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[1]

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 CareFirst's Motion to Exclude in Part the Proposed Expert Testimony of Debbie Feinstein and an accompanying memorandum in support. ECF Nos. 447–48. Therein, CareFirst seeks to exclude in part Feinstein's opinions on the grounds that they are

[1] The Court redacted information in this Opinion and Order consistent with the Court's orders finding the information should remain under seal.

unreliable, unhelpful to the jury, and unfairly prejudicial. J&J filed a memorandum in opposition, ECF No. 541, and CareFirst filed a reply, ECF No. 619.

Accordingly, the Motion to Exclude is fully briefed and ripe for disposition. For the reasons explained below, the Motion, ECF No. 447, is **GRANTED IN PART** and **DENIED IN PART**.

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." *Id.* (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." *Id.* (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." *Id.* (internal quotations and citation omitted). Ultimately, if an opinion is not relevant to a fact at issue, it must be excluded. *Id.*

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." *Id.* 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." *In 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.'" *Id.* (quoting *Daubert*, 509 U.S. at 596).

II. ANALYSIS

J&J proffers Debbie Feinstein as an antitrust law expert. ECF No. 459, attach. 8 at 2. Feinstein has practiced antitrust law for over thirty-five years and is a partner at Arnold & Porter, where she serves as the Global Chair of the Antitrust Practice. *Id.* Prior to being elected to the firm's partnership, Feinstein alternated between positions at Arnold & Porter and the Federal Trade Commission ("FTC") in the Bureau of Competition. *Id.* at 2–3. While working at the FTC, Feinstein served as the Director of the Bureau of Competition. *Id.*

Feinstein's expert report provides two opinions responding to two opinions offered by Todd Clark, CareFirst's pharmaceutical business expert. *Id.* at 3. The two opinions offered by Clark that Feinstein responds to are:

> (1) a reasonable company in J&J's position could have chosen not to take possession of four patents related to the manufacture of biologics (the "Momenta Patents") at the time of the Momenta acquisition, excluded them from the transaction, or divested them upon completing the acquisition; and
>
> (2) a reasonable company in J&J's position could have chosen not to maintain rights to the Momenta Patents or voluntarily surrendered them.

Id. at 3–4. Feinstein responds with the following two opinions:

> (1) a reasonable company in J&J's position would not have carved out the Momenta Patents from the Momenta acquisition or divested them pre- or post-acquisition; and
>
> (2) the FTC's decision to promptly clear the transaction without raising any competitive concerns underscores the reasonableness of J&J's decision to acquire and retain the Momenta Patents.

Id. at 6, 14. CareFirst's Motion seeks to prohibit Feinstein from testifying about three issues:

> (1) the DOJ's or FTC's decision not to challenge J&J's Momenta acquisition,
>
> (2) any implications that can be drawn from that inaction, including whether or not it is evidence that J&J's failure to divest, suspend, or otherwise surrender the Momenta biosimilar patents was reasonable, and
>
> (3) elements of the Momenta acquisition (including J&J's specific intent and the level of competition at the time of acquisition) irrelevant to the plaintiffs' claims.

ECF No. 448 at 20. The Court addresses each issue in turn below.

A. Agency Inaction During the Momenta Acquisition

CareFirst argues that Feinstein's testimony about agency inaction is inadmissible under Rule 702 as irrelevant (*id.* at 12–14) and under Rule 403 as unfairly prejudicial (*id.* at 17–20). Specifically, CareFirst argues that her opinion about the reasonableness of J&J's retention of the Momenta patents rests on the incorrect premise that federal agency inaction in challenging a proposed acquisition reflects the agency's views on the legality of the acquisition. *Id.* at 11.

For the reasons explained below, the Court finds that Feinstein's testimony is inadmissible to the extent that she opines that agency inaction underscores or otherwise establishes that J&J's decision to acquire and not divest the Momenta patents was reasonable. However, to the extent she opines that agency inaction would give a reasonable company in J&J's position no reason to think that the acquisition was anticompetitive, such an opinion is admissible.

i. Feinstein's Testimony is Admissible in Part Under Rule 702

CareFirst argues that Feinstein's testimony about agency inaction is incorrect as a matter of law and risks misleading the jury to believe that "a federal agency *approved* J&J's acquisition of the biosimilar patents as procompetitive, reasonable, and ultimately lawful." *Id.* at 14. In response, J&J argues that CareFirst mischaracterizes Feinstein's opinion and overlooks its purpose, which is to explain that if federal agencies like the FTC do not express concerns with a

transaction, it would then be unreasonable for a company to divest patents to address any speculative anticompetitive concerns. ECF No. 541 at 14–15.

CareFirst's argument—that Feinstein's opinion is contrary to law because agency inaction cannot be used to prove the legality of a transaction and is therefore unhelpful to the jury—mischaracterizes most of Feinstein's testimony. Feinstein does not opine that the Momenta acquisition or the Momenta patents themselves were lawful or non-anticompetitive, and she further does not opine that the FTC's decision not to challenge the acquisition rendered the transaction lawful or affirmatively approved. Feinstein specifically opines that a reasonable company would not have taken the "highly unusual step" of carving out the Momenta patents from the acquisition in part because "the FTC did not raise any questions or concerns with J&J about the Momenta transaction" after acquisition paperwork was filed with the FTC. ECF No. 459, attach. 8 at 16. Thus, her opinion is narrower: in light of the FTC's inaction in challenging the Momenta acquisition, a company in J&J's position would have had no reason to believe that retaining the Momenta patents, rather than divesting them before the transaction was finalized, was unreasonable. This opinion is helpful for the jury considering Feinstein addresses Clark's view that J&J could have carved out the Momenta patents or divested them. By offering her opinion on this point, Feinstein addresses whether a reasonable company in J&J's position should or would have considered retention of the Momenta patents to be anticompetitive in light of agency inaction. ECF No. 619 at 8.

However, to the extent that Feinstein opines that agency inaction is *evidence* of reasonableness, that testimony is impermissible. CareFirst correctly observes that agency inaction cannot be treated as affirmative evidence that a company's conduct was reasonable. To the extent Feinstein opines that the FTC's decision not to challenge the acquisition, on its own, establishes

J&J's conduct as reasonable—such as her claim that the FTC allowing the Momenta acquisition to proceed without imposing any conditions "alone refutes Mr. Clark's claim that a reasonable company in J&J's position would have identified the allegedly serious antitrust problems with the transaction"—such testimony would be impermissible. ECF No. 459, attach. 8 at 16. Both CareFirst and J&J acknowledge that the law prohibits expert testimony that seeks to prove a transaction's legality based on agency inaction. *See* ECF No. 448 at 12 (citing *Steves & Sons, Inc. v. JELD-WEN, Inc.*, 988 F.3d 690, 714 (4th Cir. 2021)); ECF No. 541 at 14 (same). Opining that agency inaction is evidence of a reasonable transaction or reasonable conduct would therefore risk misleading the jury.

Accordingly, Feinstein's testimony is inadmissible to the extent that she opines that J&J's decision not to divest the Momenta patents was reasonable *because* the FTC and DOJ did not challenge the acquisition. However, any opinion that this inaction would give a reasonable company in J&J's position no reason to think that the acquisition was anticompetitive is admissible as relevant under Rule 702.

ii. Feinstein's Testimony is Admissible Under Rule 403

CareFirst also challenges Feinstein's testimony about agency inaction as unfairly prejudicial under Rule 403. CareFirst argues that there is no probative value in opining on agency inaction in this context because agency inaction "reflects nothing about an agreement's legality" and because Feinstein fails to establish that the agencies were aware of the relevant competitive concerns—acquiring the Momenta patents—during their review. ECF No. 448 at 17–18. CareFirst further argues that, by "attempt[ing] to use her former position at the FTC to speculate on what review the agency *actually conducted*," Feinstein creates a "significant" risk of prejudice that outweighs any probative value and therefore warrants exclusion under Rule 403. *Id.* at 19.

In response, J&J argues that Feinstein's testimony has probative value because it explains, consistent with real-world antitrust practice, why a reasonable company in J&J's position would not have divested assets absent some regulatory concern. ECF No. 541 at 18–19. J&J further contends that Feinstein's testimony remains probative even if the FTC did not consider CareFirst's specific theory of harm because Feinstein does not claim agency approval. *Id.* at 19. Instead, she explains why reasonable companies do not mitigate speculative risks that agencies themselves never pursued. *Id.* Finally, J&J maintains that Feinstein's testimony on this issue is not unfairly prejudicial because it does not suggest FTC approval, poses no risk of inflaming the jury, and any potential for confusion is outweighed by the probative value. *Id.* at 20–21.

CareFirst's argument for exclusion under Rule 403 is unpersuasive in part because it rests on a mischaracterization of Feinstein's testimony regarding agency inaction. As previously discussed, CareFirst correctly points out that agency inaction is not evidence of legality—but Feinstein does not offer her opinion for that purpose. Instead, she addresses an issue raised by CareFirst's own expert, Todd Clark: whether J&J acted reasonably in not carving out or divesting the Momenta patents during its acquisition. *Id.* at 19. In that context, the absence of any competitive concern raised by the FTC is probative of how companies assess risk and decide whether to take mitigation measures such as divesting assets. *Id.* at 18. Additionally, Feinstein's testimony does not assume that agencies approved CareFirst's theory of harm but rather explains why companies do not act on speculative theories that regulators themselves did not flag. *Id.* at 19.

Nor has CareFirst shown a risk of unfair prejudice that substantially outweighs this probative value. In her report, Feinstein describes the FTC's merger review process and explains that, in her experience, the FTC generally conducts a careful review of all proposed pharmaceutical

transactions. ECF No. 459, attach. 8 at 15–16. This is permissible testimony from an expert whose over thirty-five years of experience supports her conclusions, which do not attempt to discuss the specifics of the FTC's review process in *this* acquisition or suggest affirmative agency approval. Because Feinstein's testimony permissibly relies on her experience to explain real-world antitrust practice, it does not invite the jury to draw impermissible inferences such that it is unfairly prejudicial. Accordingly, the balance under Rule 403 favors admissibility.

B. J&J's Intent in Acquiring Momenta and the Extent of Competition Between J&J and Momenta

CareFirst argues that Feinstein's testimony about J&J's intent in acquiring Momenta and the extent to which there was any competition between J&J and Momenta at the time is unreliable and unhelpful to the jury. ECF No. 448 at 14. Feinstein opines that "there was no reason for J&J to consider whether its acquisition of the Momenta Patents might impact competition for Stelara" because (1) [redacted], and (2) at the time of the transaction, J&J was not competing with Momenta. ECF No. 459, attach. 8 at 8. CareFirst contends that this testimony misconstrues antitrust law by focusing on the legality of the overall Momenta acquisition rather than the challenged acquisition of the Momenta patents (ECF No. 448 at 14), improperly discusses J&J's intent into a Sherman Act Section 2 analysis where intent is not an element (*id.* at 15), and incorrectly treats the absence of competition between J&J and Momenta as dispositive (*id.* at 15–16), thereby misstating the relevant legal inquiry and risking jury confusion.

In response, J&J argues that CareFirst misstates antitrust law and that Feinstein's testimony is relevant because monopolization claims require proof of willful conduct, making any evidence bearing on J&J's intent and business justifications—such as [redacted]—properly within the scope of expert

testimony. ECF No. 541 at 15–16. J&J further argues that Feinstein's testimony does not opine on the legality of the Momenta acquisition but rather addresses CareFirst's expert's view that J&J could have divested patents based on hypothetical future harm. *Id.* at 16. Finally, J&J argues that the absence of any horizontal or vertical competition between J&J and Momenta at the time of the acquisition is a relevant factor in assessing whether a reasonable company could have perceived anticompetitive concerns with a particular transaction and divested assets as a result. *Id.* at 17–18.

The Court disagrees with CareFirst's arguments for exclusion here. CareFirst contends that Feinstein's testimony misconstrues antitrust law by improperly discussing intent, competitive overlap, and overall transaction "reasonableness." But as J&J correctly explains, CareFirst's monopolization claim requires proof of willful conduct, and expert testimony bearing on whether J&J's actions were reasonable is relevant to that inquiry. Certainly, [redacted] is relevant to willfulness.

Additionally, Feinstein does not opine on the ultimate legality of the Momenta acquisition or assert that "'good intentions' immunize anticompetitive acts." *See* ECF No. 448 at 15. Rather, she addresses whether a reasonable company could have perceived anticompetitive concerns at the time of acquisition and taken certain "extraordinary steps," such as divesting patents, to avoid speculative antitrust liability (ECF No. 541 at 6). This testimony helps counter the testimony of Todd Clark, CareFirst's expert, and helps the jury evaluate willfulness, an issue directly presented by CareFirst's monopolization claim.

Nor does Feinstein's reliance on the absence of competition between J&J and Momenta at the time of the acquisition render her opinions contrary to law or misleading. CareFirst is correct that horizontal or vertical competition at the time of acquisition is not a prerequisite for liability, but the level of competition between merging parties is nonetheless a factor recognized in antitrust

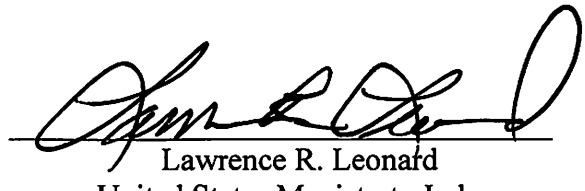
law as well as agencies' antitrust risk assessments. *See Brown Shoe Co. v. United States*, 370 U.S. 294, 317 (1962) (noting "economic concentration" as one of the primary antitrust concerns in merger clearance); U.S. Dep't of Just. & Fed. Trade Comm'n, Merger Guidelines 2 (2023), https://www.ftc.gov/system/files/ftc_gov/pdf/2023_merger_guidelines_final_12.18.2023.pdf [https://perma.cc/22QJ-DLJQ] (noting that a merger raises a presumption of illegality when it "significantly increases concentration and creates or further consolidates a highly concentrated market"). Feinstein does not suggest that the absence of competition forecloses liability; instead, she explains why that fact would have informed a reasonable company's assessment of antitrust risk and due diligence obligations. ECF No. 541 at 18. Framed in this way, her testimony does not misstate antitrust principles or confuse the jury about the proper inquiry into competitive effects but rather provides context for evaluating whether J&J's conduct was willful and unreasonable as alleged. Accordingly, Feinstein's testimony about J&J's intent in acquiring Momenta and the extent to which there was any competition between J&J and Momenta at the time is admissible.

III. CONCLUSION

For the reasons explained above, CareFirst's Motion to Exclude in Part the Proposed Expert Testimony of Debbie Feinstein, ECF No. 447, is **GRANTED IN PART** and **DENIED IN PART**.

The Clerk is **DIRECTED** to forward a copy of this Order to all counsel of record.

It is so **ORDERED**.



Lawrence R. Leonard
United States Magistrate Judge

Norfolk, Virginia
December 23, 2025