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**

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 Dr. Aaron Kesselheim and an accompanying memorandum in support. ECF Nos. 427–28. Therein, J&J seeks to exclude both of Dr. Kesselheim's opinions on the grounds that they are unreliable or unhelpful to the jury. CareFirst filed a memorandum in opposition, ECF No. 556, and J&J filed a reply, ECF No. 599.

Accordingly, the Motion to Exclude is fully briefed and ripe for disposition. For the reasons explained below, the Motion, ECF No. 427, 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." *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

CareFirst proffers Dr. Aaron Kesselheim as a pharmaeconomics expert. ECF No. 428, attach. 2 at 7. Dr. Kesselheim is a Professor of Medicine at Harvard Medical School, a Visiting Professor of Law at Yale Law School, and has practiced internal medicine at Brigham and Women's Hospital for over 20 years. *Id.* at 4. He holds an M.D. and J.D. from the University of Pennsylvania as well as an M.P.H. from Harvard. *Id.* Dr. Kesselheim assisted in founding the Center for Bioethics at Harvard Medical School and has published over seven hundred scholarly articles. *Id.* at 4–5. Dr. Kesselheim's expert report provides background information and two opinions related to the pricing of pharmaceutical drugs. *See* ECF No. 428, attach. 2. J&J's Motion seeks to exclude both opinions on reliability and relevancy grounds as well as background information Dr. Kesselheim provides regarding certain "life cycle management" strategies employed in the pharmaceutical industry. The Court addresses each opinion in turn below.

A. Dr. Kesselheim's First Opinion

Dr. Kesselheim's first opinion discusses the historical impacts of "biosimilar competition on the market for biologic drugs" since the passage of the Biologics Price Competition and Innovation Act (BPCIA). ECF No. 428, attach. 2 at 7. Specifically, Dr. Kesselheim opines that, in the fifteen years since BPCIA's passage, "[b]iosimilar competition has an impact on pricing." *Id.* at 34. Dr. Kesselheim bases his first opinion "largely" on two studies he co-authored in 2021 and 2024, which examined two non-Stelara biologics and studied "how market structures altered by the BPCIA affected prices for biologics subject to biosimilar competition." *Id.*

J&J argues that Dr. Kesselheim's first opinion regarding biosimilar competition generally should be excluded because it merely repeats findings from his two studies on other biologic drugs and makes no effort to reliably extrapolate those findings to Stelara. ECF No. 428 at 9. J&J further argues that Dr. Kesselheim's first opinion would leave the jury to speculate as to whether his two prior studies were applicable comparators, thereby requiring its exclusion as irrelevant and unreliable under Rule 702 and more confusing than probative under Rule 403. *Id.* at 10–11.

In response, CareFirst contends that Dr. Kesselheim relies on fifteen years "of available data from the biologics marketplace" to study the impact that biosimilar competition would have had on Stelara, and that a Stelara-specific study is not necessary in order for him to opine on "the likely impact of competition on Stelara prices in a hypothetical but-for scenario." ECF No. 556 at 9–10. CareFirst also contends that the "consistent finding" from Dr. Kesselheim's prior research that "biologic drugs experience price declines and payer savings increase upon biosimilar entry" will help the jury contextualize how the pharmaceutical industry generally functions absent allegedly anticompetitive interference. *Id.* at 10.

As CareFirst notes, J&J's arguments to exclude Dr. Kesselheim's first opinion go to the weight of his testimony rather than its admissibility. *See id.* at 12. Dr. Kesselheim's first opinion is grounded in fifteen years of research and peer-reviewed studies examining how biological drug markets respond to biosimilar competition, and Dr. Kesselheim clearly applies those industry patterns to a hypothetical but-for scenario. J&J argues that Dr. Kesselheim should have performed an analysis beyond repeating the findings of his studies or ran "new regression models" more specific to Stelara. ECF No. 428 at 10. However, Dr. Kesselheim's role is to explain market behavior based on consistent historical experience and thus is not required to have performed new

quantitative analysis. ECF No. 556 at 6. Accordingly, any alleged gaps in Dr. Kesselheim's analysis go to weight and can be addressed on cross-examination.

Additionally, Dr. Kesselheim's first opinion is helpful for the jury because it bears directly on what would have happened to Stelara prices absent the alleged anticompetitive conduct. Dr. Kesselheim's first opinion situates Stelara within the broader context of a competitive biologics market, including comparator biologics such as Humira and J&J's own Remicade. Thus, Dr. Kesselheim provides the jury with a framework for understanding how a competitive biologics market typically functions. Because Dr. Kesselheim's first opinion is grounded in established research that will assist the jury, J&J's motion to exclude that opinion is denied.

B. Dr. Kesselheim's Second Opinion

Dr. Kesselheim's second opinion discusses the likely "effects of biosimilar competition on the ustekinumab market if one or more biosimilars launched in or around September 25, 2023." ECF No. 428, attach. 2 at 39. Dr. Kesselheim opines that if one or more biosimilars launched at that time, "there would have been a meaningful lowering of spending related to this drug by all different categories of payors in the U.S." *Id.*

J&J seeks to exclude Dr. Kesselheim's second opinion on the grounds that it is unreliable and unhelpful speculation. J&J argues that Dr. Kesselheim utilized no specific methodology or analysis to draw his conclusions. ECF No. 428 at 11. According to J&J, Dr. Kesselheim's conclusions rest on analogies to other drugs such as Humira, ignore available evidence from actual biosimilar entry, and amount to impermissible *ipse dixit*. *Id.* at 12–14.

In response, CareFirst argues that Dr. Kesselheim's second opinion is reliable because it is grounded in "empirical analyses of prior biosimilar launches," accepted pharmaeconomics methods, and documented patterns of biosimilar entry lowering biologic drug prices, including

with closely analogous drugs such as Humira. ECF No. 556 at 13. CareFirst further argues that his opinion is relevant and non-speculative because he explains why Stelara shares key market features with its comparators, situates his conclusions within Congress's policy decisions behind the BPCIA, and his predictions were confirmed by actual Stelara pricing data that became available later in 2025 following biosimilar entry. *Id.* at 13–14.

As with Dr. Kesselheim's first opinion, J&J's objections to his second opinion go to weight rather than admissibility. Dr. Kesselheim's conclusion that earlier biosimilar entry would have led to a meaningful reduction in Stelara's net price is grounded in reliable, peer-reviewed research as well as consistent historical experience across biologic drug markets. Dr. Kesselheim's conclusions are not merely speculation, as J&J contends. Rather, in his report, Dr. Kesselheim synthesized data from multiple biosimilar launches and explained why Stelara shares salient market characteristics with comparator drugs such as Humira. ECF No. 428, attach. 2 at 39–40. This is not only reliable expert testimony but also relevant context for the jury to understand how biosimilar entry affects biologic pricing. ECF No. 556 at 14–15. Thus, any disagreement about Dr. Kesselheim's predicted price effects goes to the weight of his second opinion rather than its admissibility and does not warrant its exclusion.

Furthermore, the Court is not persuaded by J&J's argument that Dr. Kesselheim's opinion is faulty because he did not specifically examine the data following the entry of a biosimilar drug to ustekinumab in January 2025. Given the timing of the events in this litigation, such data simply was not available when Dr. Kesselheim prepared his report in March 2025. To the extent the subsequent data differs from Dr. Kesselheim's analysis, that subject can be addressed on cross-examination.

C. Dr. Kesselheim's Discussion of Life Cycle Management Strategies

Apart from the two opinions in his expert report, Dr. Kesselheim opines on how "life cycle management" strategies in the pharmaceutical industry are an important factor affecting biosimilar availability. ECF No. 428, attach. 2 at 29–30. Dr. Kesselheim opines that "life cycle management" strategies is a "broad term" describing "drug manufacturers' strategic efforts to extend their drugs' market exclusivities, prolong commercial viability, or strengthen their competitive positions in a market." *Id.* J&J seeks to exclude these observations on the grounds that they are "not grounded in the facts of this case" and are unhelpful to a jury. ECF No. 428 at 14. J&J argues that these "generalized musings" are untethered to either of CareFirst's theories of liability in this case and thus would risk misleading the jury by introducing irrelevant industry practices that CareFirst does not allege are unlawful. *Id.* at 14–15.

In response, CareFirst argues that Dr. Kesselheim's observations on pharmaceutical life cycle management are reliable because they are grounded in his "decades of studying" this precise topic and experiential experts "are not required to rely on testable scientific data" to nonetheless be qualified under Rule 702. ECF No. 556 at 15–16. CareFirst further argues that his testimony on this issue is relevant because it provides necessary context about how secondary patents and related strategies are used to delay biosimilar competition, helping the jury understand how J&J's alleged conduct "fits established patterns of using life-cycle management to delay competition." *Id.* at 17.

Dr. Kesselheim's observations on pharmaceutical life cycle management are admissible as reliable and relevant testimony. Dr. Kesselheim's opinions on this issue are grounded in specific academic research examining how branded drug manufacturers use secondary patents and related strategies to extend market exclusivity and delay biosimilar competition. *Id.* at 15. This type of

experiential expert testimony does not need to rest on quantitative analysis specific to Stelara to be reliable. Instead, Dr. Kesselheim appropriately draws on his specialized knowledge of industry practices and incentives to provide context for why J&J's alleged conduct fits within established industry patterns. J&J's objections that Dr. Kesselheim "was not even aware of the biologic manufacturing patents at issue" and "did not review any of the settlements that J&J entered with biosimilar manufacturers" go to weight, not admissibility. *See* ECF No. 428 at 14–15.

III. CONCLUSION

For the reasons explained above, J&J's Motion to Exclude Expert Testimony of Dr. Aaron Kesselheim, ECF No. 427, is **DENIED**.

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