26-1194(L)

26-1228(Con), 26-1251(Con), 26-1275(Con)

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

LOUISIANA HEALTH SERVICE & INDEMNITY COMPANY, D/B/A BLUE CROSS & BLUE SHIELD OF LOUISIANA, HMO LOUISIANA, INC., DAVID MITCHELL, individually and on behalf of all others similarly situated,

Plaintiffs-Appellants,

NEW YORK HOTEL TRADES COUNCIL & HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated, CENTERWELL PHARMACY, INC., THE CIGNA GROUP,

Consolidated Plaintiffs-Appellants,

v.

CELGENE CORPORATION, BRISTOL-MYERS SQUIBB COMPANY, ANTHONY INSOGNA, JEROME ZELDIS,

Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of New York
No. 1:23-cv-07871-ER

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the Pharmaceutical Research and Manufacturers of America states that it has no parent corporation, and no corporation or publicly held company owns 10% or more of its stock.

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT i

TABLE OF AUTHORITIES iv

INTEREST OF *AMICUS CURIAE* 1

SUMMARY OF ARGUMENT 2

ARGUMENT 6

I. The District Court Correctly Held That Appellants Lack Antitrust Standing to Pursue *Walker Process* Claims. 6

A. Courts Have Uniformly Held That Indirect Purchasers Do Not Have Standing to Assert *Walker Process* Claims 7

B. The "Efficient Enforcer" Factors Foreclose Appellants' Claims. 8

II. Extending *Walker Process* Standing to Indirect Purchasers Would Distort Settled Constitutional and Antitrust Standing Principles and Disincentivize Innovation 20

A. Appellants' State-Law Standing Theory Cannot Be Reconciled with *AGC* or *Noerr-Pennington*'s First Amendment Protections. 20

B. The Court Should Not Countenance Different Antitrust Standing Rules for the Pharmaceutical Industry. 23

C. Downstream Treble-Damages Exposure Would Erode the Patent Predictability That Sustains Biopharmaceutical Innovation. 26

D. Exposing Patentholders to Claims by Remote Downstream Purchasers Could Chill Legitimate Patent Enforcement. 30

CONCLUSION 31

CERTIFICATE OF COMPLIANCE 32

CERTIFICATE OF SERVICE 33

TABLE OF AUTHORITIES

Page(s)

Cases

In re Am. Express Anti-Steering Rules Antitrust Litig.,
19 F.4th 127 (2d Cir. 2021) 9, 10, 11, 16, 17

Am. Original Corp. v. Jenkins Food Corp.,
696 F.2d 1053 (4th Cir. 1982) 21

Apple Inc. v. Pepper,
587 U.S. 273 (2019).....24

Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters,
459 U.S. 519 (1983).....5, 13, 19

Atl. Richfield Co. v. USA Petroleum Co.,
495 U.S. 328 (1990).....25

Bank of Am. Corp. v. City of Miami,
581 U.S. 189 (2017).....10

Bath Petroleum Storage, Inc. v. Mkt. Hub Partners, LP,
229 F.3d 1135, 2000 WL 1508873 (2d Cir. Oct. 11, 2000) 21

Bell Atl. Corp. v. Twombly,
550 U.S. 544 (2007).....30

Bigelow v. RKO Radio Pictures, Inc.,
327 U.S. 251 (1946).....17

Blue Shield of Va. v. McCready,
457 U.S. 465 (1982).....11

In re Ciprofloxacin Hydrochloride Antitrust Litig.,
363 F. Supp. 2d 514 (E.D.N.Y. 2005) 8

Coll v. First Am. Title Ins. Co.,
642 F.3d 876 (10th Cir. 2011) 22

In re Dairy Farmers of Am., Inc. Cheese Antitrust Litig.,
2015 WL 3988488 (N.D. Ill. June 29, 2015).....22

Davric Me. Corp. v. Rancourt,
216 F.3d 143 (1st Cir. 2000).....21

In re DDAVP Direct Purchaser Antitrust Litig.,
585 F.3d 677 (2d Cir. 2009) .....*passim*

Del. Valley Surgical Supply Inc. v. Johnson & Johnson,
523 F.3d 1116 (9th Cir. 2008) 24

Dippin' Dots, Inc. v. Mosey,
476 F.3d 1337 (Fed. Cir. 2007) 20

EmblemHealth, Inc. v. Alexion Pharms., Inc.,
813 F. Supp. 3d 205 (D. Mass. 2025).....7

Farag v. Health Care Serv. Corp.,
2017 WL 2868999 (N.D. Ill. July 5, 2017) 7, 10

FMC Corp. v. Manitowoc Co.,
835 F.2d 1411 (Fed. Cir. 1987) 26

Free Speech Coal., Inc. v. Paxton,
606 U.S. 461 (2025).....22

Gatt Commc'ns, Inc. v. PMC Assocs., LLC,
711 F.3d 68 (2d Cir. 2013) 8, 9, 10, 25

In re Humira (Adalimumab) Antitrust Litig.,
465 F. Supp. 3d 811 (N.D. Ill. 2020), *aff'd sub nom. Mayor & City Council of Balt. v. AbbVie Inc.*, 42 F.4th 709 (7th Cir. 2022).....8

Ill. Brick Co. v. Illinois,
431 U.S. 720 (1977).....13, 18, 24

IQ Dental Supply, Inc. v. Henry Schein, Inc.,
924 F.3d 57 (2d Cir. 2019) 15, 16

In re K-Dur Antitrust Litig.,
2007 WL 5297755 (D.N.J. Mar. 1, 2007) 8, 14, 15

Kaiser Found. v. Abbott Lab'ys,
2009 WL 3877513 (C.D. Cal. Oct. 8, 2009).....8

Kanne v. Visa U.S.A. Inc.,
723 N.W.2d 293 (Neb. 2006) 22

Kansas v. UtiliCorp United, Inc.,
497 U.S. 199 (1990).....24

Kottle v. Nw. Kidney Ctrs.,
146 F.3d 1056 (9th Cir. 1998) 21

Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,
475 U.S. 574 (1986).....24

Octane Fitness, LLC v. ICON Health & Fitness, Inc.,
572 U.S. 545 (2014).....20

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555 U.S. 438 (2009).....23

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22 F.4th 103 (2d Cir. 2021) 16

SCM Corp. v. Xerox Corp.,
645 F.2d 1195 (2d Cir. 1981) 13

Simon v. KeySpan Corp.,
694 F.3d 196 (2d Cir. 2012) 11, 24

Tremont Pub. Advisors, LLC v. Conn. Res. Recovery Auth.,
217 A.3d 953 (Conn. 2019) 22

United Food & Com. Workers Unions & Emps. Midwest Health Benefits Fund v. Novartis Pharms. Corp.,
2017 WL 2837002 (D. Mass. June 30, 2017), *aff'd*, 902 F.3d 1 (1st Cir. 2018).....21

Volvo N. Am. Corp. v. Men's Int'l Pro. Tennis Council,
857 F.2d 55 (2d Cir. 1988) 9, 12

Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.,
382 U.S. 172 (1965).....5, 7, 23

Warren Gen. Hosp. v. Amgen Inc.,
643 F.3d 77 (3d Cir. 2011) 19, 25

Constitutional Provisions

U.S. Const. amend. I 22

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Statutes

15 U.S.C. § 2 7

15 U.S.C. § 15 .....11, 12

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42 U.S.C. § 262(l)(8)-(9) 29

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PhRMA, *About PhRMA* 1

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INTEREST OF *AMICUS CURIAE*

Pursuant to Federal Rule of Appellate Procedure 29, *amicus curiae* Pharmaceutical Research and Manufacturers of America ("PhRMA") submits this brief in support of Defendants-Appellees Celgene Corporation and Bristol-Myers Squibb Company (collectively, "Celgene") and affirmance.[1]

PhRMA is a voluntary, nonprofit association representing the country's leading innovative biopharmaceutical research companies.[2] PhRMA member companies develop innovative medicines that transform lives and improve health, and PhRMA advocates for public policies that encourage innovation in life-saving and life-enhancing medicines. PhRMA member companies have long been at the forefront of developing new treatments and cures. Over the last decade, PhRMA member companies have invested more than $900 billion in biopharmaceutical research and development, supporting nearly five million jobs in the United States. That innovation depends heavily on private investments, which in turn depend on strong intellectual property rights.

PhRMA member companies have a significant interest in preventing an unwarranted expansion of antitrust standing that would increase the risks associated

[1] No counsel for any party authored this brief in whole or in part, and no entity or person other than *amicus*, its members, or its counsel made any monetary contribution intended to fund this brief's preparation or submission. The parties have consented to this filing.

[2] *See* PhRMA, *About PhRMA*, https://bit.ly/4k1v4Pr (last visited Nov. 3, 2026).

with legitimate patent enforcement. Licensing, prosecuting, and enforcing patents are foundational to PhRMA member companies' efforts to bring new therapies to patients. Sustaining the substantial investments required to develop new treatments depends on strong intellectual property protections and reasonable predictability concerning the enforcement of patent rights. PhRMA therefore has a compelling interest in ensuring that antitrust rules do not unnecessarily deter legitimate patent enforcement or diminish the incentives those rights provide for biopharmaceutical innovation.

SUMMARY OF ARGUMENT

Appellants' position, if adopted, would have a profound chilling effect on the biopharmaceutical industry.[3] The resulting uncertainty and increased antitrust exposure are particularly consequential in the innovative pharmaceutical industry. Patent protection and enforcement are integral to the lengthy, costly, and uncertain process of developing new therapies, and the ability to enforce those rights is critical to their value. Extending *Walker Process* standing beyond competitors and direct purchasers to indirect purchasers whose alleged injuries arise far downstream of the challenged patent conduct would substantially enlarge the universe of potential antitrust plaintiffs and the attendant threat of treble-damages liability. Such an

[3] *Amicus* uses "Appellants" to refer to the end-payor Plaintiffs-Appellants: Louisiana Health, HMO Louisiana, and NYHTC & HANYC Benefits Fund.

expansion would upset the careful balance between deterring genuine abuse of the patent system and preserving the ability of biopharmaceutical manufacturers to obtain and enforce patents without facing antitrust claims from increasingly remote parties.

The resulting uncertainty and antitrust exposure are not theoretical risks. Biopharmaceutical manufacturers invest billions of dollars each year to achieve breakthroughs in science to revolutionize patient care with the understanding that they will be able to enforce their intellectual property rights against free riding. If these manufacturers must anticipate that enforcing patent rights could expose them to *Walker Process* claims not only by directly affected competitors or purchasers, but also by potentially numerous downstream entities, the risks associated with patent enforcement would increase substantially. That uncertainty threatens to deter legitimate patent enforcement and the investment, collaboration, and innovation that patent protection is designed to encourage. As explained below, established antitrust and First Amendment principles and sound public policy compel rejection of Appellants' position.

Before the instant lawsuit, the United States Patent and Trademark Office ("PTO") awarded Celgene nine patents related to its drug Pomalyst® after several years of patent prosecution. Celgene satisfied the PTO during examination that the claims in each patent were novel and non-obvious over the prior art. Celgene

asserted its patents in litigation against nine generic manufacturers—*none* of whom claimed fraud on the PTO or succeeded in invalidating any of the patents. Now, several years later, Appellants, who are neither competitors nor customers of Celgene, allege that Celgene's purported scheme to defraud the PTO caused them to pay higher reimbursement rates for Pomalyst—a scheme that allegedly went undetected by every patent examiner, each of whom had a duty to conduct a thorough and complete search of the prior art, and every generic manufacturer, each of whom had every incentive to seek to invalidate the patents.

The District Court dismissed Appellants' antitrust claims premised on a *Walker Process* fraud theory of monopolization with prejudice because the District Court correctly determined that Appellants, as indirect purchasers, lack standing to bring *Walker Process* claims. This Court should affirm the District Court's opinion and clarify the scope of the antitrust standing doctrine.

First, the Court should affirm the District Court's ruling because Appellants are not efficient enforcers of *Walker Process* claims. *In re DDAVP Direct Purchaser Antitrust Litigation*, 585 F.3d 677 (2d Cir. 2009), makes clear that a private antitrust plaintiff must suffer an antitrust injury *and* be a proper plaintiff in light of the four "efficient enforcer" factors. The District Court properly measured Appellants' standing to assert *Walker Process* claims based on their status in the marketplace and found that Appellants' alleged injuries are indirect, remote, and speculative; that

more direct plaintiffs were (and are) naturally positioned to challenge the alleged fraud on the PTO; and that extending standing to Appellants would compound the problems of administrability and duplicative recovery.

Second, the Court should reject the propositions that antitrust standing for *Walker Process* claims should be analyzed under individual state laws and subject to a relaxed standard where the defendant is a pharmaceutical manufacturer. Appellants' claims are based on federal patent-related conduct governed by *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), which established an exception to *Noerr-Pennington*—the doctrine that immunizes First Amendment petitioning activity from the reach of federal *and* state law. Broadening or relaxing the antitrust standing doctrine would not only effectively eviscerate *Noerr-Pennington*'s protections, but it would also undermine the concerns that animated the Supreme Court's promulgation of the antitrust standing doctrine in *Associated General Contractors of California, Inc. v. California State Council of Carpenters* ("*AGC*"), 459 U.S. 519 (1983). Ultimately, adopting Appellants' position would transform antitrust standing from an objective limitation on the class of proper private enforcers into a moving target and risk chilling legitimate patent enforcement.

Finally, the Court should reject Appellants' attempt to expand indirect-purchaser standing and clarify that indirect purchasers lack standing *per se* to assert

Walker Process claims. Allowing entities at the very end of the distribution chain to assert remote and speculative injuries based on patent-related conduct—often claiming fraud, as in this case, several years after patent issuance and despite public records of patent prosecutions—would open the floodgates to unmanageable, far-fetched indirect-purchaser suits. And importantly, that expansion would chill legitimate patent enforcement and impede the commercialization of life-saving therapies.

For these reasons, and those set forth more fully below, *Amicus* urges this Court to affirm the District Court's holding that Appellants lack antitrust standing, to confirm that antitrust standing for *Walker Process* damages claims must be measured according to the efficient-enforcer principles, and to clarify that indirect purchasers lack standing to assert *Walker Process* claims brought under either federal or state law.

ARGUMENT

I. The District Court Correctly Held That Appellants Lack Antitrust Standing to Pursue *Walker Process* Claims.

The District Court's conclusion follows a well-settled principle: Antitrust law does not confer a private right of action on every plaintiff economically affected by allegedly anticompetitive conduct. The Clayton Act's extraordinary remedies are reserved for plaintiffs sufficiently close to the alleged violation to serve as efficient

enforcers. Appellants—third-party payors that provided indirect reimbursement for pharmaceuticals—are not those plaintiffs.

A. Courts Have Uniformly Held That Indirect Purchasers Do Not Have Standing to Assert *Walker Process* Claims.

Since the Supreme Court decided that "the maintenance and enforcement of a patent obtained by fraud on the [PTO]" may form the basis of an action under Section 2 of the Sherman Act, *Walker Process*, 382 U.S. at 173, courts have measured a party's standing to assert *Walker Process* claims based on their status in the marketplace. Thus, for example, only competitors initially had standing to assert such claims. This is because a *Walker Process* claim is meant to permit a competitor to seek redress under the antitrust laws if it is excluded from the market by fraudulent patent procurement and the threat of subsequent patent litigation. *See id.* at 175-77 (discussing the jurisprudential consistency in allowing those sued for infringement to recover treble damages when fraudulent procurement is coupled with a Section 2 violation).

Although courts have since extended that standing to direct purchasers, *see infra* I.B.2, federal courts presented with the question have refused standing for indirect purchasers. *See, e.g.*, *EmblemHealth, Inc. v. Alexion Pharms., Inc.*, 813 F. Supp. 3d 205, 219-21 (D. Mass. 2025); *Farag v. Health Care Serv. Corp.*, 2017 WL 2868999, at *5 (N.D. Ill. July 5, 2017) ("Plaintiffs are indirect purchasers with respect to Novartis, and courts confronted with such situations decline to find *Walker*

Process standing."); *Kaiser Found. v. Abbott Lab'ys*, 2009 WL 3877513, at *3-5 (C.D. Cal. Oct. 8, 2009) (denying *Walker Process* standing for end-payors "preserves the appropriate balance between antitrust and patent law"); *In re K-Dur Antitrust Litig.*, 2007 WL 5297755, at *18-19 (D.N.J. Mar. 1, 2007) (dismissing *Walker Process* claim by indirect purchasers).[4]

Each of those courts was guided by the factors delineated in *AGC* and found that extending *Walker Process* standing to indirect purchasers would invite precisely the remote and sprawling antitrust litigation that the efficient-enforcer principles are designed to prevent.

B. The "Efficient Enforcer" Factors Foreclose Appellants' Claims.

A complaint that fails to plausibly satisfy the "threshold, pleading-stage inquiry" of antitrust standing must be dismissed as a matter of law. *Gatt Commc'ns, Inc. v. PMC Assocs., LLC*, 711 F.3d 68, 75 (2d Cir. 2013) (citation omitted). Private

[4] *See also DDAVP*, 585 F.3d at 691 ("[W]e do not pass lightly over the defendants' objections to expanding the universe of patent challengers. The risk of disturbing the incentives for innovation dictates that we tread carefully."); *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 831 n.11 (N.D. Ill. 2020) ("[T]he complaint does not assert a *Walker Process* claim . . . likely because these [indirect purchaser] plaintiffs would lack standing to do so."), *aff'd sub nom. Mayor & City Council of Balt. v. AbbVie Inc.*, 42 F.4th 709, 713 (7th Cir. 2022) ("[I]t is far from clear that payors would have standing to make such an argument."); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 547-48 (E.D.N.Y. 2005) (granting motion to dismiss *Walker Process* claims raised by indirect purchasers on preemption grounds and expressing doubt that indirect purchasers could have standing).

antitrust plaintiffs must therefore plead both (1) antitrust injury and (2) that they are "efficient enforcers" of the antitrust laws. *Id.* at 76 (citation modified).

This Court has long considered four factors, derived from *AGC*, in determining whether plaintiffs are efficient enforcers: "(1) the directness or indirectness of the asserted injury; (2) the existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement; (3) the speculativeness of the alleged injury; and (4) the difficulty of identifying damages and apportioning them among direct and indirect victims so as to avoid duplicative recoveries." *DDAVP*, 585 F.3d at 688 (quoting *Volvo N. Am. Corp. v. Men's Int'l Pro. Tennis Council*, 857 F.2d 55, 66 (2d Cir. 1988)).

The District Court analyzed these factors and correctly concluded that Appellants are not efficient enforcers of *Walker Process* claims. JA081-84. This Court should affirm.

1. Appellants' Injuries Fail the "First-Step Rule."

The first factor, directness of injury, "turns on 'familiar principles of proximate causation.'" *In re Am. Express Anti-Steering Rules Antitrust Litig.* ("*Amex*"), 19 F.4th 127, 139 (2d Cir. 2021) (citation omitted). In the context of antitrust standing, proximate cause generally follows the "first-step rule." *Id.* "Under the rule, injuries that happen at the first step following the harmful behavior

are considered proximately caused by that behavior." *Id.* at 140; *see also Gatt*, 711 F.3d at 78 ("Directness in the antitrust context means close in the chain of causation.").

The District Court determined that Appellants cannot satisfy the first-step rule because they are several steps too far down the causal chain. Celgene's alleged misconduct occurred before the PTO. The alleged conduct would have directly impacted Celgene's competitors. But Appellants are customers who purchased Pomalyst from pharmacies or entities that reimbursed such customers. JA081. In other words, Appellants' "only connection to the patentee is as an indirect purchaser of products covered by the patent." *See Farag*, 2017 WL 2868999, at *6. This is insufficient to "establish the 'direct relation' between injury and antitrust violation that the first-step rule requires." *See Amex*, 19 F.4th at 141 (quoting *Bank of Am. Corp. v. City of Miami*, 581 U.S. 189, 202 (2017)). The District Court therefore correctly recognized that the connection between Appellants' injuries and the challenged conduct is "too remote." JA083-84.

Appellants misread *DDAVP*'s discussion of derivative injury. *DDAVP* dealt with direct purchaser standing and does not establish a principle that courts should continually identify the market participant currently most eager to enforce the antitrust laws. There, the panel explained that, with respect to the directness of injury, "even though the plaintiffs' injuries were derivative of the direct harm

experienced by the defendants' competitors, harming competitors was simply a means for the defendants to charge the plaintiffs higher prices" and concluded that this factor supported the plaintiffs' standing. 585 F.3d at 688. Appellants are wrong that this "logic applies with even greater force" here. La. Health Opening Br. ("LHSIC Br.") 37. That health benefit plans may sit at the "last stop in the drug payment chain" and allegedly "bear the full burden" of any overcharge, *see id.* at 37-38 (quoting SJA453), had no bearing on the decision in *DDAVP*, where plaintiffs purchased directly from the defendants. *See* 585 F.3d at 687-88; *see also Simon v. KeySpan Corp.*, 694 F.3d 196, 204 (2d Cir. 2012) (declining to find antitrust standing for indirect purchaser who alleged 100% pass-through of costs).

As this Court explained in *Amex*, "[g]iven the 'ripples of harm' that antitrust violations may have in the economy, the Supreme Court has said that '[i]t is reasonable to assume that Congress did not intend to allow every person tangentially affected by an antitrust violation to maintain an action to recover threefold damages for the injury to his business or property.'" 19 F.4th at 139 (quoting *Blue Shield of Va. v. McCready*, 457 U.S. 465, 476-77 (1982)). In other words, "despite the broad wording of § 4 [of the Clayton Act], there is a point beyond which the wrongdoer should not be held liable." *McCready*, 457 U.S. at 477. Indirect purchasers' purported injuries from years-old alleged fraud-on-the-PTO lie well beyond that point.

2. Better-Situated Plaintiffs Can Vindicate Walker Process *Violations.*

The District Court determined that the second factor—whether there is "an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement," *DDAVP*, 585 F.3d at 688 (quoting *Volvo*, 857 F.2d at 66)—also weighs against standing because more direct parties are naturally positioned to challenge the alleged patent misconduct. The District Court recognized that "more efficient alternate enforcers, such as the generics" could challenge Celgene's patents. JA083. Appellants argue that *DDAVP* requires only a class "naturally motivated" to sue and does not demand the plaintiff most motivated to enforce the antitrust laws. LHSIC Br. 38-39 (citing *DDAVP*, 585 F.3d at 689). But the District Court did not treat the existence of better enforcers as dispositive. Rather, it properly considered that factor as one part of the overall efficient-enforcer inquiry. JA083-84.

Indeed, it is Appellants who seek to convert *DDAVP* from a decision about the standing of direct purchasers into a roving mandate to identify the most motivated plaintiff, regardless of the plaintiff's place in the pharmaceutical distribution chain. The upshot of *DDAVP* was that the court must assess whether the plaintiff before it is proper under Section 4 of the Clayton Act. There, the plaintiff's direct-purchaser status itself provided a conventional basis for antitrust standing, and yet this Court still engaged with the efficient-enforcer analysis.

Limiting standing to more directly injured parties promotes effective antitrust enforcement. As the Supreme Court recognized, antitrust enforcement functions better when the law "concentrates" recovery in the plaintiff best positioned to sue instead of dispersing it across the distribution chain. *See Ill. Brick Co. v. Illinois*, 431 U.S. 720, 735 (1977) ("[T]he antitrust laws will be more effectively enforced by concentrating the full recovery for the overcharge in the direct purchasers rather than by allowing every plaintiff potentially affected by the overcharge to sue only for the amount it could show was absorbed by it."); *AGC*, 459 U.S. at 543 ("The indirectness of the alleged injury also implicates the strong interest . . . in keeping the scope of complex antitrust trials within judicially manageable limits.").

The direct target of allegedly wrongful patent enforcement (*i.e.*, the generic competitor) is the natural and efficient private enforcer of a *Walker Process* claim. Consequently, this Court has recognized that while denying direct purchasers "a remedy in favor of a suit by competitors" would "be 'likely to leave a significant antitrust violation undetected or unremedied,'" *DDAVP*, 585 F.3d at 689 (quoting *AGC*, 459 U.S. at 542), expanding standing to "purchaser plaintiffs" inherently risks "disturbing the incentives for innovation," *id.* at 691; *see also SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) ("If the threat of treble damage liability . . . were imbedded in the minds of potential patent holders as a likely prospect . . ., the efficacy of the economic incentives afforded by our patent system

might be severely diminished."). The Court thus "decline[d] to decide whether purchaser plaintiffs *per se* have standing to raise *Walker Process* claims" and took a measured approach in allowing the direct purchasers' suit to go forward. *DDAVP*, 585 F.3d at 691-92.

Whatever the scope of direct-purchaser standing, the considerations that informed *DDAVP* weigh decisively against extending *Walker Process* standing further down the distribution chain to indirect purchasers. As one district court acknowledged, affording standing to indirect purchasers to bring *Walker Process* claims "would turn antitrust policy on its head, and extend antitrust standing to an extraordinary level . . . [because] as compared to competitors and direct purchasers, indirect purchasers have certainly been less 'directly harmed' than their counterparts." *K-Dur*, 2007 WL 5297755, at *17-19. Denying standing to indirect purchasers does not create the potential enforcement vacuum that concerned this Court in *DDAVP*. Instead, it properly channels enforcement to parties whose injuries are closest to the conduct. Because end-payors are the "last stop" in the pharmaceutical distribution chain, the risk of an "undetected or unremedied" antitrust violation is not present. Direct purchasers have the incentives to stand in any potential gap between the harm to competitors and harm to consumers.

Even so, Appellants argue that indirect purchasers are now "more motivated than the direct drug purchasers" because of alleged changes in market dynamics,

LHSIC Br. 39, suggesting that indirect purchasers should have *Walker Process* standing because direct purchasers might choose not to sue, but that conflates an enforcer's motivation to sue with its fitness to do so. The efficient-enforcer factors address structural characteristics of the plaintiff's relationship to the alleged antitrust violation. Appellants' theory would effectively add another consideration to that analysis: Which potential plaintiff presently has the greatest subjective economic incentive to bring this particular lawsuit? But as the District Court explained, "standing hinges not on who is able to certify the broadest class action, but whether there are more efficient enforcers [who] have the 'self-interest [to] motivate [it] to vindicate the public interest in antitrust enforcement.'" JA351 (quoting *IQ Dental Supply, Inc. v. Henry Schein, Inc.*, 924 F.3d 57, 66 (2d Cir. 2019)).

Furthermore, Appellants' rule would invite satellite litigation about the incentives of nonparties. Whether an indirect purchaser could sue would depend not on its causal proximity to the alleged violation, but on the prevailing economic incentives of wholesalers and generic manufacturers at a particular moment. *See K-Dur*, 2007 WL 5297755, at *18 ("I do not believe that antitrust policy or patent law contemplates a scenario in which parties only tangentially affected by a patent holder's suit to enforce a patent against its competitors, regardless of whether the patent was fraudulently procured, which is ultimately settled by the original litigants, may be relitigated by consumers or indirect purchasers. Not only would such a result

likely discourage settlement and inject a significant level of uncertainty into the process of adjudicating patent disputes, it would become exponentially more costly for all parties involved.").

A rule that makes standing contingent on relative litigation incentives would replace a doctrine designed in part to identify administrable limits on private antitrust enforcement with collateral inquiries into the commercial relationships and litigation strategies of absent market participants—a result that is irreconcilable with *AGC*.

3. Appellants' Theory Depends on a Speculative Chain of Causation.

The District Court correctly determined that the third factor—"speculativeness" of the alleged injury—also weighed against Appellants' standing. Appellants' theory "necessarily involves intermediaries and intervening factors," creating "accompanying uncertainty" and "requir[ing] the court to speculate" about how those intermediaries would have behaved had the patents never issued. JA083-84 (quoting *Amex*, 19 F.4th at 142; *Schwab Short-Term Bond Mkt. Fund v. Lloyds Banking Grp. PLC*, 22 F.4th 103, 119 (2d Cir. 2021)).

The District Court's conclusion should not be disturbed. Indirect-purchaser *Walker Process* claims such as Appellants' create unusually difficult causation problems. Where the harm to a plaintiff results from injury to an intermediary, this Circuit has repeatedly held that that plaintiff is not an efficient enforcer because its antitrust claims are "derivative and indirect." *See, e.g.*, *IQ Dental*, 924 F.3d at 65

(holding that plaintiff, though injured by a boycott of the third-party online portal through which it sold its goods, lacked antitrust standing to challenge that boycott); *Amex*, 19 F.4th at 140 (collecting cases).

Appellants' reliance on *DDAVP*'s observation that the price effects of earlier generic entry can be "sufficiently estimated and measured," *see* LHSIC Br. 40 (quoting 585 F.3d at 689), is misplaced because *DDAVP* involved direct purchasers. Here, by contrast, Appellants must trace the effects of Celgene's alleged patent misconduct through additional transactions and reimbursement decisions before arriving at their own asserted injuries. Likewise, Appellants' reliance on *Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251 (1946), is misplaced. *See* LHSIC Br. 40. The rule that a wrongdoer bears the uncertainty created by its misconduct does not relieve a plaintiff of establishing that it is a proper party to recover for such misconduct.

4. Extending Standing to Appellants Would Compound the Problems of Administrability and Duplicative Recovery.

The District Court correctly concluded that the fourth *DDAVP* factor—"the difficulty of identifying damages and apportioning them among direct and indirect victims so as to avoid duplicative recoveries," *DDAVP*, 585 F.3d at 688—weighs against Appellants' standing because "the requested relief exacerbates manageability issues without providing any clear benefit." JA084.

This factor is particularly relevant to the standing analysis because barring indirect purchasers from bringing *Walker Process* claims prevents duplicative recovery and inconsistent liability findings. Where the allegedly excluded competitor brings its own *Walker Process* claim and end-payors separately pursue claims premised on higher prices caused by that same exclusion, the asserted injuries differ, but they derive from the same alleged conduct. Permitting increasingly remote plaintiffs therefore creates risks that undermine the Supreme Court's conception of effective antitrust enforcement: separate lawsuits over the same patent enforcement; inconsistent findings concerning causation and competitive effects; overlapping theories of damages; and multiplying treble-damages exposure based on the same predicate conduct. *See Ill. Brick*, 431 U.S. at 737, 745 (rejecting downstream damages litigation in part because it introduces "whole new dimensions of complexity" and "massive evidence and complicated theories"). Even when considering only the presence of excluded competitors, this factor reinforces the conclusion that indirect purchasers lack standing to bring *Walker Process* claims.

Appellants' argument that a competitor would seek lost profits rather than overcharge damages, *see* LHSIC Br. 42, does not address the separate risk presented by the possibility of both direct and indirect purchasers seeking relief, as is the case in this very action. Unlike in *DDAVP*, the potential for duplicative recovery among direct and indirect purchasers is high here because the overlap in claimed overcharge

damages would be significant, if not complete, and apportioning those damages would be highly complex. *Cf. DDAVP*, 585 F.3d at 689 ("Even assuming some overlap between lost profits and overcharges (as could occur if generic manufacturers charged more than the competitive price), the two are conceptually different measures that we think can be fairly apportioned in order to avoid duplicative recoveries."); *see also AGC*, 459 U.S. at 545 (explaining that *Illinois Brick*'s pass-on concerns "should guide" courts in determining whether a party is a proper plaintiff because apportioning damages among direct and indirect purchasers creates "massive and complex damages litigation" that "not only burdens the courts, but also undermines the effectiveness of treble-damages suits").

Moreover, private treble-damages suits are not the only means of antitrust enforcement, and courts should not expand standing simply because the plaintiffs before them contend that other potential plaintiffs lack sufficient commercial motivation. *See, e.g.*, *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 95 (3d Cir. 2011) ("[E]ven if we agreed that the middleman purchaser was unable or unwilling to bring a suit, that conclusion does not necessarily weigh in favor of giving the indirect purchaser standing."); *see also supra* I.B.2. The perceived desirability of additional antitrust enforcement cannot itself supply standing that is otherwise absent.

II. Extending *Walker Process* Standing to Indirect Purchasers Would Distort Settled Constitutional and Antitrust Standing Principles and Disincentivize Innovation.

Standing for end-payor plaintiffs would open the floodgates to similarly remote, far-fetched indirect-purchaser suits. The influx of such suits would undermine the First Amendment protections guaranteed by *Noerr-Pennington*, push *Walker Process* beyond its carefully circumscribed domain, undermine incentives for innovation, and chill legitimate patent enforcement.

A. Appellants' State-Law Standing Theory Cannot Be Reconciled with *AGC* or *Noerr-Pennington*'s First Amendment Protections.

Even though Appellants' claims are premised on federal patent-related conduct, Appellants argue that their claims should be analyzed pursuant to each individual state law's antitrust standing doctrine. LHSIC Br. 31-35. But that is not supported by the law—courts have consistently determined that the *AGC* antitrust standing doctrine governs this issue. *See supra* I.A. Appellants' position also ignores the policy concerns and First Amendment principles that animate the *Noerr-Pennington* doctrine.

First, *Walker Process* is one of the "narrow" exceptions to the *Noerr-Pennington* doctrine. *See, e.g.*, *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 556 (2014) (explaining that *Noerr-Pennington* exceptions are designed to be "narrow" "to avoid chilling the exercise of the First Amendment right to petition the government for the redress of grievances"); *Dippin' Dots, Inc. v.*

Mosey, 476 F.3d 1337, 1347 (Fed. Cir. 2007) (describing the "heightened standard of materiality" for *Walker Process* claims); *Am. Original Corp. v. Jenkins Food Corp.*, 696 F.2d 1053, 1060 (4th Cir. 1982) (party asserting *Walker Process* fraud "has a heavy burden in establishing it"). *Walker Process* must remain an exception with narrow, discernible boundaries.

Second, because Appellants' claims are based on federal patent-related conduct, federal standards, and the principles underlying them, are central to the analysis. The majority of circuits, including the Second Circuit, have recognized that *Noerr-Pennington* derives from the First Amendment's guarantee of the right to petition the government, and thus immunizes such conduct from the reach of both federal and state law. *See, e.g.*, *Bath Petroleum Storage, Inc. v. Mkt. Hub Partners, LP*, 229 F.3d 1135 (Table), 2000 WL 1508873, at *1 (2d Cir. Oct. 11, 2000) ("*Noerr Pennington* immunity is applicable to RICO actions and to state-law claims such as fraud and tortious interference."); *Davric Me. Corp. v. Rancourt*, 216 F.3d 143, 148 (1st Cir. 2000) (applying *Noerr-Pennington* to both state and federal antitrust claims); *United Food & Com. Workers Unions & Emps. Midwest Health Benefits Fund v. Novartis Pharms. Corp.*, 2017 WL 2837002, at *9 (D. Mass. June 30, 2017) (recognizing that the majority of circuits consider *Noerr-Pennington* to apply to state law claims as well as federal claims), *aff'd*, 902 F.3d 1 (1st Cir. 2018); *Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056, 1059 (9th Cir. 1998) (*Noerr-Pennington* "sweeps

broadly and is implicated by both state and federal antitrust claims that allege anticompetitive activity.").

Because the *Walker Process* doctrine is an *exception* to the protection of First Amendment petitioning immunity, if a plaintiff cannot overcome that First Amendment immunity to assert a federal claim, it similarly cannot assert a state law claim because state law claims inconsistent with the First Amendment are barred as a matter of the First and Fourteenth Amendments. *See Free Speech Coal., Inc. v. Paxton*, 606 U.S. 461, 470 (2025) ("The First Amendment, which applies to the States through the Fourteenth Amendment, prohibits laws 'abridging the freedom of speech.'"); *Coll v. First Am. Title Ins. Co.*, 642 F.3d 876, 895 (10th Cir. 2011) ("[T]he *Noerr-Pennington* doctrine is based upon the First Amendment, which applies to [states] through the Fourteenth Amendment."). Therefore, while *Illinois Brick* repealer statutes authorize indirect purchasers to sue for state antitrust violations, they do not relieve plaintiffs of their burden to establish standing for claims premised on federal patent-related conduct.[5] *Cf. In re Dairy Farmers of Am., Inc. Cheese Antitrust Litig.*, 2015 WL 3988488, at *6 (N.D. Ill. June 29, 2015) (collecting cases holding that "*Illinois Brick* and *AGC* present separate, distinct inquiries").

[5] Tellingly, courts in repealer states frequently find no standing based on the *AGC* principles. *See, e.g.*, *Kanne v. Visa U.S.A. Inc.*, 723 N.W.2d 293, 297-300 (Neb. 2006) (applying *AGC* and finding no antitrust standing for plaintiffs with "derivative and remote" claims); *Tremont Pub. Advisors, LLC v. Conn. Res. Recovery Auth.*, 217 A.3d 953, 966 (Conn. 2019) (similar).

This Court should again preserve the breathing room that *Noerr-Pennington* creates for protected petitioning. As this Court has explained, *Walker Process* "reflects a willingness to let antitrust liability impact the patent system," but it "also noted that allowing antitrust recovery 'accord[ed]' with the 'long-recognized procedures' that controlled how parties could challenge a patent's validity, thereby suggesting that the Court may not have envisioned expanding the universe of potential patent challengers." *DDAVP*, 585 F.3d at 691 (quoting *Walker Process*, 382 U.S. at 176-77). The universe has already been expanded to include direct purchasers, but nothing justifies expanding it further.

B. The Court Should Not Countenance Different Antitrust Standing Rules for the Pharmaceutical Industry.

Appellants suggest that antitrust standing principles should be different for the pharmaceutical industry because competitors and wholesalers allegedly have less incentive to enforce due to a purported "shift" in the "factual landscape." *See* LHSIC Br. 39-40. In essence, Appellants advocate for a relaxed antitrust standing standard for *Walker Process* claims involving pharmaceutical manufacturer defendants. This is untenable and entirely without basis, as the law makes clear that the antitrust laws can be effectively enforced by private plaintiffs only if that enforcement is governed by clear, nondiscriminatory rules.

The Supreme Court has "repeatedly emphasized the importance of clear rules in antitrust law." *E.g.*, *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438,

452 (2009). Clear, administrable rules provide innovators with needed certainty, while limiting the burdens on the courts and the parties. *See, e.g.*, *Apple Inc. v. Pepper*, 587 U.S. 273, 285 (2019) (reaffirming bright-line rule against "engag[ing] in 'an unwarranted and counterproductive exercise to litigate a series of exceptions'" (quoting *Kansas v. UtiliCorp United, Inc.*, 497 U.S. 199, 217 (1990))). That concern is particularly acute where uncertainty may "chill the very conduct the antitrust laws are designed to protect." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986).

The nature of pharmaceutical competition supplies no reason to dilute ordinary principles of antitrust standing. Antitrust standing exists precisely to determine which injuries are sufficiently direct to support private treble-damages actions regardless of the economic importance of the underlying product. Indeed, *Illinois Brick* specifically rejected attempts to carve out pass-on exceptions depending upon particular market characteristics, reasoning that litigating which markets justify exceptions recreates the complexity the rule was supposed to avoid. *See* 431 U.S. at 744-45; *see also, e.g.*, *Simon*, 694 F.3d at 201-04 (declining to expand exception to indirect-purchaser bar to account for nuances of regulated utilities markets); *Del. Valley Surgical Supply Inc. v. Johnson & Johnson*, 523 F.3d 1116, 1122-25 (9th Cir. 2008) (rejecting exception to indirect-purchaser bar supposedly "better attuned to the business relationships between health care

providers and manufacturers" because courts cannot "make a policy determination on a case-by-case basis . . . [based on] special business arrangements"); *Warren Gen.*, 643 F.3d at 91-96 (similar).[6]

Therefore, this Court should continue to be guided by the foundational distinction between antitrust injury and a private right to recover for that injury. Alleged economic injury is not synonymous with antitrust standing. *See Gatt*, 711 F.3d at 76 (Private plaintiffs cannot recover "merely by showing injury causally linked to an illegal presence in the market." (quoting *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990))). The question is who can bring an antitrust cause of action for treble damages. That distinction appears explicitly in *Illinois Brick*: The Supreme Court acknowledged that its rule denies recovery to indirect purchasers who may actually have suffered injury, but concluded that standing, and therefore the right to recovery, should be concentrated in those directly harmed, rather than requiring courts to attempt to allocate damages among everyone who absorbed some portion of an overcharge. *See supra* I.B.2.

Appellants' "changed factual landscape" argument identifies a purported change in incentives, not a change in causation. Consider the causal chain: The manufacturer defrauds the PTO and enforces the resulting patent to exclude a generic

[6] Moreover, to the extent that the healthcare or pharmaceutical landscape has changed, industry evolution is better addressed by Congress or public enforcement than by relaxing limitations on private plaintiffs' standing.

competitor, allowing it to charge wholesalers higher prices. Wholesalers resell to retailers; pharmacy benefit managers negotiate prices, rebates, and formularies; and retailers sell to patients. Only then do end-payors reimburse. Changing the motivation of direct purchasers does not erase the doctrinal distinction between parties directly harmed by the alleged fraud and those several steps down the distribution chain.

Indeed, the treble-damages remedy strengthens the case for an objective, limiting principle. The more potent the private remedy, the greater the need for principled rules identifying the plaintiffs entitled to wield it. Because § 4 provides treble damages, expanding the universe of plaintiffs does more than facilitate compensation—it substantially expands the potential consequences associated with a single allegedly unlawful course of conduct.

C. Downstream Treble-Damages Exposure Would Erode the Patent Predictability That Sustains Biopharmaceutical Innovation.

The patent system affirmatively grants exclusionary rights and depends upon patentees being willing to enforce those rights. *Walker Process* strikes a careful balance. Genuinely fraudulent use of the patent system may lose antitrust protection, but ordinary patent use and enforcement do not thereby become an invitation to sprawling antitrust liability. *See, e.g.*, *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1418 n.16 (Fed. Cir. 1987) (explaining that it is the *enforcement* of a patent procured by fraud that may give rise to a Sherman Act claim; mere procurement without more

"cannot in itself violate the antitrust laws"). Allowing increasingly remote plaintiffs to invoke the exception would upset that calibration.

Predictable patent rights encourage biopharmaceutical innovation by increasing the likelihood that innovators can recoup the substantial cost of developing new treatments. Expanding antitrust liability arising from the enforcement of those rights would increase the cost and uncertainty associated with patent enforcement, thereby weakening incentives to innovate.

Biopharmaceutical innovation requires enormous investments in research and development. Over the last decade, PhRMA member companies have invested more than $900 billion in new treatments and cures, including more than $100 billion annually from 2021 through 2024.[7] Indeed, the biopharmaceutical sector is the most R&D-intensive industry in the nation, investing six times more in research than any other manufacturing sector.[8] Those investments helped fund the development of nearly 900 new medicines approved by the FDA since 2000; in 2025 alone, PhRMA member companies received FDA approval for 52 medicines.[9]

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[7] PhRMA, *Research and Development Policy Framework*, https://bit.ly/4i3s4jd (last visited Nov. 3, 2026); *see also* PhRMA, *2025 PhRMA Annual Membership Survey* 3 tbl. 1 (July 14, 2025), https://bit.ly/3WnfZOx.

[8] *Research and Development Policy Framework*, *supra* note 7.

[9] Sophie E. Knox et al., *FDA Approval of Specialty Drugs, 2000-2024*, Health Affs. Scholar, Feb. 2026, at 1, https://bit.ly/4BHi9J0; Kristen Booze, PhRMA, *Advancing Patient Care: A Look at New Medicines Approved in 2025* (Jan. 30, 2026), https://bit.ly/4dtfdFV.

The magnitude of those investments is all the more striking given the extraordinary cost and uncertainty of developing a new medicine. On average, developing and obtaining FDA approval of a new medicine costs $2.6 billion.[10] And the overwhelming majority of medicines entering clinical trials—more than 90%—do not reach FDA approval.[11] Yet FDA approval does not guarantee success: Only one in five approved medicines will ever generate revenues that exceed average development costs.[12]

Copying a successful medicine, by contrast, costs a fraction of developing one.[13] Patent protection is therefore critical to preserving the expected return necessary to justify biopharmaceutical research. Firms deciding whether to

[10] *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25-26 (2016), https://bit.ly/30UAIdg.

[11] Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), https://bit.ly/2Y2gwEK; *see also* Aroon D. Hingorani et al., *Improving the Odds of Drug Development Success Through Human Genomics: Modelling Study*, 9 Sci. Reps. 18911, at 2 (2019), https://bit.ly/4tPPOej (discussing failure rate of over 96%).

[12] John A. Vernon et al., *Drug Development Costs When Financial Risk Is Measured Using the Fama-French Three-Factor Model*, 19 Health Econ. 1002, 1004 (2010), https://bit.ly/4tY8RmW.

[13] Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. 849, 851-52 (2002) (noting generic compound development "only takes a few years and costs $1-2 million," while enjoying a high probability of success), https://bit.ly/3Wb3plx; Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1616-17 (2003) ("[T]he ratio of inventor cost to imitator cost . . . is quite large in the absence of effective patent protection," making it "likely that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection."), https://bit.ly/4islPWg.

undertake or finance research must consider whether successful inventions can be protected and enforced within reasonably predictable legal boundaries.

Congress reinforced that principle in the Hatch-Waxman Act and Biologics Price Competition and Innovation Act by creating specialized mechanisms for resolving patent disputes before generic or biosimilar entry. Rather than require an innovator to wait until a competing product launches and infringement has already occurred, Congress made certain premarket regulatory submissions themselves an artificial act of infringement, enabling innovators to enforce, and courts to adjudicate, patent rights before a competitive launch. *See* 35 U.S.C. § 271(e)(2); 42 U.S.C. § 262(l)(8)-(9). That design recognizes the importance of providing innovators greater certainty about patent rights before the enormous investments embodied in a successful medicine are exposed to competition from entities like generic and biosimilar manufacturers that rely on the innovators and do not themselves invest in novel therapies.

Appellants' proposed expansion of standing would undermine that predictability. Indeed, Appellants' attempt in this case to step into the enforcer role years later, from the far end of the distribution chain, highlights precisely why courts have refused to expand *Walker Process* standing to indirect purchasers. Allowing multiple layers of downstream purchasers to pursue treble-damages claims would increase the potential consequences associated with otherwise legitimate patent

enforcement, which is, by congressional design, *encouraged*, if not expected. That additional exposure would diminish the expected value of patent protection and, at the margins, weaken incentives to undertake and invest in biopharmaceutical innovation.

D. Exposing Patentholders to Claims by Remote Downstream Purchasers Could Chill Legitimate Patent Enforcement.

A biopharmaceutical manufacturer deciding whether to enforce a patent already knows that an accused infringer can challenge the patent's validity, assert inequitable conduct, and, where the demanding requirements are met, bring a *Walker Process* claim. Indeed, *Walker Process* claims ordinarily arise as counterclaims in patent litigation.

Allowing remote purchasers to sue adds a qualitatively different risk: Patent enforcement against one competitor could expose the patentholder to damages litigation from downstream entities with whom it may have no direct relationship. Such claims would subject patentholders to costly and onerous antitrust discovery regardless of the underlying merits. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007). And such claims would inflate the expected cost of enforcing a patent according to the number and configuration of downstream purchasers economically connected to the product. That incongruity would make the cost of legitimate patent enforcement turn on the happenstance of downstream distribution, thereby chilling the legitimate exercise of patent rights.

The Court should therefore heed *DDAVP*'s warning that courts must "tread carefully" before disturbing the balance Congress struck under Hatch-Waxman. 585 F.3d at 691. Opening the door to indirect-purchaser standing would not simply increase the number of plaintiffs able to challenge alleged fraud; it would materially increase the cost and uncertainty attendant to the exercise of patent rights, jeopardizing the very litigation expressly contemplated by Hatch-Waxman.

CONCLUSION

For the foregoing reasons, *Amicus* urges this Court to affirm dismissal of Appellants' monopolization claims based on a *Walker Process* fraud theory for lack of antitrust standing, to confirm that antitrust standing for *Walker Process* damages claims must be measured according to the federal antitrust standing doctrine, and to clarify that indirect purchasers lack standing to assert *Walker Process* claims under both federal and state law.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because it contains 6,993 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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Dated: November 3, 2026

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CERTIFICATE OF SERVICE

I hereby certify that on November 3, 2026, the foregoing brief was filed with the Clerk of Court for the U.S. Court of Appeals for the Second Circuit and served on all counsel who have entered an appearance in this action via the Court's CM/ECF system.

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