

Dr. Arie Michelsohn



Dr. Arie Michelsohn offers B2B legal analysis and writing, legal-knowledge management, and legal technology consulting services as Founding Principal at LexLaw.Consulting and the Law Offices of Arie M. Michelsohn. Dr. Michelsohn is a seasoned patent lawyer and litigator with over 20 years of in-the-trenches experience. He has been engaged for numerous litigation, transactional, and strategic counseling matters on behalf of entities ranging from start-ups to Fortune 100 multinational corporations, particularly in the biopharmaceutical, medical diagnostics, agrosiences, and industrial chemistry patent spaces. Dr. Michelsohn holds a J.D. with high



honors, Order of the Coif, from the George Washington University Law School as well as a Ph.D. in molecular neurobiology from Caltech, and is a former judicial law clerk to the Honorable Raymond C. Clevenger, III, of the United States Court of Appeals for the Federal Circuit. He also is co-developer (with Michael M. Costa) of the LEgal Organizer ("LEO") platform for knowledge management, resource creation, and controlled communication, and its associated Application called LexLab. LexLab is the build engine that drives LexLaw.Consulting's legal and technology education website, resipsaloquitour.tech, as well as the Patent Ph.D. (Prosecution history Digest) Report, and serves as the cornerstone of the lexlaw.io container-based lawyer workspace system, which is currently under development.

Contact me:

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My [LinkedIn Profile](#)

Legal Analysis & Writing

- ◆ Senior-level legal expertise for special projects in litigation, advocacy, and IP clearance and due diligence matters
- ◆ Strategic evaluation of patent quality, litigation position, and deal value
- ◆ Preparation and strategic evaluation of papers before the Patent Trial & Appeal Board (PTAB)
- ◆ Drafting of amicus briefs
- ◆ Research, digesting of legal authority and technical evidence, data visualizations, and interactive website production for virtual exhibits and presentations, legal-knowledge databases, and legal education
- ◆ Counsel to the Situation for mediation-modeling of patent disputes
- ◆ "The Deposer" fact and expert witness deposition training and mock depositions and trials
- ◆ Patent drafting, prosecution, and strategic counseling for broad-ranging and foundational inventions in the biological sciences and medicine

Legal Knowledge Management

- ◆ Comprehensive approaches to knowledge management for lawyers, designed to maximize efficiency of work product development, production, and communication
- ◆ Streamlined integration of legal knowledge management and information technology solutions to promote maximum efficiency in collaborations between legal and IT professionals

Legal Technology

Explore our developing suite of open-source solutions for legal knowledge management, workflow efficiency, and secure communications, including:

- ◆ The LEO (LEgal Organizer) platform
- ◆ LexLab lawyer workspace
- ◆ Patent Ph.D.: Machine intelligence for patent-lawyer workflow
- ◆ lexlaw.io container-based systems for law firms and corporate legal departments
- ◆ resipsaloquitour.tech channel-based engine for public dissemination of legal information and educational materials
- ◆ The Legal Information Organizing Network (LION): A vision for a creative commons and secure communications distributed network for the legal profession

Legal expertise:

- ◆ Hatch-Waxman ANDA litigation (pharmaceuticals)
- ◆ Biotechnology and chemical patent litigation, including biosimilars (BPCIA cases), diagnostics, agrobiotechnology, and industrial chemistry
- ◆ Proceedings before the United States Patent & Trademark Office, including the Patent Trial & Appeal Board (PTAB) (formerly the Board of Patent Appeals and Interferences)
- ◆ Intersection of patent, FDA, and antitrust law as applied to pharmaceuticals, diagnostics, and medical devices
- ◆ IP due diligence investigations in the pharma, biotech, and industrial chemistry patent spaces
- ◆ Substantial experience in all phases of a case from case assessment through trial, post-trial proceedings, and appeals to the U.S. Court of Appeals for the Federal Circuit
- ◆ Highly adept at recruiting and working with expert witnesses to prepare expert reports and prepare for depositions and trial
- ◆ Highly adept at taking depositions and performing cross-examinations - known as "The Deposer" and called upon to conduct mock depositions and cross-exams of fact and expert witnesses in preparation for depositions and trial

Judicial Clerkship

Law Clerk to the Honorable Raymond C. Clevenger III, Circuit Judge, United States Court of Appeals for the Federal Circuit (1998-1999)

BAR ADMISSIONS

U.S. District Court for the District of Columbia, 2007

District of Columbia, 2002

U.S. Court of Appeals for the Federal Circuit, 1999

New York, 1999

USPTO, 1996

EDUCATION

The George Washington University Law School, Washington, DC

J.D., May 1998, with High Honors; Order of the Coif; Honors in Trial Advocacy; Writing Fellow

California Institute of Technology, Pasadena, CA

Ph.D., Biology, June 1992 (thesis in developmental molecular neurobiology)

M.S., Biology, June 1986

Columbia College of Columbia University, New York, NY

B.A., Chemistry/Biochemistry, May 1982

Gamma Chapter, Phi Lambda Upsilon Honorary Chemical Society, elected 1982

Parkinson's Disease Research Foundation Undergraduate Fellowship, Mount Sinai School of Medicine, 1981

Representative Engagements

Special projects in litigation, due diligence, and advocacy, as well as writing on matters pertaining to the intersection of pharmaceutical patents and antitrust and on matters pertaining to legal-knowledge management and law and legal technology

(Ongoing projects, writing engagements, and software development)

ANDA Patent Litigation

Wiley Rein, LLP, Washington, DC, (Oct. 2016 – June 2017, Consulting Counsel):

When the ANDA litigation group at Wiley, Rein LLP needed competent reinforcements during a grueling period of peak demand, I came on board as Consulting Counsel and helped carry the load to get the work done, with aplomb.

- Drafted a non-infringement and invalidity opinion regarding an Orange-Book listed patent in the analgesic space, and prepared an associated Paragraph-IV Notice Letter, on behalf of a generic drug company client
- Conducted a comprehensive review and analysis of an ANDA Plaintiff's production documents in a case involving antiviral (HIV) drugs, and uncovered information leading to the development of a strongly-fortified, offensive position regarding invalidity of the core compound patents-in-suit
- Worked closely with senior associates on the antiviral drug case to help expand their capacity in the drafting of final invalidity contentions, and in the preparation of detailed deposition outlines for all defensive and offensive fact-witnesses
- Recruited and worked closely with a key expert witness to develop and produce an approximately 100-page expert report in support of invalidity of the Orange-Book listed, antiviral drug patents-in-suit.

Strategic counseling and patent drafting

Marquardt Law, Washington, DC, Apr. 2014 – Sept. 2016, as Special Counsel:

- Counseled a biotechnology startup company on strategic development of its initial patent filings and portfolio

- Drafted a 50-page Provisional Patent Application for a biotechnology startup company regarding novel detection methods for low-level expression of nucleic acids
- Counseled a financial services industry client on patentability of financial business methods
- Served as a U.S. patent law expert and drafted an extensive Expert Report on behalf of a university client in conjunction with a German patent litigation proceeding regarding a cancer therapeutic
- Counseled two equity research clients regarding ongoing BPCIA litigations and PTAB proceedings involving biosimilar drugs

Patent litigation: ANDA, agrobiotechnology, and industrial chemistry cases

As a senior member of the patent litigation team at Milbank, Tweed, Hadley & McCloy, LLP, Washington, DC, Sept. 2007 – July 2013:

- *Bayer CropScience v. Dow AgroSciences* (Multi-forum litigation regarding transgenic plants resistant to several herbicides) (two Delaware District Court actions and ICC arbitration proceeding) responsible for pre-litigation investigation, development of case strategy, and drafting of initial pleadings for first Delaware action; retained key expert witnesses and managed development and production of four expert reports; conducted direct and cross-examinations of two expert witnesses at a four-day Markman hearing structured as a mini-trial; took and defended depositions of key fact and expert witnesses; drafted two summary judgment motions. Conducted intensive series of mock cross-examinations of all Bayer fact and expert witnesses in preparation for ICC hearing as consultant following my departure from Milbank) (ICC judgment for Bayer, affirmed by the Federal Circuit)
- *Bayer CropScience v. Albaugh, Inc.* (District Court (SDIa) Section 1782 action regarding discovery for use in a Scottish litigation) (Lead counsel; drafted all papers in the action and argued two hearings before the court; conducted three depositions of defendant's fact and Rule 30(b)(6) witnesses; coordinated strategy with Scottish counsel) (successfully obtained document and deposition discovery; settled favorably to client)
- *Osmose v. Arch Chemicals* (District Court (EDVa) litigation regarding micronized copper wood preservatives) (Second chair; conducted 9 of the 12 offensive depositions in the case; managed development and production of all affirmative and rebuttal technical expert reports; argued half of the Markman hearing in the case) (obtained favorable claim construction and settled favorably to client one month before trial)
- *AstraZeneca v. Teva Pharmaceuticals, Ltd. and Dr. Reddy's Laboratories* (ANDA litigation (DNJ) regarding Nexium®) (Senior member of the litigation team, responsible for all aspects of litigation of process patent asserted in tandem with Orange Book-listed patents; drafted all Markman papers and managed development and production of key affirmative and rebuttal expert report for the process patent; took all offensive depositions regarding the process patent and took the majority of fact depositions regarding the asserted Orange Book-listed patents) (settled favorably to client)

- *Bayer CropScience v. Nufarm* (District Court (EDVa) litigation regarding insecticidal fertilizers) (deposed accused infringer's chief scientist and conducted Rule 30(b)(6) deposition of accused infringer's COO; drafted Markman brief, motion for summary judgment of infringement, motion to dismiss a false marking counterclaim on grounds of unconstitutionality, discovery motions, Plaintiff's Prior Art Statement, and letters to opposing counsel; primary responsibility for working with key expert witnesses in drafting expert reports) (settled favorably to client prior to expert depositions)

- *Etigra v. Bayer CropScience* (District Court (MDNC) (DJ action) litigation regarding insecticidal fertilizers) (deposed accused infringer's CEO, conducted Rule 30(b)(6) deposition of accused infringer's COO, and deposed accused infringer's third-party witness; drafted Markman brief, motion for summary judgment of no tortious interference with business practice, motion for summary judgment of infringement, discovery motions, and letters to opposing counsel; primary responsibility for working with key expert witnesses in drafting expert reports) (settled favorably to client prior to expert depositions)

Due Diligence Investigation

- While at Milbank, led an IP due diligence team for a transaction involving one of the world's largest chemical companies, including review of over 1000 patents

Patent litigation (ANDA and biotechnology cases), interferences, due diligence investigations, patent counseling and prosecution

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, Aug. 1999 – Sept. 2007

(Of Counsel)

- Conducted five large-scale IP due diligence investigations for major pharmaceutical company transactions; primary responsibility for drafting of all due diligence written reports to client; team leader for two of those investigations

- *Novartis Vaccines v. Institut Pasteur* (Section 146 action (D.D.C.) regarding invention of the DNA-based AIDS test) (drafted initial pleadings, developed case strategy, responsible for all communications with opposing counsel, drafted motion to dismiss on grounds of estoppel)

(Associate)

- *In re Certain Automotive Parts* (Ford v. *Keystone* ITC litigation regarding design patents on automotive parts) (drafted two summary determination motions)

- *Astellas v. Sicor* (ANDA litigation regarding cardiovascular imaging agent) (managed second attorney review of document discovery and editorial content of privilege log)

- *Wyeth v. Teva* (ANDA litigation (D.N.J.) regarding antidepressant Effexor XR®) (participated extensively in all phases of the case; second chair for offense; drafted pleadings, motions, and correspondence; drafted Markman brief; drafted findings of fact and conclusions of law for all

issues on which patentee had burden of proof; worked with experts to develop offensive positions and draft expert reports; second chaired approximately 15 fact and expert depositions; member of second attorney review team for document production and privilege log; managed compilation of trial exhibit list; worked with graphics experts to develop trial exhibits; worked with fact and expert witnesses to prepare for trial) (settled on eve of trial favorably to client)

- *Eli Lilly & Co. v. Zenith & Dr. Reddy's* (ANDA litigation (S. D. In.) regarding schizophrenia drug Zyprexa®) (defense: early case development, managed initial document production, deposition preparation of fact and expert witnesses and second chair for approximately 10 defensive depositions and depositions of two experts; drafted summary judgment motion of noninfringement; worked with two experts on development of positions and drafting of expert reports)

- *Oxford Gene Technology v. Affymetrix* (District Court (N.D. Ca.) patent litigation regarding DNA arrays) (drafted all motion papers that quashed Affymetrix subpoenas for third party discovery of two genomics company clients, *Agilent Technologies* and *Rosetta Inpharmatics* (now Merck))

- *General Technology Applicants v. Conoco* (Federal Circuit appeal involving polymer chemistry) (drafted sections of Appellee brief)

- *In re Inland Steel* (Federal Circuit appeal involving steel production technology) (drafted Appellant's Reply Brief)

- *Stratagene v. Eppendorf* (District Court patent litigation regarding instrumentation for PCR) (responsible for negotiating favorable settlement early in discovery)

- *Stratagene v. Prolume* (District Court patent litigation regarding fluorescent proteins) (drafted successful jurisdictional motion)

- *GlaxoSmithKline v. Apotex* (District Court (NDIL) ANDA litigation regarding antidepressant drug Paxil®) (member of document review team, participated in preparation of fact witnesses for defensive depositions)

- USPTO Interference involving DNA arrays (backup counsel; favorable settlement at conclusion of preliminary motion practice)

- Performed extensive landscape mapping of patent portfolios for two clients in the biotechnology industry and one client in the beverage industry

Law Clerk Experience

United States Court of Appeals for the Federal Circuit, Washington, DC Aug. 1998 – Aug. 1999,
Law Clerk to the Honorable Raymond C. Clevenger III, United States Circuit Judge:

- Drafted bench memoranda and initial draft opinions for Judge Clevenger and participated in day-to-day discussions in Chambers regarding cases before the Court

Patent Agent Experience

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC Aug. 1995 – Aug. 1998, Student Associate:

- USPTO Interference involving gene therapy (drafted two preliminary motions) (favorable settlement)
- USPTO Interference involving a small molecule pharmaceutical (drafted reply to preliminary motion) (awarded priority)
- Drafted several opinions on patent infringement, validity, and freedom to operate in such technical areas as small molecule pharmaceuticals, recombinant genes and gene products, antibodies, molecular diagnostics and probes, bioinformatics, transgenic plants, agrochemicals, RNA interference, and DNA microarrays
- Prosecuted an extensive docket of patent applications for small-molecule neurobiology-related drugs on behalf of a major pharmaceutical client and several HIV-related biotechnology applications on behalf of a major academic institution

Patent Examiner Experience

United States Patent and Trademark Office, Washington, DC Aug. 1994 – July 1995, Patent Examiner in Biotechnology, Art Unit 1812:

- Examined patent applications in the field of molecular biology, particularly neurobiology and hormone-related systems

PUBLICATIONS

Michelsohn, A.M., "Reflections on Drug Patents and the High Cost of Healthcare," IPWatchdog, July 13, 2018. Available at: <http://www.ipwatchdog.com/2018/07/13/reflections-drug-patents-high-cost-healthcare/id=99167/>

Michelsohn, A.M., "Drug Patents and the High Cost of Healthcare: Case of Over-Advocacy for Under-Patentability," IPWatchdog, May 10, 2018. Available at: <http://www.ipwatchdog.com/2018/05/10/drug-patents-high-cost-healthcare/id=96938/>

Michelsohn, A.M., "The Abuse of Orange Book Listings By Branded Pharmaceutical Companies," IPWatchdog, April 4, 2018. Available at: <http://www.ipwatchdog.com/2018/04/04/abuse-orange-book-listings/id=95555/>

Michelsohn, A.M., "Drug-Patent Abuse and the High Cost of Healthcare: Case of the Double-Half Dose-Time Injection," IPWatchdog, March 20, 2018. Available at: <http://www.ipwatchdog.com/2018/03/20/drug-patent-abuse-high-cost-healthcare/id=95056/>

Michelsohn, A.M., "To Make Healthcare More Affordable, Fight Drug-Patent Abuse with a Fury," IPWatchdog, March 14, 2018. Available at: <http://www.ipwatchdog.com/2018/03/14/make-healthcare-affordable-fight-drug-patent-abuse/id=94731/>

Michelsohn, A.M., "FTC can play a critical role in making health care more affordable," The Hill, February 26, 2018. Available at: <http://thehill.com/opinion/healthcare/375633-the-ftc-can-play-a-critical-role-in-making-health-care-more-affordable>

Michelsohn, A.M., "The Lawyer's Robotic Apprentice," LinkedIn, Aug. 18, 2017, available at: <https://www.linkedin.com/pulse/lawyers-robotic-apprentice-arie-michelsohn/>

Michelsohn, A.M., "The 5 Qualities of the Scientific Lawyer," LinkedIn, Aug. 15, 2017, available at: <https://www.linkedin.com/pulse/five-5-essential-qualities-scientific-lawyer-arie-michelsohn/>

Michelsohn, A.M., "The Physics of Justice in the Quantum-State Court," The Robot Associates Are Coming! Chapter 5.2, LinkedIn, Nov. 28, 2015, available at: <https://www.linkedin.com/pulse/physics-justice-quantum-state-court-arie-michelsohn/>

Michelsohn, A.M., "From the Science of Legal Curation to the Art of Robotic Lexography," The Robot Associates Are Coming! Chapter 5.1, LinkedIn, Nov. 13, 2015, available at: <https://www.linkedin.com/pulse/from-science-legal-curation-art-robotic-lexography-arie-michelsohn/>

Michelsohn, A.M., "Machine Learning: LEO Goes to Law School," The Robot Associates Are Coming! Chapter 4, LinkedIn, Nov. 7, 2014, available at: <https://www.linkedin.com/pulse/20141107195957-24942309-machine-learning-leo-goes-to-law-school/>

Michelsohn, A.M., "Dawn of the DLE: The Makers of LEO: The World's First Robot Associate," The Robot Associates Are Coming! Chapter 3, LinkedIn, Oct. 28, 2014, available at: <https://www.linkedin.com/pulse/20141028203541-24942309-the-makers-of-leo-the-world-s-first-robot-associate/>

Michelsohn, A.M., "(Pre-History) Before LegalSpend Was Spent, When Robot Associates Were Human," The Robot Associates Are Coming! Chapter 2, LinkedIn, Oct. 21, 2014, available at: <https://www.linkedin.com/pulse/20141021133304-24942309-the-robot-associates-are-coming/>

Michelsohn, Arie M., "The Value of a Lawyer's Good Judgment," The Robot Associates Are Coming! A Brief History of the Dawn of the Age of the Digital Legal Enlightenment (DLE), Chapter 1, LinkedIn, Oct. 14, 2014, available at: <https://www.linkedin.com/pulse/20141014131436-24942309-technology-for-the-way-lawyers-think-and-work-a-story-for-our-time/>

Michelsohn, A.M., "The Biosimilar Ballet: Patent Litigation Under the 2010 Health Care Reform Act" Corporate Counsel, January 6, 2011, available at: <https://resipsaloquitour.tech/roar/mT>

Michelsohn, A.M., "Follow-on Biologics: What Will It Take?" The SciTech Lawyer, 5(2):4-9 (2008).

Michelsohn, A.M., "Reaching Opposite Findings On Inequitable Conduct," National Law Journal, April 10, 2006.

Editor, Finnegan, Henderson Biotechnology and Pharmaceutical Federal Circuit Review 2004-2006

Romary, J.M. and Michelsohn, A.M., "Claim Interpretation After Markman: How the Federal Circuit Interprets Claims," 46 American Univ. L. Rev. 1887 (1997)

Speaking Engagements

Invited Speaker, "Follow-on Biologics: What Will It Take?" Roundtable on Follow-on Biologics at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS), Atlanta, GA, November 2008.

Invited Speaker, "The Future of Follow-on Biologics," Roundtable on Follow-on Biologics at the National Biotechnology Conference of the AAPS, Toronto, Canada, June 2008.

Invited Speaker, "Follow-on Biologics: The Branded Perspective," American Conference Institute conference on patent portfolio management in the biotechnology and pharmaceutical industries, New York, February 2007.

Invited Speaker, Committee on Intellectual Property in Genomic and Protein Research and Innovation, National Academy of Sciences, August 2004.

Invited Scholar, von Humboldt Foundation symposium on Biotechnology and Society, Berlin/Potsdam, November 2003.

Invited Panelist, Biotech-Israel 2003 conference, Tel Aviv, May 2003 (panel speaker, session on intellectual property protection).

Panel Chair, "Is Effective Due Diligence Possible?" BIO-Windhover Partnering Conference, Washington, D.C., April 2003

Panel Chair, "The Changing Relationship Between PhRMA and Biotech," BIO CEO & Investor Conference, February 2003.

Faculty, Barnett International Course on Intellectual Property Strategy, Boston, June 2002 and San Diego, November 2002.

Faculty, BIO CEO Boot Camp, September 2001.

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