



## Claire Fundakowski

Partner

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Claire draws on her experience as a pharmacist to represent clients in intellectual property litigation, with a focus on Hatch-Waxman litigation and appeals. On two occasions, Am Law Litigation Daily mentioned Claire as a “Litigator of the Week” runner-up in connection with her case victories. Prior to joining the firm, Claire served as a law clerk to Chief Judge Kimberly A. Moore at the U.S. Court of Appeals for the Federal Circuit.

Claire practices patent litigation and appeals with an emphasis on the pharmaceutical and medical device sector. She also routinely advises clients on competitive product development strategies in view of Orange Book patent listings and FDA regulations.

Coupled with her extensive knowledge on patent law, Claire leverages her background as a pharmacist to defend generic and biosimilar pharmaceutical companies in matters concerning an array of scientific issues. She has represented pharmaceutical companies in countless patent cases, including cases involving injectable, oral, and topical pharmaceutical compositions and concerning patents directed to polymorphs, stereoisomers, formulations, processes for preparing compounds, downstream purification processes, and methods of treatment. In this capacity, she has represented clients in matters related to the Hatch-Waxman Act, Biologics Price Competition and Innovation Act, and before the Patent Trial and Appeal Board.

As an experienced patent litigator, Claire has obtained multiple victories for clients across industries. She has experience throughout every stage of district court litigation, including taking and defending depositions, constructing invalidity and non-infringement defenses, authoring critical briefs, arguing substantive motions, and examining witnesses at trial. Claire has particular experience in the District of Delaware, where she has litigated over a dozen distinct patent cases involving numerous technologies.

Claire's experience extends to cases before the Federal Circuit, where she has authored numerous briefs and regularly advises on appellate strategy. She clerked for Chief Judge Moore at the Federal Circuit for 20 months before joining the firm.

## Key Matters

Claire's representative experience includes the following:

- Core member of a trial team that obtained invalidation of six patents for obviousness—affirmed on appeal—in a case involving a drug with annual sales of approximately US\$1B.
- Core member of a trial team that obtained a judgment of non-infringement of all asserted claims relating to the drug compound's polymorphic form.
- Orally argued and briefed claim construction on behalf of a generic pharmaceutical company to obtain a construction narrowed by prosecution history disclaimer.
- Orally argued and briefed a successful *Daubert* motion on behalf of a medical device company.
- Briefed successful patent challenges before the Patent Trial and Appeal Board to invalidate dozens of claims across six patents relating to methods of expressing enzymes in fungal cells.

Claire has also helped secure several favorable outcomes for her pro bono clients, including:

- At the Supreme Court, briefed successful *amicus* brief outlining why the rescission of DACA was arbitrary and capricious in view of the government's failure to consider serious reliance interests unique to DACA recipients and their families.
- Briefed successful *amicus* brief on behalf of various civil rights organizations to support commuting a prisoner's wrongful conviction through executive clemency.
- Briefed successful *amicus* brief in appellate court to support protecting prisoners from the physical and psychological harms of solitary confinement.

## Recognitions

- *The American Lawyer*, "Litigator of the Week" Runner-Up (Jan. 2022; May 2022)
- *Best Lawyers: Ones to Watch in America*®, Patent Litigation (2022–2024)
- *Best Lawyers: Ones to Watch in America*®, Litigation - Intellectual Property (2024)
- *Best Lawyers: Ones to Watch in America*®, Intellectual Property Law (2021–2024)
- *Super Lawyers*, Washington, D.C. "Rising Stars" (2020–2022)
- Patexia, "Top ANDA Litigator" (2020–2023) and "Top 25 for Best Performance" (2023)
- American Society for Pharmacy Law's "Larry M. Simonsmeier Writing Award" (2014)

# Credentials

## EDUCATION

Claire received her Pharm.D., *cum laude*, from Massachusetts College of Pharmacy and Health Sciences in 2010. She received her J.D., *cum laude*, from Georgetown University Law Center in 2014, where she was notes editor of *Georgetown Journal of Legal Ethics*.

Claire is also a Registered Pharmacist in Virginia, where she practiced before obtaining her law degree.

## ADMISSIONS

- District of Columbia
- Maryland

## CLERKSHIPS

- USCA - Federal Circuit for the Chief Judge Kimberly A. Moore

## Related Insights & News

### Publications

- Eric Weisblatt & Claire Frezza, Who to Sue and Where in ANDA Litigation: Personal Jurisdiction Post-Daimler, 69 *FOOD & DRUG L.J.* 351 (2014)
- James Wallace Jr., Eric Weisblatt, & Claire Frezza, Patent Eligibility Post-Alice: The Lower Courts' Response, 89 *PAT. TRADEMARK & COPYRIGHT J.* (BNA) 324 (2014)
- Claire Frezza, Medical Marijuana: A Drug Without a Medical Model, 101 *GEO. L.J.* 1117 (2013)
- A. Claire Frezza, Counseling Clients on Medical Marijuana: Ethics Caught in Smoke, 25 *GEO. J. LEGAL ETHICS* 537 (2012)

### Speaking Engagements

- Moderator, Judicial Panel: PTAB's LEAP Initiative for NextGen Lawyers (2020)

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## SPONSORSHIP

Winston Charlotte Hosts Global ChIPs Leadership Retreat

APRIL 16, 2024

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## RECOGNITIONS

Three Winston Teams Featured in Litigator of the Week Column

SEPTEMBER 29, 2023

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## RECOGNITIONS

Winston Attorneys Recognized in *Best Lawyers: Ones to Watch® in America* 2024

AUGUST 17, 2023

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## **SPONSORSHIP**

Winston & Strawn Sponsors 2023 Federal Circuit Bar Association Bench & Bar Conference

JUNE 28, 2023

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## **RECOGNITIONS**

Winston Attorneys Recognized in Litigator of the Week Column

JANUARY 6, 2023

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## **PRESS RELEASE**

Winston & Strawn Names 19 New Partners

DECEMBER 6, 2022

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## **RECOGNITIONS**

Winston & Strawn Attorneys Recognized in *Best Lawyers: Ones to Watch in America* 2023

AUGUST 18, 2022

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## **RECOGNITIONS**

A Team Led by Chuck Klein Highlighted in Litigator of the Week Column

MAY 27, 2022

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## **BLOG**

PTAB Engages in a § 112-Centric Analysis to Deny Institution

MARCH 1, 2022

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## **RECOGNITIONS**

Teams Led by Chuck Klein and Michael Elkin Recognized in *The American Lawyer's* Litigator of the Week Column

JANUARY 7, 2022

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## **RECOGNITIONS**

Winston & Strawn Attorneys Recognized in *Best Lawyers: Ones to Watch in America* 2022

AUGUST 19, 2021

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## **RECOGNITIONS**

Winston Women Recognized in the 2021 Women in the Law edition of *Best Lawyers*

JULY 1, 2021

# Capabilities

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Patent Litigation

Appellate & Critical Motions

Intellectual Property

Medical Devices

Life Sciences