



DONALD R. WARE

PARTNER
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Don Ware is Co-Chair of the firm's Patent Litigation practice, and is a past member of the firm's Executive Committee. Don represents leading biopharma manufacturers, research institutions, and universities in patent and inventorship disputes, technology transfer issues, and intellectual property strategy. He also advises clients on FDA matters, including the FDA's regulatory pathway for approval of biosimilars, and issues arising under the Bayh-Dole Act. He has represented the patent holders in several Bayh-Dole March-In proceedings, including the first such proceeding, [In re CellPro, Inc.](#)

Don was named the 2021 General Patent Litigator of the Year – New England by *LMG Life Sciences* in recognition of his notable work, dedication to clients and significant influence on the life sciences industry. *Chambers USA* reports "The spectacular Donald Ware is recognized for his strength handling patent infringement claims. Commentators say "He is very, very smart, very litigation savvy, an exceptionally good writer of briefs and papers, and a good litigation strategist." *IAM's Patent 1000* describes Don as "imaginative and solutions-oriented," quoting clients as saying he makes opposing parties "crazy in the best possible way. He is always out in front of issues. Litigating against him is like playing chess - it is necessary to think at least [t] several moves ahead, which makes him a challenging opponent." Don is also ranked as a leading IP attorney in *The Best Lawyers in America*, *Managing Intellectual Property's IP Stars* and *Massachusetts SuperLawyers*.

Don's patent litigation experience involves a wide range of technologies. In the field of life sciences, he has successfully litigated major cases involving recombinant DNA, monoclonal antibodies, fusion proteins, siRNAs, small molecule compounds, drug delivery, molecular diagnostics, research tool patents, and medical devices. Don has also litigated patent disputes in a variety of other fields, ranging from Internet search engines to integrated circuits.

In addition to his trial practice, Don has extensive experience in appellate litigation, including appearances before the United States Supreme Court, the U.S. Court of Appeals for the Federal Circuit, and many other state and federal courts. He is also experienced in alternative dispute resolution, including mediation and arbitration, both as party counsel and as an arbitrator in the International Chamber of Commerce and the International Centre for Dispute Resolution.

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EDUCATION

- Harvard Law School, J.D., *magna cum laude*
- Yale College, A.B., *magna cum laude*

BAR AND COURT ADMISSIONS

BAR ADMISSIONS

- Massachusetts

COURT ADMISSIONS

- U.S. District Court for the District of Massachusetts
- U.S. District Court for the Eastern District of Texas
- U.S. Court of Appeals for the Federal Circuit
- U.S. Court of Appeals for the First Circuit
- U.S. Court of Appeals for the Ninth Circuit
- Supreme Court of the United States

EXPERIENCE

- Represented Dana-Farber Cancer Institute in patent litigation against Bristol-Myers Squibb and Ono Pharmaceutical concerning inventorship and ownership of groundbreaking patents directed to PD-1/PD-L1 cancer immunotherapy. As lead counsel in 9-day federal court trial, obtained judgment for Dana-Farber correcting inventorship, making Dana-Farber a co-owner of all the patents. The Court of Appeals for the Federal Circuit affirmed the judgment in all respects, 964 F.3d 1365 (Fed. Cir. 2020), and the United States Supreme Court denied Defendants' petition for writ of certiorari (May 2021).
- Defended Biogen in a litigation brought by Knopp Neurosciences concerning ownership of patient biosamples obtained by Biogen in a phase 3 clinical trial investigating the treatment of ALS. Obtained dismissal with prejudice of Knopp's claim just before trial.

- Represented Becton, Dickinson and Company in a patent infringement suit brought by Gen-Probe involving methods of automating nucleic acid diagnostic assays and related consumable products. Obtained favorable settlement, including global license to patent estate, just before trial.
- Represented Biogen in a patent litigation with Sanofi-Aventis involving patents directed to human CMV regulatory sequences. Obtained Writ of Mandamus ordering transfer of venue from Eastern District of Texas. 566 F.3d 1338 (Fed. Cir. 2009). Obtained judgment of non-infringement, affirmed on appeal. 473 Fed. Appx. 885 (Fed. Cir. Mar. 22, 2012)
- Represented University of Massachusetts Biologic Laboratories in dispute with MedImmune over royalty obligations under technology license agreement covering MedImmune's Synagis® drug for treatment of RSV. Obtained judgment after trial requiring MedImmune to continue paying eight-figure royalties. Judgment affirmed on appeal.
- Represented Johns Hopkins University and Xanthus Pharmaceuticals in Delaware Court of Chancery in a dispute over ownership of intellectual property relating to a novel method of treating autoimmune disorders, resulting in negotiation of patent license.
- Defended University of Massachusetts (UMass) in federal court action brought by Max Planck Institute and Alnylam Pharmaceuticals against three co-owners of patent applications directed to therapeutic uses of RNA interference. Obtained judgment in favor of UMass on all damages claims asserted against it. Thereafter, negotiated global settlement agreement by which UMass became a co-owner of Max Planck's competing patent applications on RNA interference.
- Represented Biogen, Genzyme and Baxter Healthcare in multidistrict litigation challenging Columbia University's Axel patent on recombinant DNA technology, resulting in a grant of a royalty-free covenant not to sue.
- Defended Becton, Dickinson in a patent infringement suit brought by Enzo Biochem involving nucleotide sequences used in genetic probes. Summary judgment of invalidity affirmed in Enzo Biochem, Inc. v. Gen-Probe, Inc. et al., 424 F.3d 1276 (Fed. Cir. 2005)
- Represented Johns Hopkins University and Baxter Healthcare in patent litigation against CellPro involving human stem cell technology. Won jury verdict of willful infringement and awards of treble damages and attorneys' fees. Judgments affirmed in Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342 (Fed. Cir. 1998).
- Author of numerous amicus briefs on behalf of professional and trade associations, including Supreme Court briefs in Amgen v. Sandoz, Cuozzo Speed Technologies, LLC v. Lee, Octane Fitness v. Icon, Mayo Clinic v. Prometheus Laboratories, and Microsoft v. i4i.

HONORS & INVOLVEMENT

HONORS

- Listed in Who's Who Legal 2022: Life Sciences – Patent Litigation (Global Guide)
- Recognized as General Patent Litigator of the Year 2021 – New England by LMG Life Sciences
- Recognized by IAM Patent 1000 as a top-ranked patent litigator and life sciences patent litigator
- Recognized by The Best Lawyers in America for intellectual property law
- Recognized by Chambers USA: America's Leading Lawyers for Business as a Band 1 intellectual property lawyer
- Listed in Massachusetts Super Lawyers for intellectual property
- Profiled in IP Law and Business ("The Science Guy," September 2003)

- Editor, Harvard Law Review, Harvard Law School

BAR INVOLVEMENT

- American Intellectual Property Law Association, Committee on Legislation
- BIO Intellectual Property Counsels Committee
- Federal Circuit Bar Association, Member
- Boston Patent Law Association, Member
- Boston Bar Association, Member

COMMUNITY INVOLVEMENT

- Board of Advisors, Yale School of Drama
- Board of Overseers, WGBH (public television and radio)
- Board of Trustees, The Nature Conservancy, New Hampshire
- Past Chairman of Board of Trustees, American Repertory Theater

SPEAKING ENGAGEMENTS

- Frequent speaker on patent law issues and biosimilars legislation at conferences and hearings, including: Co-Chairman, ACI's Annual Summit on Biosimilars; FTC Hearings on the Evolving IP Marketplace; BIO Annual Meeting; BIO IP Counsels Committee; AIPLA; Licensing Executives Society; ACI's FDA Boot Camp; Windhover's FDA/CMS Summit; NACUA Workshops; Suffolk Law School IP Conferences; CBI's Biopharma Forum, and others.