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Irena Royzman is the head of Life Sciences at Kramer Levin. She concentrates on pharmaceutical and biotech patent litigation and proceedings before the Patent Trial and Appeal Board. Irena holds a Ph.D. in biology from MIT and the Whitehead Institute, where she was a NSF fellow. She represents plaintiffs and defendants in some of the most complex pharmaceutical and biotech patent cases.

Irena has litigated a wide range of subject matters, including small molecules, biologics, recombinant DNA technology, gene therapy, gene editing, manufacturing processes, formulations and drug-eluting medical devices. Irena has significant experience in litigation under the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA).

For plaintiffs, Irena has successfully defended against generic challenges to patents protecting blockbuster medical therapies, including a multi-billion dollar anti-psychotic drug and a best-selling HIV protease inhibitor. She has also represented an innovator in some of the first cases under the BPCIA, including the first involving an antibody. For defendants, she recently defeated a \$530 million claim of patent infringement of a competitor's biotech patent, obtaining dismissal of all claims and discovery sanctions against the patent owner. In another high-stakes case, she obtained summary judgment of noninfringement and exclusion of plaintiff's experts under *Daubert* as well as a full award of attorneys' fees.

A registered patent attorney, Irena also handles *inter partes* review (IPR) proceedings. For patent owners, she has obtained denial of IPR for patents protecting blockbuster drugs, and has leveraged IPR for defendants to obtain freedom to operate.

Irena also coordinates US proceedings with parallel ex-US litigation and proceedings in foreign patent offices. She provides strategic counseling in the area of biologics and pharmaceuticals and advises clients on their IP portfolios and transactions. Irena also represents clients in high-stakes license disputes involving biotech patents, and, in a dispute concerning the use of a recombinant protein as an enzyme replacement therapy, obtained one of the largest settlement awards over the life of the contract.

Chambers USA has recognized Irena as a leading lawyer in intellectual property, where she is described as "knowledgeable, aggressive" and "an incredibly smart lawyer." *Benchmark Litigation* named her one of the "Top 250 Women in Litigation" for the last four years and a litigation star in intellectual property in New York. Irena was also named to the Crain's New York Business 2021 list of Notable Women in Law.

Irena writes and lectures widely on patent issues. She has been principal counsel on amicus briefs to the United States Supreme Court in some of the most important life sciences cases. Irena also is frequently quoted on patent-related issues, including in the *Washington Post*, *Nature Biotechnology* and *Pink Sheet*.