



Warren K. MacRae

Partner

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Industries

Life Sciences

Practice Areas

Intellectual Property

Bar Memberships

New York

Warren has an extensive breadth and depth of knowledge and experience dealing with every issue involving or related to patent law.

Warren's practice involves providing strategic and due diligence counseling in complex and complicated situations entailing all aspects of patent law and intellectual property rights, particularly to the pharmaceutical industry and with a focus on chemical patent matters. He has represented Big Pharma in multiple potential and completed business acquisitions and ventures; advised Big Pharma and biotech companies regarding pre-litigation and ongoing litigation analyses and strategies in preparing for and defense of potential litigations; and assisted in the management of patent dockets of many multinational companies. Additionally, he has guided clients in structuring, preparing, and negotiating agreements for a broad range of intellectual property and technology-centered transactions, including licenses, technology transfers, complex partnerships, strategic alliances, royalty monetization, and merger and acquisition transactions.

Over the course of his decades-long career, he has also successfully prosecuted strategically important patents for his clients, as well as led the training of associates and agents in the art of patent prosecution. He has effectively argued numerous appeals before the Board of the United States Patent and Trademark Office (USPTO), and he has argued before the United States Court of Appeals for the Federal Circuit. Additionally, he has successfully litigated contested proceedings, such as *inter partes* reviews and multiparty interferences, before the USPTO Board.

Additionally, Warren is a highly experienced litigator, having litigated numerous high-stakes patent cases, successfully defending patents covering hundred-million and billion dollar drug products and representing leading pharmaceutical companies in Hatch-Waxman cases concerning compounds, compositions, and usage methods. He started his career representing generic drug companies in famous cases, but then switched to representing innovator drug companies.

As a partner, he has litigated against dozens of generic companies and has been the primary attorney responsible for developing strategies to defeat generic challenges to infringement, validity, and enforceability of his clients' patents. He is particularly known for his intuitive and artful deposition skills, having taken and defended every important expert and fact deposition in every case that he has been involved in as a partner. For example, he took the winning deposition of the leading adverse-expert witness that enabled his client to obtain a preliminary injunction against generic companies that blocked the marketing of a generic competitor product.

Some of the sub-specialty areas that Warren routinely counsels on include: pharmaceuticals, diagnostics, antibody therapies, gene therapies, cancer therapies, polymer chemistry and catalysts, food chemistry, nutraceutical and vitamin compositions, organoleptics, liquid crystal technology, and medical devices.

Warren has moderated at ACI Paragraph IV Dispute conferences in areas including standards for establishing inequitable conduct. He is also a lecturer at CLE conferences concerning developments in patent law.

Other Info About Warren

Experience

- *Hoffmann-La Roche, Inc. et al. v. Apotex Inc. et al.*, 07-cv04417 (SRC) (D.N.J.), (concerning the prescription osteoporosis drug Boniva® (Ibandronate))

- *Warner Chilcott Co., LLC et al. v. Teva Pharms. USA, Inc. et al.*, 08-cv-627-LPS (D. Del), (concerning the prescription osteoporosis drug Actonel® (Risedronate))
- *Hoffmann-La Roche, Inc. and Genentech, Inc. v. Airis Pharma Private Ltd.*, 17-cv-7912 (KBF) (S.D.N.Y.), (concerning the prescription drug Valcyte® (Valganciclovir hydrochloride), an oral antiviral medication used for the treatment and prevention of cytomegalovirus (CMV) infections)
- *Gilead Sciences, Inc., Hoffmann-La Roche, Inc., F. Hoffmann-La Roche Ltd. and Genentech, Inc. v. Lupin Pharmaceuticals, Inc. et al.*, 15-cv-01956-JFM and 15-cv-02793-JFM (D. Md.), (concerning the prescription drug Tamiflu® (oseltamivir phosphate), an oral anti-viral drug approved for the treatment of acute, uncomplicated influenza)
- *Genentech, Inc. and InterMune, Inc. v. Apotex Inc., et al.*, 19-cv-00078 (RGA) (D. Del.), (concerning the prescription drug Esbriet® (pirfenidone), an oral medication used for the treatment of idiopathic pulmonary fibrosis)
- *Zeavision, LLC v. Roche Vitamins, Inc.*, 4:03-cv-212 (DJS) (E.D. Mo.), (representing F. Hoffmann-La Roche AG, Roche Vitamins, Inc., and Roche Vitamins, Ltd., concerning compositions and methods for treating macular degeneration employing zeaxanthin)
- *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, 563 F.Supp.2d 1016 (N.D. Cal. 2008), (providing strategic counseling regarding patents concerning HIV test kits, including a PCR assay)
- *Montell North America, Inc. v. The Dow Chemical Company, Inc.*, 4:97-cv-87 (S.D. Tex.) (concerning pioneer inventions to production of polymers)
- *Mead Johnson & Co. v. Barr Laboratories*, 97-cv-6317 (JES) (S.D.N.Y.) (concerning trazadone)
- *Smithkline Beecham Corp. v. Synthron Pharmaceuticals, Ltd.*, 1:00-cv-01179 (M.D.N.C.) (concerning Paxil® (paroxetine mesylate derivative))

- *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (concerning Prozac®)
- *Metso Minerals, Inc. v. Powerscreen Int'l Distrib. Ltd.*, 06-cv-1446,(E.D.N.Y.) (concerning conveyor machines for separating materials)
- *In re Basell Poliolefine, Italia S.p.A.*, 547 F.3d 1371 (Fed. Cir. 2008) (concerning a patent issued after pending for 50 years, and covering Prof. Giulio Natta's Nobel Prize winning invention for the production of polyethylene)

PTAB Experience

- *Actelion Pharmaceuticals Ltd v. ICOS Corp.*, Nos. IPR2015-00561 and IPR2015-00562 (PTAB) (prevailed in two IPRs concerning the drug sildenafil citrate)

Multiparty Interferences

- *Anderson, et al. v. Morgan et al.*, Interference No. 104,712, (involving *Anderson, et al.*, Gene Therapy, U.S. Patent No. 5,399,346, the first U.S. patent ever issued for gene therapy treatment)
- *Staehelin et al. v. Secher et al.*, Interference No. 101,597, (involving monoclonal antibodies produced by a murine derived hybrid cell line wherein the antibody is capable of specifically binding to at least one antigenic determinant of interferon-alpha)
- *Bryce, et al. v. Kligman*, Interference No. 102,638, (involving retinoids for photodamaged skin)
- *Harris, et al. v. Dobrusin, et al.*, Interference No. 104,798, (involving 9 – cis retinoic acid)
- *Evans, et al. v. Bollag, et al.*, Interference (involving use of retinoids for the treatment of premalignant epithelial lesions and malignant tumors of epithelial origin, particularly testicular cancer)
- *Higuchi, et al. v. Mitoma, et al.*, Interference No. 103,489 (involving use of PCR technology for homogenous nucleic acid amplification and detection)

- *Palackal et al. v. Resconi et al.*, (interference concerning metallocenes for preparing polymers)

Strategic Counseling and Due Diligence

- Representing Big Pharma in numerous potential and completed business ventures, including acquisitions of companies and detailed analysis of intellectual property rights
- Counseling Big Pharma and Biotech companies regarding strategic pre-litigation and ongoing litigation analyses involving many of their branded drug products in preparation for and defense of potential litigations, including Hatch-Waxman specific suits and biotechnology-related suits in defense of their branded drug products
- Writing numerous opinions concerning FTO, infringement, and validity for Big Pharma companies
- Advised hedge funds regarding potential outcomes of patent litigation cases for investment purposes

Managed and Assisted in the Management of Patent Dockets, Prosecuted Patents to Allowance, and Prevailed in Multiple Appeals to the PTO Board

- Rolic Ltd. (the former Liquid Crystal Group of F. Hoffmann–La Roche)
- Givaudan–Roure (a Swiss multinational manufacturer of flavors, fragrances, and active cosmetic ingredients)
- Roche Vitamins, Inc. (nutraceutical and vitamin compositions)
- Big Pharma companies (assisted in the prosecution and provided strategic counseling regarding strategically important applications for certain pharmaceutical products)
- Successfully prosecuted and appealed multiple strategically important patent applications for *Basell Poliolefine, Italia S.p.A.*, (now LyondellBasell) to allowance
- Successfully prosecuted and appealed multiple patent applications to allowance for the Swiss giant Nestlé (Nestec S.A.)

- Drafted and prosecuted patent applications for Tufts University and Columbia University

Education

St. John's University School of Law, J.D.

St. John's University Graduate School of Arts and Science, M.S.,
organic chemistry

St. John's University, B.S., *cum laude*, with honors in chemistry

Courts

United States District Court for the Southern District of New York

United States District Court for the Eastern District of New York

United States District Court for the Western District of New York

United States Court of Appeals for the Federal Circuit, United States
Patent & Trademark Office

PTAB Bar Association (including pro bono), Supreme Court of the
United States

Professional Affiliations

American Bar Association

New York State Bar Association

PTAB Bar Association

American Mensa Society

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