No. 26-1248

In the United States Court of Appeals for the Fourth Circuit

CAREFIRST OF MARYLAND, INC.; GROUP HOSPITALIZATION & MEDICAL SERVICES, INC.; CAREFIRST BLUECHOICE, INC.,
on behalf of themselves and all others similarly situated,
Plaintiffs-Appellants,

v.

JOHNSON & JOHNSON; JANSSEN BIOTECH, INC.,
Defendants-Appellees.

On Appeal from the United States District Court
for the Eastern District of Virginia
Case No. 23-cv-629 (The Hon. Jamar K. Walker)

REDACTED FINAL FORM OPENING BRIEF OF PLAINTIFFS-APPELLANTS

THOMAS M. SOBOL
HANNAH W. BRENNAN
REBEKAH GLICKMAN-SIMON
HAGENS BERMAN SOBOL SHAPIRO LLP
1 Faneuil Hall Square, 5th Floor
Boston, MA 02109
(617) 482-3700

PETER D. ST. PHILLIP
URIEL RABINOVITZ
LOWEY DANNENBERG, PC
44 South Broadway, Suite 1100
White Plains, NY 10601
(914) 997-0500

MATTHEW W.H. WESSLER
MATTHEW GUARNIERI
STEFANIE OSTROWSKI
GUPTA WESSLER LLP
1400 16th Street, NW
Suite 225
Washington, DC 20036
(202) 888-1741
matt@guptawessler.com

(*Additional counsel on inside cover*)

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Counsel for Plaintiffs-Appellants

JOHN D. RADICE
RADICE LAW FIRM PC
475 Wall Street
Princeton, NJ 08540
(646) 245-8502

MARC C. GRECO
KIP A. HARBISON
MICHAEL A. GLASSER
GLASSER AND GLASSER PLC
Crown Center, Suite 600
580 East Main Street
Norfolk, VA 23510
(757) 625-6787

Counsel for Plaintiffs-Appellants

CORPORATE DISCLOSURE STATEMENT

Plaintiff-Appellant CareFirst BlueChoice, Inc. is owned by CareFirst Consolidated, Inc., which is owned by CareFirst Holdings, LLC. CareFirst Holdings, LLC is owned by Plaintiff-Appellant Group Hospitalization and Medical Services, Inc. and Plaintiff-Appellant CareFirst of Maryland, Inc., which are in turn both wholly owned by CareFirst, Inc.

CareFirst, Inc. has no parent corporation, and no publicly held company holds 10% or more of its stock. No other publicly held corporation has a direct financial interest in the outcome of the litigation by reason of a franchise, lease, other profit-sharing agreement, insurance, or indemnity agreement.

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INTRODUCTION

For over a century, the Supreme Court has made clear that a monopolist violates Section 2 of the Sherman Act, 15 U.S.C. § 2, when the monopolist knowingly commits an act with anticompetitive effects—whether or not it intended its conduct to have those effects. The crux of this appeal is the district court's departure from that settled rule in favor of a specific-intent requirement that the court admitted was "inconsistent with Supreme Court precedent." JA40 n.19.

Johnson & Johnson developed the drug ustekinumab, patented it, and obtained approval from the Food and Drug Administration to sell it for the treatment of Crohn's disease and other serious autoimmune disorders. Under federal law, those efforts were richly rewarded: For a fixed period, only J&J was authorized to sell ustekinumab in the United States. From its position of market exclusivity, J&J was able to charge thousands of dollars for each injection of the drug, which it marketed under the brand-name Stelara. J&J earned billions of dollars annually on ustekinumab sales, with gross profit margins hovering around 99%. For much of this time, ustekinumab was J&J's best-selling product.

J&J's period of lawful market exclusivity ended on September 25, 2023, when the company's patent on ustekinumab expired. At that point, J&J could and should have faced competition from other drug companies making FDA-approved generic versions of ustekinumab, known as "biosimilars." But rather than compete, in the

years before the looming loss-of-exclusivity date, J&J schemed to maintain and prolong its monopoly profits.

J&J pursued two tracks to extend its ustekinumab monopoly. On one, J&J acquired a biosimilar drugmaker, Momenta, and its entire patent portfolio—including four patents covering technologies for making biosimilar versions of already-known drugs like ustekinumab. J&J had no interest in using those patents to make biosimilars. But as a monopolist seeking to maintain its exclusivity over ustekinumab, J&J could—and did—weaponize the four Momenta patents to prevent *competitors* from using Momenta's technologies to create biosimilars of ustekinumab. On the other track, J&J defrauded the Patent and Trademark Office into issuing a new patent, with a later expiration date, covering a method of using ustekinumab to treat ulcerative colitis. J&J obtained that patent only by withholding from the PTO critical information the company had submitted to the FDA four years earlier.

With both the Momenta and fraudulently acquired ulcerative colitis patents in hand, J&J was able to exclude biosimilar competitors from the market. J&J sued or threatened to sue seven biosimilar competitors and then extracted agreements from each to delay their market entry. When ustekinumab biosimilars finally entered the market in January 2025—a fifteen-month extension of J&J's monopoly—the list price of the drug plunged by over 80%.

CareFirst brought this certified class action under Section 2 of the Sherman Act and parallel state laws to seek redress for the overpayments that CareFirst and other health benefit providers made for ustekinumab as a direct result of J&J's anticompetitive conduct.

J&J's conduct constitutes a straightforward violation of the Sherman Act. J&J had monopoly power in the relevant market, and it used anticompetitive means to prolong and maintain that power. Under *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), a monopolist may be held liable for anticompetitive conduct involving a patent procured by fraud. And a monopolist's acquisition and use of patents to entrench or prolong monopoly sales is an accepted form of anticompetitive conduct for which J&J may also be held liable. The district court agreed at the motion-to-dismiss stage, and the case proceeded through full discovery.

At summary judgment, the district court was prepared to allow CareFirst to present its *Walker Process* theory to a jury (although the court erroneously narrowed that theory in some respects). But the court refused to allow the Momenta aspect of the monopolization scheme to proceed. The court's sole reason for abruptly derailing the case before trial was a legal mistake: The court wrongly understood a recent decision of this Court to impose a novel specific-intent requirement in monopolization cases. Under the district court's misreading of that decision, a

monopolization claim requires proof not only that the monopolist engaged in conduct that had anticompetitive effects, but also that the monopolist intended its conduct to have those effects. Neither party had urged that standard, and the district court acknowledged that proof of specific intent is "certainly not required" under Supreme Court precedent. JA41 n.19.

Indeed, the Supreme Court has long made clear that only the offense of *attempted* monopolization requires proof of the defendant's "specific intent to monopolize" the relevant market. *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). For the offense of *completed* monopolization, proof of anticompetitive intent is "merely relevant," not required. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602 (1985). The Sherman Act draws that distinction because the Act's fundamental purpose is to protect the competitive process itself. If the plaintiff proves that the defendant possessed monopoly power and acquired or maintained that power through anticompetitive means, the competitive process has been harmed—regardless of the monopolist's good or bad intentions.

The Supreme Court, this Court, and other courts of appeals have all uniformly adhered to that understanding of the Sherman Act for decades. The district court erred in adopting a new specific-intent requirement, and the judgment below rests on nothing else. This Court should therefore vacate and remand for trial.

JURISDICTIONAL STATEMENT

The district court had federal-question jurisdiction over CareFirst's Sherman Act claims. 28 U.S.C. §§ 1331, 1337. The court had supplemental jurisdiction over CareFirst's state-law claims, and jurisdiction under the Class Action Fairness Act. *Id.* §§ 1332(d), 1367. The court entered its amended final judgment on February 11, 2026. JA84. CareFirst filed a timely notice of appeal on March 3, 2026. JA2278. This Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF ISSUES

1. Whether the district court erred in holding that monopolization is a specific-intent offense, requiring proof of the monopolist's intent to exclude rivals on some basis other than efficiency.

2. Whether a reasonable jury could find that J&J committed *Walker Process* fraud where J&J employees with a duty of candor withheld from the PTO information that J&J had submitted to the FDA four years earlier and made contradictory representations to the patent examiner.

STATEMENT OF THE CASE

A. Legal background

Federal law classifies drugs into two categories: (1) conventional, small-molecule drugs, like aspirin, that are chemically synthesized, and (2) "biologic" drugs derived from biological sources, like antibodies, that tend to be larger and more

complex. *See* FDA, *What Are "Biologics" Questions and Answers* (2018), perma.cc/EA8J-5MKE.[1]

When a company develops a new drug and invests in the clinical trials necessary for FDA approval, federal law rewards the company with a period of exclusivity. But recognizing that competition among drug makers can benefit consumers through lower prices, Congress has enacted laws that encourage the development and sale of "generic version[s]" of FDA-approved "brand-name drug[s]" after the period of exclusivity ends. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-05 (2012). For biologic drugs, the relevant statute is the Biologics Price Competition and Innovation Act of 2009 (BPCIA), Pub. L. No. 111-148, 124 Stat. 119, 804. The BPCIA creates an "abbreviated process" for the FDA to approve generic versions of biologics (called "biosimilars") after an initial 12-year period of regulatory exclusivity for the brand-name manufacturer. *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 7 (2017).

Competition has a profound effect on the price of drugs—especially biologics, which are typically far more expensive than conventional drugs. The Department of Health and Human Services found that biologics accounted for only "5% of prescriptions in the U.S." in 2024 but "51% of total drug spending." HHS, *Fact Sheet:*

[1] Unless otherwise specified, all internal quotation marks, emphases, alterations, and citations are omitted from quotations throughout this brief.

Bringing Lower-Cost Biosimilar Drugs to American Patients (2025), perma.cc/9PSJ-2Y79. HHS also found that the price of biosimilars is "on average 50% less" than the price for the brand-name biologic before facing any biosimilar competition. *Id.*

B. Factual background

1. J&J's monopoly on the market for ustekinumab

In 2009, J&J launched a biologic drug called ustekinumab, sold under the brand-name Stelara. JA2. Ustekinumab targets two proteins that activate the human body's inflammation response to infection. JA736-738. Some people overproduce those proteins, leading to disorders in which the immune system attacks healthy tissue. JA736-738. By 2016, the FDA had approved Stelara to treat three conditions: plaque psoriasis, psoriatic arthritis, and Crohn's disease. JA2633-2635.

From 2009 until 2024, J&J was the sole U.S. supplier of ustekinumab. JA2. While the BPCIA generally allows the FDA to begin licensing biosimilars 12 years after approving a new biologic, *see Sandoz*, 582 U.S. at 7, J&J enjoyed an even longer period of exclusivity by obtaining a patent on ustekinumab—U.S. Patent No. 6,902,734 (the '734 patent). The '734 patent gave J&J the exclusive right to make, use, and sell ustekinumab in the United States until the patent expired on September 25, 2023. JA2. [redacted]

[redacted] The overwhelming patient need for the drug made Stelara J&J's best-selling product from at least 2019 to 2023, with annual sales growing from $4.3 billion to $7.0 billion in the U.S. alone. JA828-830. [redacted]

2. J&J's multi-pronged scheme to prolong its monopoly

For years, J&J schemed to prolong its monopoly over the ustekinumab market *after* the loss-of-exclusivity date. The scheme had two main parts: (1) acquiring a patent portfolio of biosimilar technologies as a part of J&J's acquisition of a biosimilar company, Momenta, and (2) defrauding the PTO into issuing a new patent with a later expiration date. J&J then used the patents it wrongfully acquired to prevent competition from biosimilars.

The Momenta manufacturing patents. Momenta was founded as a biotechnology startup "focused on developing biosimilar" versions of existing drugs. JA239. As part of that focus, Momenta developed and patented technologies useful for "creat[ing] biosimilar copies of biologic drugs." JA5. Four of those patents claimed technologies that make it easier to produce near-identical copies of monoclonal antibodies, like ustekinumab. JA746-753; *see* JA5 (listing the four patents

and explaining that they "relate[] to cell culture media used in the manufacturing process of biologic drugs"). Those four patents are primarily useful for making biosimilar versions of already-known biologics, like Stelara. JA754-755, JA778-786.

In 2019, J&J began exploring whether to acquire Momenta and its patent portfolio. JA5. J&J wished to acquire a specific biologic (nipocalimab) that Momenta was developing, and J&J internally attributed 95% of the value of the deal to that drug. JA5. But the acquisition would also give J&J ownership of Momenta's entire portfolio of over 500 patents—including the four Momenta manufacturing patents described above. JA5. [redacted] acquiring the Momenta manufacturing patents would allow J&J to prevent anyone *else* from using Momenta's biosimilar-facilitating inventions to develop ustekinumab biosimilars that would compete with Stelara.

It is undisputed that J&J knew it was acquiring the Momenta manufacturing patents in the merger. JA5. The relevant four patents were all identified in lists incorporated into the draft and final merger agreements. JA5; *see* JA3457, JA3504, JA3543, JA3614-3615, JA3381-3391. J&J executed the merger agreement in August 2020, and the merger closed in October 2020. JA5-6.

Before the acquisition closed—as J&J's Global Head of IP Litigation, Denise DeFranco, [redacted]

[redacted] *see* JA5.

Since the 2020 acquisition, J&J has never used the Momenta manufacturing patents for any commercial purpose *except* to assert them in actual or threatened patent-infringement litigation against biosimilar competitors to Stelara, as described below (at 13-15). JA3852, JA789, JA2112.

The '307 patent. To further entrench its monopoly after the September 2023 expiration of the '734 patent, J&J defrauded the PTO into issuing a new patent with an expiration date in 2039—U.S. Patent No. 10,961,307 (the '307 patent)—which claimed the use of ustekinumab to treat ulcerative colitis. JA1242, JA2, JA4. In prosecuting this patent, J&J deliberately withheld from the PTO information that it had submitted to the FDA four years earlier, showing that J&J's supposed invention was obvious—and therefore unpatentable—based on what was already known about ustekinumab, ulcerative colitis, and Crohn's disease.

[redacted] The FDA's approval process can take years and generally requires three phases of clinical trials, JA1316, [redacted]

[redacted]

J&J laid all of this out for the FDA again in its 2016 clinical trial protocol—a blueprint for its proposed trial. *See* JA1476, JA1493-1494, JA1509, JA1585. Persuaded of the trial's likely success, the FDA approved J&J's direct-to-phase-3 approach and later approved Stelara as a treatment for ulcerative colitis. JA2291-2292, JA569, JA714.

In 2018, J&J employees used the clinical trial protocol and other clinical trial documents to draft the application that led to the '307 patent, copying verbatim large sections of the clinical documents into the application's background section. But they specifically *deleted* the passages where J&J scientists had told the FDA that they expected the direct-to-phase-3 trial to be successful—*i.e.*, their reasonable expectation that ustekinumab would work to treat ulcerative colitis. The patent application drafters also deleted citations to scientific studies supporting that expectation of success. *Compare* JA1610-1613 (provisional patent application), *with* JA1476, JA1493-1494, JA1509, JA1585 (clinical trial protocol); *see also* JA1713-1735 (showing differences between the materials submitted to the FDA and those

submitted to the PTO). And they falsely told the PTO that "no studies had been conducted with ustekinumab for [ulcerative colitis]," JA1612, despite J&J's knowledge that a researcher had published a study in 2018 finding that the precise dosage of ustekinumab claimed in the patent application successfully treated several patients' ulcerative colitis. JA1236-1238 (Ochsenkühn study), JA38.

The patent examiner initially rejected J&J's application. JA1381-1387. The examiner found some public information about J&J's direct-to-phase-3 clinical trial on a government website (clinicaltrials.gov), despite J&J's failure to bring any information about that trial to the examiner's attention. JA1386, JA1388. The examiner concluded that the website page rendered J&J's supposed invention unpatentable as both "anticipated" and "obvious." JA1386; *see* 35 U.S.C. §§ 102-103 (novelty and non-obviousness requirements for patentability).

To overcome the rejection, one of the application drafters—J&J's patent agent, Eric Dichter—followed up with the examiner. JA1426. Dichter argued that the mere fact of the ongoing clinical trial did "not anticipate or render obvious" the use of ustekinumab to treat ulcerative colitis because clinical trials are "uncertain[]" and often "fail[]." JA1427; *see also* JA1396 (examiner summarizing Dichter as having explained that "it would not have been obvious" that the trial would succeed). But Dichter didn't tell the examiner that J&J had made a very different representation to the FDA—arguing that *this particular* clinical trial was likely to succeed given what

was already known about ustekinumab, ulcerative colitis, and Crohn's disease. After meeting with Dichter, the examiner granted the application. JA1378, JA1430, JA1243.

3. J&J's exclusion of competitors from the market

J&J wasted no time in deploying the '307 and Momenta patents to block potential rivals to Stelara. In November 2022, Amgen notified J&J that it intended to launch an ustekinumab biosimilar in May 2023, upon expected FDA approval. JA6. J&J responded by suing Amgen for infringing the soon-to-expire '734 patent and the just-issued '307 patent. JA6; *see* JA1241. [redacted] J&J then relied on two of the Momenta patents—and only those patents—to move for a preliminary injunction to block Amgen from entering the market. JA3720-3724.

While that motion was pending, J&J and Amgen entered into a settlement under which Amgen agreed not to sell its ustekinumab biosimilar until January 1, 2025, in exchange for J&J's agreement to grant Amgen a license to all the patents J&J had asserted in the litigation. JA6.

J&J successfully deployed similar tactics against six other companies seeking to sell ustekinumab biosimilars. JA6-7. J&J used the threat of litigation to compel the companies to delay their market entry in exchange for licenses to the '307 and

Momenta patents. JA6-7, JA3984-3985. The settlements prohibited J&J's competitors from launching their biosimilars until various dates within the first half of 2025. JA6-7; *see* JA3669-3670, JA3677-3679, JA3681-3682.

The '734 patent on ustekinumab expired on September 25, 2023. JA2. But by wielding the '307 and Momenta patents against its rivals, J&J cleared the field of any biosimilar competition for Stelara until January 2025—an additional 15 months of exclusivity, in which J&J was able to continue to charge supra-competitive prices for the drug. *See* JA6-7, JA47-48.

4. Market entry by biosimilar competitors

When J&J finally faced biosimilar competition for Stelara, the price it was able to charge for the drug plummeted. Before Amgen's biosimilar entered the market, J&J sold Stelara at a sticker (list) price of [redacted] per syringe. JA2696. Amgen's initial sticker price for its ustekinumab was [redacted]. JA2839. As more competitors entered the market in the following months, [redacted]

C. Procedural background

1. CareFirst's Sherman Act claims

CareFirst brought this class action against J&J in the Eastern District of Virginia, alleging violations of Section 2 of the Sherman Act, 15 U.S.C. § 2, and various state laws. JA235, JA240-241. CareFirst alleged that J&J had "implemented a scheme to unlawfully prolong its patent protection, and therefore its monopoly, over ustekinumab," beyond the expiration of the '734 patent. JA1784-1785. The monopolization scheme was accomplished through both J&J's acquisition of the Momenta manufacturing patents and J&J's fraud on the PTO in procuring the '307 patent. JA1785-1787, JA1824-1888. CareFirst alleged that J&J's scheme cost ustekinumab purchasers billions due to the higher prices that J&J was able to charge in the absence of competition. JA1881-1886.

In August 2024, the district court largely denied J&J's motion to dismiss. JA235-305. The court explained that a monopolization claim under Section 2 requires proving that the defendant had "monopoly power … in the relevant market" and that the defendant engaged in "anticompetitive or exclusionary conduct." JA242. "Simply put," the court observed, "a § 2 violation has two elements: power and conduct." JA242.[2] And the court found both of CareFirst's theories valid.

[2] For a private plaintiff to recover for injuries caused by an unlawful monopoly, the plaintiff must also show "antitrust injury." *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 109-11 (1986).

First, the district court explained that "the acquisition of patents can constitute an antitrust violation." JA262. When a firm already has monopoly power and "acquire[s] exclusive rights in a patent related to the subject matter" of its existing monopoly, the patent acquisition itself "can constitute anticompetitive conduct." JA267 (citing 14 Phillip Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 707a (5th ed. 2026) (Areeda & Hovenkamp)). The court found CareFirst's allegations of such conduct plausible, based on four sets of allegations: (1) that J&J was a monopolist; (2) that J&J acquired exclusive rights to patents covering "some of the processes used to make biosimilars," (3) that J&J was not a "biosimilar producer[]," and (4) that J&J "asserted the acquired patents in subsequent litigation." JA267.

Second, the district court recognized that a monopolist "is not shielded from antitrust liability" when it enforces a patent it "obtained … through fraud." JA246 (citing *Walker Process*, 382 U.S. at 177). To prove "*Walker Process* fraud," the district court explained, "requires a showing that the patentee obtained their patent by knowingly and willfully misrepresenting facts to the PTO." JA246. The district court found that the complaint plausibly alleged that J&J committed *Walker Process* fraud in obtaining the '307 patent. JA255-261.[3]

[3] In its motion-to-dismiss decision, the district court initially cabined CareFirst's *Walker Process* theory based on an allegation in the then-operative

2. Summary judgment

In December 2025, the district court certified a class with respect to CareFirst's Sherman Act claims and parallel state-law antitrust claims. JA2272. Later that month, on cross-motions for summary judgment, the district court found triable issues of fact on J&J's market power and CareFirst's antitrust injury, JA9-25, JA45-48—two of the three elements of a private party's monopolization claim.

As to anticompetitive conduct, the court separated the alleged scheme into distinct components. For the acquisition of the Momenta patents, it imposed a new intent requirement—advanced by neither party—that had to be satisfied at the moment J&J acquired title to the patents. JA39-41. The court held that a monopolization claim requires proof not only of anticompetitive conduct, but also that the monopolist "*intended* to 'exclude rivals on some basis other than efficiency.'" JA40 (emphasis added) (quoting *2311 Racing LLC v. Nat'l Ass'n for Stock Car Auto Racing, LLC*, 139 F.4th 404, 410 (4th Cir. 2025)). The court acknowledged that its standard was "inconsistent with Supreme Court precedent," under which proof of the monopolist's intent to exclude rivals is "certainly not required." JA40 n.19. The

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complaint that the patent examiner had reviewed the clinical trial protocol. JA257. But the court later allowed CareFirst to amend its complaint to allege that the examiner did not review the protocol itself but rather a government website that lacked key disclosures contained in the protocol. JA28, JA1834-1836, JA1838-1840.

district court nonetheless considered itself bound to apply a specific-intent requirement based on this Court's decision in *2311 Racing*. JA40.

Initially, the district court found that CareFirst had presented sufficient evidence to reach the jury even under the court's specific-intent requirement. JA42-45. The court relied in part on a privilege log that J&J had produced during discovery, which the court understood to show that Ms. DeFranco had "an email with the subject/file name" of one of the Momenta manufacturing patents in "June 2020." JA44. The court also noted that the relevant patents "were listed in the draft and executed merger agreement"; DeFranco had admitted that J&J's "pre-litigation diligence" regarding potential biosimilar competitors had begun around the time of the Momenta acquisition; and DeFranco acknowledged receiving a list of the patents in 2020, though she claimed not to have "look[ed] at" or "stud[ied]" them. JA43-44.

With respect to *Walker Process* fraud, the district court denied J&J's request for summary judgment but narrowed the scope of the fraud theory that CareFirst could present to the jury. JA26-39. The court agreed with CareFirst that a reasonable jury could conclude that J&J employees deliberately withheld the Ochsenkühn study from the PTO with the specific intent to deceive the examiner and that the study was material. JA37-38. The court likewise found that a reasonable jury could conclude that J&J employees committed fraud in falsely stating that "no studies had been conducted with ustekinumab for [ulcerative colitis]." JA29-30, JA38-39.

Nonetheless, the court refused to allow CareFirst to proceed to trial on the theory that J&J's decision to withhold from the PTO information it had submitted to the FDA constituted fraud. JA32-34. And the court rejected CareFirst's related theory that it was deceptive to tell the PTO that ustekinumab's efficacy in treating ulcerative colitis was novel and uncertain after assuring the FDA that it was "reasonable" to assume that ustekinumab would be effective in treating ulcerative colitis. JA27-29. The court took the view that whether J&J lied to the examiner about the clinical trial's likelihood of success was irrelevant because the examiner had "the fact of and details about" the clinical trial before him (via the clinicaltrials.gov website) and thus could assess the truth of J&J's statements for himself. JA29. And the court concluded that J&J's omission of the full clinical trial protocol was immaterial in light of information contained in the patent's specification and on the clinicaltrials.gov website. JA32-33.

3. Reconsideration and final judgment

The upshot of the district court's summary-judgment decision was that the case could proceed to trial on both the Momenta and *Walker Process* aspects of the monopolization scheme. JA48-49. But a few weeks later, J&J filed a motion for reconsideration. JA4383. J&J argued that the court's prior decision had been based on a misapprehension of the privilege log and that the admissible evidence failed to

create any genuine issue of material fact about J&J's specific intent to exclude rivals at the time it acquired the Momenta manufacturing patents. JA4401-4402.

The district court granted J&J's motion in relevant part and entered summary judgment for J&J with respect to any liability based on its acquisition of the Momenta manufacturing patents. JA74. On reconsideration, the court found that the privilege log on which it had relied showed only that DeFranco had received an email in 2023 that attached a PDF of the patent that had itself been created or last edited in 2020. *See* JA59-61.[4] The court also concluded that the subject matter of certain entries on J&J's privilege log would not be admissible into evidence and that, without those entries, CareFirst's other evidence was insufficient to create a genuine dispute of material fact under the court's specific-intent standard. JA60-69.

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[4] The court stated that an exhibit CareFirst submitted had "misled the Court" into believing that the privilege log showed that DeFranco "possessed" a copy of one of the Momenta manufacturing patents in 2020. JA60 & n.10. In J&J's privilege log, emails and their attachments were listed on separate lines of a spreadsheet but identified as belonging together in "families." *See* JA4072, JA4236-4239. [redacted] CareFirst relied on the privilege log excerpt to argue [redacted] CareFirst acknowledged in a sur-reply that [redacted] CareFirst continued to argue, however, that a reasonable jury could infer from [redacted] Accordingly, the complete briefing before the district court made clear that CareFirst was arguing about reasonable inferences from the log and other evidence, not seeking to mislead the court about the log itself.

CareFirst then filed its own motion for reconsideration. JA4438. CareFirst explained that there was sufficient evidence to satisfy the district court's novel specific-intent requirement, which CareFirst had not submitted at summary judgment because neither party had been advocating for the specific-intent standard. JA4442-4447. For example, CareFirst proffered evidence that in July 2020, Momenta directed J&J to a "virtual data room" that contained an [redacted] *see* JA4423, JA4413-4428. J&J also reviewed [redacted] *see* JA4435-4437. The district court declined to consider CareFirst's additional evidence and denied CareFirst's motion. JA79.

After the district court's reconsideration orders, the parties jointly requested that the court enter final judgment for J&J because, as CareFirst had acknowledged in prior briefing, the antitrust claims could not succeed without the Momenta aspect of the monopolization scheme. *See* JA2273-2274. The court entered final judgment on February 11, 2026. JA81-84.

SUMMARY OF ARGUMENT

I. The district court erred in holding that a monopolization claim requires proof that the defendant acted with intent to exclude competitors from the market.

A. Section 2 of the Sherman Act makes it unlawful to "monopolize" or "attempt to monopolize" a market in interstate commerce. 15 U.S.C. § 2. Although a plaintiff seeking to prevail on a theory of *attempted* monopolization must show that the monopolist acted with the specific intent to harm competition, the "textbook rule" of antitrust law is that "only general intent is required to establish" *completed* monopolization. 2 Earl W. Kintner et al., *Federal Antitrust Law* § 16.17 (2025). A plaintiff asserting a monopolization claim need not show that the monopolist specifically intended its conduct to have anticompetitive effects. It is sufficient that such effects were in fact the "consequence of [the] defendant's conduct." *United States v. Griffith*, 334 U.S. 100, 105 (1948). That understanding of the Sherman Act is deeply rooted in Supreme Court precedent, and this Court has long adhered to it.

B. The district court erroneously held that J&J could be found liable for monopolization only if the company "intended to exclude rivals on some basis other than efficiency." JA40. The court acknowledged that its approach was "inconsistent with Supreme Court precedent." JA40 n.19. But it thought that this Court's decision in *2311 Racing LLC v. National Association for Stock Car Auto Racing, LLC*, 139 F.4th 404 (4th Cir. 2025), required it to apply a specific-intent standard. That was error. *2311*

Racing did not announce a new specific-intent requirement. The district court wrongly seized on a single sentence in that opinion, which referred in passing to "inten[t] to exclude" but did not purport to require proof of specific intent in all monopolization cases. The defendant's intent was not even at issue *2311 Racing*. And under the prior-panel rule, *2311 Racing* could not overrule prior decisions recognizing that monopolization is a general-intent offense.

C. This Court should reverse and remand for trial. Under the correct legal standard, a reasonable jury could find that J&J acted with general intent when it knowingly acquired the Momenta manufacturing patents. Contrary to J&J's contentions below, CareFirst does not also need to prove that J&J was aware of the substance of the patents before acquiring them. Nor should the inquiry be focused solely on the moment of the acquisition. J&J engaged in a years-long monopolization scheme that must be viewed as a whole: J&J knowingly bought the patents, held onto them, and used them to exclude biosimilar rivals from the market. Accepting J&J's contrary approach would harm competition and invite gamesmanship by monopolists regarding attorney-client privilege, as this case illustrates.

II. The district court further erred in narrowing the scope of J&J's *Walker Process* fraud that the jury will be allowed to consider.

A. *In Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), the Supreme Court held that a monopolist may be held liable under the

Sherman Act if it uses a patent obtained by fraud to harm competition. To prove *Walker Process* fraud, a plaintiff must show that the defendant made a material misrepresentation or omission to the PTO with the intent to deceive.

B. A reasonable jury could conclude that several of J&J's omissions and affirmative misstatements meet the *Walker Process* fraud standard.

In its 2016 protocol for the clinical trial testing ustekinumab's efficacy in treating ulcerative colitis, J&J told the FDA that the available science made it "reasonable to assume" that the drug would be effective for that purpose. JA1509. Two years later, it told the PTO the opposite, and it never disclosed its prior representations to the FDA. A reasonable jury could conclude that those related misstatements and omissions were material. The examiner recognized that the clinical trial's likelihood of success was the key to patentability. Had J&J told the PTO what it told the FDA, the PTO would have denied the patent application.

A reasonable jury could also conclude that J&J acted with the specific intent to deceive the PTO. J&J knew that its trial was likely to succeed and leveraged that fact before the FDA to expedite its trial. But it took the opposite position before the PTO. J&J has offered no explanation for this about-face other than its desire to convince the PTO to grant its patent application.

C. The district court granted summary judgment to J&J as to these statements and omissions because it thought they were not material. In so doing, the district court resolved a series of factual disputes that should have gone to a jury.

STANDARD OF REVIEW

This Court "review[s] the district court's grant of summary judgment *de novo*," applying the same legal standards and "constru[ing] all facts and reasonable inferences in the light most favorable to the nonmoving party." *Wannamaker-Amos v. Purem Novi, Inc.*, 126 F.4th 244, 254 (4th Cir. 2025).

ARGUMENT

I. The district court erred in holding that a monopolization claim requires proof that the defendant acted with specific intent to exclude competitors from the market.

The district court's fundamental error at summary judgment was to impose a specific-intent requirement that has no basis in law. The Supreme Court has long held that the Sherman Act prohibits a monopolist from engaging in anticompetitive conduct even absent proof that the monopolist specifically intended to, in the district court's words, "exclude rivals on some basis other than efficiency." JA40. The dispositive issue is the monopolist's conduct and its effect on competition, not the monopolist's good or bad intentions.

The district court acknowledged those principles in a footnote but nonetheless concluded that it was bound to apply a specific-intent requirement under this Court's

decision in *2311 Racing LLC v. National Ass'n for Stock Car Auto Racing, LLC*, 139 F.4th 404 (4th Cir. 2025). That decision had nothing to do with intent and does not support the district court's express departure from Supreme Court precedent. Under the correct legal standard, a reasonable jury could find that J&J's acquisition of the Momenta manufacturing patents was anticompetitive and, indeed, an integral step in J&J's scheme to maintain its monopoly over the U.S. market for ustekinumab.

A. Monopolization is not a specific-intent offense.

1. Section 2 of the Sherman Act makes it unlawful to "monopolize" or "attempt to monopolize" a market in interstate commerce. 15 U.S.C. § 2. The offense of monopolization has two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966); *accord Duke Energy Carolinas, LLC v. NTE Carolinas II, LLC*, 111 F.4th 337, 353 (4th Cir. 2024). The conduct element requires proof that a monopolist abused its market power "to foreclose competition, to gain a competitive advantage, or to destroy a competitor." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 482-83 (1992). But it does *not* require proof that the monopolist specifically intended that its conduct have those harmful effects.

Instead, the "[t]he textbook rule of antitrust law is that only general intent is required to establish monopolization." 2 Earl W. Kintner et al., *Federal Antitrust Law* § 16.17 (2025) (Kintner). And "general intent," in this context, means that the monopolist acted with "intent to perform the exclusionary acts." *Id.* So long as the monopolist intended to do the anticompetitive acts at issue, no further "showing of unlawful intent is necessary." 14 Areeda & Hovenkamp ¶ 805a. Thus, "absent some anomalous accident or involuntary spasm of industrial consequence," a monopolist cannot escape liability for its anticompetitive conduct by claiming "good faith" or lack of bad intentions. *United Food & Com. Workers Local 1776 v. Takeda Pharm. Co.* (*UFCW Local*), 11 F.4th 118, 137 (2d Cir. 2021).

By contrast, the offense of *attempted* monopolization requires proof that the defendant acted with "specific intent to monopolize" the relevant market. *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 459 (1993). The differing mental states required for the two offenses reflect a fundamental distinction under the Sherman Act. Proof of specific intent is required in attempted monopolization cases because in those cases the harm to competition has not yet occurred and may never occur. *See, e.g.*, *Swift & Co. v. United States*, 196 U.S. 375, 396 (1905). That is not true for *completed* monopolization cases, which require proof that the defendant actually harmed competition. *Grinnell Corp.*, 384 U.S. at 570. Whether the defendant specifically intended that harm makes no difference once the harm has occurred and

competition has suffered—just as a party's "good intention" cannot "save an otherwise objectionable" restraint of trade. *Bd. of Trade of City of Chi. v. United States*, 246 U.S. 231, 238 (1918). The "critical point" in monopolization cases is "the nature and consequences" of the monopolist's conduct, "not the purpose or intent" behind it. 14 Areeda & Hovenkamp ¶ 651c.

2. Those principles are deeply rooted in Supreme Court precedent. The Court first linked the specific-intent requirement to attempted monopolization in *Swift & Co. v. United States*, *supra*, which was decided within the first two decades of the Sherman Act's existence. In *United States v. Aluminum Co. of America* (*Alcoa*), 148 F.2d 416 (2d Cir. 1945), Judge Hand reviewed *Swift* and drew from it that proof of "specific intent" is *not* required for the completed offense of monopolization. *Id.* at 432. For the completed offense, the only intent a plaintiff must prove is general intent: "the mere intent to do the act." *Id.* The general-intent standard is not difficult to satisfy in most monopolization cases because, in Judge Hand's memorable formulation, "no monopolist monopolizes unconscious of what he is doing." *Id.*

The Supreme Court endorsed that understanding of the Sherman Act three years later in *United States v. Griffith*, 334 U.S. 100, 105 (1948), *abrogated on other grounds by Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752 (1984). Quoting *Alcoa*, the Supreme Court held that "[i]t is … not always necessary to find a specific intent to restrain trade" to find monopolization. *Id.* Instead, it is "sufficient that a … monopoly results

as the consequence of a defendant's conduct." *Id.*; *see United States v. Paramount Pictures*, 334 U.S. 131, 173 (1948) ("specific intent is not necessary"); *United States v. United Shoe Mach. Corp.*, 110 F. Supp. 295, 346 (D. Mass. 1953) ("Defendant having willed the means, has willed the end."), *aff'd*, 347 U.S. 521 (1954) (per curiam).

In *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), the Supreme Court once again confirmed that monopolization is not a specific-intent offense. The Court reiterated that attempted monopolization requires proof of "specific intent to accomplish the forbidden objective." *Id.* at 602. But for the completed offense, the Court explained, "evidence of intent is merely relevant," insofar as it can help show that the monopolist's acts were "exclusionary or anticompetitive." *Id.* So long as the monopolist's conduct is shown to be anticompetitive in its effects, however, proof of intent is not required. As far as the Sherman Act is concerned, "[i]mproper exclusion (exclusion not the result of superior efficiency) is always deliberately intended." *Id.* at 603 (quoting Robert Bork, *The Antitrust Paradox* 160 (1978)).

3. Given the clarity of the Supreme Court's precedent, it should come as no surprise that this Court and its sister circuits have repeatedly recognized that the offense of monopolization does not require proof of specific intent. The leading case in this circuit is *Greenville Publishing Co. v. Daily Reflector, Inc.*, 496 F.2d 391 (4th Cir. 1974). The Court observed there that certain evidence in the record was relevant to proving

"either the *specific intent* required to prove an illegal *attempt* to monopolize or the *general intent* which, accompanied by monopoly power, constitutes the offense of *monopolization*." *Id.* at 396 (emphases added). Although brief, that discussion confirms that proof of "specific intent" is required only in attempt cases, and that proof of "general intent" is sufficient in monopolization cases. *Id.*

This Court has adhered to that distinction ever since, observing just last year that proof of a civil violation of the Sherman Act can be based on "proof of an anticompetitive effect," "without proof of intent." *Williams v. Martorello*, 143 F.4th 555, 569 n.8 (4th Cir. 2025); *see M&M Med. Supplies & Serv., Inc. v. Pleasant Valley Hosp., Inc.*, 981 F.2d 160, 166 (4th Cir. 1992) (en banc) (identifying "specific intent" as an element of "attempted monopolization"); *id.* at 172-73 (Luttig, J., dissenting) (agreeing on that point and explaining that, in contrast to a monopolization claim, attempted monopolization requires more than "[m]ere proof of an intent to do the act").

Other circuits uniformly follow the same rule. The Second Circuit recently confirmed that the only proof of intent required for a monopolization claim is the "mere intent to do the act," *i.e.*, general intent. *UFCW Local*, 11 F.4th at 137 (quoting *Alcoa*, 148 F.2d at 432). The Third Circuit too has held that specific intent "is not an element" of monopolization. *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 263 (3d Cir. 2017). And in its epochal case about Microsoft's browser monopoly, the en banc D.C. Circuit confirmed that specific intent is not required: "Evidence of the intent behind

the conduct of a monopolist is relevant only to the extent it helps us understand the likely effect of the monopolist's conduct." *United States v. Microsoft Corp.*, 253 F.3d 34, 59 (D.C. Cir. 2001) (en banc); *see also Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 893 n.3 (9th Cir. 2008); *Dimmitt Agri Indus., Inc. v. CPC Int'l Inc.*, 679 F.2d 516, 531-32 (5th Cir. 1982).

The leading treatises all reflect the same understanding—that proof of the monopolist's intent to harm competition is not required to prove monopolization. *See* 14 Areeda & Hovenkamp ¶¶ 651c, 805a; Kintner § 16.17; 2 Julian O. von Kalinowski et al., *Antitrust Laws and Trade Regulation* § 25.04[3] & n.33 (2d ed. 2026); ABA, Antitrust Law Section, *Monopolization and Dominance Handbook* § IV.A.3 (2d ed. 2021).

B. The district court misread *2311 Racing*.

The district court adopted a specific-intent requirement that cannot be squared with the longstanding precedent of the Supreme Court and this Court. The district court held that J&J could be found liable for monopolization only if J&J "intended to 'exclude rivals on some basis other than efficiency.'" JA40 (quoting *2311 Racing*, 139 F.4th at 410). The court acknowledged that neither party had advocated for that standard. JA39-40. And it recognized that this approach was "inconsistent with Supreme Court precedent," under which proof of the monopolist's specific

intent is "certainly not required." JA40 n.19.[5] But the court nonetheless asserted that it was duty-bound to apply this Court's "most recent, and thus controlling, articulation of the willfulness standard" in *2311 Racing*. JA40.

The district court was wrong to attribute its own legal error to this Court, which did not adopt a specific-intent requirement in *2311 Racing*. In that case, two stockcar racing teams sued NASCAR on the theory that NASCAR is an illegal monopoly, yet they also sought to participate in NASCAR races while the litigation was ongoing. 139 F.4th at 407-08. As a condition of participation, NASCAR required them to sign a release of liability covering their antitrust claims. The district court granted a preliminary injunction ordering NASCAR to allow them to participate without releasing their claims. *See id.* On appeal, this Court vacated the injunction—for reasons having nothing to do with intent. Instead, as the Court explained, the injunction was improper because the plaintiffs had not shown that they were likely to succeed on the novel theory that the liability release was itself "anticompetitive conduct." *Id.* at 409; *see id.* at 409-11.

NASCAR's intent was not at issue on appeal in *2311 Racing*. In passing, however, this Court observed that "Section 2 requires that the defendant have

[5] Even as it correctly recognized that it was departing from Supreme Court precedent, the district court misdescribed that precedent—reciting the standards the Supreme Court has used in Section 1 cases (not Section 2 monopoly cases) to distinguish between practices that are "*per se* illegal" and those that are subject to a "rule of reason analysis." JA40 n.19.

engaged in anticompetitive conduct—*i.e.*, conduct intended to 'exclude rivals on some basis other than efficiency.'" *Id.* at 410 (quoting *Aspen Skiing*, 472 U.S. at 605). The district court here wrongly seized on two words in that statement—"conduct intended"—to impose its specific-intent requirement. But the portion of *Aspen Skiing* that this Court was quoting in *2311 Racing* makes the unremarkable point that intentionally exclusionary conduct *can* be a violation: "If a firm has been attempting to exclude rivals on some basis other than efficiency, it is fair to characterize its behavior as predatory." 472 U.S. at 605. That observation was couched in terms of *attempted* monopolization ("attempting to exclude rivals") and follows the Supreme Court's earlier discussion explicitly distinguishing between the intent required for completed monopolization ("mere intent to do the act") and attempted monopolization ("specific intent"). *Id.* at 602-03, 605. *Aspen Skiing* makes abundantly clear that proof of anticompetitive intent is "merely relevant," not invariably required, to prove the completed offense of monopolization. *Id.* at 602.

The district court offered no good reason to read this Court's passing reference to "intent" in *2311 Racing* as departing from the very Supreme Court precedent this Court was quoting. And nothing else about *2311 Racing* suggests that this Court intended to adopt a novel specific-intent requirement for monopolization claims, in conflict with other circuits and the Supreme Court (*see supra* 25-31).

The district court's misreading of *2311 Racing* also fails to give effect to the principle that a panel of this court may not "overrule another panel." *Payne v. Taslimi*, 998 F.3d 648, 654 (4th Cir. 2021). When faced with a single, ambiguous reference to "inten[t] to exclude" in *2311 Racing*, the district court should have adhered to the prior panel decision in *Greenville Publishing*, *supra*, as well as the decades of Supreme Court precedent on this precise point.[6]

Finally, even if the issue were up for debate, it would be unsound as a matter of antitrust law and policy to require proof of specific intent in monopolization cases. Requiring proof of specific intent would allow a monopolist who *in fact* harms competition to nonetheless escape liability by claiming "benign intent," *UFCW Local*, 11 F.4th at 137, or by hiding its true intent. *See* Richard Posner, *Antitrust Law* 214-15 (2d ed. 2001) (explaining that a "firm with executives sensitized to antitrust problems will not leave any documentary trail of improper intent"). That is why the Supreme Court has recognized that requiring proof of specific intent in monopolization cases would "cripple" the Sherman Act. *Griffith*, 334 U.S. at 105.

[6] Although the district court did not rely on them, other decisions of this Court also refer to a monopolist's intent to exclude rivals. *See Duke Energy*, 111 F.4th at 353 ("conduct intended to exclude rivals"); *Cavalier Tel., LLC v. Verizon Va., Inc.*, 330 F.3d 176, 183 (4th Cir. 2003) (similar). But like *2311 Racing*, none of those decisions adopted a requirement for proof of specific intent in all monopolization cases.

C. This Court should reverse and remand for trial with respect to the Momenta manufacturing patents.

The district court's legal error on the intent standard was the sole basis for its entry of judgment in favor of J&J with respect to the Momenta manufacturing patents. *See* JA69, JA81-82. For all the reasons discussed above, proof of J&J's specific "intent to exclude rivals on some basis other than efficiency," JA68, is not an element of a monopolization claim. The purported absence of such proof is therefore not a proper basis for summary judgment. This Court should reverse the judgment with respect to the Momenta manufacturing patents and remand for trial on CareFirst's Sherman Act claim and corresponding state law claims. Viewed in the light most favorable to CareFirst, the evidence is more than sufficient for a reasonable jury to conclude that J&J acted with "general intent," *Greenville Publ'g*, 496 F.2d at 396, and that its conduct was anticompetitive.

1. The relevant conduct for this aspect of J&J's monopolization scheme was its acquisition of the four Momenta manufacturing patents, which it then used to maintain its monopoly over the ustekinumab market even after the September 2023 loss-of-exclusivity date. As the district court recognized, a monopolist's "enforcement and acquisition of patents are 'not immune from antitrust laws.'" JA245 (quoting *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1205 (2d Cir. 1981)); *see United States v. Singer Mfg. Co.*, 374 U.S. 174, 193-95 (1963); JA262-266 (citing additional case law). Under the established theory on which CareFirst relies, a plaintiff can prove a prima facie

monopolization violation by showing that a monopolist acquired "exclusive rights in related patents" with the anticompetitive effect of "increas[ing] or prolong[ing] the monopolist's market power." 14 Areeda & Hovenkamp ¶ 707a; *cf. SCM Corp.*, 645 F.2d at 1207-09; *Image Tech. Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1216 (9th Cir. 1997).

A reasonable jury could find each of those requirements satisfied. J&J had a monopoly over the U.S. market for ustekinumab when it acquired the Momenta manufacturing patents. Those patents cover technologies related to the market J&J had already monopolized because they are primarily useful for making biosimilar copies of already-known biologics, such as Stelara. J&J was not in the business of making biosimilars, but it nonetheless retained the Momenta manufacturing patents. And when the '734 patent expired, J&J used the Momenta manufacturing patents to delay biosimilar entry for another 15 months, costing purchasers of ustekinumab billions of dollars in the form of supra-competitive prices. *See supra* 8-10, 14. The patent acquisition therefore had the anticompetitive effect of prolonging J&J's monopoly beyond the period of exclusivity allowed by the '734 patent.

J&J is free to dispute those facts at trial and to argue that it had procompetitive justifications for the patent acquisition. *See* 14 Areeda & Hovenkamp ¶ 707f. But the district court erred in inventing its own specific-intent requirement and then relying on that requirement to derail the case before it could reach a jury.

2. J&J had the requisite "intent to do the act" for monopolization liability. *Aspen Skiing*, 472 U.S. at 602. A reasonable jury could find general intent because J&J knew it was acquiring the Momenta manufacturing patents as part of the Momenta deal and then kept them until asserting the patents to keep biosimilar rivals out of the market. The patent acquisition was not some "anomalous accident." *UFCW Local*, 11 F.4th at 137. J&J knew before it purchased Momenta that it was acquiring all of Momenta's patents as part of the deal.

Before J&J acquired Momenta, it reviewed a draft merger agreement that disclosed all the patents that J&J would acquire in the deal, including the four Momenta manufacturing patents that J&J later used to exclude biosimilar rivals to Stelara. *See* JA5 (undisputed fact ¶ 17). And Momenta gave J&J access to [redacted] *Supra* 21.[7]

3. J&J argued below that it could not be held liable for the anticompetitive effects of its patent acquisition unless CareFirst could prove that [redacted]

[7] The district court declined to consider any of the new evidence as a basis for reconsideration. JA78-79. Nonetheless, the proffered evidence would be relevant and admissible at trial.

[redacted] Section 2 requires neither showing.

First, again, the completed monopolization offense requires proof only of J&J's general intent to engage in conduct that is shown to have anticompetitive effects. *See, e.g.*, *Paramount Pictures*, 334 U.S. at 173 ("[T]he requisite 'purpose or intent' is present if monopoly results as a necessary consequence of what was done."). The general-intent standard is satisfied when a firm knowingly acquires patents, even if the firm is not aware of the substance of the patents—just as a person who buys a book does so with the general intent to acquire the book, even if she hasn't cracked the cover. The acquisition is deliberate, not accidental.

Second, focusing myopically on J&J's knowledge of the substance of the patents at the precise moment of their acquisition disregards the "foundational" principle of antitrust law "that alleged anticompetitive conduct must be considered as a whole." *Duke Energy*, 111 F.4th at 354. CareFirst's theory of this case has always been that J&J was engaged in a "complex … exclusionary campaign," *id.*, to maintain and prolong its monopoly after the expiration of the '734 patent—a monopolization scheme that unfolded over years. *See, e.g.*, JA244-245 (district court acknowledging CareFirst's theory of a single overarching "scheme" with multiple parts). In a case involving "a scheme or course of conduct," the monopolist's "exclusionary efforts" must be "considered in their totality." *Duke Energy*, 111 F.4th at 355.

The totality of J&J's anticompetitive conduct extends beyond the moment of the Momenta acquisition. After acquiring the relevant patents, J&J never divested them and never sought to commercialize them through bona fide licensing. In fact, it never put them to any commercial use *except* asserting them against biosimilar rivals to Stelara. *See supra* 10. Even taking the facts in the light most favorable to J&J (contrary to the summary-judgment standard) and assuming *arguendo* that J&J was unaware of the substance of the Momenta patents before acquiring them in 2020, J&J indisputably came to that knowledge at some point between 2020 and 2023—when it wielded the patents to prolong its monopoly. JA6-7. Considering the scheme "holistically," *Duke Energy*, 111 F.4th at 355, a reasonable jury could find that J&J deliberately acquired and held onto the patents and that its overall course of conduct had anticompetitive effects.

4. J&J's contrary approach would allow a monopolist who acquires patents and uses them to stifle competition to nonetheless escape liability by feigning ignorance of the substance of the patents at the time of the acquisition. A sophisticated firm could hide the relevant internal deliberations behind the veil of attorney-client privilege because the firm's evaluation of any patents would almost certainly involve counsel. J&J is no exception in that respect: Any inquiry into when the company learned of the substance of the Momenta patents necessarily implicates

questions about what J&J's *lawyers* knew and when they knew it—hence the district court's focus on Ms. DeFranco, J&J's Global Head of IP Litigation. JA64-69.

J&J's approach would therefore all but guarantee gamesmanship by monopolists asserting attorney-client privilege, as this case illustrates. J&J invoked attorney-client privilege to limit discovery into when its employees became aware of the Momenta manufacturing patents, their contents, and their potential use in litigation against biosimilar competitors—only to then turn around and argue that it could not be held liable for monopolization because there was supposedly no evidence that J&J employees understood the substance of the patents at the time of their acquisition. *See* JA4356-4357. CareFirst moved in limine to preclude such abuse of the privilege. See JA4356-4357. The district court did not resolve that motion. In its reconsideration order, however, the court granted J&J's competing motion to preclude CareFirst from relying on (unprivileged) information in J&J's privilege log to support inferences about its employees' knowledge. JA61-63.

If this Court vacates and remands, the district court will be free to revisit those evidentiary questions before trial. This Court should make clear that J&J cannot put its putative lack of knowledge at issue and simultaneously use the attorney-client privilege to prevent any discovery into that knowledge. The attorney-client privilege "cannot at once be used as a shield and a sword." *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991). And the prospect of similar gamesmanship in future cases

furnishes yet another reason to reject J&J's unduly narrow focus on its knowledge of the contents of the Momenta patents at one moment in time.

II. The district court further erred in narrowing the scope of J&J's *Walker Process* fraud that the jury will be allowed to consider.

J&J also sought to prolong its monopoly over the market for ustekinumab by defrauding the PTO into issuing the '307 patent. At summary judgment, the district court correctly held that a reasonable jury could find that J&J committed *Walker Process* fraud in obtaining the'307 patent. But the court erroneously narrowed the universe of misstatements and omissions that CareFirst could put before the jury to prove that fraud. This Court should reverse the district court's partial grant of summary judgement with respect to *Walker Process* fraud and remand for trial on the fuller scope of J&J's fraud outlined below.

A. Under *Walker Process*, a monopolist may be held liable for using a patent obtained by fraud to harm competition.

In *Walker Process*, the Supreme Court held that a company's fraud on the PTO can be a basis for imposing Sherman Act liability, if the other elements of a monopolization claim are also satisfied. 382 U.S. at 173, 177-78. To demonstrate *Walker Process* fraud, an antitrust plaintiff must show: "(1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, (4) but for which misrepresentation or deliberate omission the patent would not have

been granted." *Regeneron Pharms., Inc. v. Novartis Pharma AG*, 96 F.4th 327, 341 n.9 (2d Cir. 2024). A misstatement or omission meets the but-for materiality standard if "the patent would not have been granted" had the patent examiner known the truth. *Glob. Tubing LLC v. Tenaris Coiled Tubes LLC*, 167 F.4th 1357, 1370 (Fed. Cir. 2026).

Taking one position before the FDA and another before the PTO to deceive the latter into issuing a patent is a well-recognized species of fraud. In *Belcher Pharmaceuticals, LLC v. Hospira, Inc.*, for example, the Federal Circuit affirmed the district court's finding of fraud where a patent applicant said one thing to the FDA in order to "expedite FDA approval," but then "performed an about-face" and advanced the opposite argument "[w]hen later drafting the patent application" and in discussions with the examiner after an initial rejection. 11 F.4th 1345, 1353-54 (Fed. Cir. 2021); *cf. Therasense, Inc. v. Becton, Dickinson & Co.* (*Therasense II*), 864 F. Supp. 2d 856, 862 (N.D. Cal. 2012) (finding that applicant committed fraud where it characterized the prior art one way before the European Patent Office and then assumed the opposite position before the PTO).

B. A reasonable jury could conclude that J&J's misstatements and omissions about the clinical trial were fraudulent.

The district court already concluded—correctly—that a reasonable jury could find that J&J committed *Walker Process* fraud by deliberately withholding the Ochsenkühn study from the PTO and falsely representing that "no studies" had previously examined the use of ustekinumab to treat ulcerative colitis. JA27, JA29-32.

As the court explained, a reasonable jury could find the "no studies" statement false and misleading because: (1) Ochsenkühn was itself such a study, (2) J&J employees with a duty of candor to the PTO knew about the Ochsenkühn study, and (3) the PTO rejected a nearly identical J&J patent application as obvious in light of that study, demonstrating its materiality. JA29-32, JA38-39. The district court also recognized that a reasonable jury could find that J&J had the specific intent to deceive the PTO. JA37-39. The same considerations support allowing CareFirst to present the following additional misstatements and omissions to the jury.

Misstatements and omissions. In its 2016 clinical trial protocol, J&J explained to the FDA why it was "reasonable to assume"—based on published scientific studies—that ustekinumab would be "effective" in treating ulcerative colitis. JA1509. Two years later, when drafting the application that became the '307 patent, J&J's patent agent, [redacted] JA4121-4122, JA4133-4134, JA4141-4144, JA1713-1735. But Ralat carefully excised the sentence admitting it was "reasonable to assume" ustekinumab would work to treat ulcerative colitis and citations supporting that reasonable expectation. *Supra* 11-12. The patent's prosecutors and inventors also withheld the protocol itself from the PTO. And when the patent examiner initially denied J&J's application, Eric Dichter—J&J's patent prosecutor—doubled down, telling the PTO that there was *no* reasonable expectation that ustekinumab would be

effective to treat ulcerative colitis. *Supra* 12-13. This reversal, in service of additional years of patent exclusivity, constitutes fraud. With respect to this theory of fraud, CareFirst alleges that J&J made two affirmative misstatements and one omission.

First, Dichter met with the patent examiner after the examiner's initial rejection and represented, according to the examiner's notes, that "it would not have been obvious that the [clinical trial] endpoints would have been met by the claimed antibody." JA1396. A patent application must be rejected if the claimed invention would have been "obvious" to a "person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. In the pharmaceutical context, a rejection for obviousness does not require "[c]onclusive proof" that a drug will be effective; there need only be "reasonable expectation of success." *Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1331 (Fed. Cir. 2014). So when J&J represented that its invention was "not obvious," it was representing that there was no "reasonable expectation" that the claimed invention would have been successful. That representation was false. J&J had told the PTO the opposite in its clinical trial protocol.

Second and similarly, Dichter told the examiner that that existence of the then-ongoing clinical trial didn't render the invention obvious because the results of clinical trials are "uncertain[]." JA1427. But, again, J&J deliberately withheld from

the examiner the statements J&J had previously made to the FDA explaining why *this* clinical trial was likely to succeed.

Third, J&J failed to disclose to the PTO the clinical trial protocol itself, which laid out the reasons ustekinumab could reasonably be expected to treat ulcerative colitis. In the 2016 protocol, J&J explained to the FDA that the "similarities in the genetics and biology" of Crohn's disease and ulcerative colitis made it "reasonable to assume" that ustekinumab would be "effective" in treating ulcerative colitis. JA1509. J&J also explained that data from a clinical trial of ustekinumab as a treatment for Crohn's disease, "along with the shared biology and the similar response to current treatments between Crohn's disease and [ulcerative colitis], provide[d] a substantial scientific and clinical rationale" for proceeding directly to a phase 3 trial. JA1476. And J&J cited two prior studies (one by Jostins, the other by Granlund) as demonstrating that the "inflammatory mechanisms" of Crohn's disease and ulcerative colitis are "largely the same." JA1493, JA1585.

A reasonable jury could find that the patent examiner never saw any of those statements because J&J withheld the protocol from the PTO. JA1398-1400. The omission was plainly deliberate. As previously explained, [redacted], quoted above, explaining why ustekinumab was likely to treat ulcerative colitis. *See* JA1713-1735.

Materiality. Dichter's statements to the patent examiner satisfied the but-for materiality standard. The examiner reconsidered his initial position—that the patent should be denied—only *after* Dichter convinced him that it was "uncertain[]" whether the clinical trial would succeed. *Supra* 13. Accordingly, a reasonable jury could find that "the examiner allowed the [patent] claims only after accepting" Dichter's argument. *Belcher Pharms.*, 11 F.4th at 1353.

J&J's omissions regarding the clinical trial protocol—its failure to disclose the protocol itself, and its selective deletions in copying some of the protocol's text into the patent application—were also material. Like the protocol, the patent application disclosed that ustekinumab successfully treats Crohn's disease, and that some therapies effective in treating ulcerative colitis are also effective in treating Crohn's. JA1612. But the patent application omitted the clinical protocol's explanation of why that was the case and the citations to studies connecting the dots about the two diseases' shared inflammatory mechanisms. And the application omitted J&J's statement that "it is reasonable to assume" ustekinumab would "be effective" in treating ulcerative colitis. JA1509.

A reasonable jury could conclude that if J&J hadn't withheld the protocol, the examiner would have denied the application as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Ltd.*, 98 F.4th 1056, 1061-62 (Fed. Cir. 2024) (affirming finding that patent was invalid as obvious due to clinical trial protocol and related study); *Alexion*

Pharms., Inc. v. Samsung Bioepis Co., 2024 WL 2111988, at *3 (D. Del. 2024) (recognizing that a "person of ordinary skill in the art" would have had "reason to expect successful treatment" of the disease using the relevant drug where the "mechanism of that disease" had previously been identified).

A claimed method of treatment is obvious if skilled artisans would have had a "reasonable expectation" that the method would succeed based on the prior art, *Hoffmann-La Roche Inc.*, 748 F.3d at 1331—and that is exactly what J&J told the FDA it could "assume" with respect to this method of treatment. JA1509. The protocol thus confirmed that the examiner's initial rejection on obviousness grounds was correct. And had J&J submitted it, the protocol would have provided the examiner with the disclosure he needed to stand firm on his rejection: J&J's own admission showing that the use of ustekinumab to treat ulcerative colitis was obvious. *Cf. Therasense II*, 864 F. Supp. 2d at 863 (omission was material where omitted materials would have "reinforced the examiner's expressed concern").

Intent to deceive. A reasonable jury could also conclude that "the single most reasonable inference able to be drawn from the evidence" is that J&J employees responsible for '307 patent acted with the "specific intent to deceive" the PTO, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc)—as the district court already concluded with respect to the Ochsenkühn omission and J&J's related "no studies" statement. JA34, JA37-39.

J&J employees who owed a duty of candor to the PTO knew that the clinical trial was likely to succeed. Patent applicants—including a patent's inventors, prosecutors, and agents—"are required to prosecute patent applications in the PTO with candor, good faith, and honesty." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). [redacted] were part of the J&J team responsible for obtaining FDA approval of the direct-to-phase-3 clinical trial, well before J&J applied for the '307 patent. JA4181-4183, JA4188, JA4051, JA4209, JA4217, JA4222, JA4224-4227, JA4138-4139. In internal presentations, [redacted] And they relied on that similarity when asking the FDA to fast-track the trial. *See supra* 11. Indeed, a [redacted]

A reasonable jury could also find that J&J's patent agent, Ralat, acted with deceptive intent based on his "selective[] disclos[ure]" of the protocol language in the application. *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1376 (Fed. Cir. 2000); *see Am. Calcar, Inc. v. Am. Honda Motor Co.*, 768 F.3d 1185, 1190 (Fed. Cir. 2014) ("Partial disclosure of material information about the prior art to the PTO

cannot absolve a patentee of intent if the disclosure is intentionally selective."). The fact that J&J "chose to disclose" certain information "to the FDA, but not to the PTO, certainly supports a finding of deceptive intent." *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005); *see also Belcher Pharms.*, 11 F.4th at 1354 (affirming factfinder's conclusion that deceptive intent was the "single most reasonable inference" from company's taking one position before the FDA and another before the PTO); *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989) (inference of deceptive intent was supported by "damning" evidence that included the "simultaneous submission of … data to FDA and its withholding from the PTO"). After all, there was a "substantial incentive" not to tell the PTO that the trial was likely to succeed. *Kaiser Found. Health Plan, Inc. v. Abbot Labs., Inc.*, 552 F.3d 1033, 1051 (9th Cir. 2009).

Tellingly, J&J has offered no competing explanation for these selective withholdings. When asked about his conduct, Ralat testified that his "goal" before the FDA was different than his "goal" before the Patent Office. JA4116-4117, JA4158, JA4161-4162. That's a confession, not an explanation. J&J told the FDA that ustekinumab was highly likely to treat ulcerative colitis when doing so helped it secure FDA approval, but J&J told the PTO this efficacy was "uncertain" and not "obvious" when doing so helped it secure a patent. At a minimum, a jury could find an intent to deceive because neither Ralat nor any other J&J employee can offer an

innocent reason for the company's contradictory statements to the FDA and PTO. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1072 (Fed. Cir. 1998) (fact that applicant "could not explain, even in retrospect, why he deleted" citations from an earlier draft of the patent application could support finding of specific intent to deceive).

J&J can't argue that it somehow thought clinical protocols were irrelevant or unimportant because the company disclosed a different—and far less relevant—protocol concerning a clinical trial of ustekinumab's ability to treat lupus. JA1399, JA1422. The fact that J&J disclosed a protocol about ustekinumab's ability to treat *lupus* but not a protocol about ustekinumab's ability to treat *ulcerative colitis*—the precise disease at issue in the patent—suggests that the omission was intentional. *Cf. Kaiser Found.*, 552 F.3d at 1051 (submission of an English translation of a study's abstract for one patent but not another suggested the applicant understood the translation would be "fatal to the patentability of" the second patent).

Finally, J&J understood that the likelihood of success of the clinical trial was the key to patentability. That's why Dichter specifically sought to convince the examiner that nobody knew the trial was going to succeed—despite J&J's opposite representation to the FDA. *See LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992) (holding that deceptive intent may be inferred where an applicant "mak[es] an argument for patentability which could not have been made"

had the relevant material been disclosed); *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 522, 528 (D.N.J. 2000) (similar).

C. The district court's contrary reasoning does not withstand scrutiny.

1. The district court took the view that J&J's selective deletions from the text of the clinical protocol were not material omissions because the "material details" about the protocol were "available to the patent examiner" through clinicaltrials.gov. JA32-33. That was error at summary judgment.

To the extent the district court concluded that the examiner in fact reviewed the protocol, the court improperly resolved a disputed issue of fact that should go to a jury. Viewed in the light most favorable to CareFirst, the evidence shows that the examiner never reviewed the clinical protocol. J&J never disclosed the protocol to the PTO, JA1398-1400, and the examiner never listed it in the materials he reviewed, JA1388. Although the examiner indicated that he reviewed the clinicaltrials.gov webpage corresponding with J&J's ustekinumab clinical trial, JA1388, that webpage is distinct from the clinical protocol itself. JA2571-2572, JA2593-2596, JA2618-2619. And while it is *possible* the examiner accessed the protocol through the webpage without disclosing that he did so, J&J cannot point to any facts suggesting that he did. This is a factual question for the jury.

The district court also stated that whether the examiner reviewed the protocol was not material because the information conveyed in the omitted statements was

"before the examiner" in the patent application. JA33. But "the scope and content" of a particular reference "are questions of fact." *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1319 (Fed. Cir. 2006). And a reasonable jury could find that the protocol's statements were not cumulative of the information in the patent application.

The district court pointed out that both the protocol and the patent application disclosed that ulcerative colitis and Crohn's disease are "mediated by Th1 or TH17 cells." JA4, JA33. But only the protocol went on to explain that this "suggest[ed]" that "the inflammatory mechanisms at the mucosal level between the two diseases are largely the same." JA1493. The district court was likewise mistaken to stress the patent application's statement that "biologic therapies that are currently approved for the treatment of [ulcerative colitis] have also demonstrated efficacy in Crohn's disease." JA4, JA33. The protocol included the more relevant fact that the diseases have "similar response[s] to current treatment" in general. JA1476, JA1494. And only the protocol cited the Jostins and Granlund studies, which explained the genetic similarities between Crohn's disease and ulcerative colitis and therefore supported the notion that ustekinumab would effectively treat ulcerative colitis. JA1493, JA1585.[8]

[8] In its reconsideration order, the district court stated that the Jostins and Granlund studies are "not at issue in this case" as a "separate source or theory of

J&J also omitted the statement in the protocol most important to patentability: that the shared "genetics and biology" of the two diseases made it "reasonable to assume" that ustekinumab would effectively treat ulcerative colitis. JA1509. J&J made no such admission in its patent application (and the district court didn't purport to find any analogue there). Nor did the patent application contain any statement comparable to the protocol's insistence that there was a "substantial scientific and clinical rationale" to expect the clinical trial to succeed. JA1476, JA1494.

The protocol thus went far beyond the information disclosed in the patent application. *See* JA2617-2619. At the very least, a reasonable jury could so find. *See Chevron (HK) Ltd. v. One World Techs., Inc.*, 2025 WL 2630497, at *8-9 (D. Del. 2025) (holding that whether omitted illustration was cumulative of text was a question for the factfinder); *EIS, Inc. v. IntiHealth Ger GmbH*, 2023 WL 6799332, at *6 (D. Del. 2023) (holding that whether a full article was cumulative of its abstract was a question for the factfinder). Whether the protocol was merely "cumulative" of the patent application was thus "not properly decided at summary judgment." *Digit. Control*, 437 F.3d at 1319.

2. With respect to Dichter's misrepresentations about whether the trial was likely to succeed, the district court perceived the statements as immaterial because

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fraud" based on the court's prior rulings on motions to amend the complaint. JA69-70. But the court explicitly left open the possibility that the studies could be relevant and admissible to support *other* theories of *Walker Process* fraud. JA71.

the examiner "had the fact of and details about" the clinical trial before him. JA29. According to the court, the examiner was therefore "free" to "reach [his] own conclusion and accept or reject J&J's claims that [the clinical trial protocol] did not render the '307 patent obvious." JA29.

But the information that J&J kept from the examiner would have changed his conclusion. That is the very essence of fraud and why Dichter's statements meet the materiality standard. Dichter essentially told the examiner that there was no knowing whether the clinical trial would succeed. The examiner would have rejected that reasoning had J&J disclosed the statements it made to the FDA taking the opposite position. And nothing on clinicaltrials.gov gave any indication that *this* trial, unlike others, was a sure bet. *See In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 313 (D.R.I. 2019) (holding that evidence that company "steered the patent examiner away" from the relevant conclusion precluded summary judgment on *Walker Process* fraud); *Alcon Rsch., Ltd. v. Apotex, Inc.*, 2013 WL 2244338, at *8 (S.D. Ind. 2013) (rejecting argument that examiner should have "understood" on its own a conclusion that was not disclosed by the applicant).

CONCLUSION

The district court's judgment should be vacated and the case remanded for further proceedings.

Respectfully submitted,

THOMAS M. SOBOL
HANNAH W. BRENNAN
REBEKAH GLICKMAN-SIMON
HAGENS BERMAN SOBOL SHAPIRO LLP
1 Faneuil Hall Square, 5th Floor
Boston, MA 02109
(617) 482-3700

PETER D. ST. PHILLIP
URIEL RABINOVITZ
LOWEY DANNENBERG, PC
44 South Broadway, Suite 1100
White Plains, NY 10601
(914) 997-0500

MARC C. GRECO
KIP A. HARBISON
MICHAEL A. GLASSER
GLASSER AND GLASSER PLC
Crown Center, Suite 600
580 East Main Street
Norfolk, VA 23510
(757) 625-6787

/s/ Matthew M.H. Wessler
MATTHEW W.H. WESSLER
MATTHEW GUARNIERI
STEFANIE OSTROWSKI
GUPTA WESSLER LLP
1400 16th Street, NW
Suite 225
Washington, DC 20036
(202) 888-1741
matt@guptawessler.com

JOHN D. RADICE
RADICE LAW FIRM PC
475 Wall Street
Princeton, NJ 08540
(646) 245-8502

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Counsel for Plaintiffs-Appellants

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 12,913 words excluding the parts of the brief exempted by Rule 32(f). This brief complies with the typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6) because this brief has been prepared in proportionally spaced typeface using Microsoft Word in 14-point Baskerville font.

September 8, 2026

/s/ Matthew W.H. Wessler
Matthew W.H. Wessler

CERTIFICATE OF SERVICE

I hereby certify that on September 8, 2026, I electronically filed sealed and redacted public versions of the foregoing final form brief with the Clerk of the Court for the U.S. Court of Appeals for the Fourth Circuit by using the CM/ECF system. I further certify that I caused a copy of the sealed version of the brief to be served via email, with prior written consent, to the following counsel of record:

George G. Gordon (george.gordon@dechert.com)
Michael H. McGinley (michael.mcginley@dechert.com)
Julia Chapman (julia.chapman@dechert.com)
David M. Costigan (david.costigan@dechert.com)
Dechert, LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104-2808

Steven A. Engel (steven.engel@dechert.com)
Dechert, LLP
1900 K Street, NW
Washington, DC 20006-1110

/s/ Matthew W.H. Wessler
Matthew W.H. Wessler