RAYMOND DOSS

During his eight years in private practice as a patent agent and attorney, Raymond M. Doss counseled clients in the fields of pharmaceuticals, biotechnology, flavor development, medical devices, and engine technologies in connection with intellectual property issues. Raymond worked with clients to establish strategies for developing patent portfolios while considering the competitive patent landscape, competitors, 3rd party collaborations, and other business considerations. In addition to aiding clients in securing sound and enforceable patent rights, Raymond drafted freedom-to-operate, invalidity, and patentability opinions.

For the past six years, Raymond has been Senior Counsel in Amgen's IP Law group where most of his efforts have been focused in the field of biotechnology and oncology. As in-house counsel, Raymond has had the opportunity to work with clients in developing patent prosecution and FTO strategies for programs as they progress through preclinical, clinical, and marketing stages of development. Raymond has also supported deals and negotiations with 3rd parties. In addition, Raymond has taken an interest in encouraging scientists to think about intellectual property as they progress research programs, including developing forums where the intersection of research and patent law is discussed and the "patent process" is "demystified."

Association for Accessible Medicines

Your Generics & Biosimilars Industry

Karin Hessler

Vice President & Deputy General Counsel

Association for Accessible Medicines (AAM)

Karin Hessler is Vice President & Deputy General Counsel for the Association for Accessible Medicines (AAM). She provides legal advice to AAM staff and member company representatives on issues relating to generic and biosimilar medicines in the U.S. She works on advocacy strategy and engagement, provides advice on Hatch-Waxman and pharmaceutical patent issues and helps manage amicus briefs on behalf of AAM.

Before joining AAM in March 2019, Karin was a partner at Wiley Rein LLP, where she represented clients on intellectual property matters, with a special focus on patent litigation in the biotechnology and medical device industries. She has played a lead role in all phases of numerous Hatch-Waxman litigations, including expert discovery, fact discovery, claim construction, trials, regulatory analysis and settlement negotiations. Karin has significant experience in FDA regulatory issues as well as IPR process.

Karin received her J.D. from NYU School of Law, an M.A. in biochemistry from Duke and her B.S. in biochemistry from Lafayette College.

Margareta Sorenson

Margareta Sorenson is Senior Director of Intellectual Property at Amicus Therapeutics, where she handles IP for key biologics programs, including enzyme replacement and gene therapies. Her work includes securing patent and trademark protection as well as freedom-to-operate. She also assists with licensing and collaboration agreements.

Prior to joining Amicus, Margareta worked on both patent litigation and prosecution in private practice. She worked extensively on biosimilar litigation and *inter partes* review proceedings, but also on infringement and Hatch-Waxman litigation. Her prosecution experience spans many areas including antibodies, gene therapy, plants, cosmetics and materials. Her *pro bono* work includes several successful social security appeals for clients with disabilities, including a child with a rare genetic disorder. She currently volunteers for the CORONA project, a comprehensive literature review to identify drugs that can be repurposed for COVID-19.

Before becoming a patent attorney, Margareta earned her Ph.D. from the Rockefeller University, where she solved the x-ray crystal structure of a protein-protein complex. She continued to study protein structure as a postdoctoral fellow at Harvard Medical School before escaping the lab to pursue a legal career.

RACHEL TUROW

Rachel Turow is Associate General Counsel, Regulatory Law & Policy at Teva Pharmaceuticals USA, Inc. and Head, U.S. Regulatory Policy. In this role, Rachel provides regulatory legal support to Teva's specialty and generic pharmaceutical businesses, and supports Teva's drug-device combination products and digital health projects. Rachel also serves as head of regulatory policy for the U.S. Previously, Rachel was Director, Regulatory Policy, at Novo Nordisk Inc. Prior to joining Novo Nordisk, Rachel spent five years at FDA. She was a Regulatory Counsel in CDER's Office of Regulatory Policy and she served as Special Assistant to Jeff Shuren, Director of CDRH. Rachel holds a JD and MPH from the University of Michigan and a BA in Biology from Stanford University.

Moderator HUIYA WU

Huiya Wu, a partner in Goodwin's IP Litigation practice, is a member of the firm's Life Sciences Disputes group and is an intellectual property litigator who has spent more than 20 years litigating and trying cases in both federal and state courts, and has appeared before the Patent and Trademark Office (PTO), the Patent Trial and Appeal Board (PTAB), as well as the International Trade Commission (ITC). She has represented clients in a wide range of technologies, including pharmaceuticals, analytical devices, medical devices, automotive parts, and internet business methods, and has particular expertise in litigation under the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act.

Ms. Wu has been recognized in *Intellectual Asset Management's Patent 1000*, an annual listing of the world's leading patent practitioners, in which clients have described her as "super-clever, highly persuasive and thoughtful," "a top-notch advocate and trusted adviser who helps you achieve your key business objectives," and having "first-rate technical expertise and an appealing and effective courtroom presentation manner," and "an excellent attorney who can always be trusted to put her clients' needs first."

She has an active pro bono practice, including her work with the Legal Services NYC, Project Citizenship, Joyful Heart Foundation, and My Sisters' Place, and is a recipient of the New York City Bar Association's Thurgood Marshall Award for her work defending individuals in capital punishment cases.