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PRECEDENTIAL VALUE	unpublished district court opinion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)

OPINION

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA Norfolk Division CAREFIRST OF MARYLAND, INC., et al., on behalf of themselves and all others similarly situated, Plaintiffs, v. Case No. 2:23cv629 REDACTED! JOHNSON & JOHNSON and JANSSEN BIOTECH, INC., Defendants. OPINION & ORDER This is an antitrust action filed by Plaintiffs CareFirst of Maryland, Inc., Group Hospitalization and Medical Services Inc., and CareFirst Bluechoice Inc. (collectively, “CareFirst”) alleging that Defendants Johnson & Johnson and Janssen Biotech, Inc. (collectively, “J&J") used monopoly power to unlawfully delay the introduction of biosimilar competitors for their drug ustekinumab (sold under the brand name “Stelara”).

CareFirst alleges J&J did so by: (1) defrauding the United States Patent and Trademark Office to obtain its method-of-use patent (“the °307 patent’) that covers the use of ustekinumab to treat ulcerative colitis (Walker Process fraud); (2) acquiring a portfolio of biosimilar manufacturing patents from Momenta; and (3) enforcing those patents to delay biosimilar competition from the market.

Presently before the Court is J&J’s Motion to Exclude Expert Testimony of Mr. Todd Clark and an accompanying memorandum in support. ECF Nos. 425—26. Therein, J&J seeks to exclude ' The Court redacted information in this Opinion and Order consistent with the Court’s orders finding the information should remain under seal. all four of Clark’s opinions on the grounds that they are unreliable or unhelpful to the jury.

CareFirst filed a memorandum in opposition, ECF No. 553, and J&J filed a reply, ECF No. 595. Accordingly, the Motion to Exclude is fully briefed and ripe for disposition. For the reasons explained below, the Motion, ECF No. 425, is DENIED.

I. LEGAL STANDARD Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. Under Rule 702, a witness may be qualified as an expert by “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702.

The proponent of the expert must demonstrate it is more likely than not that: (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert’s opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702; see also United States v. Wilson, 484 F.3d 267, 274-75 (4th Cir. 2007). Accordingly, the Court is tasked with “a special gatekeeping obligation on the trial judge to ensure that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.” Sardis v. Overhead Door Corp., 10 F 4th 268, 281 (4th Cir. 2021) (cleaned up).

The reliability of expert testimony is a "flexible inquiry" that requires the Court to ensure an expert's opinion is "based on scientific, technical, or other specialized knowledge and not on belief or speculation." Jd. (emphasis in original) (quotation omitted). Trial courts have "broad latitude" to determine "reasonable measure of reliability in a particular case," which can "depend on[] the nature of the issue, the expert's particular expertise, and the subject of [the expert's] testimony." Jd. (alteration in original) (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999)).

The relevancy of expert testimony depends on whether the opinion "has 'a valid scientific connection to the pertinent inquiry" to "ensure that the expert helps the trier of fact to understand the evidence or to determine a fact in issue." Jd. (internal quotations and citation omitted). Ultimately, if an opinion is not relevant to a fact at issue, it must be excluded.

Jd. While some experts may proffer "[p]urely scientific testimony... characterized by its falsifiability or refutability, or testability," other experts may proffer testimony based on their experience, which does not "rely on anything like the scientific method." Wilson, 484 F.3d at 274.

In those instances, it is a function of the Court's gatekeeping role to "make certain that an expert employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 200 (4th Cir. 2001) (quoting Kumho Tire Co., 526 U.S. at 152).

Thus, an experiential expert must still "explain how [his] experience leads to the conclusion reached, why his experience is a sufficient basis for the opinion, and how his experience is reliably applied to the facts." Wilson, 484 F.3d at 274 (citation and quotation omitted).

As emphasized by the Fourth Circuit, in cases where expert testimony is challenged on relevance or reliability grounds, the district court's gatekeeping function is "indispensable" and "cannot be overstated." Jd. at 283-84.

However, "the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system, and consequently, the rejection of expert testimony is the exception rather than the rule." Jn re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig., 892 F.3d 624, 631 (4th Cir. 2018) (quoting United States v. Stanley, 533 F. App'x 325, 327 (4th Cir.

2013) (per curiam) (unpublished)). "Indeed, Daubert itself stressed the importance of the 'conventional devices' of '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof (rather than wholesale exclusion by the trial judge) as 'the traditional and appropriate means of attacking shaky but admissible evidence.'" Jd. (quoting Daubert, 509 U.S. at 596).

II. ANALYSIS CareFirst proffers Todd Clark as a pharmaceutical business expert. ECF No. 426, attach. 2 at 7. He has over thirty years of experience in the pharmaceutical industry. Jd. at 4.

Before founding his own advisory firm, Clark served as Vice President of Business Development and Director of Media Services for Medicus NY, then the world's largest pharmaceutical marketing firm.

Jd. Clark's expert report provides four opinions related to causation, all of which are premised on the assumption that the jury finds J&J's challenged conduct was unlawful under antitrust law. ECF No. 553 at 10. J&J's Motion seeks to exclude all four opinions on reliability and relevancy grounds.

The Court addresses each opinion in turn below. A. Clark's "Reasonable Company" Framework J&J's first objection applies to all four of Clark's opinions. J&J argues that Clark's opinions should be excluded on the ground that they are all predicated on an unreliable framework that Clark utilized in his opinions: what a "reasonable" pharmaceutical company could have done.

ECF No. 426 at 13-16. J&J advances the following grounds for why this framework is unreliable: (1) Clark created the "reasonable company" framework solely for this litigation (id. at 14); (2) the framework lacks any recognized methodology or supporting authority (id. at 14-15); and (3) Clark admitted he could not apply key parts of his own framework, including assessing legality or rational business decision making (id.

15-16). Because all four of Clark's opinions rest on this defective framework, J&J argues they should be excluded entirely. In response, CareFirst argues that Clark properly applies the "reasonable company" framework, which asks how a rational, profit-maximizing company would behave absent anticompetitive conduct and is well-established by case law and industry experts.

ECF No. 553 at 13-14. CareFirst also rebuts J&J's claims that Clark invented the framework solely for this litigation and failed to properly define the framework, arguing that he accurately described the framework in his deposition in a manner consistent with precedent, and that deposition testimony is a valid part of expert disclosure. Jd. at 14-15.

The Court rejects J&J's overarching argument that Clark's "reasonable" pharmaceutical company is unreliable. Clark's focus on the conduct of a "reasonable" company reflects a well- established approach in the antitrust context for evaluating corporate decision making. See, e.g., In re Zetia (Ezetimibe) Antitrust Litigation, No. 18-md-2836, 2022 WL 4362166, at *9 (E.D.

Va. Aug. 15, 2022) ("The relevant question is how a reasonable profit-maximizing company would behave without the alleged anti-competitive conduct.... Antitrust cases 'presume the existence of rational economic behavior in the hypothetical free market.'" (cleaned up)). Clark draws on his over thirty years of experience to offer a range of business options through the lens of industry practice.

This approach falls within the province of acceptable testimony from an experiential expert, and it provides a reliable framework for assisting the jury in understanding the options available to companies in J&J's position. That Clark applies this framework to the facts of this case does not render it unreliable, especially since Clark does not purport to give an opinion on what J&J actually knew or would have actually done absent the challenged misconduct.

B. Clark's First Opinion Clark's first opinion is that "[a] reasonable company in J&J's position had options other than asserting the biosimilar manufacturing patents" that "therefore would have avoided the allegedly anticompetitive actions associated with the Momenta biosimilar patents." ECF No. 426, attach. 2 at 38. This opinion is assumes that (1) "the jury finds J&J violated antitrust law with respect to both the '307 patent and the Momenta biosimilar manufacturing patents such that, as of the end of September 2023, J&J would have no lawful basis to assert patent protection for Stelara," and that (2) "the Court rules that the plaintiffs must also show the way or ways in which the Momenta biosimilar manufacturing patents would not have otherwise precluded earlier biosimilar entry." /d. at 11.

In his first opinion, Clark offers five alternative options "available to J&J or a reasonable company in the same position that would not have involved asserting the biosimilar manufacturing patents against biosimilar manufacturers and therefore would have avoided the allegedly anticompetitive actions associated with the Momenta biosimilar patents." Jd.

The five options that Clark offers are: 1) "[a] reasonable company in J&J's position could have chosen not to take possession of the biosimilar manufacturing patents at the time of the Momenta acquisition or to divest them upon completing the acquisition"; 2) "[a] reasonable company in J&J's position could have chosen not to maintain rights to the biosimilar manufacturing patents"; 3) "[a] reasonable company in J&J's position could have chosen not to assert the biosimilar manufacturing patents"; 4) "[a] reasonable company in J&J's position could have licensed the biosimilar manufacturing patents to ustekinumab biosimilar makers without also negotiating delayed market entry"; and 5) "J&J could have chosen to license or divest the biosimilar manufacturing patents to another party." Id. at 38-43.

J&J argues that each option provided by Clark should be excluded because, generally, they "amount to nothing more than conclusory assertions," are "unsupported by any methodology," and would not help the jury because Clark provides options other than "asserting" the Momenta patents yet Plaintiffs have expressly disavowed any challenge to J&J's assertion of these patents.

ECF No. 426 at 19. J&J then advances arguments for exclusion specific to each of Clark's five options. Clark's first option—not taking possession of the biosimilar manufacturing patents or divesting them after completing acquisition—is speculative because Clark did not review the Momenta biosimilar manufacturing patents or analyze what they claimed prior to providing his opinion. /d. at 16-17.

Clark's second option—surrendering the rights to the Momenta biosimilar manufacturing patents—is unsupported because Clark has no experience with such a patent surrender and conducted no analysis in support of providing this opinion. /d. at 17. Clark's third option—not asserting the Momenta biosimilar manufacturing patents—is unsupported because Clark is not a lawyer and therefore could not assess the legal consequences of pursuing this option.

Jd. at 17- 18. Clark's fourth option—licensing the Momenta patents to biosimilar makers—is unsupported because Clark conducted no analysis showing that this would have been a rational option, such as performing a valuation on the patents or analyzing the market "to discern the terms of other biosimilar manufacturing patent licenses." Jd. at 18.

Finally, Clark's fifth option—licensing or divesting the Momenta biosimilar manufacturing patents—is unsupported because Clark conducted no analysis to determine whether any third party would have been willing to enter into such a license or what the value of that transaction would have been. /d. at 18-19.

In response, CareFirst argues that (1) Clark's first opinion is helpful in providing the jury with "multiple rational options" available to a pharmaceutical company in J&J's position (ECF No. 553 at 18); (2) Clark is relying on his experience rather than ipse dixit to develop the five options that a reasonable company in J&J's position could have pursued absent the challenged conduct (id.); and (3) Clark does not need to be a lawyer to opine on how a reasonable company could have acted regarding the Momenta patents and is sufficiently qualified to provide those options (id. at 18-19).

The Court is unpersuaded by J&J's arguments for excluding Clark's first opinion and the five options he provides therein. J&J argues that these options are unsupported by any methodology and are therefore merely conclusory.

However, Clark's experience provides a sufficient foundation for developing these five options. Clark is an experiential expert, so his over thirty years of experience provides a foundation for understanding the business incentives around patent ownership and divestiture. Drawing on that experience, Clark identifies five options that a reasonable company in J&J's position could have pursued.

Instead of opining which option should have been pursued, Clark's opinion merely explains the range of non-anticompetitive choices that were available. Because Clark's opinion is based on his experiential judgment rather than on scientific or technical analysis, he was not required to employ a separate scientific methodology to support his first opinion or the five options it contains.

Furthermore, J&J argues that Clark's options are speculative because Clark did not review the Momenta biosimilar manufacturing patents or analyze what they claimed prior to providing his opinion. J&J also argues that because Clark is not a legal expert or a lawyer, he has no basis from which he can opine the rationality of any option he provides.

On the contrary, Clark does not need to assess patent validity, nor does he need to have legal expertise. Clark's purpose in identifying five options available to a reasonable pharmaceutical company is to explain some of the business incentives that companies in J&J's position face.

Because his analysis concerns business decision making rather than legal risk assessment, Clark does not need legal expertise to support his opinions. Finally, J&J argues that Clark's first opinion should be excluded because it is not relevant and would mislead the jury. J&J contends that the five options would mislead the jury because Clark provides options other than "asserting" the Momenta patents yet CareFirst has expressly disavowed any challenge to J&J's assertion of these patents.

This objection misses the point. Clark's testimony is not offered to condemn patent assertion in isolation but rather to address antitrust causation with a counterfactual. By explaining what a reasonable company could have done instead of the challenged conduct, Clark's testimony helps the jury understand the competitive landscape and the range of options available to companies in J&J's position.

As CareFirst notes, Clark does not opine whether a reasonable company in J&J's position "would choose a particular option, but rather that there were multiple rational business options available" and that "none of those options would unlawfully delay biosimilar entry." ECF No. 553 at 21.

Thus, Clark's testimony provides helpful context for the jury to evaluate whether the challenged conduct was exclusionary, and any risk of confusion can be addressed through cross-examination rather than exclusion. Accordingly, Clark's first opinion is the proper subject of expert testimony because it relies on his extensive experience working with pharmaceutical companies and is relevant to understanding the range of options available to companies in J&J's position.

C. Clark's Second Opinion As for his second opinion, Clark opines that "[b]iosimilar manufacturers could have obtained FDA approval and launched with labels that carved out ulcerative colitis treatment as covered by the '307 patent."? ECF No. 426, attach. 2 at 49. This opinion assumes that "the jury finds J&J violated antitrust law with respect to the biosimilar manufacturing patents but not the?

In his report, Clark explains that labels carving out potentially infringing language related to indications are known as "skinny labels." ECF No. 426, attach, 2 at 13, 49. '307 patent, such that, as of the end of September 2023, J&J would have had no lawful basis to assert patent protection for Stelara other than the '307 method-of-use patent." Jd. at 12-13.

J&J challenges Clark's second opinion on the following two grounds: (1) because Clark is not a lawyer, he is unqualified to opine the legal risks of using a labeling carve-out, thereby making his opinion mere speculation (ECF No. 426 at 21); and (2) Clark utilized no specific methodology to

conclude that skinny labels could avoid infringement, instead basing his opinion on the fact that the FDA has approved biosimilars with labeling carve-outs in the past (id. at 21-22).

In response, CareFirst argues that (1) Clark does not provide a legal opinion but rather offers information on the business incentives that companies face when launching under a labeling carve-out (ECF No. 553 at 21); and (2) Clark uses a well-supported methodology in assessing the business risks associated with launching under a labeling carve-out (id. at 21-22).

J&J's arguments for the exclusion of Clark's second opinion mischaracterize the nature of the opinion as well as the methodology applied. First, Clark does not purport to offer a legal opinion about patent infringement or to assess the ultimate "legal risks" of labeling carve-outs, an issue he appropriately acknowledged during his deposition would be addressed by patent counsel.

ECF No. 426, attach. 14 at 102-03 (explaining that, if a pharmaceutical company approached him for help assessing the risks of launching a product with a labeling carve-out, he could "offer information on the business risk aspect of it" but that "the actual legal risk is outside [his] domain and should be handled by a patent lawyer").

Here, Clark offers an opinion squarely within his expertise: whether, as a matter of regulatory practice and business risk, reasonable biosimilar manufacturers would have viewed a launch under a labeling carve-out as a viable strategy notwithstanding the °307 patent.

In forming this opinion, Clark draws from well-established regulatory principles and industry practice, such as how carving out a patented indication removes 10 that patent as a barrier to FDA approval under 21 U.S.C. § 355G)(2)(A)(viii).. ECF No. 553 at 21.

Thus, Clark does not need to be a lawyer or legal expert to recognize this basic feature of the approval pathway created by Congress. Second, Clark's opinion rests on a sufficiently reliable methodology. His report devotes substantial analysis to the history and mechanics of labeling carve-outs, the FDA's guidance encouraging such practices, and the real-world experience of biosimilar and generic manufacturers launching under a labeling carve-out.

See ECF No. 426, attach. 2 at 22-25. In doing this analysis, Clark relies on empirical observations, including the frequency of at-risk launches, the routine use of skinny labels in both the biosimilar and generic contexts, and the near absence of damages awards or injunctive relief arising from such launches, particularly where the potentially infringing indication is carved out.

See id. This comparative, experience-based assessment of risk is a reliable methodology for evaluating business incentives in the pharmaceutical industry. Clark also relies on FDA guidance and historical practice behind labeling carve-outs to assess whether biosimilar manufacturers would reasonably perceive carve-outs as a viable path to market. See id. Thus, his consideration of

how often at-risk launches have resulted in adverse consequences is directly relevant and well within his professional expertise.

Clark applies a reasoned, experience-based methodology to answer a business and regulatory question, not a legal one. Any concern that J&J has with his conclusions goes to weight, not admissibility. D. Clark's Third Opinion As for his third opinion, Clark opines that "[a]bsent the allegedly anticompetitive behavior, there would have been no patent-related barrier to earlier availability of ustekinumab biosimilars." ECF No. 426, attach.

2 at 51. Specifically, had J&J or a reasonable company in its position pursued 11 one of the options Clark provided in his first opinion, "there would have been no patent-related barriers to other companies launching biosimilar versions of ustekinumab when they received licensure from the FDA." Jd. This opinion assumes that "the jury finds J&J violated antitrust law with respect to both the '307 patent and the Momenta biosimilar manufacturing patents such that, as of the end of September 2023, J&J would have no lawful basis to assert patent protection for Stelara." Jd. at 11.

J&J challenges Clark's third opinion as conclusory, arguing that it should be excluded because (1) Clark is not an expert in the pertinent art of biosimilar manufacturing and thus is unqualified, and (2) Clark did not conduct any analysis that would allow him to conclude whether biosimilar manufacturers faced patent-related barriers to entry. ECF No. 426 at 20-21.

In response, CareFirst briefly argues that Clark's third opinion should not be excluded because it does not require expertise in biosimilar manufacturing but rather rests on a straightforward assessment of the patent landscape during the relevant period, when no patents other than those at issue could have delayed biosimilar entry. ECF No. 553 at 11. CareFirst further argues that Clark has a reliable foundation for his third opinion, which is rooted in record evidence concerning J&J's statements as to the scope and utility of the relevant patents as well as Clark's own industry experience.

Jd. at 19-20. Clark's third opinion concerning patent-related barriers to biosimilar entry is appropriate expert testimony because it does not purport to resolve questions of patent infringement but instead offers an industry-based assessment of the patent landscape absent the alleged misconduct.

First, Clark does not opine whether any biosimilar would infringe particular patent claims or analyze biosimilar manufacturing methods—tasks that would require the legal or technical expertise he does not claim to possess. Rather, his opinion is limited to whether, during the relevant period, 12 any patents other than those challenged here would have presented a practical barrier to biosimilar entry once FDA licensure was obtained.

Where the record shows that no other unexpired Stelara patents could have delayed competition, Clark's expertise in pharmaceutical markets is sufficient to support that conclusion. Second,

Clark's opinion is reliable and is not, contrary to J&J's argument, unsupported ipse dixit. He grounds his analysis in contemporaneous evidence, including J&J's own statements, litigation positions, and employee testimony describing the scope and significance of the relevant patents.

See ECF No. 426, attach. 2 at 19 (relying on a deposition transcript and J&J's own pleadings). Drawing on that record evidence as well as his experience evaluating how patent portfolios affect market entry decisions, Clark reasonably concludes that absent J&J's challenged conduct, patents would not have posed a barrier to biosimilar launch. Rule 702 does not require Clark to conduct a prior art search or perform infringement analyses of hypothetical biosimilar products where his opinion concerns the business reality of the patent landscape and the incentives facing market participants.

J&J's objections therefore go to the weight of Clark's testimony, not its admissibility, and provide no basis for exclusion. E. Clark's Fourth Opinion As for his fourth opinion, Clark opines that a "reasonable company in J&J's position would have launched an 'authorized biologic' if only one biosimilar had entered the market following expiration of the '734 patent." ECF No. 426, attach.

2 at 51. J&J argues Clark's fourth opinion is (1) not reliable because Clark merely recites record evidence in concluding that J&J would have launched an authorized biologic version of Stelara, and (2) not helpful for the jury because reciting the facts of a case without any analysis does nothing to assist the jury. ECF No. 426 at 22-23.

In 13 response, CareFirst argues that (1) Clark is not simply reciting the contents of J&J's documents but is instead contextualizing J&J's statements to explain the incentives facing a reasonable company in J&J's position, and (2) Clark's experiential and evidence-based analysis will help the jury understand the business incentives and reasoning behind when and why companies launch authorized biosimilars, particularly in response to a competing ustekinumab biosimilar.

ECF No. 553 at 22-24. Regarding reliability, Clark does not merely summarize J&J's internal materials. Rather, he synthesizes those materials with his extensive experience in pharmaceutical markets and his review of industry literature to explain why, under well-understood competitive dynamics, a reasonable company in J&J's position would have had strong incentives to launch an authorized biologic if only a single biosimilar entered the market in September 2023.

For example, after an extensive review of J&J's internal materials and deposition transcripts, Clark explains how fewer biosimilars in the market increase the commercial opportunity for an authorized biologic—an inference that requires specialized industry knowledge and would not be self-evident to a lay jury. See ECF No 426, attach. 2 at 59 ("With fewer competitors, a rational company in J&J's position would expect to capture greater market share at higher prices.").

Thus, J&J's objections improperly demand a level of analysis that Rule 702 does not require. Accordingly, because Clark explains the rationale behind his conclusions and applies his specialized knowledge to interpret complex business records and competitive incentives, his testimony will help the jury understand when and why companies launch authorized biologics.

J&J's objections therefore go to the weight of the evidence, not its admissibility, and provide an insufficient basis for exclusion. 14 F. Due Diligence Process Finally, the parties disagree over whether the opinions Clark offers in his rebuttal expert report concerning the Momenta acquisition due diligence process are supported.

In his rebuttal report, Clark opines that, through its pre-acquisition diligence process, "J&J could draw a connection between [the Momenta manufacturing patents] and the potential to delay follow-on versions of Stelara from reaching the market" at the time it acquired Momenta. ECF No. 426, attach. 15 at 13. Relying on Momenta's 2017 and 2019 Form 10-K Annual Reports filed with the SEC and deposition testimony from multiple J&J witnesses, Clark further opines that it would have been reasonable for J&J "to further investigate the Momenta/Mylan project and the associated biosimilar manufacturing patents" and "to conclude, as J&J ultimately did, that the patents might affect Stelara's competitive environment." Jd. at 13-14.

J&J challenges Clark's opinions about the Momenta acquisition due diligence process as speculative and unsupported. J&J argues that (1) Clark is not qualified to opine on J&J's diligence process because he has never personally counseled clients on conducting pre-acquisition due diligence, particularly as regarding a "multi-billion-dollar transaction like this one" (ECF No. 426 at 24), (2) his opinions lack foundation because ee EE (£2. at 24-25), and (3) Clark's opinion that a connection could be drawn between the Momenta manufacturing patents and the potential to delay biosimilars is unreliable since Clark never reviewed the patents at issue and conceded that he is not a person of ordinary skill in the art with respect to these patents (id. at 25).

In response, CareFirst argues that Clark's opinions on the Momenta acquisition due diligence process are admissible because they are grounded in extensive contemporaneous evidence showing that a reasonable company in J&J's position could have been prompted to 15 investigate these patents during due diligence. CareFirst argues that these opinions have sufficient foundation because Clark relies on Momenta's public 10-K filings, J&J's own descriptions of the patents, deposition testimony reflecting awareness of the Momenta-Mylan biosimilar project, and the patent schedules attached to J&J's acquisition agreement with Momenta.

ECF No. 553 at 25. CareFirst argues that, drawing on this record as well as his experience advising companies on acquisition due diligence, Clark permissibly opines on what reasonable options were available— not on J&J's subjective knowledge—making any remaining disputes appropriate for cross- examination rather than exclusion. Jd. at 26.

The Court agrees with CareFirst: J&J's objections to Clark's opinions regarding the Momenta acquisition due diligence process go to weight, not admissibility, and are therefore appropriate for cross-examination rather than exclusion. Clark's rebuttal opinions are grounded in record evidence, and they address what a reasonable company in J&J's position could have discerned or investigated during the pre-acquisition due diligence process.

As CareFirst notes, his opinions do not go to what J&J's actual subjective knowledge or intent was. Accordingly, Rule 702 does not require Clark to have personally conducted J&J's due diligence, reviewed the patents as a person of ordinary skill in the art, or opined on patent infringement. It requires only that his opinions be supported by sufficient facts and reliable reasoning, which the Court finds that they are here.

Il. CONCLUSION For the reasons explained above, J&J's Motion to Exclude Expert Testimony of Mr. Todd Clark, ECF No. 425, is DENIED. 16 The Clerk is DIRECTED to forward a copy of this Order to all counsel of record. It is so ORDERED. Lo R. Leonard United States Magistrate Judge Norfolk, Virginia December 23, 2025 17