Nathan A. Beaver

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Nathan A. Beaver is a partner with Foley & Lardner LLP and is a member of the firm's Government & Public Policy and FDA Practices, and the Food & Beverage Industry and Life Sciences Industry Teams.

Mr. Beaver's practice focuses on the representation of manufacturers whose products and activities are regulated by the Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), and the Federal Trade Commission (FTC). He advises clients on regulatory issues affecting prescription and over-the-counter drug products (including animal drugs), medical devices, dietary supplements, cosmetics, and foods with special emphasis on the strategic considerations involving the approval process and patent and exclusivity issues related to the Hatch-Waxman Act.

Mr. Beaver was named a 2012 *BTI Client Service All-Star*, one of only 272 attorneys so honored throughout the United States, as a result of unprompted positive feedback from *BTI's* interviews with nearly 300 corporate counsel from *Fortune* 1000 companies. He is a frequent speaker at the Food and Drug Law Institute events and the author or co-author of the following published articles:

- Book Chapter: "Recent Developments in Food and Drug Law," *"Natural" Claims: The Current Legal and Regulatory Landscape*, Aspatore Publishing, 2013
- "Trends in 'All Natural' Class Actions," *Law360*, November 2011
- "Certifying to Medical Necessity Under FDA," *Law360*, April 2011
- "New Legal Pathway for Biosimilars Creates Opportunities and Challenges for Biological Manufacturers – A Guide to the Legislation," *Bloomberg Law Reports*, August 2010
- "The FDA Stance on High-Fructose Corn Syrup," *Law360*, October 2009"The Future of Drug and Biologics Approvals: Will Congressional Legislation Change the Landscape of Hatch-Waxman," *BNA Health Care Policy Report*, September 2002
- "Fundamentals of Law and Regulation: An in-depth look at the 1997 Food and Drug Administration Modernization Act of 1997"

Mr. Beaver also has significant experience in FDA and Hatch-Waxman cases involving drug approvals, withdrawals and other types of litigation involving FDA regulated products.

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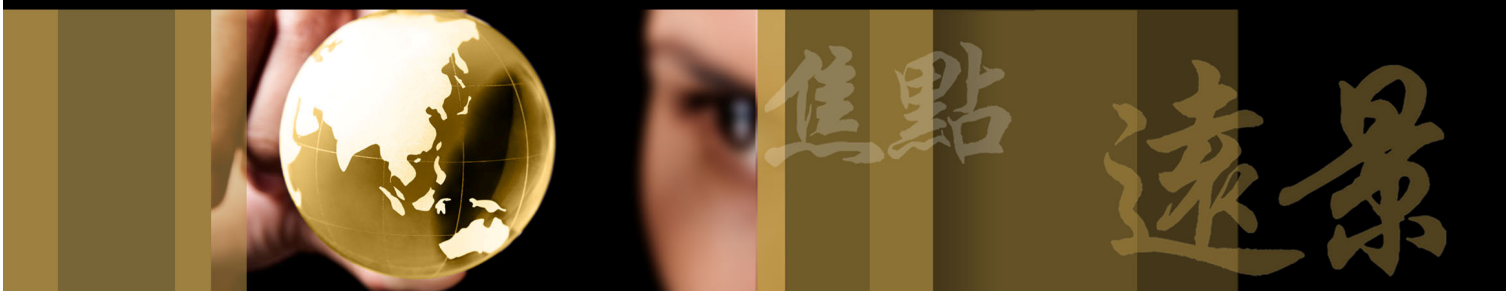

Reported and Other Cases:

- *Zeneca, Inc. v. Shalala*, 213 F.3d 161 (4th Cir. 2000). Intervened on behalf of generic drug maker where plaintiff was seeking to have agency withdraw generic approval. Obtained summary judgment dismissal of case at district and appellate level.
- *Pharmanex, Inc. v. Shalala*, 221 F.3d 1151, (10th Cir. 2000). Filed Amicus brief for National Organization of Rare Disorders, won reversal of adverse district court decision.
- *Teva Pharmaceuticals USA, Inc. v. FDA*, 182 F. 3d 1003 (D.C. Cir. 1999). Successfully sued the agency to recognize the dismissal of a declaratory judgment action as a "court decision" under Hatch-Waxman statute and approve client's drug product.
- *Pfizer, Inc. v. Shalala*, 182 F.3d 975 (D.C. Cir. 1999). Intervened on behalf of generic drug maker where plaintiff was seeking to have agency withdraw generic approval. Obtained summary judgment dismissal.

Administrative Litigation:

- *In the Matter of: Enrofloxacin for Poultry Withdrawal of Approval for New Animal Drug Application NADA 140-848*, FDA Docket 00N-1571 (2003). Defended client in animal drug withdrawal process.

Mr. Beaver earned his J.D. from Georgetown University Law Center in 1997. He graduated *cum laude* in 1994 from the University of Arizona with a Bachelor of Arts degree in interdisciplinary studies.

Mr. Beaver is admitted to practice in the District of Columbia.

Andrew S. Baluch

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Andrew Baluch is an Intellectual Property law special counsel with Foley & Lardner LLP and serves as vice chair of the firm's Patent Office Trials Group. He advises companies on global IP strategies, including international portfolio management, IP diligence reviews, opinions, licensing, litigation, patent reexamination, and trade secret protection. As a member of the firm's China practice, Mr. Baluch provides clients with information on the impact of the Chinese legal environment and consultancy on international conventions, including the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

Mr. Baluch is a former director of international IP enforcement in the White House Office of the IP Enforcement Coordinator. In this role, he oversaw the implementation of all international IP enforcement initiatives in the U.S. Government's Joint Strategic Plan on IP Enforcement and coordinated U.S. Embassy personnel stationed in 17 priority countries, including China, Brazil, Russia and India. His responsibilities also included convening inter-agency teams to assist companies facing IP theft abroad and participating in all major bilateral trade dialogues with China, including the U.S.-China Joint Commission on Commerce & Trade (JCCT) and the U.S.-China Strategic & Economic Dialogue (S&ED).

Prior to his White House appointment, he was an expert legal advisor to the under secretary and director of the U.S. Patent & Trademark Office (USPTO). During his tenure with the USPTO, he participated in numerous trade missions to China, advised the director on IP litigation, drafted regulations for public comment, and helped draft the USPTO's 2010-2015 Strategic Plan. In this role, he gained particular experience in post-grant patent disputes handled within the USPTO.

Mr. Baluch served as a law clerk to Judge Richard Linn of the U.S. Court of Appeals for the Federal Circuit and was an associate with Foley before this service.

In the area of nanotechnology, he is managing editor of *Nanotechnology Law & Business* and conducted graduate research in the field of molecular nano-electronics.

Mr. Baluch holds degrees in materials science engineering from Northwestern University (B.S., M.S.) and Boston University School of Law (J.D.), where he served as editor of the *Boston University Law Review*.

Mr. Baluch is admitted to practice in the District of Columbia, Massachusetts, the U.S. Court of Appeals for the Federal Circuit, and the USPTO.

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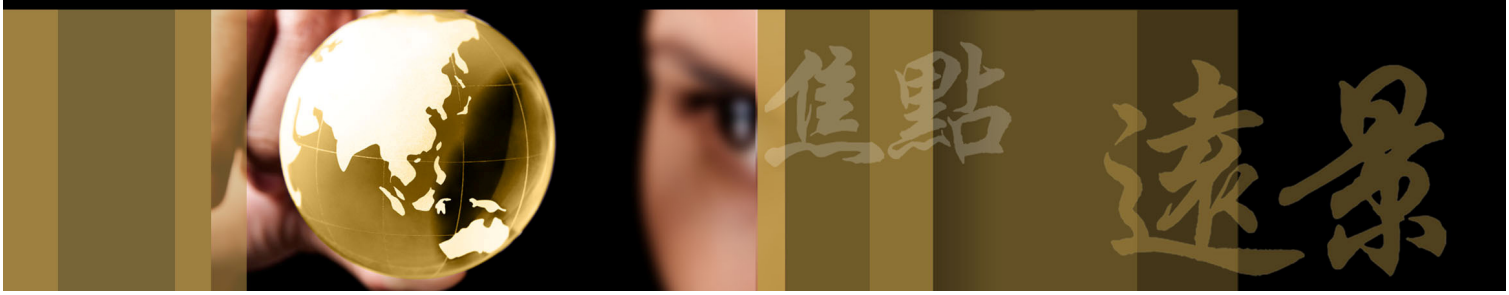

Representative Matters:

Takeda Pharm. Co. v. Doll, 561 F.3d 1372 (Fed. Cir. 2009). Drafted Federal Circuit brief in civil suit against USPTO Director, resulting in favorable 2-1 precedential decision vacating USPTO's rejections against client's patented blockbuster drug. All claims were confirmed as patentable on remand.

Nichia Corp. v. Seoul Semiconductor, No. 06-cv-0162 (N.D. Cal.). Drafted petitions resulting in complete termination of infringer's *inter partes* reexam challenge against client's patents in USPTO, thereby preserving client's favorable jury verdict of infringement.

In re Certain Semiconductor Chips, ITC Inv. No. 337-TA-630, *aff'd*, 646 F.3d 1357 (Fed. Cir. 2011). Participated in discovery and ITC briefing phase on behalf of Japanese respondent, resulting in favorable determination of no infringement under a patent "exhaustion" defense.

Selected Publications:

"The Surprising Efficacy of Inter Partes Patent Reexamination," 9 *Patent Strategy & Management* 1 (2008) (cited by court in *ACCO Brands v. PC Guardian Anti-Theft Prods.*, 592 F.Supp.2d 1208 (N.D. Cal. 2008))

"Patenting Graphene: Opportunities and Challenges," 5 *Nanotechnology Law & Business* 289 (2008)

"Seed Exhaustion: Quanta's Effect on Biotech Patents," *IP Law360* (2008)

"Negative differential resistance through individual organic molecules bound to the Si(111)-7×7 surface," *TMS Letters*, 1, 125 (2004)

"Atomic-level robustness of the Si(100)-2×1:H surface following liquid phase chemical treatments in atmospheric pressure environments," *Journal of Vacuum Science and Technology A*, 22, L1 (2004)

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Alex Y. Nie, an associate with Foley & Lardner LLP, is a member of the firm's Chemical, Biotechnology & Pharmaceutical and Electronics Practices and the Life Sciences Industry Team.

Dr. Nie's practice entails the procurement of patents and related counseling in matters in life science and information technology.

With respect to life science, Dr. Nie's focus is on personalized medicine, computational biology and chemistry, *in vitro* diagnostics and stem cell technology in addition to conventional biotechnology and pharmaceuticals.

Within information technology, Dr. Nie's practice relates to general software and hardware, such as those involving machine learning methods, encryption technologies, mobile platform and digital circuit design.

Prior to his legal career, Dr. Nie was a senior scientist with Johnson & Johnson Pharmaceutical R&D, L.L.C. During his seven year-tenure at the company, Dr. Nie developed new biomarkers for drug safety evaluation using genomics, machine learning and statistical approaches. He was a Johnson & Johnson representative to the Critical Path Institute, an industry-wide collaborative effort to improve the drug approval process.

Dr. Nie earned his J.D. degree from Rutgers School of Law – Newark. He is a graduate of Rutgers – New Brunswick (Ph.D. in biochemistry and M.S. in computer science). Dr. Nie received an M.S. degree in molecular biology from the University of Science & Technology of China and a B.S. degree in biochemistry from Wuhan University.

Dr. Nie has published 25 peer-reviewed scientific articles and two book chapters. He received an NIH grant and has served as a committee member for various scientific organizations, including the International Life Science Institute/Health and

- Nie, "USPTO's 2010 – 2015 Strategic Plan," published in *Foley & Lardner LLP Fall 2010 edition of Legal News: China Quarterly Newsletter, Eye on China* (October 2010)
- Best, Carsten and Nie, "Ninth Circuit," Ch. 10 in *Patent Obviousness in the Wake of KSR International Co. v. Teleflex Inc.,* (Paul. M. Rivard and Alan Gardner, eds., 2010)
- Wright Bonnilla, Brinckerhoff, Konski and Nie, "Patent Eligibility of Personalized Medicine Method Claims Confirmed by Federal Circuit in Prometheus Labs., Inc. v. Mayo," published in *Foley & Lardner LLP Legal News Alert: Biotechnology & Pharmaceutical* (September 2009)

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- Konski, Brinckenhoff and Nie, "Genes Under the Microscope – Novel or Not?" published in *Intellectual Property Today* (July 2009)
- Nie, "Introduction to the U.S. Patent Reform Act of 2009," published in *Foley & Lardner LLP Summer 2009 Eye on China Newsletter* (August 2009)
- Zhao, Nie and Tang, "PRC Supreme People's Court Patent Infringement Enforcement Guidance: The "Draft" Published for Comments by the Patent Community," published in *Foley & Lardner LLP Legal News Alert: China* (July 2009)
- Fielden and Nie *et al*., "Interlaboratory evaluation of genomic signatures for predicting carcinogenicity in the rat," published in *Toxicological Sciences* (vol 103, pages 28-34, 2008)
- Nie *et al*., "Predictive Toxicogenomics Approaches Reveal Underlying Molecular Mechanisms of Nongenotoxic Carcinogenicity," published in *Molecular Carcinogenesis* (vol 45, pages 914-933, 2006)
- Nie, McMillian and Lord, "Toxicogenomics in Drug Safety Evaluation: Bridging Drug Discovery and Development," published in Carmen and Hardiman eds. *Biochips as Pathways to Drug Discovery*. Florida: Taylor & Francis Group (pages 69-96, 2006)

Speeches and Presentations:

- "U.S. Perspective of Patent Enforcement in China," 2009 U.S.-China Legal Exchange, Los Angeles, California (October 12, 2009)
- "An Analysis of the Characteristics of Licensed Clean Tech Patents from Publicly Announced Commercialization Deals," the 5th International Congress of Nano-Bio Clean Tech 2008 conference, San Francisco, California (October 27-30, 2008)
- "Preparing the Critical Path to Acceptance of Toxicogenomic Data in Drug Safety Evaluation," the 2007 Joint Statistics Meeting, Salt Lake City, Utah (July 26 – August 2, 2007)
- *"Bioinformatics Lighting a New Path to Better Drug Development," the Drug Information Association 18th Annual EuroMeeting, Paris, France (March 6-8, 2006)*

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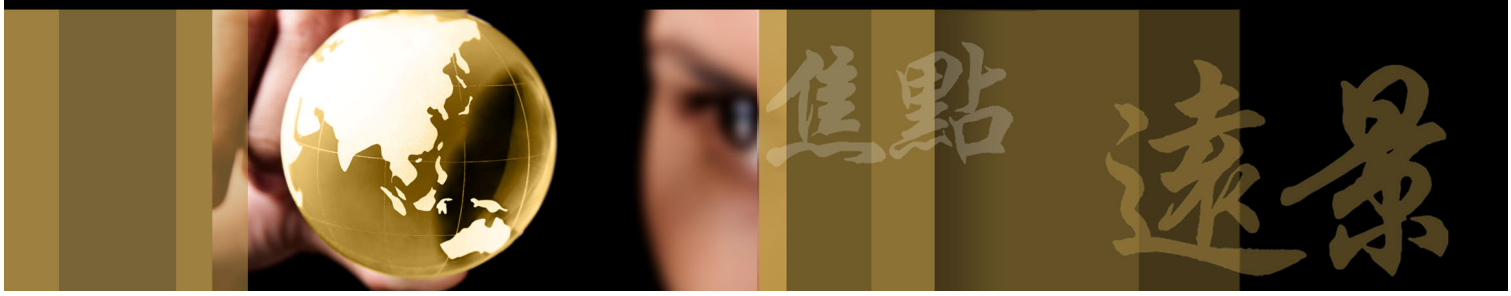

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Song (Max) Lin is a China associate with Foley & Lardner LLP, where his practice focus is on intellectual property (IP) law relating to China. Mr. Lin has experience with a broad spectrum of patent and trademark issues. He is also a member of the Nanotechnology Industry Team.

Prior to joining Foley, Mr. Lin was an intern at a leading Chinese law firm dedicated exclusively to intellectual property matters. During his internship, Mr. Lin worked on litigation, licensing, opinion and patent prosecution matters in the areas of patent and trademark law. While in law school, Mr. Lin published several articles involving patent and trademark law.

Mr. Lin received his undergraduate degree in biotech engineering from Hebei University and his Master of Law degree from Peking University School of Law with first-class honors. He passed the Chinese Bar Examination in 2006 and the Chinese Patent Bar Examination in 2010. Mr. Lin does not hold a current certificate to practice law in China.

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