Michael Sitzman

Partner

US CHAIR LIFE SCIENCES PATENT LITIGATION

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For more than 25 years, Michael has represented biotechnology and pharmaceutical companies in high stakes patent litigation and other intellectual property matters. Michael has litigated cases involving recombinant DNA, CAR-T technology, glycobiology, antisense technology, protein synthesis and regulation and immunological markers for such companies as Allergan, Alza, Depomed, Genentech, Gilead, Janssen Pharmaceuticals, Medicis, Merck Serono, Novo Nordisk and Ultragenyx.

RELATED SERVICES

- Intellectual Property and Technology

Michael represents brand-name and innovator pharmaceutical companies in biologic and drug patent litigation, including ANDA litigation. Michael was one of the chief architects of the strategy for Novo Nordisk that culminated in the Supreme Court's first substantive review of the Hatch-Waxman Act.

Before becoming an attorney, Michael worked at the UC Davis Plant Growth Laboratory and Biogenex, combining the fields of immunology, histology and general chemistry.

Michael regularly appears *pro hac vice* in the district courts of New Jersey, Delaware, Maryland and the Southern District of New York. He is a Global Fellow of the Federal Circuit Bar Association and speaks regularly at PLI and ACI conferences on issues of biotechnology and pharmaceutical patent law.

EXPERIENCE

- *Allergan, Inc. and Medytox v. Daewoong Pharm and Evolus* (Int'l Trade Comm'n 2020) – dispute over genetic origin of C. Botulinum toxin strain and process parameters used to manufacture botulinum neurotoxin product
- *Takeda, Millennium Pharm. v. Genentech, Inc.* (Del. Ch. 2018) – licensing dispute over patents claiming the use of monoclonal antibodies with high levels of fucose in order to decrease ADCC activity and corresponding levels of inflammation
- *Juno Therapeutics & Memorial Sloan Kettering v. Kite Pharma* (C.D. Cal. 2017) – biologic patent litigation involving chimeric antigen receptor technology (CAR-T) for T-cells targeting CD19 and FDA's first approved CAR-T, axicabtagene ciloleucel (YESCARTA™), for the treatment of non-Hodgkin lymphoma
- *Depomed v. Actavis, Roxane & Alkem* (Fed. Cir. 2017; D.N.J. 2016) — ANDA litigation against generic applicants for various

dosage forms of tapentadol hydrochloride (NUCYNTA®) for the treatment of polyneuropathic pain and diabetic peripheral neuropathy

- *Shire Pharm. v. Ultragenyx Pharm.* (D.Mass. 2017) – trade secret litigation involving the ultra-rare disease mucopolysaccharidosis VII (MPS VII) and its first treatment, MEPSEVII
- *Oakwood Labs v. Aurobindo Pharma.* (D.N.J. 2017) – trade secret litigation involving formulation of peptide-based microspheres encapsulating leuprolide and octreotide for injectable devices
- *Takeda v. Burwell* (D.D.C. 2014; D.C. Cir. 2016) – challenging FDA's improper approval of 505(b)(2) generic colchicine drug (Colcrys®) without requiring patent certification to method of use patents
- *Almha v. Allergan* (D. Kan. 2013) – defense of patent infringement allegations concerning structural elements of an improved inframammary breast prosthesis
- *Medicis v. GlaxoSmithKline & Stiefel* (W.D. Tex. 2012, D.N.J. 2012) – patent litigation against 505(b)(2) competitor using the patented formulation for Ziana® product
- *Medicis v. Actavis* (D. Del. 2012) – ANDA litigation against generic applicant for drug combination clindamycin phosphate/tretinoin topical gel for dermatological applications
- *Novo Nordisk v. Caraco Labs & Sun Pharm.* (S.Ct. 2011; Fed. Cir. 2010; E.D. Mich. 2009) – litigation and appeals concerning the change in use code narrative associated with Novo Nordisk's Prandin®
- *Novo Nordisk v. Caraco, Sun, Mylan, Paddock, Sandoz & Aurobindo*, (Fed. Cir. 2012; E.D. Mich. 2011 & 2012; D.N.J. 2009; D. Minn. 2011) – ANDA litigation against generic applicants for repaglinide (PRANDIN®) for the treatment of Type 2 diabetes when used in combination with metformin
- *Novo Nordisk v. Actavis, Sandoz & Lupin* (S.D.N.Y. 2011) – ANDA litigation against generic applicants for the single dose combination product repaglinide/metformin (Prandimet®) for the treatment of Type 2 diabetes
- *Isis Pharmaceutical v. Santaris Pharma A/S* (S.D. Cal. 2012) – defense of patent infringement allegations arising out of the development of antisense oligonucleotides (LNAs) for the treatment of various diseases and medical conditions
- *Biogen IDEC MA v. Merck Serono* (D.N.J. 2011) – defense of patent infringement allegations arising out of the production of interferon-β in CHO cells under the biologics license granted by FDA
- *In re: Ditropan Litigation* (N.D. Cal. 2008) – defense of antitrust claims arising out of ANDA litigation concerning generic oxybutynin for the treatment of urological disorders
- *Thoratec v. Bodycote* – defense of patent infringement allegations concerning a biocompatible coating used in cardiovascular implantable devices
- *C.R. Bard v. AHI Cardiovascular Surgeons, Inc.* (D. Ariz.) – patent litigation arising out of inventorship and ownership claims to original patented stent technology
- *Impra, Inc. v. Endomed* (D. Ariz.) – defense of patent infringement and trade secret misappropriation allegations arising out of the design of polytetraflouroetheylene (PTFE) vascular grafts

CREDENTIALS

Admissions

- California
- Supreme Court of the United States
- United States Patent and Trademark Office

Education

- J.D., University of the Pacific, McGeorge School of Law
  Order of the Coif
- B.S., Molecular Genetics, University of California at Davis

Courts

- All California state and federal district courts
- United States Court of Appeals for the Federal Circuit

INSIGHTS

Publications

Valeant v. Mylan: What venues are left for Hatch-Waxman cases?

10 November 2020
The decision substantially limits the number of venues where Hatch-Waxman cases may be brought.

Edwards Lifesciences v. Meril Life Sciences: Another ripple in the Safe Harbor?

26 October 2020
Navigating the contours of the Safe Harbor provision in view of recent Federal Circuit decisions will be a complicated, uncertain process.

Is subject matter jurisdiction under the Hatch-Waxman Act expanding?

6 May 2020
Can non-Orange Book patents be asserted?

NEWS

Michael Sitzman joins DLA Piper's Intellectual Property and Technology practice in Northern California

4 November 2019

DLA Piper announced today that Michael Sitzman has joined the firm's Intellectual Property and Technology practice as a partner in Northern California, based in the San Francisco office.