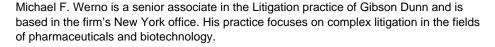
Michael Werno

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Michael has experience litigating cases arising under both the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA). His experience includes developing strategies on validity and infringement, taking and defending depositions, drafting appellate briefs, and leading work with expert witnesses at multiple trials. He has represented life sciences companies in litigations involving pharmaceutical formulations, therapeutic antibodies, biotechnology, and medical devices .

Michael's experience includes*:

- Represented BioNTech SE in a patent infringement action concerning its SARS-CoV-2 vaccine Comirnaty®
- Represented Amgen and Horizon Therapeutics in multiple Hatch-Waxman patent litigations concerning their nephropathic cystinosis medication Procysbi®
- Represented Arbor Pharmaceuticals and Azurity Pharmaceuticals in multiple Hatch-Waxman patent litigations concerning challenges to patents protecting concerning their best-in-class antihypertensive medications Edarbi® and Edarbyclor®
- Represented Boehringer Ingelheim in a BPCIA litigation concerning its biosimilar version of Humira®
- Represented Mitsubishi Tanabe in the first virtual Hatch-Waxman patent trial in the District of New Jersey to challenges of patents covering the first-in-class diabetes medications, Invokana® and Invokamet®
- Represented Zimmer Biomet in patent litigation concerning its Vanguard® knee systems and PSI Shoulder for Trabecular Metal™ Reverse Glenoid shoulder systems
- Represented Orexigen Therapeutics in a Hatch-Waxman patent litigation concerning challenges to patents protecting its anti-obesity drug Contrave®
- Represented Helsinn Healthcare in a Hatch-Waxman patent litigation concerning challenges to patents protecting its Aloxi® antiemetic drug
- Represented Amgen regarding a contractual dispute concerning their blockbuster monoclonal antibody drugs Xgeva® and Prolia®

Michael received his law degree from Boston University School of Law in 2015, where he served as Executive Editor of the *Journal of Science & Technology Law*. He earned a Masters of Physiology degree from North Carolina State University in 2010, and a B.S. in Biological Anthropology and Anatomy from Duke University in 2008. Michael is admitted to



Capabilities

Intellectual Property Life Sciences Litigation Trials

Credentials

Education

Boston University - 2015 Juris Doctor North Carolina State University - 2010 Masters

Duke University - 2008 Bachelor of Science

Admissions

New York Bar New Jersey Bar the New York State Bar, the New Jersey State Bar, and the United States District Court for the District of New Jersey. Michael is also admitted to practice before the United States Patent and Trademark Office.

*Includes recent experience prior to joining Gibson Dunn.

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