 4th, 3rd, and 2nd editions)
- Co-author, "[Lessons Learned from IPR Proceedings in the Life Sciences](#)," Bloomberg BNA Patent, Trademark & Copyright Journal (January 30, 2015)
- Quoted, "[Biosimilars – Blood on the Patent Dance Floor](#)," Managing Intellectual Property (December 9, 2014)
- Quoted, "Original-Patent Rule Dooms Drug Injection Complaint," Law360 (November 17, 2014)
- Mentioned, "Appeals court won't stop Medac from selling injectable drug," Reuters Legal (November 17, 2014)
- Quoted, "Pharma Sector Takes a Dose of Post Grant Patent Review," Corporate Counsel (September 9, 2014)
- Quoted, "Sanofi-Aventis loses isolated DNA sequence appeal," Intellectual Property Magazine (November 7, 2013)
- Quoted, "Pfizer wins IL-13 priority over Sanofi," Life Sciences Intellectual Property Review (November 6, 2013)
- Quoted, "Pfizer Beat Sanofi To Isolated DNA Patent, Fed. Circ. Says," Law360 (November 5, 2013)
- Quoted, "Stem Cell Patent Case Will Be Early Test of Myriad's Reach," Law360 (June 10, 2013)

## Professional Activities

- Lieutenant Commander United States Navy (1969-1976)
- Member, United States Office of Technology Assessment, Advisory Panel, "The Human Genome Project and Patenting Human DNA Sequences" (1993-94)
- Panel of Arbitrators, American Arbitration Association

## Memberships

- American Intellectual Property Law Association
- The New York Intellectual Property Law Association
- Intellectual Property Owners Association (IPO)

## Honors & Awards

- *LMG Life Sciences: Hall of Fame* (2015)
- PLC Global Counsel's Top 10 Patent Lawyers Worldwide (2002)
- *Antares Pharma, Inc. v. Medac* (2015), LMG Patent Impact Case of the Year
- *The Best Lawyers in America* (since inception)
- *Managing Intellectual Property: IP Stars* (2019-2021)
- *Chambers USA: America's Leading Lawyers in Business* (2005-2018)
- *New York Super Lawyers* (2006-2019)
- *Euromoney's Guide to the World's Leading Patent Law Experts* (since inception)
- *Chambers Global: The World's Leading Lawyers in Business* (2006-2015)
- New York Super Lawyers (2006-2021)
- *IAM Patent 1000 – The World's Leading Patent Practitioners* (2013-2019)
- *LMG Life Sciences: "Life Sciences Star"* (2013, 2016, 2019)
- *PLC Which Lawyer*
- *International Who's Who of Patent Lawyers* (2006-2018)
- *International Who's Who of Life Sciences* (2007-2018)
- *IAM Life Sciences* (2010-2018)
- *Legal 500* (2016)
- *Who's Who Legal: Life Science* (2014-2021)
- *Who's Who Legal: Patents* (2018-2019)
- *Global Counsel: Life Sciences Industry Report* - Leading Lawyer in Life Science - Intellectual Property
- *Global Counsel Life Sciences Specialist 500 –The Super League*
- Acquisition International - Specialist Patent Prosecutor of the Year 2019 - USA

## Education

- Ph.D., Organic Chemistry, 1975, Brandeis University
- J.D., 1975, Suffolk University Law School, *magna cum laude*
- B.S., Chemistry, 1967, University of Notre Dame