UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA

# CareFirst of Maryland, Inc., et al. v. Johnson & Johnson and Janssen Biotech, Inc.

CareFirst of Maryland, Inc. v. Johnson & Johnson and Janssen Biotech, Inc., Case No. 2:23cv629 (E.D. Va. Dec. 23, 2025) · No. 2:23cv629 · Decided December 23, 2025

## SUMMARY

The United States District Court for the Eastern District of Virginia denies Johnson & Johnson and Janssen Biotech's motion to exclude the expert testimony of Todd Clark in an antitrust action concerning delayed biosimilar competition for ustekinumab (Stelara). The court holds that Clark's experience-based opinions regarding pharmaceutical-company decision-making, labeling carve-outs, patent-related barriers, and authorized biologics are sufficiently reliable and relevant under Federal Rule of Evidence 702. The opinion also addresses Clark's rebuttal opinions concerning due diligence in J&J's acquisition of Momenta.

## CASE DETAILS

| | |
|---|---|
| COURT | United States District Court for the Eastern District of Virginia |
| WRITING FOR THE COURT | R. Leonard |
| JURISDICTION | United States District Court for the Eastern District of Virginia, Norfolk Division |
| DECIDED | December 23, 2025 |
| DOCKET | 2:23cv629 |
| DISPOSITION | denied |
| PROCEDURAL POSTURE | Plaintiffs brought an antitrust action concerning alleged efforts to delay biosimilar competition for ustekinumab. Defendants moved under Federal Rule of Evidence 702 to exclude the opinions of plaintiffs' pharmaceutical business expert, Todd Clark. The district court denied the motion. |
| STANDARD OF REVIEW | Federal Rule of Evidence 702 governs the admissibility of expert testimony. The district court applies its gatekeeping function to determine whether expert testimony is relevant and rests on a reliable foundation, while retaining broad latitude in determining the appropriate measure of reliability. |

| | |
|---|---|
| **PRECEDENTIAL VALUE** | unpublished district court opinion |

## TOPICS

daubert standard | expert testimony | evidence | commercial litigation | intellectual property

## PRACTICE AREAS

antitrust | expert testimony | pharmaceutical regulation | biosimilars | patent-related competition

## QUESTIONS PRESENTED

1. Whether Todd Clark's expert opinions were admissible under Federal Rule of Evidence 702.
2. Whether Clark's reasonable-company framework was sufficiently reliable and relevant.
3. Whether Clark's opinions concerning alternative business options, biosimilar labeling carve-outs, patent-related barriers, authorized biologic launch decisions, and acquisition due diligence were supported by sufficient facts and reliable reasoning.

## HOLDINGS

1. An experiential pharmaceutical-industry expert may use a reasonable, profit-maximizing-company framework to explain the range of business options available absent alleged anticompetitive conduct when the framework is grounded in the expert's industry experience and does not purport to determine a party's actual knowledge or conduct.
2. An experiential expert may testify about multiple rational business options that a reasonable pharmaceutical company could have pursued instead of challenged conduct without employing a separate scientific methodology, where the testimony is grounded in relevant industry experience and assists the jury with antitrust causation and counterfactual analysis.
3. A pharmaceutical business expert may opine on whether biosimilar manufacturers would have viewed a labeling carve-out as a viable business and regulatory strategy without offering a legal opinion on patent infringement or legal risk.
4. A pharmaceutical-markets expert may offer an industry-based assessment of whether patents other than those challenged would have presented a practical barrier to biosimilar entry, without resolving patent infringement or conducting a technical prior-art analysis, when the opinion is grounded in record evidence and industry experience.
5. A pharmaceutical business expert may synthesize company documents, deposition testimony, and industry literature with specialized market experience to explain why a reasonable company might launch an authorized biologic in response to limited biosimilar competition.
6. An expert may opine on what a reasonable company could have investigated or discerned during acquisition due diligence when the opinions are grounded in contemporaneous records, witness testimony, and reliable industry reasoning, even if the expert does not offer an opinion on the company's actual subjective knowledge or patent infringement.

## KEY QUOTATIONS

> *"the rejection of expert testimony is the exception rather than the rule."* (Opinion & Order, section I)

> *"Because his analysis concerns business decision making rather than legal risk assessment, Clark does not need legal expertise to support his opinions."* (Opinion & Order, section II.B)

> *"Clark applies a reasoned, experience-based methodology to answer a business and regulatory question, not a legal one."* (Opinion & Order, section II.C)

## FACTUAL BACKGROUND

CareFirst alleges that Johnson & Johnson and Janssen Biotech used monopoly power to delay biosimilar competition for ustekinumab, marketed as Stelara. The alleged conduct included obtaining the '307 method-of-use patent through Walker Process fraud, acquiring biosimilar manufacturing patents from Momenta, and using those patents in ways that allegedly delayed market entry. CareFirst offered Todd Clark, a pharmaceutical business expert with more than thirty years of industry experience, to address counterfactual business options, labeling carve-outs, patent-related barriers, authorized biologics, and acquisition due diligence.

## PROCEDURAL HISTORY

CareFirst filed an antitrust action alleging that Johnson & Johnson and Janssen Biotech unlawfully delayed biosimilar competition for Stelara through alleged Walker Process fraud, acquisition of biosimilar manufacturing patents, and enforcement of those patents. Defendants moved to exclude all four of Clark's opinions on reliability and relevance grounds. After briefing, the court denied the motion to exclude.

## DISPOSITION

denied

## CASES CITED

- United States v. Wilson, 484 F.3d 267, 274-75 (4th Cir. 2007)
- Sardis v. Overhead Door Corp., 10 F.4th 268, 281, 283-84 (4th Cir. 2021)
- Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141, 152 (1999)
- Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 200 (4th Cir. 2001)
- In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Products Liability Litigation, 892 F.3d 624, 631 (4th Cir. 2018)
- United States v. Stanley, 533 F. App'x 325, 327 (4th Cir. 2013) (per curiam) (unpublished)
- Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 596 (1993)
- In re Zetia (Ezetimibe) Antitrust Litigation, No. 18-md-2836, 2022 WL 4362166, at *9 (E.D. Va. Aug. 15, 2022)