



BERNARD RHEE

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Bernard Rhee is a registered patent attorney who focuses his practice on resolving business issues for clients.

He counsels clients on complex technology licensing arrangements, research and development collaborations, clinical trials, and regulatory issues often involving pharmaceuticals, biotechnology, medical devices, and electronic health information.

Mr. Rhee routinely drafts and negotiates agreements for clients in these situations.

He also advises clients on product manufacturing, commercialization, supply, and distribution issues. He concentrates on complex business transactions which frequently involve technology and intellectual property rights such as patents.

Mr. Rhee has extensive experience analyzing individual patents and complex patent portfolios for institutional investors and other parties. He frequently conducts patent due diligence and risk assessment investigations in the context of mergers and acquisitions, and also provides strategic legal advice with respect to business matters.

He has rendered opinions on patentability, validity, infringement, licensing, and right-to-use issues. In addition, he has experience in the litigation of patent infringement disputes. He has advised both patent holders and patent infringers during pre-litigation and litigation phases.

He has assisted companies in fulfilling their business objectives within a complicated United States Food & Drug Administration (FDA) regulatory framework. From different types of drug and medical device applications to Hatch-Waxman Act issues, “Orange Book” listings, and enforcement actions, Mr. Rhee has advised clients on FDA issues affecting product development, clinical trials, product approvals, and commercial distribution. He has also testified before FDA on regulatory issues regarding follow-on biologics (e.g., biosimilars).

He has assisted companies in complying with numerous provisions governing electronic data security, privacy, and breach issues with a focus on regulations under the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act. His experience includes assisting clients with data sharing and data use of electronic health records (EHR) and protected health information (PHI). He routinely advises covered entities and business associates on a wide range of regulatory issues.

Mr. Rhee brings a strong background in biochemistry, health care, medical devices, pharmaceuticals, and pharmacology. He has experience with antibody-antigen interactions, biologics manufacturing, polypeptide chemistry (vaccines and therapeutics), cancer immunotherapies, and recombinant DNA technology.

He has also assisted clients in the automotive technology and racing industries with legal concerns often involving trade secrets, confidentiality, patents, and other intellectual property issues. He has significant practical experience in these industries having been involved in automobile racing for five years.

Mr. Rhee was a licensed pharmacist for eight years before becoming an attorney. During this time, he gained considerable experience in clinical settings, traditional community pharmacies, and in the management of a pharmacy corporation.

Prior Legal Experience

- DLA Piper
- Venable LLP
- Powell Goldstein LLP (now Brian Cave LLP)
- Shanks & Herbert (now Reed Smith LLP)
- Saul Ewing LLP

Bar Admissions

- Maryland
- District of Columbia
- United States Patent and Trademark Office
- United States District Court for the District of Maryland

Education

- J.D., University of Baltimore School of Law, 2000
- B.S., University of Maryland School of Pharmacy, 1991

Professional and Civic Activities

- Member, Greater Baltimore Medical Center (GBMC) Board Quality Committee and Medication Safety Committee
- Member, Calvert School Buildings and Grounds Committee
- Supporter, Team USA Racing Scholarship
- Past Member, Alumni Board of Governors, Gilman School (Past President)
- Past Member, Board of Trustees, Gilman School (Financial Aid Committee and Executive Committee)
- Appointed to the Trial Courts Judicial Nominating Commission by Maryland Governor Martin O'Malley in 2007, and reappointed in 2011 (4-year terms)
- Licensed Pharmacist (Maryland)

Publications

- Co-author, *IP Representations in Business Agreements*, Maryland Bar Bulletin (March 2008)
- Co-author, *Bringing Your Medical Device to Market* (2006) - Mr. Rhee authored chapters on intellectual property rights (patents, copyrights and trademarks) and related business strategies for commercialization.
- Co-author, *Pfizer/Pharmacia Merger - The Biggest Just Got Bigger*, FindLaw (May 2003)
- Co-author, *FTC-Rambus Trial To Set The Standard For Antitrust-IP Overlap*, FindLaw (May 2003)
- Co-author, *FTC Brushes Off Bristol's Attempt to Scrub Generic Competition*, FindLaw (April 2003)