



## Aydin H. Harston, Ph.D.

Member

Aydin Harston combines his love for science and technology with legal expertise to advocate for his clients in all matters necessary to grow, protect, and defend their businesses. With a Ph.D. in biochemistry and numerous scientific and legal publications, Aydin seeks to produce creative and effective approaches to achieve his clients' goals as efficiently as possible.

Aydin focuses on patent prosecution, post-grant proceedings, patent litigation, and patent portfolio evaluations and opinions. He routinely handles many aspects of patent prosecution, from pre-application counseling, to application preparation, worldwide filings, prosecution, and post-grant procedures. He also handles many aspects of patent litigation from discovery disputes, claim construction issues, brief writing, expert witness preparations, trials, and appeals.

Since joining the firm in 2007, Dr. Harston has been involved in intellectual property matters in the context of PTAB proceedings, pharmaceutical litigations, and patent prosecution. His legal work for clients covers an array of technological fields, including: pharmaceuticals including biologics, immunotherapies, cell therapies, small-molecules, and conjugates; biotechnology; medical devices; medical materials; organic and inorganic chemistry; materials science; polymer chemistry and product manufacturing.

His work in the genetics realm includes: gene therapies; CRISPR technologies; genetic reprogramming; genetic engineering; and recombinant DNA technology.

In the realm of pharmaceuticals, biotechnology and medicine, his work has involved: antibody and biologic drugs; biosimilars; antibodies including bispecific and multispecific antibodies; fusion proteins; small molecule pharmaceuticals; deuterated drugs; continuous glucose sensors; medical devices and equipment; biological purification systems and methods; peptide and protein engineering; contraceptive formulations; antihistamine and asthma drugs; multiple sclerosis, neurological, and cancer treatments; vaccines; liposome-, vesicle-, microsphere- and bacterial ghost-encapsulated drugs; isomeric drugs; prodrugs; implants; transplants; and wound healing materials.

His work in the food science and plant field includes: herbicidal, fungicidal, plant growth compositions; supplements; and nutraceuticals.



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### Education

J.D., with Honors, The George Washington University Law School

Ph.D., Biochemistry, University of Maryland, College Park

B.S., Biochemistry, University of Maryland, College Park

### Bar Admissions

Bar Admissions

District of Columbia

Virginia

U.S. Patent and Trademark Office

### Court Admissions

Supreme Court of Virginia

United States District Court for the Eastern District of Virginia

United States Court of Appeals for the Federal Circuit

Firm and Ten  
Partners Ranked in  
2021 IAM Patent  
1000



19 Attorneys  
Named to 2021  
Washington, DC



In the fields related to chemical, mechanical, electronic and industrial devices, his work has involved: hydrocarbon recovery compositions and methods; OLEDs, LCDs and LEDs; laminates and films for solar and display devices; imaging; electrochromic devices and dyes; robotic systems; corrosion-prevention; aircraft and satellite technology; quantum cascade laser technologies; various mechanical devices; and methods; devulcanization techniques; conveyor systems; lubricant formulations; vehicle air management systems; electronic components; and printer inks and toners.

Dr. Harston is actively involved in various bar and professional organizations. He is Co-Chair of the Biotechnology, Healthcare Technology, and Medical Devices Committee of the ABA's Science & Technology Law Section. He serves co-editor of BiosimilarsIP.com and RFEMerge.com.

### Relevant Experience

Dr. Harston has prosecuted over a thousand patent applications in chemical, pharmaceutical, biotechnology, and mechanical fields and handled numerous IP diligence projects. Dr. Harston has participated in litigation teams representing clients in Federal district courts and at the Court of Appeals for the Federal Circuit. Dr. Harston has also represented clients in inter partes review, appeal, and reexamination proceedings before the U.S. Patent & Trademark Office.

#### Representative cases:

- In *Fresenius Kabi USA Inc. v. Coherus BioSciences, Inc.* (PGR2019-00064), Aydin represented Coherus in defending its adalimumab formulation patent number U.S. 10,155,039 covering a biosimilar of the top-selling drug in the world, Humira®. In its Final Written Decision, the Board agreed with the arguments written by Aydin and the team in the Patent Owner's Response and denied all of the challenges to Coherus' patent.
- In *Acrux DDS Pty Ltd. v. Kaken Pharm. Co. Ltd.* (IPR2017-00190), Aydin represented Acrux in successfully challenging the seminal patent covering the blockbuster drug, Jublia®, in IPR2017-00190 before the Patent Trial & Appeal Board. The Board agreed with Acrux's challenge and cancelled all of the claims of the patent to help clear the path for generic entry. Since the victory, at least 22 other generic drug makers have filed applications to make generic versions of Jublia®.
- In *Galderma Labs. LP v. Actavis Labs. UT, Inc.*, No. 1:15-cv-00232 (D. Del.), Aydin represented Actavis in challenging patents leading to settlement on patents covering the rosacea treatment Mirvaso®.
- In *Sunovion Pharm., Inc. v. Watson Pharms.*, No. 1:12-cv-00993 (D. Del.), Aydin represented Watson (Actavis) in Hatch-Waxman litigation leading to settlement after trial on the patent covering Xopenex® allowing launch of generic versions of the asthma drug.
- In *Sunovion Pharm., Inc. v. Synthon Pharm., Inc.*, No. 5:08-cv-179-H(3) (E.D.N.C.), Aydin represented Synthon in Hatch-Waxman litigation leading to settlement on patent covering Xyzal® allowing Synthon to launch its generic version of the anti-allergy drug.
- In Appeal No. 2018-005516 (Appl. No. 15/154,458), Aydin represented Agienic before the Board on its oil field proppant

technology, resulting in reversal of all rejections and issuance of U.S. Pat. No. 10,208,241.

- In Appeal No. 2015-007342 (Appl. No. 13/219,394), Aydin represented RegeneRx Biopharmaceuticals before the Board on its dry eye syndrome treatment, resulting in reversal of all rejections and issuance of U.S. Pat. No. 9,821,030.
- In Appeal No. 2013-006526 (Appl. No. 10/585,970), Aydin represented IHI E&C International before the Board on its recovery of liquefied petroleum gas or natural gas liquids technology, resulting in reversal of all rejections and issuance of U.S. Pat. No. 9,360,249 after many years of erroneous rejections by the Examiner. Aydin's successful arguments resulted in the Office awarding the patentee more than 8.5 additional years of patent term to compensate for the significant delays caused by the erroneous rejections.
- In Reexamination Proceeding 90/009,946, Aydin successfully defended against challenges to his client's wine treatment technology, resulting in issuance of a re-examination certificate that confirmed patentability of all claims without any amendments or cancellations.
- In Reexamination Proceeding 90/009,947, Aydin successfully defended against challenges to his client's wine treatment technology, resulting in issuance of a re-examination certificate that confirmed patentability of all claims without any amendments or cancellations.

Prior to joining Rothwell Figg, Dr. Harston researched protein structures, interactions, and dynamics using nuclear magnetic resonance (NMR) and other biochemical techniques. He also investigated and used novel protein expression and purification techniques, particularly for increasing the purified yield of isotope-labeled proteins. Dr. Harston's dissertation focused on the molecular structures and interactions of proteins involved in cellular protein degradation pathways. His research was published in high impact journals including Nature Structural Molecular Biology and Molecular Cell. Dr. Harston also served in scientific, marketing and business development capacities at a start-up biotechnology firm in Maryland.

## Areas of Concentration

Litigation

Emerging Companies

Post-Grant Trial Practice

Hatch-Waxman Litigation

Biologics and Biosimilars

Patent Prosecution

- Biotechnology
- Chemical
- Mechanical
- Pharmaceutical

## Publications & Presentations

Harston, A., "How the U.S. Compares to Europe on Biosimilar Approvals and Products in the Pipeline," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com),

March 8, 2021.

Harston, A., "Cadent Therapeutics Acquired by Novartis for Up to \$770 Million," [www.RFEMerge.com](http://www.RFEMerge.com), December 18, 2021.

Co-author, "Lessons Learned From Centripetal's Multi-Billion Dollar Damages Award Against Cisco," [www.RFEMerge.com](http://www.RFEMerge.com), November 23, 2020.

Co-author, "Is it Time to Re-evaluate (or Create) Your Document Retention Policy?" [www.RFEMerge.com](http://www.RFEMerge.com), November 6, 2020.

Harston, A., "How the U.S. Compares to Europe on Biosimilar Approvals and Products in the Pipeline," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), October 12, 2020.

Harston, A., "Biosimilar Approvals Stall During COVID-19 Pandemic, But the Pipeline Grows," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), June 9, 2020.

Harston, A., "U.S. Biosimilar Launches Accelerate with Five Launches in Q4 2019 and early 2020," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), January 28, 2020.

Harston, A. and Lee, Alvin, "Time to Rethink 'Consisting Essentially of' as a Claim Limitation," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), November 20, 2019.

Harston, A., "FDA Approves Four Biosimilars During Summer 2019 While Europe is on Vacation," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), September 17, 2019.

Harston, A., "House Democrats Seek to Remove Biologics Exclusivity Period from USMCA," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), July 25, 2019.

Harston, A. and Teigen, A.J., "What Pharma Companies Must Do Globally to Benefit From Canada's Patent Term Extension Framework," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), July 17, 2019.

Harston, A., "Responding to Growing Criticisms, PTAB Expands Discretion to Deny Institution," [www.PTABLaw.com](http://www.PTABLaw.com), May 17, 2019.

Harston, A., "Key Takeaways from a Flurry of Precedential Decision Designations," [www.PTABLaw.com](http://www.PTABLaw.com), April 11, 2019.

Harston, A. and Teigen, A.J., "Why the Disconnect? Federal Circuit Reverses Yet Another Inherent Obviousness Decision," [www.PTABLaw.com](http://www.PTABLaw.com), March 22, 2019.

Harston, A., "Biosimilars Will Get Special Names – Suffixes are Here to Stay," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), March 15, 2019.

Harston, A., "Two Asserted Lantus Patents Cancelled – Commercial Success Evidence Insufficient Because of Blocking Patents," [www.PTABLaw.com](http://www.PTABLaw.com), January 8, 2019.

Harston, A., "USMCA Assailed as Exacerbating High Drug Prices," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), November 15, 2018.

Harston, A. (panel member), "Roundtable: Trends in Biosimilars," <https://www.financierworldwide.com/roundtable-trends-in->

biosimilars, October 2018.

Harston, A. and Allen, D.L., "Federal Circuit: No Tribal Sovereign Immunity," [www.PTABLaw.com](http://www.PTABLaw.com), July 23, 2018.

Harston, A., "Ignore PTAB Precedent at Your Peril," [www.PTABLaw.com](http://www.PTABLaw.com), May 30, 2018.

Harston, A., "Challenging Pharmaceutical Patents, New Arrows in the Quiver?" [www.PTABLaw.com](http://www.PTABLaw.com), April 10, 2018.

Harston, A., "A Rare Successful Challenge of a Patent for a Method of Manufacturing Biologic Drugs," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), March 12, 2018.

Harston, A., "Federal Circuit Revives Polaris' Claims After PTAB's Obviousness Analysis Veers Off Course," [www.PTABLaw.com](http://www.PTABLaw.com), February 23, 2018.

Harston, A., "Are Communications with Foreign Patent Agents and Attorneys Privileged in PTAB Proceedings?" [www.PTABLaw.com](http://www.PTABLaw.com), November 14, 2017.

Co-author, "Reissue Applications During Post Grant Proceedings: To Stay or Not To Stay?" [www.PTABLaw.com](http://www.PTABLaw.com), October 4, 2017.

Harston, A., "FDA Reauthorization Bill is Enacted—Changes Biosimilar User Fees and Review Model," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), August 4, 2017.

Harston, A., "An Overview of Important Changes in BsUFA II," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), June 27, 2017.

Co-author, "How the U.S. Compares to Europe on Biosimilar Approvals and Products in the Pipeline," [www.BiosimilarsIP.com](http://www.BiosimilarsIP.com), April 25, 2017.

Co-author, "Long-Lived States to Monitor Protein Unfolding by Proton NMR" *ChemPhysChem*, 12(15), (2011): 2729–2734.

Co-author, "Perturbing the Ubiquitin Pathway Reveals How Mitosis Is Hijacked to Denucleate and Regulate Cell Proliferation and Differentiation In Vivo," *PLoS ONE*, 5(10), (2010): e13331.

Co-Author, "Structure of the S5a:K48 Linked Ubiquitin Complex and Its Interaction with Rpn13," *Mol. Cell*. 35(3), (2009):280-290.

Co-Author, "Avid Interactions Underlie the K63-Linked Polyubiquitin Binding Specificities Observed for UBA Domains," *Nature Struct. Mol. Biol.* 16(8), (2009):883-889.

Haririnia, A. et al., "Mutations in the Hydrophobic Core of Ubiquitin Differentially Affect its Recognition by Receptor Proteins," *Journal of Molecular Biology* 375, (2008):979-996.

Haririnia, A. et al., "Mapping the interactions between Lys48- and Lys63-linked di-ubiquitins and a ubiquitin-interacting motif of S5a" *Journal of Molecular Biology* 368, (2007):753-766.

Co-Author, "Personal Role Management: Overview and a Design Study of Email for University Students" Kaptelinin, V., Czerwinski, M. (Editors) *Beyond the Desktop Metaphor*, MIT Press, April 1, 2007.

Co-Author, "Solution conformation of Lys63-linked di-ubiquitin chain provides clues to functional diversity of polyubiquitin signaling" Journal of Biological Chemistry 279, (2004):7055-7063.

### Professional Affiliations, Honors & Recognition

Martindale-Hubbell Client Champion Gold (2018-2021)

Washington, DC Super Lawyers "Rising Star" (2017-2021)

IAM Patent 1000: The World's Leading Patent Professionals (2021) - ranked for prosecution in the D.C. Metro Area

Co-Chair of the Biotechnology, Healthcare Technology, and Medical Devices Committee of the ABA's Science & Technology Law Section

American Intellectual Property Law Association

Intellectual Property Owners Association

American Bar Association

Federal Circuit Bar Association

PTAB Bar Association