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 (Hon. Jamar K. Walker)

REDACTED FINAL FORM RESPONSE BRIEF OF DEFENDANTS-APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Defendant-Appellee Janssen Biotech, Inc. is a wholly owned subsidiary of Defendant-Appellee Johnson & Johnson ("J&J"), which is a publicly held corporation (ticker: JNJ). The Vanguard Group, Inc. owns approximately 10% of Johnson & Johnson's 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

This straightforward, fact-bound case should be affirmed. Under well-established precedent, J&J cannot be liable for the "***willful*** acquisition" of monopoly power absent proof of general intent—i.e., that it knew the facts that made its conduct allegedly anticompetitive. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966) (emphasis added). And where a defendant "unwittingly find[s] [itself] in possession of a monopoly," *United States v. Aluminum Co. of America ("Alcoa")*, 148 F.2d 416, 429-30 (2d Cir. 1945), or acquires monopoly power by "historic accident," *Grinnell*, 384 U.S. at 571, there is no unlawful monopolization. The District Court properly applied these bedrock principles to grant summary judgment.

In so doing, the court correctly rejected Plaintiffs' efforts to radically expand antitrust liability and undermine the *Noerr-Pennington* doctrine, which generally bars antitrust liability for patent enforcement. Plaintiffs claimed that, when J&J acquired Momenta Pharmaceuticals in 2020, it unlawfully acquired four patents (the "Momenta Manufacturing Patents") that enabled J&J to extend its alleged monopoly over Stelara (ustekinumab) when it sued biosimilar Stelara manufacturers three years later. But the undisputed record showed that J&J purchased Momenta to acquire Imaavy (nipocalimab), an entirely different drug with no connection to Stelara. At the time of that acquisition, as the District Court recognized, J&J did not have "actual

knowledge of the contents of the Momenta manufacturing patents," which were buried in Momenta's portfolio of hundreds of other patents unrelated to Imaavy. JA64 [ECF.887.at.15]. Nor ***could*** J&J have known those patents might be asserted against biosimilar Stelara manufacturers years later. This case thus presented a textbook example of a defendant acquiring alleged monopoly power "unwittingly" by "historic accident," if at all.

Plaintiffs recognize that they cannot prevail under this established law. So instead, they misrepresent what the District Court held. Plaintiffs accept that *Grinnell* and *Alcoa* set forth the general-intent standard for monopolization. Pls.Br.27, 29. But they argue that the District Court required proof that J&J acquired Momenta with the "specific intent" to exclude competition in Stelara. *Id.* at 1. That is not true. The District Court's opinion turned entirely upon J&J's lack of ***knowledge*** of "the contents of the Momenta manufacturing patents," JA64_[ECF.887.at.15], not the absence of subjective intent.

This Court need not speculate about what the District Court found dispositive. The District Court initially ***denied*** summary judgment after Plaintiffs "misled the Court" over the core question of J&J's knowledge, JA60_[ECF.887.at.11 n.10], finding a factual dispute over whether J&J knew the contents of the Momenta Manufacturing Patents at the time of the acquisition. But once the court discovered that J&J did not know the patents' content until 2023, three years ***after*** the

acquisition, the court granted summary judgment. JA64-66_[ECF.887.at.15-17]. Given that the only difference between the first and second rulings were facts concerning J&J's knowledge, Plaintiffs cannot credibly argue that the decision turned upon specific intent. Had the District Court applied a specific-intent standard, it would have granted summary judgment on the first round, since Plaintiffs indisputably had no evidence that J&J acquired Momenta specifically intending to exclude competition in Stelara.

Plaintiffs ask this Court not for a general-intent standard, but for a strict-liability rule that would radically depart from existing law by making it unlawful to enforce patents acquired via a corporate acquisition—regardless of what was known about the patents or their competitive effect at the time. No court has endorsed such an unworkable standard. And doing so now would unnecessarily open a circuit conflict. "Where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981).

Nor is there any doctrinal logic to that approach. Plaintiffs' theory would capture conduct—like J&J's—where it was impossible for the acquiror to know at the time that purchasing assets might create treble-damages antitrust liability years later. It is undisputed that J&J's acquisition of the Momenta Manufacturing Patents had no anticompetitive effects in 2020. Nor were any such effects foreseeable at the

time: No competitor had sought FDA approval for biosimilar Stelara, and J&J could not know whether future biosimilar applicants, if any, would choose the specific processes covered by the Momenta Manufacturing Patents instead of other available options. Plaintiffs' novel standard is thus open-ended, providing no way to assess at the time of the acquisition whether acquiring a patent might be deemed an antitrust violation. It would be satisfied by ***any*** post-acquisition patent enforcement by an alleged monopolist, even—as here—years after the acquisition. And it would create a sea change in antitrust law, reading the word "willful" straight out of *Grinnell*. 384 U.S. at 570. There is no sound reason why the Court would break with established precedent and adopt Plaintiffs' novel standard on the facts of this case.

The District Court's decision may also be affirmed because Plaintiffs could not make their case under the rule of reason. They could not show that J&J harmed competition at the time it acquired Momenta, and to the contrary, J&J's acquisition and development of Imaavy was plainly procompetitive. These failures reflect that Plaintiffs' actual objection was not to J&J's acquiring patents in 2020, but to enforcing them years later.

Plaintiffs have contorted their case to challenge the Momenta acquisition only because the *Noerr-Pennington* doctrine bars liability for constitutionally protected patent enforcement. But Plaintiffs' rebranding cannot change the substance of their claim. Plaintiffs claim competitive harm only from patent enforcement, and *Noerr-*

Pennington thus provides yet another independent basis to affirm. And antitrust enforcers, like the Federal Trade Commission ("FTC"), do not need Plaintiffs' gambit. There are existing mechanisms to review whether patent acquisitions could have anticompetitive effects, such as by the Hart-Scott-Rodino ("HSR") process, which the Momenta transaction cleared without objection.

As for Plaintiffs' *Walker Process* fraud theory, they concede that this Court need not reach it if summary judgment is affirmed on the Momenta theory. Regardless, that theory cannot survive summary judgment because the undisputed evidence shows J&J disclosed to the United States Patent and Trademark Office ("PTO") all the information Plaintiffs claim was withheld. Thus, the District Court's decision on that claim should be affirmed as well.

STATEMENT OF ISSUES

1. Whether the District Court correctly granted summary judgment on Plaintiffs' monopolization-via-patent-acquisition claim where J&J did not know what the acquired patents claimed, and therefore lacked general intent, and where J&J could not foresee future infringement by biosimilar Stelara manufacturers and so the acquisition had no actual or reasonably foreseeable anticompetitive effects at closing.

2. Whether the *Noerr-Pennington* doctrine provides an alternative basis for affirmance when Plaintiffs' real challenge is to the enforcement, not the acquisition, of the four Momenta Manufacturing Patents.

3. Whether the District Court correctly granted partial summary judgment on Plaintiffs' *Walker Process* fraud claim where J&J disclosed the allegedly withheld information to the patent examiner.

STATEMENT OF THE CASE

I. Factual Background

Plaintiffs' claims involve Stelara (ustekinumab), a biologic drug that regulates the immune system's inflammatory response. JA310, 339_[J&J.SJ.Ex.1.at.2:38-61, 59:1-2]. Stelara "represent[ed] an important milestone in rational drug design," JA377_[J&J.SJ.Ex.2.at.5], and it was eventually approved to treat four autoimmune conditions: plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis.

J&J held several patents related to Stelara, including a composition of matter patent that expired on September 25, 2023. Plaintiffs claim that J&J sought to extend its alleged monopoly over Stelara by unlawfully obtaining five other patents—four from Momenta in 2020 and one by fraud on the PTO (the "'307 Patent"). *See* Pls.Br.1-2. The undisputed record refutes their claims.

A. J&J's Acquisition Of Momenta And Its Patents

First, Plaintiffs claim that J&J "knowingly" bought Momenta and its patents in 2020, "held onto them, and used them to exclude biosimilar rivals from the [alleged] market" for Stelara. Pls.Br.24. That characterization misrepresents the record on every point. J&J acquired Momenta for the procompetitive purpose of developing Imaavy—an entirely separate drug treating entirely different conditions from Stelara—and it did not know what the Momenta Manufacturing Patents claimed at the time, let alone that they could later be enforced against biosimilar Stelara manufacturers.

1. J&J Acquired Momenta Because Of Imaavy.

[redacted] JA3082-3085_[J&J.SJ.Ex.40.at.31:18-34:24]. [redacted] JA3082-3085_[J&J.SJ.Ex.40.at.31:18-34:24].

[redacted] JA3089-3090_[J&J.SJ.Ex.40.at.38:17-39:12]; JA3139_[J&J.SJ.Ex.42.

at.5]. [redacted] JA3083-3094_[J&J.SJ.Ex.40.at.32:6-43:6]. [redacted] JA3091_[J&J.SJ.Ex.40.at.40:5-15].

The Momenta deal was procompetitive and had clear benefits for J&J, Momenta, and patients. [redacted] JA3119-3120_[J&J.SJ.Ex.41.at.8129-8130]. [redacted] JA3095-3100_[J&J.SJ.Ex.40.at.48:15-53:15]; JA3119-3120_[J&J.SJ.Ex.41.at.8129-8130].

None of this had anything to do with Stelara or the Momenta Manufacturing Patents. [redacted] JA3110_[J&J.SJ.Ex.40.at.116:5-24]; JA3150_[J&J.SJ.Ex.43.at.5]. [redacted] JA3164-3166, JA3171, JA3176, JA3179_[J&J.SJ.Ex.44.at.51:7-52:25, 70:5-23, 117:10-15, 128:10-18,

239:25-240:24]; JA3101-3104_[J&J.SJ.Ex.40.at.75:24-76:24, 79:6-15, 89:9-16].

Even if J&J had reviewed the Momenta Manufacturing Patents, it could not have known that they might someday cover processes used by biosimilar Stelara manufacturers. Although the patents identify 29 different compounds that could be made using the claimed processes, they do not mention Stelara (ustekinumab). JA3217-3218, JA3256-3258, JA3264, JA1220-1221_[J&J.SJ.Ex.46.¶161; Ex.47.¶¶292-99; Ex.50.at.75:7-17; Ex.51.¶102]. And substantively, the patents claim only one way of designing cell culture media to manufacture biologics, relating to the amount of certain amino acids in the media. JA3256_[J&J.SJ.Ex.47.¶293]; JA3186-3191_[J&J.SJ.Ex.46.¶¶28, 68-82].

There are a multitude of other ways to design cell culture media to make biologic drugs, including Stelara, that do not read on these patents. JA3256_[J&J.SJ.Ex.47.¶293]; JA3200-15_[J&J.SJ.Ex.46.¶¶105-155]. [redacted] JA3258_[J&J.SJ.Ex.47.¶299]. [redacted] JA3119-20_[J&J.SJ.Ex.41.at.8129-30].

In 2020, J&J therefore had no way to know whether a biosimilar Stelara manufacturer would use the methods claimed in the Momenta Manufacturing Patents as opposed to many other available methods. JA3198, JA3201,

3209_[J&J.SJ.Ex.46.¶¶100-01, 109, 129]. And critically, since pharmaceutical manufacturing processes are carefully guarded confidential information, J&J had no way to know what other companies were doing. JA3199_[J&J.SJ.Ex.46.¶102]. [redacted] *See* JA3288-3289, JA3294-3309_[J&J.SJ.Ex.53.at.106:5-107:7, 243:4-258:16].

J&J's contemporaneous board documents confirm that the Momenta Manufacturing Patents played no role in the acquisition. [redacted] JA3125_[J&J.SJ.Ex.41.at.8135]. [redacted] JA3119-3131_[J&J.SJ.Ex.41]; JA3108-3112_[J&J.SJ.Ex.40.at.114:4-118:17].

Under the HSR process, J&J submitted the transaction to the FTC for antitrust review. *See* 15 U.S.C. § 18a. The FTC saw no competitive concerns and cleared the transaction without asking a single question. JA3077, JA3105-3107_[J&J.SJ.Ex.40.at.24:7-13, 111:9-113:8]; JA1201-1203_[J&J.SJ.Ex.48.¶¶33-36]. The deal closed in October 2020, and J&J continued researching, developing, and commercializing Imaavy. The FDA approved Imaavy to treat generalized

myasthenia gravis in April 2025, and J&J continues to run clinical trials for additional indications. JA1206_[J&J.SJ.Ex.49.at.1].

2. Years Later, J&J Discovered That Biosimilar Stelara Manufacturers Infringed The Momenta Manufacturing Patents.

J&J did not learn what the Momenta Manufacturing Patents claimed until after the acquisition, and it did not discover their relevance to biosimilar Stelara until [redacted] JA4100-4101_[CF.SJOpp.Ex.103.at.278:3-279:7].

Two years after the Momenta acquisition closed, Amgen became the first company to seek FDA approval for biosimilar Stelara. JA3255_[J&J.SJ.Ex.47.¶84]. J&J sued Amgen for patent infringement, but did not initially assert the Momenta Manufacturing Patents. *Janssen Biotech, Inc. v. Amgen, Inc.*, No. 22-cv-01549 (D. Del.), Dkt. No. 1, at ¶¶1-6. [redacted] JA3288-3289, JA3294-3309_[J&J.SJ.Ex.53.at.106:5-107:7, 243:4-258:16]. J&J ***then*** asserted those patents against Amgen, *Janssen Biotech*, No. 22-cv-01549, Dkt. No. 46, at ¶¶ 12-15, 61-68, and against other manufacturers whose processes infringed the patents.

None of those sophisticated biosimilar manufacturers challenged the validity of the Momenta Manufacturing Patents or claimed they were unlawfully acquired,

though they had every opportunity and incentive to do so. Presumably after assessing the strength of their potential defenses, they all chose to settle. JA1229-1231_[J&J.SJ.Ex.54.at.44:17-46:19]; JA3321-3322_[J&J.SJ.Ex.55.¶72]. Amgen ultimately launched its biosimilar Stelara product in January 2025—seven years before the Momenta Manufacturing Patents expire. JA3353_[J&J.SJ.Ex.56.at. 3583]; JA3292-3293_[J&J.SJ.Ex.53.at.115:25-116:8].

B. J&J's Prosecution Of The '307 Patent

[redacted], its scientists identified an unmet clinical need for ulcerative colitis ("UC"). JA2368_[J&J.SJ.Ex.3.at.35]. Whether Stelara would work for UC was unknown to J&J and the FDA, since no one had run a clinical trial of ustekinumab in UC. JA2431-2433, JA2438_[J&J.SJ.Ex.15.at.20:18-21:6, 28:5-24, 69:6-8]; JA2465-2466_[J&J.SJ.Ex.16.at.16:22-17:11]; JA391-393_[J&J.SJ.Ex.7. ¶¶43-48]; JA2523_[J&J.SJ.Ex.19.at.2759]; JA501-502_[J&J.SJ.Ex.7.¶431].

J&J set out to answer the question through UNIFI, the first clinical study of ustekinumab in UC. To justify going directly to a Phase III trial, J&J relied on data from its CD study and told the FDA that "it is reasonable to assume that ustekinumab will also be effective in UC" given "similarities in the genetics and biology of UC and [CD]." JA623_[J&J.SJ.Ex.10.at.8529]. The FDA permitted J&J to proceed directly to Phase III, and J&J submitted the UNIFI Protocol while posting ongoing

trial updates on the publicly available ClinicalTrials.gov ("CT.gov") website. JA564-581_[J&J.SJ.Ex.9]; JA472_[J&J.SJ.Ex.7.¶361].

UNIFI included a futility analysis to account for the possibility that Stelara would be ineffective. JA614, JA620, JA674, JA676_[J&J.SJ.Ex.10.at.8520, 8526, 8580, 8582]; JA2496_[J&J.SJ.Ex.17.at.64:13-20]. But UNIFI succeeded, demonstrating for the first time that Stelara was clinically effective for UC. JA395-402_[J&J.SJ.Ex.7.¶¶64, 66-74]. The FDA approved the UC indication on October 21, 2019, and the UNIFI results were publicly accessible on CT.gov by December 23, 2019. JA569_[J&J.SJ.Ex.9.at.6]; JA475_[J&J.SJ.Ex.7.at.135]; JA1141_[J&J. SJ.Ex.22.at.202].

J&J then filed patent applications covering the use of ustekinumab in UC, beginning with three provisional applications. JA1177-1178_[J&J.SJ.Ex.23.at. 246:12-247:12]. The first—the '501 Provisional Application—was prepared by J&J patent manager Dr. Luis Ralat. JA4117-4119_[CF.SJOpp.Ex.105.at.85-87]. Consistent with usual practice, the PTO never examined these provisional applications. *See* JA942_[J&J.SJ.Ex.22.at.3].

On September 24, 2019, a J&J patent attorney, Eric Dichter, filed the '509 Application—the non-provisional application that would eventually issue as the '307 Patent. JA942, JA1020-1029, JA1078-1083_[J&J.SJ.Ex.22.at.3, 81-90, 139-44]. The '509 Application incorporated the specification Ralat drafted for the '501

Provisional Application, but Dichter handled prosecution. Ralat was "completely disconnected" from and "had no role in" prosecuting the '509 Application. JA1774_[J&J.SJ.Ex.73.at.110:2-13]; *see also* JA4160-4161_[CF.SJOpp.Ex.105.at. 236:23-237:1].

The '509 Application disclosed the biological relationship between CD and UC underlying UNIFI. It explained that biologic therapies approved for UC had "also demonstrated efficacy in [CD]," that both diseases "were mediated by Th1 or Th17 cells," that Stelara had been approved for CD, and that Stelara "may exert its clinical effects in [CD] and [UC] through interruption of the Th1 and Th17 cytokine pathways." JA944-945, JA1041_[J&J.SJ.Ex.22.at.5-6, 102]. In other words, it corroborated J&J's statement to the FDA that "it is reasonable to assume that ustekinumab will also be effective in UC" given "similarities in the genetics and biology of UC and Crohn's disease." JA623_[J&J.SJ.Ex.10.at.8529].

The assigned Examiner was Robert Landsman. JA1183_[J&J.SJ.Ex.26.¶22]; JA307_[J&J.SJ.Ex.1.at.1]. On July 13, 2020, Landsman independently visited CT.gov, where the UNIFI Protocol and trial progress were publicly posted, and three days later issued a non-final rejection of the '509 Application because of a CT.gov posting about the UNIFI trial. JA1110, JA1115, JA1117_[J&J.SJ.Ex.22.at.171, 176,178]; JA711_[J&J.SJ.Ex.21.¶90]; JA1190-1191, JA1195-1196_[J&J.SJ.Ex.26. ¶¶125,191-192]; JA516-517_[J&J.SJ.Ex.7.¶491].

Dichter then amended the application to incorporate details on UNIFI. JA1144-1149_[J&J.SJ.Ex.22.at.205-10]. He argued that the CT.gov posting could not invalidate the claims "[d]ue to the uncertainty of clinical outcomes" in using ustekinumab to treat UC. JA1143_[J&J.SJ.Ex.22.at.204]; JA3064_[J&J.SJ.Ex.24.at.152:13-17]. That same day, he disclosed additional materials, including the CT.gov website the examiner had already visited and several scientific articles on the CD-UC genetic relationship and Stelara's CD efficacy. JA1397-1398, JA1418_[CF.SJOpp.Ex.106A.at.252-53,273]; JA1424_[CF.SJOpp.Ex.106C.at.109]; JA1127-1128_[J&J.SJ.Ex.22.at.188-90]; JA514-515, JA517-519_[J&J.SJ.Ex.7.¶¶465,494-496].

Landsman allowed the '509 Application, noting that he considered CT.gov and some articles J&J disclosed. JA1158-1161_[J&J.SJ.Ex.22.at.219-22]; JA1446-1448_[CF.SJOpp.Ex.106E.at.295-297]. He also addressed a prior-art reference and concluded it did not render the claims unpatentable. JA1159-1161_[J&J.SJ.Ex.22.at.220-22]; JA437-438_[J&J.SJ.Ex.7.¶¶268-72]. The '307 Patent issued on March 30, 2021. JA307_[J&J.SJ.Ex.1.at.1].

II. Procedural History

At summary judgment, the District Court initially found a triable issue of fact as to whether J&J knew what the Momenta Manufacturing Patents claimed when it acquired them. Applying a general intent standard, it held that J&J's acquisition of

the Momenta Manufacturing Patents could have constituted a "willful acquisition or maintenance of [monopoly] power" because there was a dispute about whether J&J knew what the Momenta patents claimed—a prerequisite to knowing whether they could be enforced against Stelara biosimilar manufacturers—in 2020. JA39, JA43_[ECF.794.at.39, 43] (quoting *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 441 (4th Cir. 2011)). But the District Court's holding turned upon Plaintiffs' misrepresentation of the record.

Plaintiffs had opposed summary judgment by inaccurately arguing that an excerpt from J&J's privilege log showed that J&J's Global Head of IP Litigation, Denise DeFranco, possessed one of the Momenta Manufacturing Patents as early as June 2020, before the acquisition closed. JA43-44_[ECF.794.at.43-44]. That was wrong. The privilege log actually showed that DeFranco attached the relevant patent to a 2023 [redacted]—***sent years after the Momenta acquisition***. There was no evidence DeFranco had the patent before sending the 2023 email. JA1777_[J&J.SJ.Ex.81].

To obscure that fact, [redacted] JA4249-4250_[ECF.566.at.3-4]. [redacted]

[redacted] JA4104-4106_[CF.SJOpp.Ex.103.at.282:6-284:25]; JA4100-4101_[CF.SJOpp.Ex.103.at.278:3-279:7].

J&J moved for reconsideration. After reviewing all the evidence, the District Court found that Plaintiffs had "misled the *Court*" into believing DeFranco possessed the patents in 2020. JA60_[ECF.887.at.11 n.10] (emphasis in original). With the record corrected, the District Court found no "evidence upon which a reasonable jury could conclude that J&J had actual knowledge of the contents of the Momenta manufacturing patents such that it could have intended to exclude rivals from any potentially relevant market" and entered judgment for J&J on the Momenta claim. JA64, JA74_[ECF.887.at.15, 25].

On Plaintiffs' *Walker Process* claims, the District Court ultimately granted partial summary judgment to J&J on several of Plaintiffs' alleged misrepresentations and omissions because they were not material. JA74-76_[ECF.887.at.25-27]; JA69-74_[ECF.887.at.20-25]. It denied summary judgment on one alleged misrepresentation and several alleged omissions, *id.*, but Plaintiffs' case could not proceed without its Momenta claim, JA81-82_[ECF.925].

The District Court denied Plaintiffs' motion for reconsideration. JA79-80_[ECF.921.at.3-4]. Final judgment entered for J&J on February 11, 2026, and Plaintiffs appealed. JA81-82_[ECF.925].

SUMMARY OF ARGUMENT

I. This straightforward, fact-bound case should be affirmed. The District Court correctly applied well-settled law to grant summary judgment because Plaintiffs could not establish that J&J knew what the Momenta Manufacturing Patents claimed in 2020, or that J&J knew (or even could know) they could be enforced against future biosimilar Stelara manufacturers. Nor was there evidence then that J&J's patent acquisition had actual or foreseeable anticompetitive effects.

A. As the District Court recognized, Section 2 of the Sherman Act requires proof that a defendant "willful[ly]" acquired monopoly power through anticompetitive conduct, as distinguished from other means, including "historic accident." *Grinnell*, 384 U.S. at 570-71. Because monopolization is a general-intent offense, a plaintiff must show that the defendant knew facts that made its conduct allegedly anticompetitive at the time. A plaintiff does not satisfy that burden where, as here, a defendant unknowingly acquires an asset that later proves to have competitive significance. That principle is deeply embedded in Section 2 precedent, as reflected by Judge Hand's holding in *Alcoa*—a seminal case that the Supreme Court has cited more than 40 times—that it would be "not only unfair, but presumably contrary to the intent of Congress" to impose liability on a firm that "unwittingly find[s] [itself] in possession of a monopoly." 148 F.2d at 429-32. And it is reinforced by the Supreme Court's holding in *Grinnell* that the willfulness

element requires that monopoly power be "consciously acquired," 384 U.S. at 576 n.7.

The District Court's application of that principle broke no new ground. Applying settled law, it correctly held that J&J could not be liable for monopolization when it did not know what the Momenta Manufacturing Patents claimed in 2020. Moreover, J&J could not have known that those patents could be enforced against Stelara biosimilars. At that time, it did not know whether there would be Stelara biosimilars, who would make them, and what manufacturing processes they would use. And the patents themselves did not identify ustekinumab among the 29 different compounds the claimed processes could be used to make. No amount of diligence could have revealed whether a future Stelara biosimilar might use the processes the Momenta Manufacturing Patents covered.

B. Plaintiffs mistakenly argue that the District Court improperly applied a specific-intent standard. But that is wrong. And it is Plaintiffs who would cast aside well-established precedent. Plaintiffs argue that they could prove their claim by merely showing that J&J knowingly purchased Momenta. For Plaintiffs, it would make no difference that J&J did not know what the manufacturing patents claimed in 2020—or that J&J could not know that biosimilar Stelara manufacturers might one day infringe them. That standard amounts to strict liability, and it is irreconcilable with *Grinnell*'s requirement of willful acquisition of monopoly

power, *Alcoa*'s warning against liability for firms that "unwittingly find themselves in possession of a monopoly," *Aspen Skiing*'s recognition that a defendant's business rationale is relevant to whether challenged conduct is "exclusionary," and the many Fourth Circuit decisions relying on those cases. *See, e.g.*, *Duke Energy Carolinas, LLC v. NTE Carolinas II, LLC*, 111 F.4th 337, 353 (4th Cir. 2024); *2311 Racing LLC v. Nat'l Ass'n for Stock Car Auto Racing, LLC*, 139 F.4th 404, 409 (4th Cir. 2025). Plaintiffs cite no case to the contrary.

C. Plaintiffs' claims fail for three additional reasons: they did not establish that (1) J&J's acquisition of Momenta had any anticompetitive effect; (2) J&J had an anticompetitive rationale for acquiring Momenta; or (3) any asserted anticompetitive harm outweighed the procompetitive benefits of J&J's acquiring Imaavy or that J&J had a less restrictive alternative. Thus, the claims fail under the rule of reason.

D. Because Plaintiffs recognize these fundamental problems with their case, they seek to contort it into something it is not. But, at bottom, Plaintiffs challenge not the acquisition, but J&J's subsequent enforcement, of the Momenta Manufacturing Patents. That is constitutionally-protected petitioning activity under the *Noerr-Pennington* doctrine, and it cannot serve as the basis for antitrust liability unless an exception to the *Noerr-Pennington* applies. None applies here. And Plaintiffs' brief ignores *Noerr-Pennington* altogether.

II. The District Court also correctly entered judgment for J&J on elements of Plaintiffs' *Walker Process* fraud claim, which Plaintiffs concede cannot survive independently of their Momenta claim.

A. A *Walker Process* claim requires proof by clear and convincing evidence that the defendant made a knowing and willful misrepresentation or omission material to patentability, with specific intent to deceive the PTO. It also requires that, but-for the alleged fraud, the PTO would not have issued the patent. Plaintiffs can satisfy none of those requirements. The District Court properly found that the allegedly withheld information—the UNIFI Protocol—was before the Examiner. Regardless, the UNIFI Protocol cannot be but-for material because it reflects J&J's subjective expectations. Plaintiffs themselves concede that J&J's subjective expectations about UNIFI's likelihood of success are irrelevant to the obviousness inquiry.

B. Nor can Plaintiffs show specific intent to deceive. J&J publicly disclosed the UNIFI Protocol on CT.gov and directed the Examiner there, and Plaintiffs identify no J&J employee who intended to conceal it or deceive the PTO. And Plaintiffs cannot show Dichter's statements were fraudulent, since they were attorney argument based on his clinical-trial experience, not factual misrepresentations.

STANDARD OF REVIEW

This Court reviews the grant of summary judgment *de novo*, recognizing "that summary judgment is 'an important tool for dealing with antitrust cases,'" which are "'particularly well-suited for [summary judgment]' due to the 'unusual entanglement of legal and factual issues' they often present." *Kolon Indus. Inc. v. E.I. DuPont de Nemours & Co.*, 748 F.3d 160, 173 (4th Cir. 2014) (citations omitted).

ARGUMENT

I. J&J Did Not Willfully Acquire Monopoly Power Through Anticompetitive Conduct.

A. The District Court Correctly Entered Judgment For J&J On Plaintiffs' Momenta Claim.

This case should be affirmed under well-established principles of antitrust law. The District Court correctly held that Plaintiffs failed to identify a material factual dispute over whether J&J had "willfully" acquired monopoly power by purchasing Momenta. It applied the general-intent standard, focusing on whether J&J knew what the Momenta Manufacturing Patents claimed at the time of the deal. Because Plaintiffs could not show J&J had such knowledge, the District Court properly entered judgment for J&J.

1. The District Court Correctly Applied A General Intent Standard.

In both summary judgment opinions, the District Court's analysis turned on whether J&J had "***actual knowledge*** of the contents of the Momenta manufacturing patents" at the time of the acquisition such that it could know the patents could be enforced against Stelara biosimilars in the future. JA64_[ECF.887.at.15] (emphasis added); *see* JA43_[ECF.794.at.43]. Just as the law requires, it "separat[ed] wrongful from 'otherwise innocent' conduct" by requiring "proof of knowledge with respect to the actus reus" of the offense. *Carter v. United States*, 530 U.S. 255, 269 (2000); *see also United States v. Bailey*, 444 U.S. 394, 404-05 (1980). Despite Plaintiffs' attempt to rewrite these opinions on appeal, they were always about whether J&J knew what the Momenta Manufacturing Patents claimed—and, consequently, whether it could have had the general intent to engage in the allegedly anticompetitive conduct.

Plaintiffs' argument that the District Court applied a specific-intent standard, *see* Pls.Br.18, misconstrues the District Court's decisions. Plaintiffs' entire argument depends on the court's initial framing of the inquiry as whether J&J "intended to 'exclude rivals on some basis other than efficiency,'" JA40-41_[ECF.794.at.40-41] (quoting *2311 Racing*, 139 F.4th at 410). Plaintiffs claim that the District Court applied this language to require proof that J&J acquired Momenta with the specific intent to exclude competition from Stelara. Pls.Br.32-

33. Tellingly though, although Plaintiffs repeatedly quote this phrase, they never actually discuss how the District Court applied the law to the facts of this case.

That is because there can be no genuine dispute that the District Court applied a general-intent standard that turned on J&J's knowledge of the Momenta Manufacturing Patents. J&J's specific intent (in the sense of its business justification for the Momenta acquisition) played no role in the court's decisions, which turned entirely upon J&J's knowledge, not its specific intent.[1]

In its first opinion, the District Court applied the *Grinnell* standard, explaining that monopolization requires a "willful acquisition or maintenance of [monopoly] power—as opposed to simply superior products or historic accidents." JA39_[ECF.794.at.39] (*citing Eastman Kodak Co. v. Image Tech Servs., Inc.*, 504 U.S. 451, 480 (1992)). It held that Plaintiffs could show willfulness with evidence of "knowledge on the part of J&J of Momenta's manufacturing patents" at the time of the Momenta acquisition. JA43_[ECF.794.at.43]. Because Plaintiffs had misrepresented the evidence, the court mistakenly thought that "DeFranco had knowledge beyond mere awareness of the patent number[s]," and thus found a

[1] Because the District Court applied the correct analysis, this Court should affirm regardless of how the relevant standard was articulated. *See, e.g.*, *Liberty Mut. Ins. Co. v. Atain Specialty Ins. Co.*, 126 F.4th 301, 306 (4th Cir. 2025). The District Court indisputably held that Plaintiffs failed to provide any evidence of J&J's knowledge, which requires affirmance.

material factual dispute over whether J&J knew what the Momenta Manufacturing Patents claimed at the time of the acquisition. JA45_[ECF.794.at.45].

On reconsideration, the District Court applied the same knowledge-based standard. After discovering Plaintiffs' misrepresentation of the privilege log, the District Court concluded that there was no evidence that DeFranco knew what the Momenta Manufacturing Patents claimed at the time of the acquisition. JA64_[ECF.887.at.15]. The evidence it relied on earlier had "no probative value" because it was "attached to 2023 emails" and "do[es] not reveal anything about J&J's knowledge at the time of the acquisition." JA66_[ECF.887.at.17.n.14]. The District Court therefore granted summary judgment because J&J did not acquire Momenta ***knowing*** of any potential competitive impact on Stelara—*i.e.*, because it did not have general intent. J&J's specific intent did not play any role at all.

2. The District Court's Standard Was Consistent With Well-Established Precedent.

The District Court's analysis was correct under long-settled antitrust principles. "To prevail under Section 2 of the Sherman Act" requires showing that the defendant "willfully acquired or maintained [monopoly] power through anticompetitive conduct." *2311 Racing*, 139 F.4th at 409. To act willfully, a defendant must have "general intent" to do the act through which it allegedly acquired monopoly power. *Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 626 (1953); *see Grinnell*, 384 U.S. at 570-71. General intent requires that the

defendant ***knew*** the facts that made its conduct allegedly anticompetitive. *See, e.g.*, *Bailey*, 444 U.S. at 405 ("'knowledge' corresponds loosely with the concept of general intent"). A defendant who does not have such knowledge cannot have acted willfully, and therefore cannot be liable under Section 2. *See Kolon Indus., Inc.*, 637 F.3d at 441.

That basic premise is well-grounded in monopolization cases. In *Alcoa*, Judge Hand explained that "no monopolist monopolizes unconscious of what he is doing," which logically requires that a monopolist knows the facts that make its conduct anticompetitive. *See Alcoa*, 148 F.2d at 429-32. Thus, anyone who "unwittingly find[s] themselves in possession of a monopoly" cannot be liable for monopolization—and imposing such liability would be "not only unfair, but presumably contrary to the intent of Congress." *Id.* at 429-30.

Grinnell confirmed this same principle in its oft-quoted articulation of the elements of monopolization. Monopolization requires "the willful acquisition or maintenance of [monopoly] power as distinguished from" among other things, "historic accident." 384 U.S. at 570-71. Whether an acquisition of monopoly power was a "historic accident" or "willful" necessarily turns on what the defendant knew when the act was committed. *See id.; see also SCM*, 645 F.2d at 1207 (focusing on knowledge "at the time of the acquisition"); *Dimmitt Agri Indus., Inc. v. CPC Int'l Inc.*, 679 F.2d 516, 531 n.17 (5th Cir. 1982) (approving jury instructions requiring

that "[the] defendant knowingly and willfully obtained, or maintained" monopoly power). *Grinnell* itself found that the defendants had "consciously acquired" monopoly power through decades of deliberately anticompetitive conduct, which obviated any inquiry into whether it was acquired via "skill, acumen," or historic accident. *Id* at 576 n.7; *see also Amphastar Pharms. Inc. v. Momenta Pharms., Inc.*, 850 F.3d 52, 54 (1st Cir. 2017) (finding antitrust violation when defendant "***knowingly*** failed to disclose to the standard-setting body that a proposed method . . . might be covered by [its] pending patent application") (emphasis added).

The knowledge requirement is no different in the patent acquisition context, where plaintiffs must show that the defendant knew what the patents claimed and that they could be enforced against its competitors "at the time of acquisition." *SCM*, 645 F.2d at 1207-08. This standard requires proof that "the dominant competitor in a market acquire[d] a patent covering a substantial share of the same market that he ***knows*** when added to his existing share will afford him monopoly power." *Id.* at 1205 (emphasis added). In other words, there must be a connection between the defendant's knowledge and the *actus reus*—the guilty act. *Id.* It would "seriously undermine" the patent system if "the threat of potential antitrust liability . . . attach[ed] upon the acquisition of a patent" when a defendant did not have such knowledge. *Id.* at 1206.

Plaintiffs are wrong to suggest that they must only show that an acquiror knew

it was acquiring patents, even if it did not know what those patents claimed or whether they could be enforced against future actors. *See* Pls.Br.38. As *SCM* recognized, "the procurement of a patent . . . will not violate § 2 even where it is likely that the patent monopoly will evolve into an economic monopoly" absent a showing of knowledge. *SCM*, 645 F.2d at 1205-06; *see also Grinnell* 384 U.S. at 571. That rule would be meaningless if simply acquiring a patent were sufficient. Plaintiffs thus argue for an unprecedented strict-liability standard, not the general-intent standard of *Grinnell* and *Alcoa*. *See infra* at pp. 33-41.

3. This Court Should Affirm Because J&J Did Not Have General Intent To Acquire Patents Covering Methods Of Manufacturing Biosimilar Stelara.

Plaintiffs cannot satisfy the general-intent standard—and this Court can affirm—for two independent reasons. ***First***, as the District Court correctly held, J&J did not know what the Momenta Manufacturing Patents claimed. ***Second***, and fundamentally, it was ***impossible*** for J&J to have that knowledge at the time of the acquisition.

a) J&J Did Not Know What The Momenta Manufacturing Patents Claimed.

The record on J&J's actual knowledge at the time of the acquisition is undisputed. That alone is sufficient for affirmance. No one at J&J reviewed the Momenta Manufacturing Patents during the acquisition or knew what they claimed. JA3164-3166, JA3171, JA3176_[J&J.SJ.Ex.44.at.51:24-52:5, 70:5-23, 117:10-15,

128:10-18]; JA3101-3103_[J&J.SJ.Ex.40.at.75:24-76:24,79:6-15]. Every witness involved in the transaction testified [redacted] JA3110, 3113-3114_[J&J.SJ.Ex.40.at.116:5-24, 120:1-121:10]; JA3164-3167, JA3171, JA3179-3180_[J&J.SJ.Ex.44.at.51:24-52:25, 70:5-23, 74:16-20, 117:10-15, 239:25-240:24].

Against this uncontradicted record, Plaintiffs attempt to manufacture a factual dispute about J&J's knowledge in several ways. All of their attempts fail, because none establishes that any competitive significance of the Momenta Manufacturing Patents was known or knowable to J&J ***at the time of the transaction***.

First, Plaintiffs argue that because the four manufacturing patents were listed by name and number in the merger agreement, J&J "knew" it was acquiring them. Pls.Br.38. But knowing the name and number of patents is a far cry from knowing what they claimed or that they could someday be enforced against biosimilar manufacturers. The anticompetitive conduct Plaintiffs have alleged—the actus reus they must establish J&J knew it was committing—is acquiring patents that could protect Stelara from biosimilar competition. Pls.Br.2, 8, 36. But Plaintiffs have no evidence that J&J knew what the Momenta Manufacturing Patents claimed, meaning that J&J could not have known of their future competitive significance. Plaintiffs cannot show J&J's general intent by a "historic accident." *Grinnell*, 384 U.S. at 571.

Second, Plaintiffs argue that [redacted] Pls.Br.38. But Plaintiffs concede [redacted]

Third, Plaintiffs point to [redacted] Pls.Br.10. But they have no evidence that [redacted] JA4100-4101_[CF.SJOpp.Ex.103.at.278:3-279:7].

Fourth, Plaintiffs argue that J&J's privilege log implies that it concealed evidence of knowledge in properly withheld attorney-client communications. But this is the same misdirection the District Court properly rejected. There is no dispute that J&J properly invoked the privilege, and Plaintiffs may not seek a negative inference from the proper invocation of attorney-client privilege. *See In re Tudor Assocs., Ltd., II*, 20 F.3d 115, 120 (4th Cir. 1994); *Parker v. Prudential Ins. Co. of Am.*, 900 F.2d 772, 775 (4th Cir. 1990). Regardless, Plaintiffs' claims are not true. There is zero evidence—in J&J's privilege log or otherwise—that anyone at J&J knew what the Momenta Manufacturing Patents claimed during the acquisition.

That is why Plaintiffs resorted to misleading the District Court to avoid summary judgment.[2]

Finally, Plaintiffs attempt to reframe the knowledge inquiry away from the patent acquisition itself, claiming that the Court should look at J&J's conduct "holistically," including J&J's failure to divest the Momenta Manufacturing Patents and its later assertion of them against Amgen. Pls.Br.40.

Plaintiffs' argument fails at the outset because the lawfulness of a patent acquisition must be assessed "at the time of acquisition," and "[w]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws." *SCM*, 645 F.2d at 1206; *see* JA42_[ECF.794.at.42]. J&J's legitimate enforcement of the patents in 2023 says nothing about what it knew in 2020 and it cannot form a basis for antitrust liability under *Noerr-Pennington*. *See Baltimore Scrap Corp. v. David J. Joseph Co.*, 237 F.3d 394, 399 (4th Cir. 2001); *infra* at pp. 48-52. Plaintiffs cannot circumvent *Noerr-Pennington* by relying on post-acquisition conduct to make a lawful acquisition seem unlawful in retrospect.

Plaintiffs' reliance on *Duke Energy* does not help them either. On the

[2] Plaintiffs now claim that they were merely "arguing about reasonable inferences" and not "seeking" to mislead the court, but do not meaningfully dispute that they did in fact do so. Pls.Br.21.n.4.

contrary, *Duke Energy* reiterated the bedrock requirement that Section 2 requires ***willful*** monopolization, i.e., that a defendant know it is or could be obtaining monopoly power. Quoting *Grinnell*, it confirmed that "a monopolist does not violate § 2" if a "'historic accident' could explain" its success, which does not support Plaintiffs' theory. *See Duke Energy*, 111 F.4th at 353. *Duke Energy* also says nothing about whether post-acquisition patent enforcement can establish pre-acquisition knowledge. Further, because it does not even involve patent law, the Court plainly was not challenging the First Amendment right to petition recognized by *Noerr-Pennington*.

b) J&J Could Not Know The Momenta Manufacturing Patents Would Cover Processes Used By Future Biosimilar Manufacturers.

This Court can also affirm because, even if J&J had known what the Momenta Manufacturing Patents claimed, it could not have known in 2020 that future biosimilar manufacturers might someday use those processes. *See SCM*, 645 F.2d at 1207 (asking whether there was a "reasonably foreseeable" effect on competition "at the time of acquisition").

Again, this is undisputed in the record. The Momenta Manufacturing Patents mention 29 different compounds, but not ustekinumab, so nothing on their face suggested that they could someday be enforced against biosimilar Stelara manufacturers. JA3186-3187, JA3191_[J&J.SJ.Ex.46.¶¶28,68-82]. [redacted]

[redacted] JA3200-3249_[J&J.SJ.Ex.46.¶¶105-249]; JA3256-3258_[J&J.SJ.Ex.47.¶¶292-99]. [redacted] JA3288-3289, JA3294-3309_[J&J.SJ.Ex.53.at.106:5-107:7, 243:4-258:16].

These circumstances illustrate the implications of Plaintiffs' theory. If knowledge is irrelevant, every corporate acquisition involving patents would create the risk of unknowingly acquiring a ticking antitrust time bomb that could explode upon later patent enforcement. That untenable standard would chill procompetitive acquisitions. And nothing in existing antitrust precedent supports that illogical view.

B. Plaintiffs Mischaracterize The District Court's Standard And Propose An Incorrect Strict Liability Standard Instead.

Faced with no basis in existing precedent, Plaintiffs' central argument is that the District Court improperly applied a "specific intent" standard to their Momenta theory. Pls.Br.26. But that argument has two main problems. *First*, it miscasts the District Court's general-intent analysis. *Second*, it collapses the general-intent standard into a strict-liability standard that erases the willfulness requirement of *Grinnell*, *Alcoa*, and decades of binding precedent.

1. The District Court Did Not Apply A "Specific Intent" Standard.

Specific intent under the antitrust laws requires more than "the mere intent to" engage in the challenged conduct.[3] *Aspen Skiing*, 472 U.S. at 602 (quoting *Alcoa*, 148 F.2d at 432). To prove specific intent, a plaintiff must show that the defendant's purpose was "to accomplish the forbidden objective"—i.e., monopolization. *Id.*; *see also M&M Med. Supplies & Serv., Inc. v. Pleasant Valley Hosp., Inc.*, 946 F.2d 886 (4th Cir. 1991). That is markedly different from whether a defendant knew the facts that made its act allegedly anticompetitive.

If Plaintiffs were correct that the District Court applied a specific-intent standard, then the court would have asked whether J&J purposefully acquired Momenta to maintain or extend its alleged monopoly over Stelara. But the District Court did no such thing. Had it considered J&J's purpose rather than its knowledge, Plaintiffs would not have survived the Court's earlier summary judgment decision because they have never put forward evidence that J&J specifically intended to acquire Momenta and its patents to block biosimilar competition for Stelara.

Instead of looking to J&J's purpose, the Court considered whether J&J knew what the Momenta Manufacturing Patents claimed at the time of the acquisition. *See* JA64_[ECF.887.at.15]; *supra* at pp. 23-25. In fact, the only reason the Court granted

[3] Completed monopolization claims require general intent, while attempted monopolization claims require specific intent. *See Aspen Skiing*, 472 U.S. at 602.

J&J's motion for reconsideration was because it realized that Plaintiffs had misled it about evidence suggesting J&J had such knowledge—not because of any evidence related to J&J's specific intent to extend its alleged monopoly over Stelara. JA39-45_[ECF.794.at.39-45].

In an effort to distract, Plaintiffs mischaracterize the District Court's reasoning. They claim that the District Court "misread" Fourth Circuit precedent and "held that J&J could be found liable for monopolization ***only*** if J&J intended to exclude rivals on some basis other than efficiency." Pls.Br.32 (emphasis added). But, as explained above, the District Court never looked for evidence regarding whether J&J "intended to exclude rivals on some basis other than efficiency." *See supra* at pp. 23-25. Rather, it focused on the general-intent inquiry, which "require[d] knowledge on the part of J&J of Momenta's manufacturing patents," JA43_[ECF.794.at.43], and it entered summary judgment because J&J had none. JA54_[ECF.887.at.5].

Relatedly, Plaintiffs are wrong that the District Court admitted it was misapplying the law by stating in a footnote that proof of intent is "certainly not required" in monopolization cases. JA40_[ECF.794.at.40.n.19]. Their argument conflates two different uses of the word "intent"—intent in the sense of "general intent," i.e., ***knowledge*** of the facts that make the act anticompetitive, and intent in the sense of purpose, i.e., J&J's business rationale for the Momenta acquisition.

The District Court's footnote was addressing the latter understanding of intent—the "why" behind J&J's patent acquisition. It explained that while proof of an exclusionary purpose is not always required for monopolization cases, it is "helpful in cases involving practices . . . which can have numerous explanations and are very difficult to characterize as competitive or anticompetitive." JA40_[ECF.794.at.40.n.19]. That is a straightforward recognition of *Aspen Skiing*'s holding that purpose evidence is "relevant" to determining "whether the challenged conduct is fairly characterized as 'exclusionary' or 'anticompetitive'"—not legal error. 472 U.S. at 602. Regardless, as discussed above, the court did not grant J&J summary judgment based on J&J's rationale for the Momenta acquisition. It relied entirely on J&J's lack of knowledge and therefore its lack of general intent.

2. Plaintiffs Incorrectly Argue For A Strict Liability Standard.

Plaintiffs say that whether J&J knew what the Momenta Patents claimed in 2020 is irrelevant, and that it is enough that J&J voluntarily acquired the patents and enforced them years later. Since enforcing patents is inherently exclusionary, Plaintiffs' standard would always be satisfied by post-acquisition patent enforcement, regardless of knowledge or market conditions at the time of the acquisition. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1368 (Fed. Cir. 1998) (discussing the "exclusionary power inherent in [a] patent" (quoting *SCM*, 645 F.2d at 1204)). Contrary to *Grinnell* and *Alcoa*, Plaintiffs' rule would bypass any

inquiry into whether J&J willfully engaged in anticompetitive conduct at the time it acquired the patents. And it would leave that inquiry open to later events, making it impossible to determine, at the time of the acquisition, whether acquiring patents was anticompetitive.

The practical effect of adopting Plaintiffs' view cannot be overstated. Plaintiffs want the Court to replace the well-established monopolization standard with strict liability. Criminal and civil liability alike recognize three distinct levels of *mens rea*: (1) the "specific requirement of purpose," (2) "the more general one of knowledge or awareness," and (3) strict liability, which attaches regardless of the defendant's mental state. *United States v. United States Gypsum Co.*, 438 U.S. 422, 441 n.17, 445 (1978).[4] The Supreme Court has been "unwilling to construe the

[4] The FTC, too, argues that liability "does not turn on" J&J's knowledge and that "[i]t is sufficient that J&J bought [the] patents." Brief of FTC as Amicus Curiae ("FTC.Br.") at 20. That is plainly a strict-liability standard. It is certainly understandable that as an enforcement agency, the FTC might prefer a strict liability standard, just as class-action plaintiffs would. Nonetheless, that is not the law, and it is inconsistent with *Grinnell*, *Alcoa*, and the other cases the FTC cites. *See* FTC.Br.7-9. They cite essentially the same cases as Plaintiffs, and their standard is wrong for all the same reasons Plaintiffs' standard is wrong. *See supra* at pp. 33-41. This is simply the latest example of the FTC pushing overly aggressive positions to expand its enforcement authority. This Court should reject it, as others have. *See* Brief for FTC as Amicus Curiae, *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017); Brief for FTC as Amicus Curiae Supporting Plaintiff-Appellant, *Mylan Pharms., Inc. v. Warner Chilcott PLC*, 838 F.3d 421 (3d Cir. 2016); Brief of Amicus Curiae FTC in Support of Plaintiffs-Appellants and Reversal, *In re Watson Lab'ys, Inc.*, 101 F.4th 223 (2d Cir. 2024); *see also FTC v. Endo Pharms. Inc.*, 82 F.4th 1196 (D.C. Cir. 2023) (affirming dismissal of FTC's antitrust complaint).

Sherman Act as mandating a regime of strict-liability criminal offenses," *id.* at 436, and there is no reason this Court should do so for civil offenses either.

Most fundamentally, Plaintiffs' proposed standard creates an irreconcilable conflict in their arguments. On the one hand, they claim their standard requires "general intent to do the act," citing *Alcoa*'s "mere intent to do the act" formulation. Pls.Br.29 (quoting *Alcoa*, 148 F.2d at 432). On the other, they claim that any knowledge of what the act entails is irrelevant, as long as you do the act. Pls.Br.38-39. That does not make sense. You cannot have general intent to do something if you do not know you are doing it. The general-intent standard requires knowledge of the nature and circumstances of the act—i.e., the facts that make it anticompetitive. *Carter*, 530 U.S. at 269; *Bailey*, 444 U.S. at 405.

Plaintiffs' strict-liability standard also conflicts with three foundational principles that run through monopolization doctrine from *Alcoa* to the present. ***First***, it excises the willfulness requirement from monopolization law. *Grinnell* requires proof that a defendant willfully acquired or maintained monopoly power, as distinguished from acquiring it through "historic accident." 384 U.S. at 570-71. Under Plaintiffs' proposed standard, any voluntary act that later has exclusionary consequences is automatically unlawful. *Grinnell*'s "historic accident" holding would be meaningless if it makes no difference whether acquiring monopoly power was accidental or deliberate. *See id.*; *SCM*, 645 F.2d at 1206-07.

Second, Plaintiffs' standard ignores *Alcoa*'s explicit warning that it would be "not only unfair, but presumably contrary to the intent of Congress" to hold a defendant who "unwittingly find[s] themselves in possession of a monopoly" liable under the antitrust laws. 148 F.2d at 429-30. Section 7 of the Clayton Act confirms that Congress knew how to create an effects-only standard when it wanted to do so. *See* 15 U.S.C. § 18 (prohibiting acquisition that "may be substantially to lessen competition, or to tend to create a monopoly."). That is not what it did for Section 2, which has been interpreted to require a "willful" acquisition of monopoly power for nearly a century.

Third, Plaintiffs' standard renders *Aspen Skiing*'s holding incoherent. *Aspen Skiing* says that a defendant's purpose is relevant to whether its conduct can be "fairly characterized as 'exclusionary' or 'anticompetitive.'" 472 U.S. at 602. That holding makes sense only if purpose can sometimes be used to characterize conduct one way or the other. Under Plaintiffs' rule, intent can never perform that function, which simply cannot be squared with *Aspen Skiing*.

Because Plaintiffs' standard has no support in the law, it is unsurprising that they can cite no case applying the strict-liability standard they urge this Court to adopt. In every case cited by Plaintiffs, the defendants knew that their conduct was exclusionary. The *Alcoa* defendant "meant to keep, and did keep" control over the ingot market by knowingly building more capacity than the market demanded,

preventing others from entering. *See Alcoa*, 148 F.2d at 432. The *Aspen Skiing* defendant "made a deliberate effort to discourage its customers from doing business with its smaller rival." *Aspen Skiing*, 472 U.S. at 610. The *Griffith* defendants knew that the exclusionary "end result" of their conduct was "the necessary and direct consequence of what [they] did." *United States v. Griffith*, 334 U.S. 100, 108 (1948). And in *Grinnell*, "the record clearly show[ed] that [defendant's] monopoly power was consciously acquired." 384 U.S. at 576 n.7.

Plaintiffs' policy argument that a knowledge requirement would incentivize corporate acquirors to stick their head in the sand, refrain from necessary diligence, or "feign[] ignorance" to avoid antitrust liability is contrary to logic and law. Pls.Br.40. A defendant could not avoid knowledge by willful blindness, and existing safeguards would preclude such conduct, including (1) basic financial and corporate governance obligations to investigate the value of assets to justify the cost of an acquisition; (2) director and executive liability for oversight failures; (3) the HSR process, which already reflects the FTC's and DOJ's antitrust enforcement policies; and (4) the required inquiry into whether the defendant knew facts that would make it "reasonably foreseeable" that its conduct could have anticompetitive effects, *see SCM*, 645 F.2d at 1208-09. The reasonable foreseeability inquiry, in particular, makes it impossible to "feign[] ignorance." Further, antitrust plaintiffs are free to develop evidence if they have grounds to believe a firm willfully curtailed or hid

diligence efforts—just as litigants do in every case in which intent or knowledge are elements of their claims, and just as Plaintiffs tried (and failed) to do here.

Regardless, Plaintiffs' policy concerns are also inapplicable in this case. It was not possible for J&J to know, at the time of the Momenta acquisition, that the manufacturing patents could be asserted against Stelara biosimilars in 2023. No amount of patent diligence in 2020 could have given J&J this knowledge, which makes it especially improper to subject it to antitrust liability here.

C. This Court Can Alternatively Affirm Because Plaintiffs' Claims Fail Under The Antitrust Rule Of Reason.

In addition to Plaintiffs' failure to establish a triable issue on willfulness, this Court could also affirm on the alternative ground that their claims founder on multiple steps under the rule of reason framework. Plaintiffs cannot establish that J&J's conduct was anticompetitive—i.e., that it "unreasonably restrained competition"—when it happened. *United States v. Microsoft Corp.*, 253 F.3d 34, 95 (D.C. Cir. 2001); *SCM*, 645 F.2d at 1210. And Plaintiffs cannot show that any competitive harm from J&J's conduct would outweigh its procompetitive benefit or that J&J could have achieved those benefits with a less restrictive alternative. *See Microsoft*, 253 F.3d at 59; *FTC v. Qualcomm Inc.*, 969 F.3d 974, 991 (9th Cir. 2020).

1. J&J's Conduct Was Not Anticompetitive At The Time Of The Transaction, Which Warrants Affirmance.

a) J&J's Conduct Was Not Anticompetitive Because The Momenta Acquisition Had No Impact On Competition For Stelara In 2020.

As an initial matter, this Court can affirm because Plaintiffs cannot show that the acquisition had any competitive effect in 2020. *SCM*, 645 F.2d at 1210. The relevant and dispositive inquiry is whether J&J's acquisition of Momenta and its patents was anticompetitive "at the time of the acquisition," and the answer is indisputably no. *SCM*, 645 F.2d at 1207. At that time, no one had started selling biosimilar Stelara or even sought FDA approval to do so. JA3255_[J&J.SJ.Ex.47.¶84]. Nor did J&J know what the Momenta Manufacturing Patents covered, or have any way to know that they would have any relation to biosimilar competition. *See supra* at pp. 28-33.

Plaintiffs nevertheless argue the acquisition was retroactively anticompetitive because it allegedly had anticompetitive effects ***years later***, when J&J enforced the patents it acquired. That is not the law. *See SCM*, 645 F.2d at 1207; *see infra* at pp. 48-52. If accepted, Plaintiffs' theory would radically expand antitrust liability to penalize acts with competitive significance unknowable at closing that could only conceivably be traced to ***future*** exclusionary effects with perfect hindsight.

b) J&J's Conduct Was Not Exclusionary Because It Had No Anticompetitive Rationale For Acquiring Momenta.

The fact that J&J acquired Momenta for ***procompetitive*** reasons entirely unrelated to Stelara is an independent reason why this Court can affirm, even though the District Court ruled based upon J&J's knowledge, not its business rationale. The Supreme Court has recognized that a defendant's motivation for engaging in the challenged act—its business rationale or purpose—is "relevant to the question whether the challenged conduct is fairly characterized as 'exclusionary' or 'anticompetitive.'" *Aspen Skiing Corp. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602-03 (1985). Under that rubric—which is separate from the question of J&J's general intent—the undisputed record on J&J's motivation allows only one conclusion: the Momenta acquisition was not an act of exclusion.

In *Aspen Skiing*, the Court held that a defendant's business rationale for engaging in allegedly anticompetitive conduct bears on whether that conduct may be fairly considered anticompetitive. 472 U.S. at 605 (holding that conduct is only anticompetitive if it "exclude[s] rivals on some basis other than efficiency"). As a result, mere possession of alleged monopoly power is not unlawful, since a defendant "does not violate Section 2" and has not engaged in anticompetitive conduct "if valid business reasons exist" for its conduct. *Id.* at 602; *see Eastman Kodak*, 504 U.S. at 483 ("Liability turns . . . on whether 'valid business reasons' can

explain [defendant's] actions."); *Grinnell*, 384 U.S. at 571 (distinguishing unlawful acquisitions from "growth or development as a consequence of a superior product, business acumen, or historic accident"); *Oksanen v. Page Mem'l Hosp.*, 945 F.2d 696, 710 (4th Cir. 1991) (en banc) (affirming summary judgment when plaintiff "failed to demonstrate the monopolistic intent necessary for a section two claim" because the defendant "had valid business . . . reasons" for its conduct); *White v. Rockingham Radiologists, Ltd.*, 820 F.2d 98, 105 (4th Cir. 1987) (requiring plaintiff to "show that a jury could find no valid business reason or concern for efficiency" in the challenged conduct). That is consistent with other bedrock monopolization cases that have also examined a defendant's rationale to determine whether its conduct was unlawfully anticompetitive. *See Grinnell*, 384 U.S. at 571 (condemning defendant's acquisitions because they were "done plainly and explicitly for a single [anticompetitive] purpose"); *Alcoa*, 148 F.2d at 429-32 (analyzing defendant's motivation for each element of the alleged scheme).

This Court can therefore affirm on the alternative ground that J&J's business rationale for the acquisition makes it impossible to fairly categorize J&J's conduct as exclusionary. The undisputed evidence shows that J&J acquired Momenta for the procompetitive purpose of developing Imaavy—a drug with therapeutic applications entirely unrelated to Stelara—not to extend any alleged monopoly over Stelara. JA3083, JA3095-3100_[J&J.SJ.Ex.40.at.32:6-18,48:15-53:15]; JA3119_[J&J.SJ.

Ex.41.at.8129]. Every witness who participated in the transaction or the due diligence process [redacted], and there is no evidence that J&J intended to exclude Stelara biosimilar manufacturers through the Momenta acquisition. JA3104, JA3110, JA3113-3114_[J&J.SJ.Ex.40.at.89:9-16, 116:5-24, 120:1-121:10]; JA3164-3166, JA3176_[J&J.SJ.Ex.44.at.51:24-52:5, 70:5-23, 117:10-15, 128:10-18]; JA3144-3159_[J&J.SJ.Ex.43].

Alcoa demonstrates how courts can properly consider intent in determining whether conduct is anticompetitive for Section 2 purposes. There, the government alleged that Alcoa had purchased bauxite deposits—the mineral from which aluminum is refined—"in excess of its needs," and it claimed that these purchases had the anticompetitive effect of blocking others from accessing a key input necessary to make aluminum and compete with Alcoa. 148 F.2d at 432-33. Even though the court elsewhere held that Alcoa acted anticompetitively by expanding its aluminum capacity in excess of what the market demanded, *id.*, it rejected this specific claim. It explained that "[t]he very statement of [the government's] charge shows that it depends upon Alcoa's intent," and that "if [Alcoa's] purchases provided for the future needs of [Alcoa's] business, or for what Alcoa honestly believed were its future needs," then "they were innocent" and could not be condemned as anticompetitive. *Id.* So too here. Plaintiffs' theory is that J&J

acquired Momenta to block biosimilar competition, but the record indisputably shows that is not true. J&J acquired Momenta for the procompetitive purpose of commercializing Imaavy, not for some anticompetitive purpose.

2. Plaintiffs Developed No Record On The Balancing Test Or Less Restrictive Alternatives, Which Separately Warrants Affirmance.

Plaintiffs' failures to establish (1) that the Momenta acquisition had anticompetitive effects in 2020 or (2) that J&J had any anticompetitive rationale for acquiring Momenta end the rule of reason inquiry, but this Court can also affirm under the rule of reason's balancing step. *See Eastman Kodak*, 504 U.S. at 483. Commercializing a novel therapeutic compound like Imaavy is the kind of procompetitive, innovation-promoting goal antitrust law does not penalize. Plaintiffs have offered no evidence that this justification was pretextual or insufficient, so the burden shifts back to them to show that any anticompetitive harm from the acquisition outweighs the procompetitive benefit of acquiring Imaavy or that J&J had a less restrictive alternative. *See Microsoft*, 253 F.3d at 59. Plaintiffs cannot satisfy that burden.

On balancing, the "harm" Plaintiffs seek to weigh against J&J's procompetitive justification is itself legally protected conduct under *Noerr-Pennington* that cannot form the basis of antitrust liability. *See Baltimore Scrap Corp.*, 237 F.3d at 399; *see infra* at pp. 48-52. Any harm Plaintiffs have alleged

happened years after the Momenta acquisition, and it does not flow from the acquisition itself—it flows from J&J's constitutionally protected enforcement of the Momenta Manufacturing Patents in the patent litigation. *Id.* Allowing Plaintiffs to challenge J&J's patent acquisition under the guise of challenging its consequences would improperly circumvent *Noerr-Pennington*.

On less restrictive alternatives, all of Plaintiffs' proposed alternatives—divesting the patents, surrendering them, or declining to assert them in litigation—reduce to the same argument: that J&J should not have enforced its lawfully acquired patents. Pls.Br.10, 38-40. Those are not less restrictive alternatives to the Momenta acquisition. They are demands that J&J forfeit lawfully acquired patents simply because it became clear—years after the acquisition—that the patents could be asserted against certain Stelara biosimilar manufacturers. The law does not impose that obligation, and "[n]o court has ever held that the antitrust laws require a patent holder to forfeit the exclusionary power inherent in his patent the instant his patent monopoly affords him monopoly power over a relevant product market." *SCM*, 645 F.2d at 1204 (2d Cir. 1981). Plaintiffs' rule would gut both the patent system and the *Noerr-Pennington* doctrine simultaneously.

D. Independently, Plaintiffs' Claims Fail Because of *Noerr-Pennington*.

Plaintiffs never mention *Noerr-Pennington* in their briefing. That omission is telling, because *Noerr-Pennington* explains why Plaintiffs have gone to great lengths

to frame their antitrust claims in terms of J&J's acquisition of the Momenta Manufacturing Patents instead of J&J's enforcement of those patents.

1. Absent Narrow Exceptions, Patent Enforcement Cannot Result In Antitrust Liability.

The Constitution gives Congress the power to secure for inventors "the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. Congress exercised that power in the Patent Act, giving patentholders the right to assign, grant and convey patents. 35 U.S.C. § 261. A patent is, by design, "an exception to the general rule against monopolies." *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965). Therefore, the exclusionary power a patent confers is not an antitrust problem. It is a policy choice Congress deliberately made.

A patent holder has a First Amendment right to enforce its statutory rights in court without threat of antitrust liability. Because the First Amendment guarantees the right to petition the government, the *Noerr-Pennington* doctrine immunizes parties from antitrust liability for doing so. *See Eastern Railroad Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). That immunity extends to patent enforcement. *Baltimore Scrap Corp.*, 237 F.3d at 399.

There are only two narrow exceptions to *Noerr-Pennington* immunity for patents. It does not apply to patent lawsuits that are both objectively baseless and

brought in subjective bad faith, and it does not apply if a patent is obtained via fraud on the PTO. *See Prof. Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49, 60-61 (1993); *Walker Process*, 382 U.S. at 172.

Both exceptions require a substantial *mens rea* showing. A sham-litigation claim requires proof of the defendant's "subjective motive" in bringing a baseless lawsuit, *Waugh Chapel S. v. United Food & Com. Workers Union Loc. 27*, 728 F.3d 354, 364 (4th Cir. 2013), while a *Walker Process* claim requires proof of "intentional fraud," 382 U.S. at 176. Tellingly, these strict requirements stand in stark contrast to the weak rule Plaintiffs propose here, which would strip patent enforcement of any *Noerr-Pennington* protection without any *mens rea* at all.

2. Plaintiffs Cannot Challenge J&J's Enforcement Of The Momenta Manufacturing Patents Through A Purported Challenge To Their Acquisition.

There is no version of Plaintiffs' theory of harm in which the Momenta acquisition itself—standing alone—caused antitrust harm. Their arguments repeatedly run into *Noerr-Pennington* because their case is not really about the Momenta acquisition, which had no actual or foreseeable anticompetitive effects. Instead, they are trying to backdoor-challenge J&J's ***enforcement*** of the Momenta Manufacturing Patents by rebranding it as a challenge to J&J's patent acquisition. But that tactic does not change the substance of their claim. To hold otherwise would make *Noerr-Pennington* a dead letter and open a circuit split. *See Mayor & City*

Council of Baltimore v. AbbVie Inc., 42 F.4th 709, 713 (7th Cir. 2022) ("Trying to conjure liability out of successful petitions for governmental aid in blocking competition runs into the *Noerr-Pennington* doctrine.").

Plaintiffs' claim also looks nothing like the rare cases holding that patent acquisitions violate the antitrust laws. Those cases share features—like horizontal "patent pooling"—entirely absent here. *See Hartford-Empire Co. v. United States*, 323 U.S. 386, 406-09 (1945); *United States v. Singer Manufacturing Co.*, 374 U.S. 174 (1963). And they typically condemn purposeful aggregation of patents among competitors to exclude others. But J&J's acquisition of the Momenta Manufacturing Patents shares none of those features, since there was no horizontal conduct, coordinated scheme, or patent pool.

Before the District Court, Plaintiffs argued that *Noerr-Pennington* does not apply based on the First Circuit's decision in *Amphastar*. That case held that, although an "infringement suit 'cannot itself be the antitrust violation without invoking *Noerr*,'" it "does not immunize [a defendant] from liability for the full amount of damages caused by their alleged antitrust violation." 850 F.3d at 57-58. In other words, if a plaintiff can ***independently*** establish an antitrust violation

involving a patent, it can use the enforcement of that patent as proof that it was harmed by that antitrust violation.[5]

But *Amphastar* does not help Plaintiffs because they cannot make that threshold showing. As the prior sections establish, J&J's acquisition of the Momenta Manufacturing Patents was not anticompetitive. *See supra* at pp. 42-46. Without an independently unlawful acquisition to serve as the anchor, Plaintiffs cannot (circularly) bootstrap subsequent exclusionary effects from J&J's patent acquisition to argue that the acquisition was unlawful in the first instance. J&J was entitled to enforce its lawfully acquired patents. *SCM*, 645 F.2d at 1206.

Finally, even if this Court were to reach the enforcement question, J&J's assertion of the Momenta Manufacturing Patents never had exclusionary effects and never kept biosimilar manufacturers off the market. As long as they received FDA approval, those manufacturers remained free to launch at risk of an adverse outcome in the patent proceeding without waiting for the enforcement litigation to conclude.[6]

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[5] In *Amphastar* itself, the antitrust violation was the defendant's "intentional deception of the standard-setting organization," which caused the standard-setting organization to adopt a method for testing a generic drug that the defendant knew was covered by one of its patents. 850 F.3d at 57. The FDA required the plaintiffs to use that method, and the defendant then sued it for patent infringement. *Id.* at 54. The antitrust violation was the intentional deception of a private standard-setting organization, not the patent enforcement.

[6] The Biologics Price Competition and Innovation Act ("BPCIA"), unlike the Hatch-Waxman framework governing small-molecule generics, imposes no

While those manufacturers chose to settle, Plaintiffs have never claimed that those settlements were anticompetitive. Nor could they, since the Supreme Court held in *FTC v. Actavis*, 570 U.S. 136, 151-52 (2013), that standard patent litigation settlements granting early market entry—where biosimilar manufacturers receive royalty-free licenses to enter ahead of patent expiration, without reverse payments—are "commonplace," lawful arrangements. *Id.* [redacted] JA3321-3322_[J&J.SJ.Ex.55.¶72]; JA3353_[J&J.SJ.Ex.56.at.3583]. That is precisely the kind of early-entry settlement *Actavis* permits.

II. This Court Should Affirm Partial Summary Judgment On Plaintiffs' *Walker Process* Claim Because J&J Did Not Engage in Inequitable Conduct Before The PTO.

Plaintiffs conceded their *Walker Process* claim cannot survive without their Momenta claim, so this Court need not reach it here. Pls.Br.22-23. Regardless, it independently fails. Plaintiffs cannot show but-for materiality for the UNIFI Protocol or any alleged misrepresentation because all relevant information was before the Examiner when he allowed the '509 application. The record also contains no evidence of specific intent to deceive.

automatic stay of FDA approval upon the filing of patent infringement litigation. *Cf.* 21 U.S.C. § 355(j)(5)(B)(iii).

To prevail on a *Walker Process* claim, Plaintiffs must show by clear and convincing evidence that J&J obtained the '307 Patent "by knowing and willful fraud" and "maintained and enforced that patent with knowledge of the fraudulent procurement." *Chandler v. Phoenix Services LLC*, 1 F.4th 1013, 1014 (Fed. Cir. 2021) (cleaned up); *see also Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011). A duty-bound individual "associated with the filing and prosecution" must have (1) "misrepresented or omitted information material to patentability" with (2) "specific intent to mislead or deceive the PTO." *Network Signatures, Inc. v. State Farm Mutual Auto. Ins. Co.*, 731 F.3d 1239, 1242 (Fed. Cir. 2013); 37 C.F.R. § 1.56(a). Plaintiffs cannot meet their burden here.

On materiality, Plaintiffs must show that the undisclosed reference was but-for material—that "the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Therasense*, 649 F.3d at 1291; *Network Signatures*, 731 F.3d at 1242. A reference cannot be but-for material if it is merely cumulative. *Global Tubing LLC v. Tenaris Coiled Tubes LLC*, 167 F.4th 1357, 1370 (Fed. Cir. 2026). Specific intent to deceive must be "the single most reasonable inference" from the evidence. *Therasense*, 649 F.3d at 1290-91.

A. The District Court Correctly Held That Plaintiffs Cannot Establish But-For Materiality.

1. The UNIFI Protocol Is Not But-For Material.

a) The "Omitted" Information Was Before The PTO.

Plaintiffs contend J&J deliberately withheld the UNIFI Protocol and other materials from the PTO, depriving the Examiner of information that would have led him to reject the '307 Patent application. Pls.Br.44-48. They are wrong.

First, the UNIFI Protocol was before the Examiner. J&J publicly disclosed it on CT.gov, it was available when the Examiner accessed CT.gov on July 13, 2020, and Dichter directed the Examiner to CT.gov in October 2020. JA516-517_[J&J.SJ.Ex.7.¶491]; JA1117_[J&J.SJ.Ex.22.at.178]; JA1190-1191, JA1195-1196_[J&J.SJ.Ex.26.¶¶125,191-192]; JA1397-1398, JA1418_[CF.SJOpp.Ex.106A.at.252-53,273]; JA1424_[CF.SJOpp.Ex.106C.at.109].

Second, the allegedly withheld information in the UNIFI Protocol was independently before the Examiner, as explained in the below chart:

Allegedly Withheld Information	Before The Examiner
CD and UC have (1) "inflammatory mechanisms at the mucosal level [that] are largely the same" and (2) "'similar response[s] to current treatment' in general." Pls.Br.53-54.	The '509 Application and '307 Patent disclosed the CD/UC genetic relationship, including that (1) CD and UC were "mediated by Th1 or Th17 cells"; (2) Stelara "may exert its clinical effects" in CD and UC by interrupting these pathways; and (3) Stelara "resulted in a decrease in inflammatory markers" for CD and UC patients. JA944-945, JA1041_[J&J.SJ.Ex.22.

Allegedly Withheld Information	Before The Examiner
	at.5-6, 102]
"[T]he protocol cited the Jostins and Granlund studies, which explained the genetic similarities between [CD] and [UC]." Pls.Br.54.	The '509 Application and '307 Patent disclose UC and CD's genetic similarities, as do articles Dichter submitted to PTO, such as the Brant article that summarized Jostins. JA944-945, JA1041, JA1127_[J&J.SJ.Ex.22. at.5-6, 102, 188]; JA509-511, JA514-515_[J&J.SJ.Ex.7.¶¶454-455, 465]
J&J's statements that (1) "the shared 'genetics and biology' of the two diseases made it 'reasonable to assume' that ustekinumab would effectively treat [UC]" and (2) "there was a 'substantial scientific and clinical rationale' to expect the clinical trial to succeed." Pls.Br.54-55	The '509 Application and '307 patent disclose the UC/CD genetic relationship, that UC therapies "have also demonstrated efficacy in [CD]," and that Stelara was approved for CD. JA944-945_[J&J.SJ.Ex.22.at.5-6]

Because the Examiner was "aware of" this allegedly withheld information, Plaintiffs cannot show but-for materiality.[7] *U.S. Water Servs., Inc. v. Novozymes A/S*, 843 F.3d 1345, 1354 (Fed. Cir. 2016); *Andrew Corp. v. Gabriel Elecs., Inc.*, 847 F.2d 819, 823-24 (Fed. Cir. 1988) (no materiality where allegedly withheld information was "disclosed generically in the patent application").

b) The UNIFI Protocol Cannot Be But-For Material.

Regardless, Plaintiffs' but-for materiality argument incorrectly assumes that the UNIFI Protocol would have led the Examiner to "den[y] the application as

[7] Plaintiffs' non-binding District Court decisions are unavailing, Pls.Br.53-55, because each involved a genuine factual dispute over materiality, whereas here the undisputed record shows the Examiner had the relevant information.

obvious." Pls.Br.48. But patent obviousness turns on what a person of ordinary skill in the art ("POSA") would have understood from prior art—"not whether [an invention] was obvious to the patentee." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007).

Therefore, even if J&J subjectively believed that UNIFI would succeed, that belief is irrelevant to obviousness and cannot render a patent invalid. *See, e.g.*, *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012) ("The inventor's own path itself never leads to a conclusion of obviousness; that is hindsight."). Indeed, Plaintiffs conceded that "what J&J subjectively thought about the likelihood [UNIFI] would succeed is not relevant to . . . obviousness under patent law." JA1756_[Dkt.552.at.16]. The UNIFI Protocol's statement that "it is reasonable to assume that ustekinumab will also be effective in UC" represents nothing more than J&J's subjective expectations about whether the trial would succeed. Since J&J's subjective belief cannot render the '307 Patent invalid, it cannot support a *Walker Process* claim. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070 (Fed. Cir. 1998) (fraud must "cause the PTO to grant an invalid patent"); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 690 (2d Cir. 2009) ("If a patent is valid, a *Walker Process* claim cannot stand.").

2. The Alleged Misrepresentations Are Not But-For Material.

Plaintiffs also cannot show Dichter's statements were actionable misrepresentations, let alone but-for material. To establish *Walker Process* fraud, Plaintiffs must show that Dichter made a false representation of a ***fact*** material to patentability. *Nobelpharma*, 141 F.3d at 1070-71. Plaintiffs' own expert conceded Dichter's statements about clinical trial uncertainty were attorney arguments, not factual representations, and thus not actionable. JA534_[J&J.SJ.Ex.8.at.99:13-23]; *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000) (argument that "merely advocat[ing] a particular interpretation of the [prior art]" cannot be a misrepresentation).

Plaintiffs argue the Examiner's access to CT.gov is irrelevant because the UNIFI Protocol called UNIFI a "sure bet." Pls.Br.55-56. But the Examiner cited CT.gov—where the UNIFI Protocol was posted—and "was free to reach his own conclusions" about Dichter's clinical-uncertainty arguments. *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007); JA29_[ECF.794.at.29]. UNIFI also included a pre-specified futility analysis to account for the possibility that Stelara would prove ineffective, corroborating Dichter's arguments. Regardless, the Examiner never mentioned any of Dichter's statements in allowing J&J's application, confirming they were immaterial. JA1159-1161_[J&J.SJ.Ex.22.at.220-22]; JA437-438_[J&J.SJ.Ex.7¶¶268-72].

B. There Is No Evidence Of Specific Intent To Deceive.

1. J&J Did Not Conceal The UNIFI Protocol.

How can a party before the PTO post a reference publicly, tell the Examiner where to find it, and yet have specific intent to conceal that document? Plaintiffs have no answer to that question. Indeed, Plaintiffs adduced no evidence that any duty-bound J&J employee withheld the UNIFI Protocol with intent to deceive. It is undisputed that J&J made the protocol publicly available on CT.gov and that Dichter directed the Examiner there while it was available. *See supra* at pp. 54-57.

Nor do Plaintiffs have evidence that the '307 Patent inventors intended to deceive anyone. They do not identify the specific inventors who purportedly withheld the UNIFI Protocol, let alone have evidence that they did so deliberately. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329 (Fed. Cir. 2009); *1st Media, LLC v. Electronic* Arts, Inc., 694 F.3d 1367, 1375 (Fed. Cir. 2012). Although Plaintiffs suggest certain inventors reviewed information on the CD/UC relationship and UNIFI's likelihood of success, Pls.Br.49-50, they offer no evidence they believed the protocol was material to patentability. *Therasense*, 649 F.3d at 1290.

Similarly, Plaintiffs have no evidence that Ralat intended to deceive the PTO. Ralat had no role in prosecuting the '509 Application and no knowledge of ***any*** pending claims, let alone what was material to their patentability. JA1774_[J&J.SJ.Ex.73.at.110:2-13]. The duty of candor applies only to those

"substantively involved" in patent prosecution and only "with respect to each *pending claim*," so Ralat's conduct is irrelevant. 37 C.F.R. § 1.56(a), (c)(3). "[T]here is no duty to submit information which is not material to the patentability of any existing claim." *Id.*

Plaintiffs' "selective deletion" theory also fails because Ralat did not "delete" anything. Pls.Br.47. He copied enough of the UNIFI Protocol into the provisional application so that "a [POSA] would understand the invention" and J&J's tempered optimism about UNIFI's likelihood of success. JA4149-4154_[CF.SJOpp.Ex.105.at.225:8-230:4]. Ralat was not obligated to use the exact words of the UNIFI Protocol. *See Andrew Corp.* 847 F.2d at 823-24. Plaintiffs are plainly wrong that J&J "offered no competing explanation" for Ralat's drafting decisions. Pls.Br.51.

Nor do Plaintiffs' cited cases support finding intent to deceive. Pls.Br.50. In *Merck*, the prosecutor and inventor knew the omitted information was material, but Ralat knew nothing about the claims. *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1420 (Fed. Cir. 1989). Plaintiffs' remaining cases found intent where the ***same individual*** caused inconsistencies across two proceedings, but Ralat was involved in neither. He did not draft the UNIFI Protocol or prosecute the '307 Patent. *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348,

1354 (Fed. Cir. 2005); *Belcher Pharm., LLC v. Hospira, Inc.*, 11 F.4th 1345, 1354 (Fed. Cir. 2021).

2. Plaintiffs Offered No Evidence Of Intent To Deceive Regarding The Alleged Misrepresentations

As explained above, Plaintiffs cannot show that Dichter's statements about clinical uncertainty were fraudulent because they were attorney argument. *See supra* at pp. 54-57. They cannot even show that they were "false," since it is undisputed that Phase III trials fail 40-50% of the time. JA2422-2423_[J&J.SJ.Ex.5.¶47]; *Nobelpharma AB*, 141 F.3d at 1070-71.

Plaintiffs also cannot show that intent to deceive is the single most reasonable inference from the evidence. Dichter's uncontradicted testimony was that he made these statements based on his extensive experience with clinical trials generally and Stelara specifically. JA3064_[J&J.SJ.Ex.24.at.152:15-17]. Plaintiffs thus cannot show deceptive intent. *Freshub, Inc. v. Amazon.com, Inc.*, 93 F.4th 1244, 1254 (Fed. Cir. 2024) (affirming rejection of inequitable conduct defense). Further, Plaintiffs are wrong that Dichter's representations contradicted the UNIFI Protocol. Pls.Br.55-56. Dichter disclosed J&J's scientific rationale for UNIFI—and thus its tempered optimism—in the '509 Application.[8] JA33_[ECF.794.at.33].

[8] Plaintiffs' cases are inapposite. Pls.Br.43. Each involved parties taking a directly contradictory position before two authorities. *Belcher,* 11 F.4th at 1353-54 (applicant told FDA pH range was "old" but told PTO it was a "'critical' innovation"); *Therasense, Inc. v. Becton, Dickinson & Co.*, 864 F. Supp. 2d 856,

CONCLUSION

For the reasons above, the Court should affirm the District Court's order granting summary judgment to J&J.

Dated: September 8, 2026

Respectfully submitted,

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861-63 (N.D. Cal. 2012) (applicant told EPO prior art sentence "unequivocally" meant a membrane was optional but told PTO it required a membrane).

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 12,927 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 Times New Roman font.

Dated: September 8, 2026

/s/ *George G. Gordon*
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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:

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